

Xpert® Mpox

REF **GXMPX-10**

Instructions for Use (IFU)

For Use Under an Emergency Use Authorization (EUA) Only

For Use with GeneXpert® Xpress System (point of care system)

IVD



In Vitro Diagnostic Medical Device

302-9630, Rev. A February 2023

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See Section 25, Revision History for a description of changes.

Xpert® Mpox

For use under the Emergency Use Authorization (EUA) only.

For *In Vitro* Diagnostic Use



1. Proprietary Name

Xpert® Mpox

2. Common or Usual Name

Xpert Mpox

3. Intended Use

The Xpert® Mpox is a real-time PCR test intended for the qualitative detection of DNA from monkeypox virus clade II and non-variola *Orthopoxvirus* DNA in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of mpox by their healthcare provider.

Testing on the GeneXpert Dx and GeneXpert Infinity instruments is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.

Testing on the GeneXpert Xpress (Hub Configuration) instrument is limited to laboratories certified under CLIA that meet requirements to perform high, moderate, or waived complexity tests. Testing on the GeneXpert Xpress (Hub Configuration) instrument is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of monkeypox virus (clade II) and non-variola *Orthopoxvirus* DNA which are generally detectable in human pustular or vesicular lesion specimens during the acute phase of infection. Positive results are indicative of the presence of monkeypox virus (clade II) and/or non-variola *Orthopoxvirus* DNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results obtained with this device do not preclude monkeypox virus (clade II) and/or non-variola *Orthopoxvirus* infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Laboratories within the United States and its territories are required to report test results to the appropriate public health authorities.

The Xpert Mpox is intended for use by trained operators who are proficient in performing a test using either GeneXpert Dx, GeneXpert Infinity and/or Gene Xpert Xpress systems.

The Xpert® Mpox test is only for use under the Food and Drug Administration's Emergency Use Authorization.

4. Summary and Explanation

Monkeypox virus (MPXV) is an enveloped double-stranded DNA virus that belongs to the *Orthopoxvirus* genus of the Poxviridae family. Mpox is a viral zoonotic disease capable of human-to-human transmission. The first human case of mpox was identified in 1970 in the Democratic Republic of the Congo (DRC). The disease is considered endemic to Central and West Africa.¹ Two clades of monkeypox virus have been described; monkeypox virus clade I (formerly Congo-basin) is associated with a higher rate of mortality compared to clade II (formerly West-African).^{1,2}

Monkeypox virus has an incubation period ranging from 5-21 days, initial symptom onset typically last 1-5 days and consists of fever, headache, myalgia, lymphadenopathy, and fatigue before the appearance of vesiculopustular rash lasting approximately 2-3 weeks.³ Human-to-human transmission occurs via direct contact with lesions or bodily fluids, through contaminated fomites, or through respiratory secretions.^{1,3} In the spring of 2022 several cases of mpox, specifically monkeypox virus clade IIb, were identified in non-endemic areas.¹ This was followed by U.S. Department of Health and Human Services declaring mpox as a Public Health Emergency

5. Principle of the Procedure

The Xpert Mpx test is an automated in vitro diagnostic test for the qualitative detection and identification of monkeypox virus (MPXV) clade II DNA and non-variola *Orthopoxvirus* DNA. The Xpert Mpx test is performed on GeneXpert® Instrument Systems.

The GeneXpert Systems automate and integrate sample preparation, nucleic acid extraction and amplification, and detection of the target sequences in simple or complex samples using real-time PCR tests. The systems consist of an instrument, computer, and preloaded software for running tests and viewing the results. The systems require the use of single-use disposable cartridges that hold the real-time PCR reagents and host the real-time PCR process. Because the cartridges are self-contained, cross-contamination between samples is minimized. For a full description of the system, see the *GeneXpert Xpress User's Guide*.

The Xpert Mpx test includes reagents for the detection of MPXV clade II (MPXV target 1 and target 2) and non-variola *Orthopoxvirus* (OPXV, OPXV-E9L NVAR) targets in lesion swab specimens.⁵ A Sample Processing Control (SPC), a Sample Adequacy Control (SAC), and a Probe Check Control (PCC) are also included in the cartridge utilized by the GeneXpert instrument. The SPC is present to control for adequate processing of the sample and to monitor for the presence of potential inhibitor(s) in the real-time PCR reaction. The SPC also ensures that the real-time PCR reaction conditions (temperature and time) are appropriate for the amplification reaction and that the real-time PCR reagents are functional. The SAC reagents detect the presence of a single copy human gene and monitor whether the sample contains human DNA. The PCC verifies reagent rehydration, PCR tube filling, and confirms that all reaction components are present in the cartridge including monitoring for probe integrity and dye stability.

The Xpert Mpx test is designed for use with lesion swabs collected by a health care provider from patients suspected of having mpx.

The specimen is collected and placed into a transport tube containing 3 mL of viral transport medium or Universal Transport Medium (VTM/UTM®). The specimen is briefly mixed by rapidly inverting the collection tube 5 times. Using the supplied transfer pipette, the specimen is transferred to the sample chamber of the Xpert Mpx test cartridge. The GeneXpert cartridge is loaded onto the GeneXpert Instrument System platform, which performs hands-off, automated sample processing, and real-time PCR for detection of viral DNA.

6. Materials Provided

The Xpert Mpx test kit contains sufficient reagents to process 10 specimens or quality control samples. The kit contains the following:

Xpert Mpx Test Cartridges with Integrated Reaction Tubes

10

- Bead 1, Bead 2, Bead 3 and Bead 4 (freeze-dried) 1 of each per cartridge
- Lysis Reagent (Guanidinium Thiocyanate) 1 mL per cartridge
- Binding Reagent 1 mL per cartridge
- Elution Reagent 3.0 mL per cartridge
- Wash Reagent 0.4 mL per cartridge

Disposable 300 µL Transfer Pipettes

2 bags of 12 per kit

Flyer

1 per kit

- Instructions to locate (and import) the Assay Definition File (ADF) and documentation such as the IFU on www.cepheid.com

Quick Reference Instructions

For use with the GeneXpert Xpress System (Hub Configuration) only

1 per kit

Note Safety Data Sheets (SDS) are available at www.cepheid.com or www.cepheidinternational.com under the **SUPPORT** tab.

