

# Xpert® Xpress MVP and the GeneXpert® Xpress System (Hub configuration)

For *In Vitro* Diagnostic Use. CLIA Complexity: Waived. A Certificate of Waiver is required to perform this test in a CLIA Waived setting\*. For use with vaginal swab specimens.

## Before you begin

- Read through the entire Quick Reference Instructions before beginning a test.
- Start the test within 30 minutes of adding the specimen to the cartridge.
- Instructions on how to prepare the specimen and the cartridge are shown in a video within the software and in these Quick Reference Instructions.
- The recommended environmental operating conditions for Xpert Xpress MVP are 15–30 °C, 20–80% relative humidity.
- Only use transfer pipettes provided in the Xpert Xpress MVP test kit.

## Storage and Handling

- Wear gloves. Change gloves between processing each sample.
- Store the Xpert Xpress MVP cartridges at 2–28 °C until the expiration date provided on the label.
- Specimens should be transported at 2–28 °C.
- Specimens placed in transport medium following collection can be stored for up to 42 days at 2–28 °C prior to testing with the Xpert Xpress MVP test.
- **DO NOT** open or alter any part of the **used** cartridge for disposal.

## 1 Patient Specimen Collection

Swab specimens must be collected by trained personnel or self-collected in a clinical setting and transported with the Xpert Swab Specimen Collection kit (catalog number SWAB/G-50-US). Refer to specimen collection instructions provided with the collection kit.

## 2 Starting the System

### A Starting the Software

- Put on a clean pair of gloves
- Turn on the GeneXpert Xpress instrument, and the Hub computer
- The Windows lock screen appears. Swipe up to continue
- Enter the Windows password
- Allow 30 seconds for the Xpress software to load

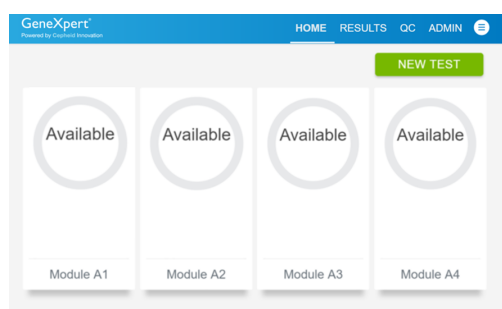
### B Enter UserID and Password

- Touch the **User Name** field to display the virtual keyboard
  - Enter your user name and password
  - Touch the **X** in the upper right of the virtual keyboard

### C Or, Use Barcode Scanner Shown Below to Scan Employee Badge or User Login Barcode




### D Home Screen Displays



## 3 Testing a Patient Specimen

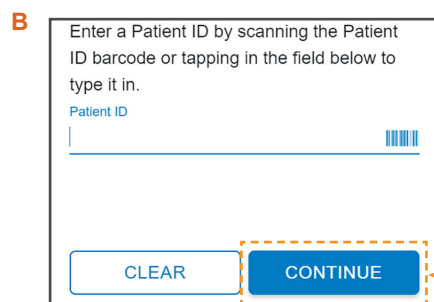
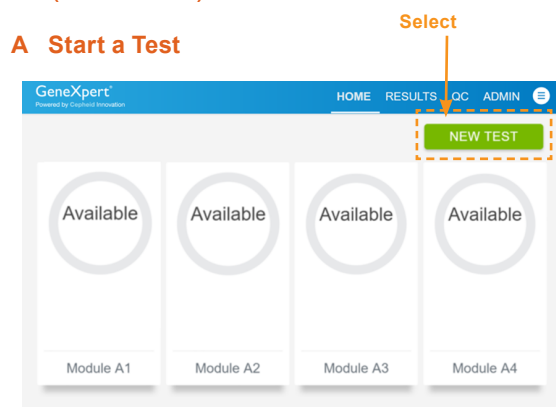
### WARNINGS

- **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.

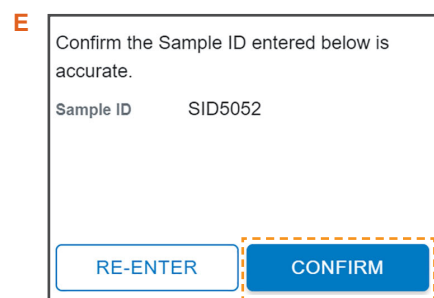
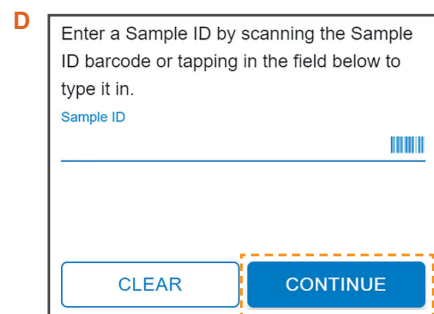
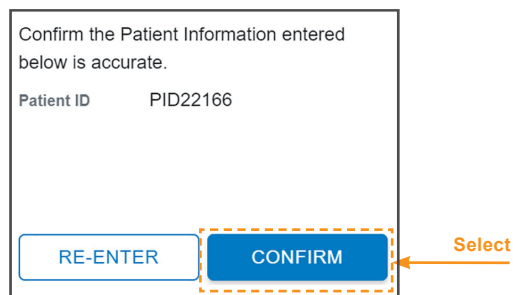
 Refer to the Instructions for Use for Warnings and Precautions, Specimen Collection and Handling, and Quality Control Testing.

