

Cepheid GeneXpert Xpress System

Tutorial

Intended Use:

This test system provides for detection and differentiation of SARS-CoV-2, Flu A, Flu B, and RSV nucleic acids in nasal swabs.



The system is made up of the top screen and barcode scanner and the bottom GeneXpert system. On/Off switches are found on the top front and on the top and bottom of the back of the system.

Specimen Collection:

Insert a nasal swab 1 to 1.5 cm into a nostril. Rotate the swab against the inside of the nostril for 15 seconds while applying pressure with a finger to the outside of the nostril.

Repeat on the other nostril with the same swab.

Place the swab into the tube containing 3 mL of viral transport medium.

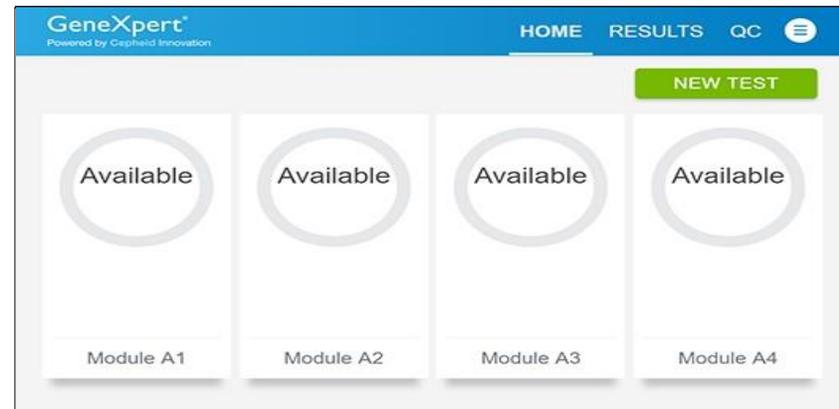
Specimen in the VTM media at room **temperature is good for 48 hours. (2-8°C) for 7 days.**



Running a Test:

This is the Home screen where you would begin to run a patient specimen by selecting New test. Invert VTM specimen 5 times.

Follow the next screens to enter or scan appropriate test, operator ID and patient ID.



Select a cartridge and transfer pipette, which are stored at room temperature

Scan cartridge

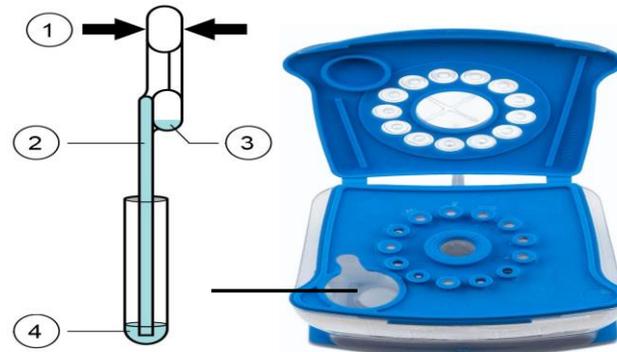
Fill transfer pipette following guidelines as indicated below.

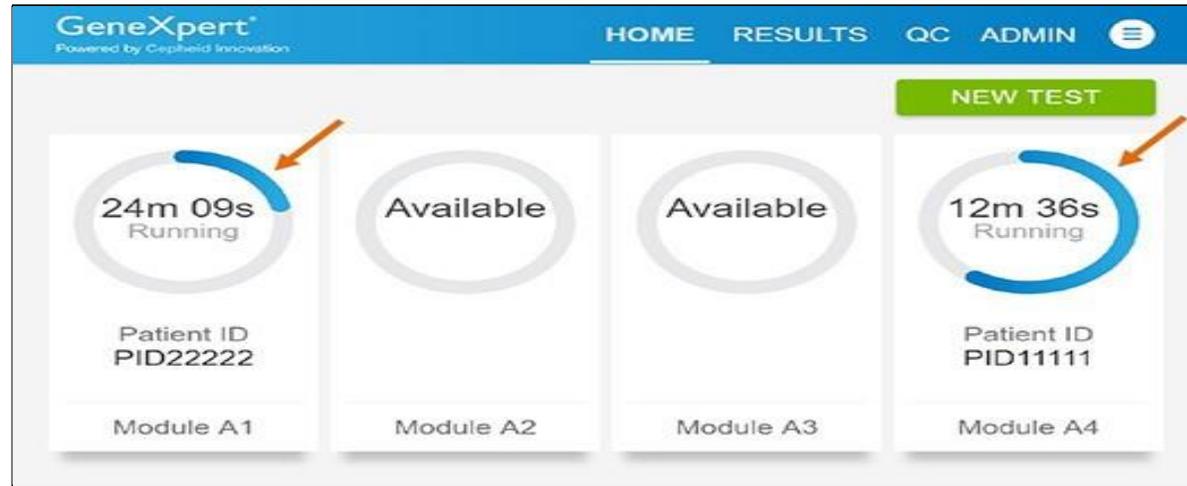
Empty contents of pipette into sample chamber of the cartridge

Cartridge must be loaded and tested within 30 minutes after adding sample

Load cartridge in door with flashing green light

Close door until it clicks





Test running screen shows time remaining on test.

While Test is running you may start another test by touching New Test, testing may be done by more than one operator

When test is completed view results, open module door and remove cartridge.

When test is complete select desired result, touch Report, swipe up and down to view Report.

Check to verify that the Sample Processing Control (SPC) and the Probe Check Control (PCC) have passed before accepting patient results.



External Controls:

Controls are run:

For each new lot and/or shipment of cartridge kits

For each new operator

If problems are suspected

External QC is run by selecting the QC icon on the Home screen

The appropriate QC test is selected

Scan the supplied Positive or Negative QC barcode

Scan the cartridge and then scan the User ID

Follow directions for preparation and loading of cartridge as previously noted

Once QC levels are completed either fill in log sheets or print results to keep the records

Reasons to Repeat testing:

Instrument error

No Result – Repeat test comment

External QC is not within required range (QC must be within range to report patient results)

To retest, a new cartridge will be needed (use leftover sample from original VTM tube or a new collection sample)