Note The bovine serum albumin (BSA) in the beads within this product was produced and manufactured exclusively from bovine plasma sourced in the United States. No ruminant protein or other animal protein was fed to the animals; the animals passed ante- and post- mortem testing. During processing, there was no mixing of the material with other animal materials.

7. Storage and Handling

- Store the Xpert Mpx test cartridges at 2–28 °C until the expiration date provided on the label.
- Do not open a cartridge until you are ready to perform testing.
- Do not use cartridges that have passed the expiration date.
- Do not use a cartridge that is wet or has leaked.

8. Materials Required but Not Provided

- Nylon flocked swab (Copan P/N 502CS01, or equivalent)
- Viral transport medium/Universal transport medium (VTM/UTM), 3 mL (Copan P/N 3C047N or equivalent)
- GeneXpert Xpress System (Hub configuration): GeneXpert Xpress instrument, GeneXpert Hub with proprietary GeneXpert Xpress Software Version 6.1 or higher, GeneXpert Hub with integrated computer, touchscreen monitor and barcode scanner, external CD drive, Getting Started Guide, and GeneXpert Xpress System User's Guide
- Printer: If a printer is required, contact Cepheid Technical Support to arrange for the purchase of a recommended printer.

9. Materials Available but Not Provided

External controls are available from ZeptoMetrix® (Buffalo, NY).

- External Positive Control: Catalog # NATMPXVPOS-6C
- External Negative Control: Catalog # NATMPXVNEG-6C

10. Warnings and Precautions

10.1 General

- For *in vitro* diagnostic use.
- For use under emergency authorization only.
- For prescription use only.
- This product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not from any other virus or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including *in vitro* diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner..
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be treated with standard precautions.
- Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention⁶ and the Clinical and Laboratory Standards Institute.⁷
- Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this test with other specimen types or samples has not been evaluated.
- Follow your institution's safety procedures for working with chemicals and handling biological samples.
- Do not allow Lysis Reagent, which contains guanidinium thiocyanate, to contact sodium hypochlorite (bleach). This mixture can produce a highly toxic gas.
- Testing of lesion swab specimens using the Xpert Mpx test run on the GeneXpert Xpress System (Hub Configurations), is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation, or laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity testing.

- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific disposal. If country or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

10.2 Specimens

- Specimen collection and handling procedures require specific training and guidance.
- For collection and transport of lesion swab specimens, use viral transport medium/universal transport medium (Copan P/N 3C047N, or equivalent) and nylon flocked swab (Copan P/N 502CS01, or equivalent).
- Specimens must be collected and tested before the expiration date of the viral transport medium (VTM/UTM) tube.
- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Section 12). Specimen stability under shipping conditions other than those recommended has not been evaluated.
- Proper sample collection, storage, and transport are essential for correct results.

10.3 Test/Reagent

- The test has been validated using Cepheid GeneXpert Xpress (Hub configuration) software version 6.1. Cepheid will validate future software versions for use with the Xpert Mpx test.
- Do not substitute Xpert Mpx test reagents with other reagents.
- Do not open the Xpert Mpx test cartridge lid except when adding sample.
- Do not use a cartridge that has been dropped after removing from the kit or shaken after the cartridge lid has been opened. Shaking or dropping the cartridge after opening the lid may yield false or non-determinate results.
- Do not place the sample ID label on the cartridge lid or on the barcode label.
- Do not use a cartridge with a damaged barcode label.
- Do not use a cartridge that has a damaged reaction tube.
- Do not use reagents beyond their expiry date.
- Each single-use Xpert Mpx test cartridge is used to process one test. Do not reuse spent cartridges.
- Each single-use disposable pipette is used to transfer one specimen. Do not reuse disposable pipettes.
- Do not use a cartridge if it appears wet or if the lid seal appears to have been broken.
- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.
- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 1:10 dilution of freshly prepared household chlorine bleach. Final active chlorine concentration should be 0.5%. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. For equipment, follow the manufacturer's recommendations for decontamination of equipment.

11. Chemical Hazards^{8,9}

- **Signal Word: WARNING**
- **UN GHS Hazard Statements**
 - Harmful if swallowed
 - May be harmful in contact with skin
 - Causes eye irritation
- **UN GHS Precautionary Statements**
 - **Prevention**
 - Wash hands thoroughly after handling.
 - **Response**
 - If skin irritation occurs: Get medical advice/attention.

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- If eye irritation persists: Get medical advice/attention.
- Call a POISON CENTER or doctor/physician if you feel unwell.

12. Specimen Collection, Transport and Storage

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 result. See Section 12.1 for lesion swab collection procedure. Lesion swab specimens can be stored at room temperature (15–30 °C) for up to 48 hours in viral transport medium (VTM/UTM) until testing is performed on the GeneXpert Instrument Systems. Alternatively, lesion swab specimens can be stored refrigerated (2–8 °C) up to seven days in viral transport medium (VTM/UTM) until testing is performed on the GeneXpert Instrument Systems.

Refer to the CDC Guidelines for Collecting and Handling Specimens for Mpox Testing

<https://www.cdc.gov/poxvirus/Mpox/clinicians/prep-collection-specimens.html>

12.1 Lesion Swab Collection Procedure

1. Using a sterile swab apply firm pressure to the lesion and swipe the swab back and forth at least 2-3 times before rotating the swab and repeating using the other side of the swab. If the lesion ruptures while swabbing, ensure to collect the lesion fluid (See Figure 1).

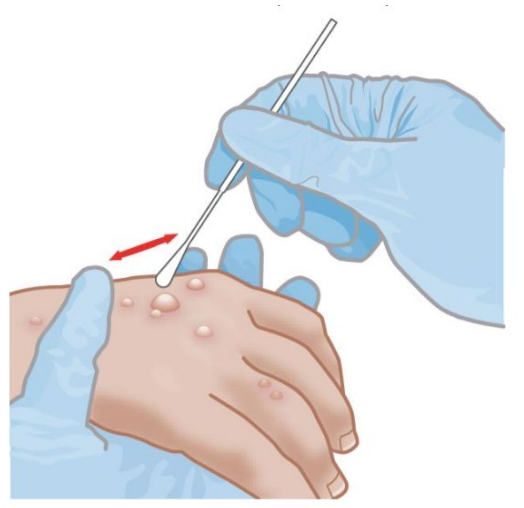


Figure 1. Lesion Swab Collection

2. Remove and place the swab into the tube containing 3 mL of viral transport medium (VTM/UTM). Break swab at the indicated break line and cap the specimen collection tube tightly.