## 3 Testing a Patient Specimen (continued)

### A Start a Test



### C Confirm patient information as it can not be altered after submission

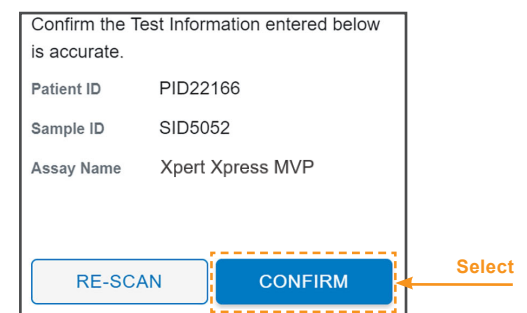


### F Scan Cartridge Barcode



## 3 Testing a Patient Specimen (continued)

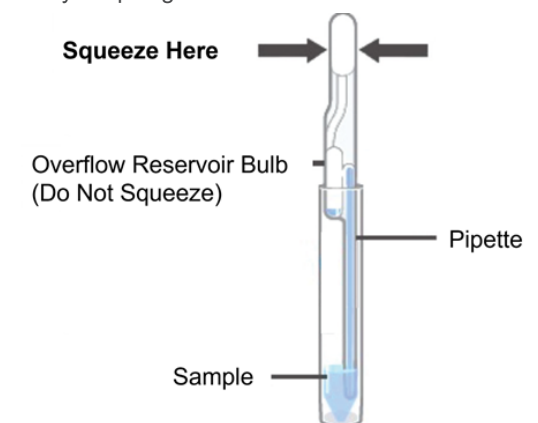
### G Enter your user name and password if prompted, then:



- H** Watch video & touch **CONTINUE** when complete
- I** Open cartridge lid
- J** Check that the specimen tube is fully capped and **vigorously shake the transport tube 3–4 times**
- K** Open tube lid

### L Fill Pipette with Sample

- Obtain a new transfer pipette provided in the Xpert Xpress MVP test kit
- Squeeze the top bulb of the pipette **completely until it 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 until the pipette is completely filled with sample** before removing it from the tube. It is okay if liquid goes into the overflow reservoir.



### M Transfer Sample to Cartridge

- Put the pipette into the large opening on the lower right corner of the cartridge (Sample Chamber). Squeeze the top bulb of the pipette **completely until it is fully flat** to empty the contents. Some liquid may remain in the overflow reservoir.
- **Continue to hold the top bulb fully flat and do not release** until the pipette is removed from the cartridge. **Do not reuse a pipette.** Dispose of the used pipette.
- Close the cartridge lid. After cartridge is prepared, touch **CONTINUE** on Cartridge Preparation screen.



### 3 Testing a Patient Specimen (continued)

#### N Load Cartridge Into Module

- Pull open the instrument door with the flashing green light
- Load the cartridge
- Close the door until it clicks
- The **Test Loading** screen will appear followed by the **Test Running** screen in less than a minute
- If performing a new test, go to Section 4 below.

#### O Results

- When the test is completed, the **Test Completed** screen appears with the test results and the instrument door will unlock.
- Or, if on the **HOME** screen, touch the **RESULTS** button to view test results.
- Confirm the test provided a positive or negative result. If **NO RESULT**, repeat test with a new cartridge.
- To print report, touch the print icon.
- Remove cartridge. Dispose of the cartridge and gloves according to your institution's policy. Go to Section 4 'How to Start a New Test While a Test is Running' if performing a new test.
- To log out, touch the User icon then select **LOGOUT**.

### 4 How To Start a New Test While a Test is Running

- Touch the **HOME** button on the Test Running screen
- The **HOME** screen will display the module status and the **NEW TEST** button
- You can now perform the same steps in Section 3 'Testing a Patient Specimen' to perform a new test. Change gloves between processing each sample.

### 5 Possible Results

For Patient Specimen or External Control

#### Results Interpretation

##### BV NEGATIVE

Negative test for Bacterial Vaginosis (BV).

##### Candida group NOT DETECTED

Candida group target DNA is not detected.

##### Candida glab-krus NOT DETECTED

*Candida glabrata/Candida krusei* target DNA is not detected.

##### TV NOT DETECTED

*Trichomonas vaginalis* (TV) target DNA is not detected.

##### BV POSITIVE

Positive test for Bacterial Vaginosis (BV).

##### Candida group DETECTED

Candida group target DNA is detected.

##### Candida glab-krus DETECTED

*Candida glabrata/Candida krusei* target DNA is detected.

##### TV DETECTED

*Trichomonas vaginalis* (TV) target DNA is detected.