13. Procedure

13.1 Starting the Hub Configuration

Important Before you start the test, make sure that:

- The system is running the correct GeneXpert Xpress software version shown in the section - Materials required but not provided
- The correct assay definition file is imported into the software.

This section lists the basic steps for running the test. For detailed instructions, see the *GeneXpert Xpress System User's Guide*.

Note The steps you follow can be different if the system administrator changed the default workflow of the system.

1. Turn on the GeneXpert Xpress instrument (in two or four modules configuration).
2. Turn on the Hub computer. The **Windows Lock** screen displays.
3. Swipe up to continue. The **Windows Password** screen displays.
4. Touch **Password** to display the **keyboard**, then type your Windows password.
5. Touch the **arrow** button at the right of the password entry area. The GeneXpert Xpress Software starts, and a **login** screen displays.
6. If enabled, you may log in by scanning a barcode on your institutional ID, using the barcode scanner (located behind the right side of the touchscreen). Then proceed to Step 9. Otherwise, follow the steps below to login manually.
7. Enter your Username and Password (the virtual keyboard displays once you touch the entry fields).
8. Touch the **X** in the upper right of the virtual keyboard. The keyboard disappears, and the **LOGIN** button displays at the bottom of the screen. Touch the **LOGIN** button to continue.
9. The **Database Maintenance Reminder** screen and the **Archive Tests Reminder** dialog boxes may display, depending on your system configuration. For more information, see the *GeneXpert Xpress System User's Guide*.

13.2 Starting a Test

Note Instructions showing how to prepare the sample and the cartridge are shown on-screen in videos and in the following procedure.

Important Start the test within 30 minutes of adding the sample to the cartridge.

1. Put on a new pair of gloves if performing a new test.
2. Touch the **NEW TEST** button on the **Home** screen (see Figure 2).

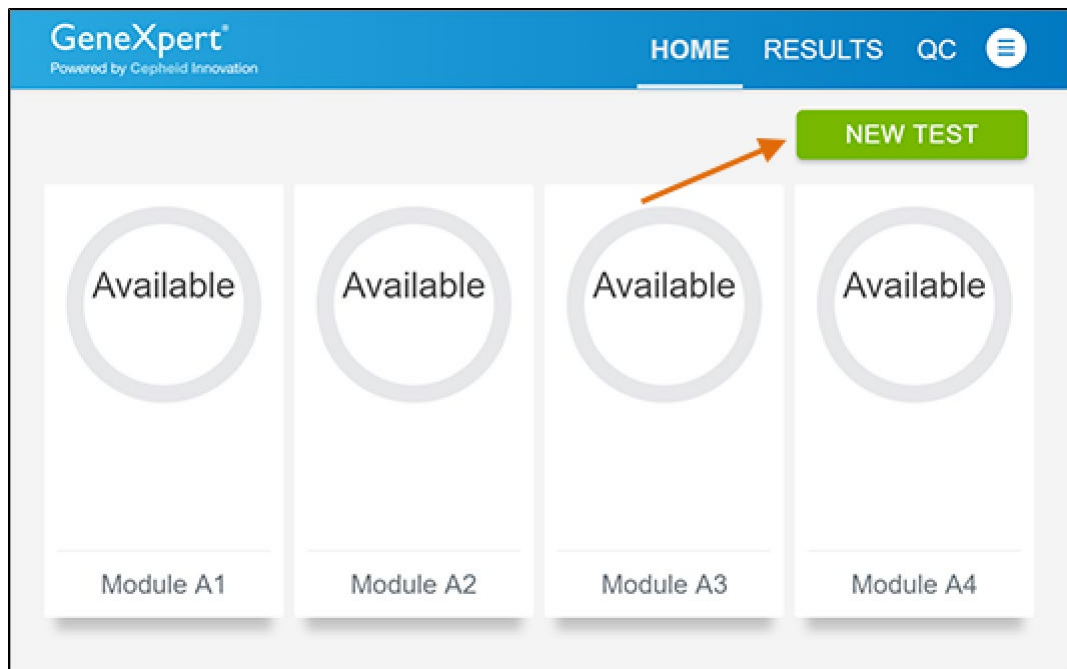


Figure 2. Home Screen

3. Check that the specimen transport medium tube cap is closed.
If Patient Information is configured by an administrator, then the **Patient Information** screen displays (see Figure 3). If Patient Information is not configured, the **Sample ID** screen displays.

4. Skip to Preparing the Specimen and Cartridge if the **Sample ID** screen displays.

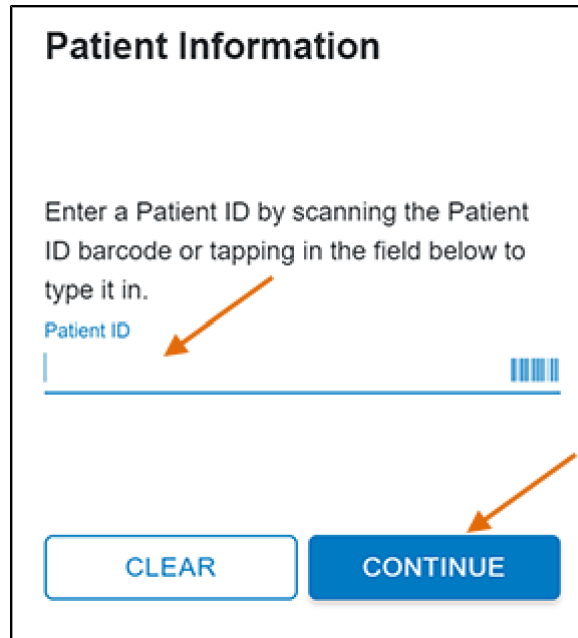


Figure 3. Patient Information Screen

5. Scan patient ID barcode or manually enter the Patient ID.
6. Touch **CONTINUE**. The Confirm **Patient Information** screen displays.
7. Verify the Patient ID and touch **CONFIRM**. The **Sample ID** screen displays.

13.3 Preparing the Specimen and Cartridge

1. Obtain the following items: Xpert Mpxx test cartridge, 300 μ L transfer pipette (provided), and an appropriately collected and labeled test sample.
2. Remove a cartridge and a transfer pipette from the cartridge kit box.
3. Inspect the cartridge for damage. If damaged, do not use it.
4. Check that the transport medium tube cap is closed. Scan Sample ID barcode or manually enter the Sample ID for patient specimen.
5. Touch **CONTINUE**. The **Confirm Sample ID** screen displays.
6. Verify the Sample ID and touch **CONFIRM**. The **Scan Cartridge Barcode** screen displays (see Figure 4).

In the following steps, keep the cartridge upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

Note

If the barcode on the Xpert Mpxx cartridge does not scan or scanning the barcode results in an error message stating that the cartridge is expired, then repeat the test with a new cartridge.

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, contact Cepheid Technical Support

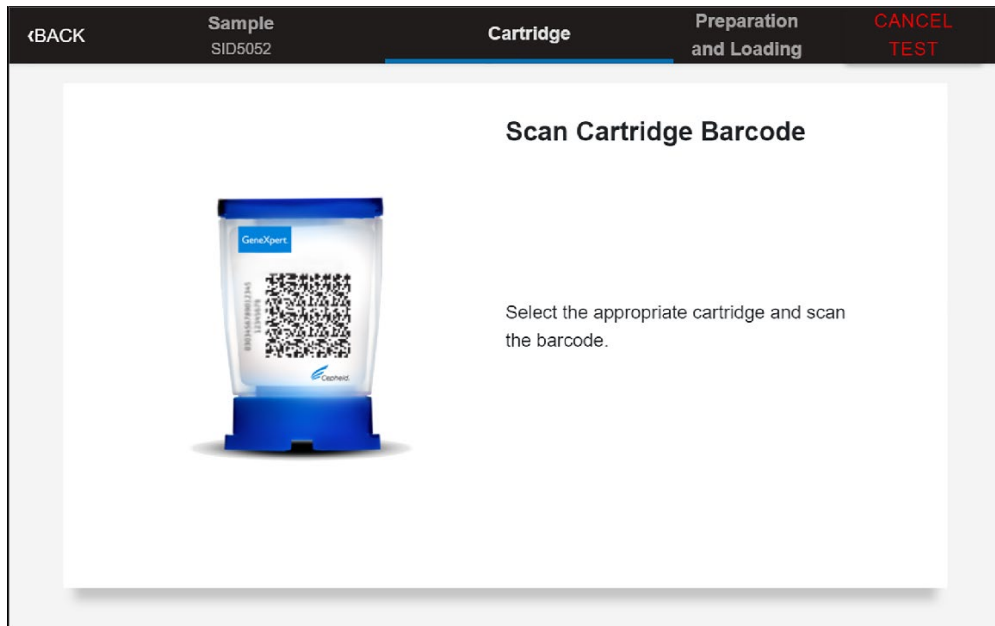


Figure 4. Scan Cartridge Barcode Screen

7. Select the appropriate cartridge with the sample and scan the cartridge barcode. After scanning, the **Confirm Test Information** screen displays.
8. Verify that the correct cartridge has been scanned and that the assay name matches the name of the assay on the cartridge.
9. Touch **CONFIRM**. Depending on your configuration, the **Enter Credentials to Continue** screen may display (see Figure 5). If enabled, you may log in by scanning your institutional ID. Otherwise, manually enter your User Name and Password and touch **LOGIN** to continue.

Enter Credentials to Continue

User Name _____

Password _____

LOGIN

[Scan Your ID Card](#)

Figure 5. Enter Credentials to Continue Screen

10. The Cartridge screen displays (see Figure 6)



Figure 6. Cartridge Preparation Screen

11. A video will begin. The video is available to view for additional cartridge preparation. The video will repeat. Touch the **CONTINUE** button to exit video.
12. Mix specimen by rapidly inverting the specimen transport tube 5 times. Open the lid on the specimen transport tube.
13. Open the cartridge lid by lifting the front of the cartridge lid.
14. Remove the transfer pipette from the wrapper.

Note Do not place unwrapped pipette on the workbench.

15. Squeeze the top bulb of the transfer pipette completely and then place the pipette tip in the specimen transport tube (see Figure 7).

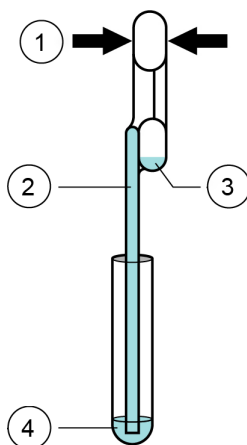


Figure 7. Transfer Pipette

Number	Description
1	Squeeze here
2	Pipette
3	Overflow Reservoir Bulb
4	Sample

16. Slowly release the top bulb of the pipette to fill the pipette before removing from the tube. After filling pipette, excess sample can be seen in the overflow reservoir bulb of the pipette (see Figure 7). Check that the pipette does not contain bubbles.

17. To transfer the patient specimen to the cartridge, squeeze the top bulb of the transfer pipette completely again to empty the contents of the pipette into the large opening (Sample Chamber) of the cartridge shown in Figure 8. Dispose of the used pipette.

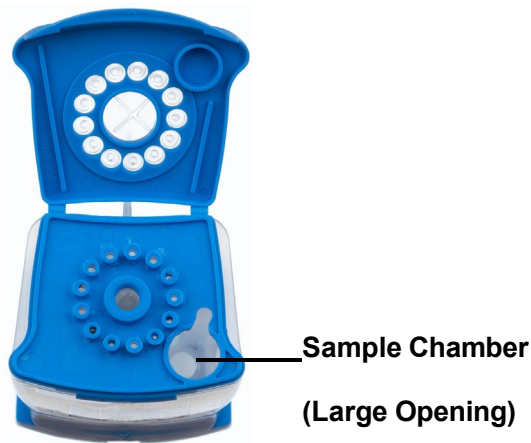


Figure 8. Xpert Mpxx Cartridge (Top View)

Note Dispense the entire volume of liquid into the Sample Chamber. False negative results may occur if insufficient sample is added to the cartridge.