##### NO RESULT - REPEAT TEST

If the result is **NO RESULT - REPEAT TEST**, then retest with a new cartridge using a new transfer pipette.

### 5 Possible Results (continued)

#### Results Interpretation

##### INSTRUMENT ERROR

Result is an instrument error. Touch **CLEAR ERROR** and follow the on-screen instructions. When the Home screen appears, repeat the test using a new cartridge and a new transfer pipette.

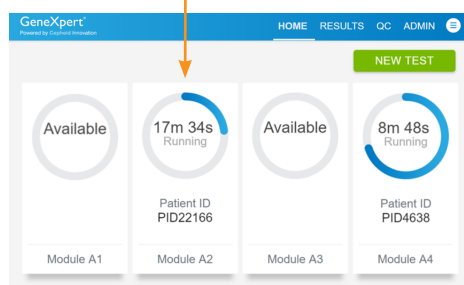
**NOTE:** If an incorrect result is provided for the external control, repeat the external control run.

### 6 How to View Status of Tests In Progress and Completed Tests

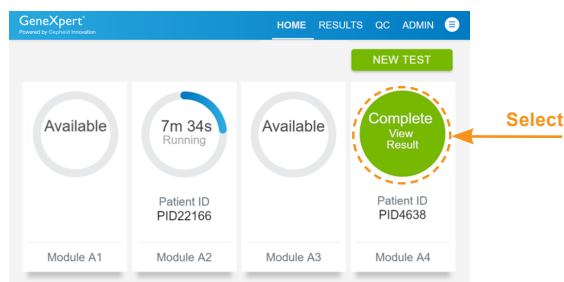
#### A Touch HOME button

- To view the status of tests in progress or completed tests.

#### B View Test In Progress Above the Module Number



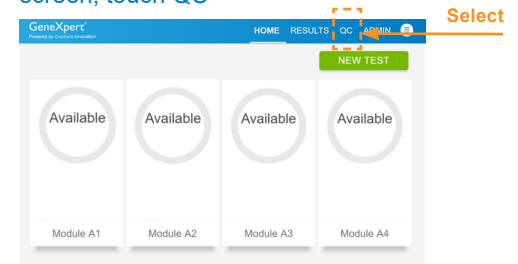
#### C View Completed Tests



**NOTE:** Refer to the Instructions for Use for information on reviewing or printing past results.

### 7 How to Run External Controls – Positive and Negative Controls (continued)

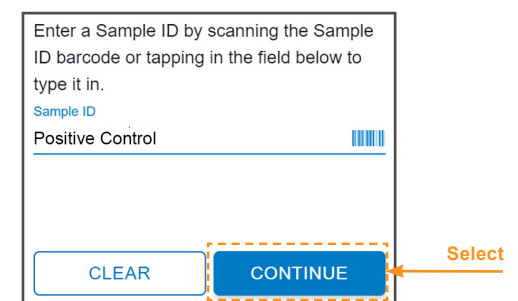
#### A On the Home screen or the Test Running screen, touch QC



#### B Select the QC list option based on the test you are performing



#### C Type Positive Control or Negative Control or scan Sample ID barcode.



#### D Confirm the Sample ID entered below is accurate.



#### E Scan Cartridge Barcode



#### F Confirm the Test Information entered below is accurate.



#### G You are running Positive Quality Control for assay [ Xpert Xpress MVP ].



#### H Proceed with steps H-O from the above Section 3 'Testing a Patient Specimen', this time for "quality control" instead of "specimen".

### 7 How to Run External Controls – Positive and Negative Controls

Note: The GeneXpert **Xpress** system must have software version 6.2 or higher to use the Xpert **Xpress** MVP test.

The following external controls are recommended for use with Xpert **Xpress** MVP:

- NATrol™ Vaginal Negative Control, ZeptoMetrix Corporation catalog number NATVNEG-6C
- NATrol™ Vaginal Positive Control, ZeptoMetrix Corporation catalog number NATVPOS-6C

It is recommended that external controls be tested at the frequency noted below.

- Each time a new lot of Xpert **Xpress** MVP kits is received.
- Each time a new shipment of Xpert **Xpress** MVP kits 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 recently).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard Quality Control (QC) procedures.

\* CLIA Waiver: To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at [www.cms.hhs.gov/CLIA](http://www.cms.hhs.gov/CLIA). Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

**IVD** In Vitro Diagnostic Medical Device

#### CORPORATE HEADQUARTERS

904 Caribbean Drive  
Sunnyvale, CA 94089 USA  
TOLL FREE +1.888.336.2743  
PHONE +1.408.541.4191  
FAX +1.408.541.4192

[www.Cepheid.com](http://www.Cepheid.com)  
Cepheid  
904 Caribbean Drive  
Sunnyvale, CA 94089  
USA

#### TECHNICAL SUPPORT

TOLL FREE +1.888.838.3222  
EMAIL [techsupport@cepheid.com](mailto:techsupport@cepheid.com)  
[www.cepheid.com/en\\_US/support/contact-us](http://www.cepheid.com/en_US/support/contact-us)