18. Close the cartridge lid.
19. Go to Section 13.5.

13.4 Running External Controls

External controls (described in Section 9) are available but not provided.

Note The positive external control should provide a "MPXV Clade II Detected" result. If a different result is obtained, repeat the positive external control run with a new positive control dilution.

Note The negative external control should provide a "MPXV Clade II NOT DETECTED, Non-variola OPXV NOT DETECTED" result. If a different result is obtained, repeat the external control run with a new vial.

Note If the expected results for the external control materials are not obtained upon repeat, contact Cepheid Technical Support.

When to Run External Controls – Positive and Negative Controls

Use external controls in accordance with local, state, and federal accrediting organizations as applicable as well as according to the frequencies indicated below.

- Each time a new shipment of Xpert Mpxx 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.

To prepare the controls:

Important Change Gloves and clean workstation between and after running the controls.

Important Dilution of the Positive Control is necessary to confirm the performance of the test. Run the Positive Control then run the Negative Control.

Positive Control (NATMPXVPOS-6C) must be diluted prior to use as follows:

1. Label a 3 ml VTM/UTM tube “Diluted Positive Control”. Uncap the tube.
2. Using an exact volume transfer pipette provided in the kit, add one draw (300 µl) of the (undiluted) Positive Control material to the VTM/UTM tube.
3. Recap the tube tightly and mix by inverting the tube 5 times.
4. Open the cartridge lid.
5. Using a **new exact volume transfer pipette** provided in the kit, transfer one draw (300 µl) of the diluted Positive Control material into the large opening (Sample Chamber) in the cartridge shown in Figure 8.
6. Close the cartridge lid.
7. Touch the **QC** button on the **HOME** screen (see Figure 9).
8. Proceed to Step 13 (**Starting the Test**).

Negative Control (NATMPXVNEG-6C) is ready to use directly. No additional preparation steps are necessary.

9. Using a new exact volume transfer pipette provided in the kit, add one draw (300 µl) of the Negative Control material into the large opening (Sample Chamber) in the cartridge shown in Figure 8.
10. Close the cartridge lid.
11. Touch the **QC** button on the **HOME** screen (see Figure 9).
12. Proceed to Step 13 (**Starting the Test**).

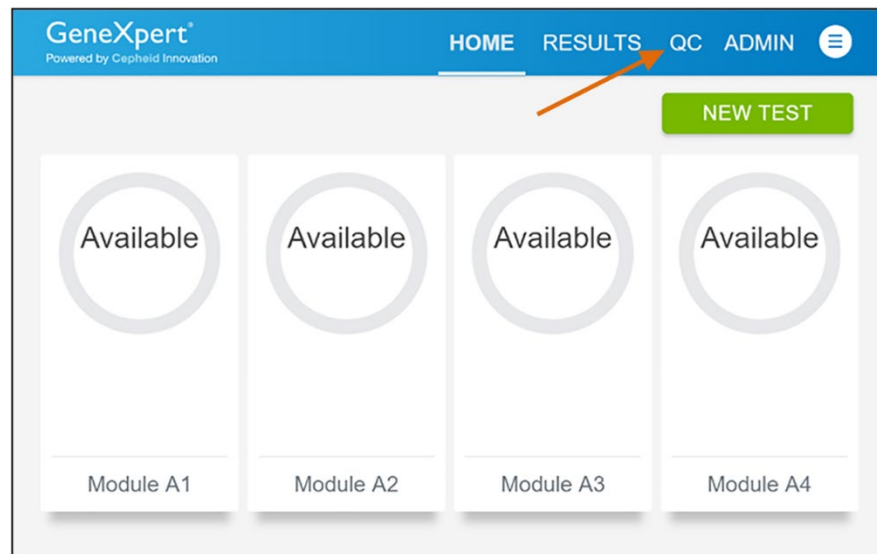


Figure 9. Home Screen

Starting the Test

13. The **Quality Control** screen displays **QUALITY CONTROL SUMMARY**, **RUN QC POSITIVE TEST**, **RUN QC NEGATIVE TEST**, and **RUN PROFICIENCY TEST** options. Touch **RUN QC POSITIVE TEST** or **RUN QC NEGATIVE TEST** options to run external control samples (Figure 10).



Figure 10. Quality Control Screen

14. The Sample ID displays.
15. Enter the Sample ID, by typing Positive Control or Negative Control or scan the Sample ID barcode.
16. Touch **CONTINUE**. The **Confirm Sample ID screen** displays.
17. Verify the Sample ID and touch **CONFIRM**. The **Scan Cartridge Barcode** screen displays (see Figure 11).

Note In the following steps, keep the cartridge upright when handling or scanning. Do not rotate or tip the cartridge, because damage to the contents or injury to personnel may occur.

If the barcode on the Xpert Mpx cartridge does not scan or scanning the barcode results in an error message stating that the cartridge is expired, then repeat the test with a new cartridge. If you have scanned the cartridge barcode in the Xpress software and the assay definition file is not available, a screen will display indicating the assay definition file is not loaded on the system. If this screen displays, contact Cepheid Technical Support.

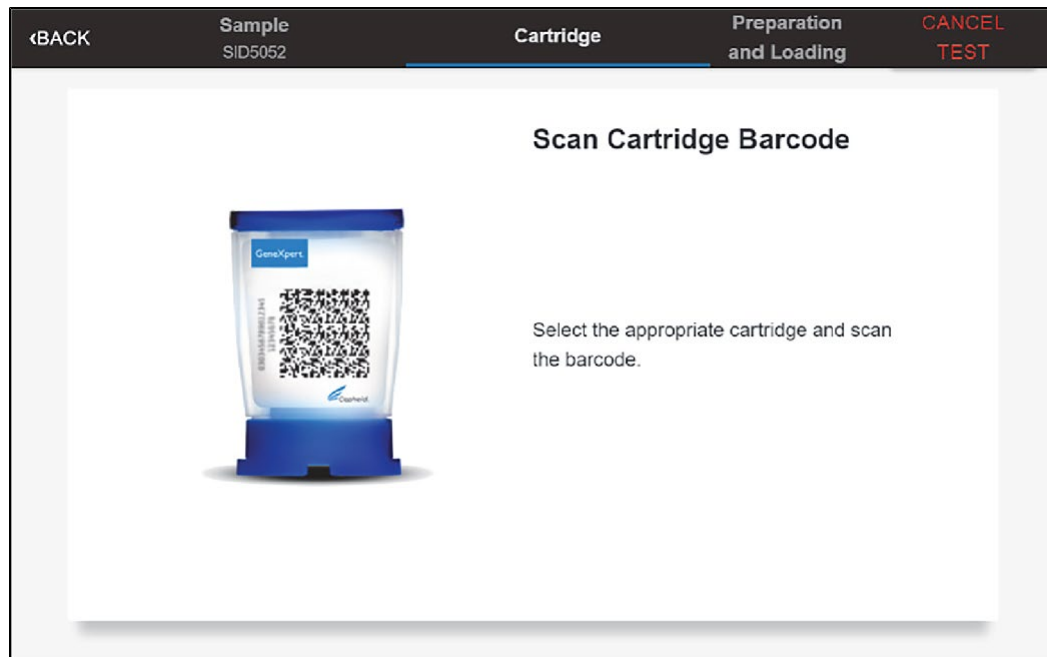


Figure 11. Scan Cartridge Barcode Screen

18. Confirm the test information is correct, then touch **CONFIRM**.
19. The confirm quality control test screen shows up. Touch **CONTINUE**.
20. A video will begin. The video is available to view for additional cartridge preparation. The video will repeat. Touch the **CONTINUE** button to exit video.
21. Go to Section 13.5.

13.5 Loading the Cartridge

1. Touch the **CONTINUE** button on the **Cartridge Preparation** screen. The **Load Cartridge into Module** screen displays (see Figure 12).
2. Open the module door with the flashing green light.



Figure 12. Load Cartridge into Module Screen

3. Load the cartridge with the barcode facing the operator on the cartridge bay platform. Do not try to insert the cartridge past the cartridge bay platform.
4. Close the door until it clicks. The green light will stop blinking and the test starts.
5. When the cartridge is loaded, the **Test Loading** screen displays, followed by the **Test Running** screen showing that the test is running. A circular graphic indicator at the right indicates the progress of the test and the time remaining until a test result is available.
6. Close the door. The test starts and the green light stops blinking. When the test is finished, the light turns off.
7. Wait until the system releases the door lock before opening the module door, then remove the cartridge.
8. Dispose of the used cartridges in the appropriate specimen waste containers according to your institution's standard practices.

Note While a test is running, you can start another test. See Section 13.6, Start a New Test While a Test is Running.

Note Do not turn off or unplug the instrument while a test is in progress. Turning off or unplugging the GeneXpert Xpress instrument or Hub stops the test. If necessary, touch the **STOP TEST** button to cancel a test while it is loading or running.

9. Touch **HOME** to go back to the **Home** screen.
10. To log out, touch the **User Menu** icon, then select **Logout**.

13.6 Starting a New Test while a Test is Running

You can start a new test while another test is in progress.

1. Touch the **HOME** button on the **Test Running** screen.
2. For a new user log in, touch the **User Menu** icon to log in.

3. Repeat the steps in Section 13.2, Starting a Test, Section 13.3, Preparing the Specimen, Section 13.4 and Loading the Cartridge, Section 13.5.
4. After a second test has started, touch the **HOME** button. The status of both tests displays. The **Home** screen displays the module(s) in use with a circular graphic indicator around each test and Patient Identification below the module graphic (see Figure 13).

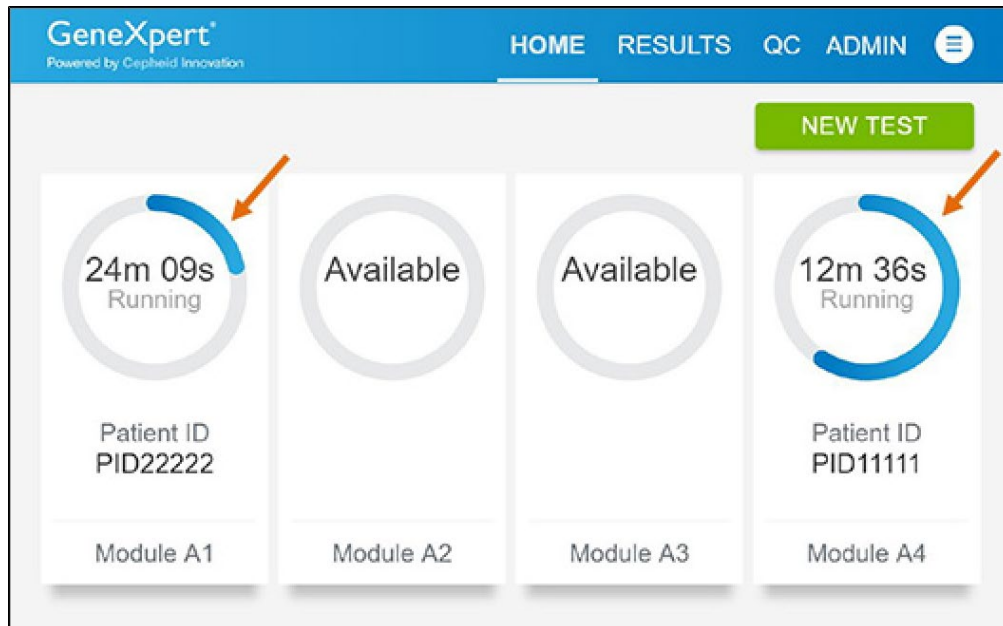


Figure 13. Home Screen showing Two Tests Running

13.7 Viewing Completed Tests

1. When a test is completed, touch **COMPLETE View Result** (see Figure 14).
2. Open the module door, remove the used cartridge, and properly dispose of the cartridge according to your institution's policy.

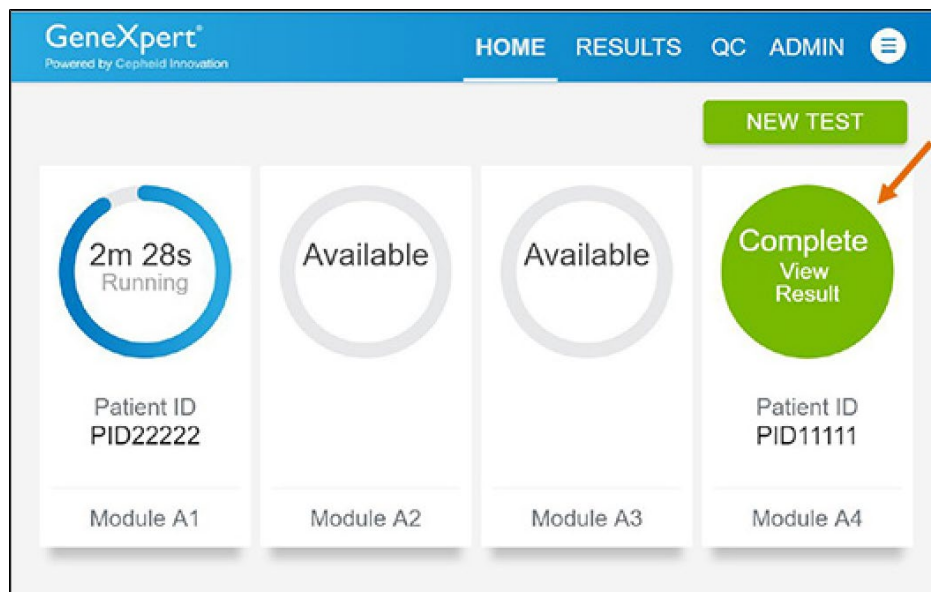


Figure 14. Home Screen with One of Two Tests Completed

14. Quality Control

14.1 Internal Controls

Each test includes a Sample Processing Control (SPC), a Sample Adequacy Control (SAC), and a Probe Check Control (PCC).

- **Sample Processing Control (SPC)**—Ensures the sample was processed correctly. The SPC verifies that sample processing is adequate. Additionally, this control detects sample-associated inhibition of the real-time PCR test, ensures the PCR reaction conditions are appropriate for the amplification reaction. The SPC should be positive in a negative sample and can be negative or positive in a positive sample. The SPC passes if it meets the assigned acceptance criteria.
- **Sample Adequacy Control (SAC)**—Detects human cells or human DNA present in the sample. This test includes primers and probe for the detection of a single copy human gene. The SAC signal is only to be considered when the sample is negative for both MPXV and OPXV analytes and SPC is positive. A negative SAC indicates that no human cells are present in the sample due to insufficient mixing of the sample or because of an inadequately collected sample.
- **Probe Check Control (PCC)**—Before the start of the PCR reaction, the GeneXpert System measures the fluorescence signal from the probes to monitor bead rehydration, reaction tube filling, and probe integrity. The PCC passes if it meets the assigned acceptance criteria.

14.2 External Controls

Use external controls in accordance with local, state and federal accrediting organizations as applicable as well as according to the frequency indicated below.

If the expected results for the external control materials are not obtained, repeat the external controls, prior to releasing patient

results. If the expected results for the external control material are not obtained upon repeat, contact Cepheid Technical Support.

When to Run External Controls – Positive and Negative Controls

The following external controls are recommended for use with the Xpert Mpox test.

- ZeptoMetrix Catalog # NATMPXVPOS-6C (positive external controls)
- ZeptoMetrix Catalog # NATMPXVNEG-6C (negative external controls)

Please see instructions in Section 13.4 on external control testing workflow and recommended testing frequency.

15. Interpretation of Results

The results are interpreted automatically by the GeneXpert System and are clearly shown in the View Results window. The Xpert Mpox test provides test results for the mpox and non-variola *Orthopoxvirus* targets, SAC, and the SPC according to the algorithms shown in Table 1.

Table 1. Xpert Mpox Result Algorithm

Result	MPXV	OPXV	SAC	SPC
MPXV Clade II DETECTED	+	+/-	+/-	+/-
Non-Variola OPXV DETECTED	-	+	+/-	+/-
MPXV Clade II NOT DETECTED, Non-Variola OPXV NOT DETECTED	-	-	+	+
INSTRUMENT ERROR or NO RESULT - REPEAT TEST	-	-	-	+/-
	-	-	+/-	-

See Table 2 to interpret test results statements for the Xpert Mpox test.

Table 2. Xpert Mpxv Result Interpretation

Result	Interpretation
MPXV Clade II DETECTED	<p>Monkeypox virus Clade II DNA DETECTED</p> <p>This specimen is POSITIVE for monkeypox virus clade II.</p> <p>Laboratories should notify appropriate Federal, State, or local public health agencies of the test results in accordance with applicable laws.</p>
Non-Variola OPXV DETECTED	<p>Non-Variola <i>Orthopoxvirus</i> Viral DNA DETECTED</p> <p>This specimen is POSITIVE for non-variola <i>Orthopoxvirus</i> DNA.</p> <p>Low levels of monkeypox viral DNA in a specimen may, on rare occasions, result in monkeypox virus clade II DNA Not Detected and non-variola <i>Orthopoxvirus</i> DNA Detected. This result may occur in the case of low monkeypox viral DNA concentrations at levels near or below the limit of detection, or may indicate another <i>Orthopoxvirus</i> infection although no other known orthopoxviruses are currently circulating in the United States.</p> <p>If clinically indicated, consider collecting another specimen.</p> <p>Laboratories should notify appropriate Federal, State, or local public health agencies of the test results in accordance with applicable laws.</p>
MPXV Clade II NOT DETECTED, Non-Variola OPXV NOT DETECTED	<p>Monkeypox Clade II Viral DNA and Non-Variola <i>Orthopoxvirus</i> Viral DNA not detected</p> <p>This specimen is NEGATIVE for monkeypox virus clade II DNA. If clinically indicated, consider collecting another specimen.</p> <p>Laboratories should notify appropriate Federal, State, or local public health agencies of the test results in accordance with applicable laws.</p>
NO RESULT – REPEAT TEST	<p>If the result is NO RESULT – REPEAT TEST, repeat the test with a new cartridge. If the result of the retest is NO RESULT – REPEAT TEST, collect new specimen and repeat the test.</p>
INSTRUMENT ERROR	<p>Result is an instrument error. Touch CLEAR ERROR and follow the onscreen instructions. When the Home screen appears, repeat the test using a new cartridge.</p>
<p>If the results of the viral targets (monkeypox virus clade II or non-variola <i>Orthopoxvirus</i>) are positive, the test can be considered valid regardless of the results for the SPC and SAC.</p>	

The Xpert Mpxv test includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens if the signal from the target nucleic acid reaches a predetermined threshold before the full 45 PCR cycles have been completed. When viral titers are high enough to initiate the EAT function, the SPC, SAC and/or other target amplification curves may not be seen, and their results may not be reported.

16. Retests

16.1 Reasons to Repeat the Test

If any of the test results mentioned below occur, repeat the test according to the instructions in Section 15.2,

- An **INSTRUMENT ERROR** result could be due to, but not limited to, Probe Check Control failed, or the maximum

pressure limits were exceeded.

- A **NO RESULT-REPEAT TEST** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress or a power failure occurred.

If an External Control fails to perform as expected, repeat the external control test and/or contact Cepheid Technical Support for assistance.

Retest Procedure

To retest a non-determinate result (**NO RESULT-REPEAT TEST, INSTRUMENT ERROR**), use a new cartridge.

Use the leftover sample from the original specimen transport tube or new external control tube (refer to the instructions in section 13.7 Running External Controls, to dilute the Positive External Control prior to use).

1. Put on a clean pair of gloves. Obtain a new Xpert Mpox cartridge and a new transfer pipette.
2. Check the specimen transport tube or external control tube is closed.
3. Mix the sample by rapidly inverting the specimen transport medium tube or external control tube 5 times. Open the cap on the specimen transport tube or external control tube.
4. Open the cartridge lid by lifting the front of the cartridge lid.
5. Using a clean transfer pipette (supplied), transfer sample (one draw) to the sample chamber with the large opening in the cartridge.
6. Close the cartridge lid

17. Limitations

- Xpert Mpox has been evaluated only for use in combination with the recommended external controls – External Positive NATMPXVPOS-6C and External Negative Control NATMPXVNEG-6C (ZeptoMetrix (Buffalo, NY), for use on the GeneXpert Dx, GeneXpert Xpress (hub configuration) and GeneXpert Infinity Systems using the procedures provided in these instructions for use only. Modifications to these procedures may alter the performance of the test.
- Xpert Mpox has only been validated for use with specimens collected from lesions using a synthetic swab (Copan P/N 502CS01, or equivalent) which is placed into UTM or VTM. Test performance has not been validated for use with other collection media and/or specimen types. Use of other collection media and/or specimen types may lead to false positive, false negative or invalid results.
- A specimen with a result of “MPXV Clade II NOT DETECTED, Non-Variola OPXV NOT DETECTED” does not preclude monkeypox virus infection and should not be used as the sole basis for treatment or other patient management decisions. Collection of multiple specimens (and specimens collected at different time points) from the same patient may be necessary to detect the virus.
- Reliable results depend on proper sample collection, storage, and handling procedures.
- Detection of monkeypox clade II viral DNA or non-variola *Orthopoxvirus* viral DNA is dependent on the number of copies present in the specimen. Detection of monkeypox clade II viral DNA or non-variola *Orthopoxvirus* viral DNA may be affected by sample collection methods (e.g., if a specimen is improperly collected, transported, or handled), patient factors (e.g., presence, type, and duration of symptoms), stage of infection (e.g., if collected too early or too late in the course of illness) and/or presence of interfering substances.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of monkeypox virus and their prevalence, which may change over time. Results from the Xpert Mpox test should be interpreted in the context of other available laboratory and clinical data.
- As with any molecular test, mutations within the target regions of Xpert Mpox could affect primer and/or probe binding resulting in failure to detect the presence of viral DNA.
- Negative results do not preclude monkeypox virus clade II and/or non-variola *Orthopoxvirus* infection and should not be used as the sole basis for treatment or other patient management decisions.
- False negative results may arise from improper sample collection, degradation of the viral DNA during shipping/storage, the presence of PCR inhibitors, and/or mutation(s) in the monkeypox virus and/or non-variola *Orthopoxvirus*.
- False positive results may arise from contamination during specimen handling or preparation, or between patient specimens.

- Results from the Xpert Mpox test should be interpreted by a trained professional in conjunction with the patient’s history and clinical signs/symptoms and epidemiological risk factors.
- Viral nucleic acid may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.
- This test has been evaluated for use with human specimen material only.
- The test performance was established during the 2022 mpox outbreak in the US. The performance may vary depending on the prevalence and population tested.
- This test is a qualitative test and does not provide the quantitative value of detected organism present.
- This test has not been evaluated for patients without signs and symptoms of monkeypox virus clade II infection.
- This test has not been evaluated for monitoring treatment of monkeypox virus clade II and/or non-variola *Orthopoxvirus* infection.
- This test has not been evaluated for screening of blood or blood products for the presence of monkeypox virus clade II and/or non-variola *Orthopoxvirus*.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described could lead to erroneous results.
- This test has not been evaluated for immunocompromised individuals.
- The current US outbreak of mpox is caused by monkeypox virus clade II. A positive result for non-variola *Orthopoxvirus* most likely represents the presence of monkeypox virus clade II, although there is a small possibility that this result could represent the presence of a different non-variola *Orthopoxvirus* detected by the non-variola *Orthopoxvirus* primer and probe set. If clinical concern for infection with an *Orthopoxvirus* other than monkeypox, healthcare providers should contact the jurisdictional public health authorities for guidance.
- Based on an *in silico* analysis, some vaccinia, cowpox and camelpox virus strains have genomic sequences containing two or more mismatches with the OPXV target primers and probe (Table 9 of Inclusivity Section below), and therefore may not be detected by the Xpert Mpox test. Wet-testing of contrived low-positive samples spiked with genomic DNA from one strain of vaccinia virus demonstrated detection of the non-variola OPXV target.
- Results from an *in silico* analysis show potential for Xpert Mpox test cross-reactivity with variola, cowpox or ectromelia viruses that could result in a false “MPXV Clade II DETECTED” result. If variola (smallpox), cowpox and ectromelia infection is suspected, the provider is advised to contact the local health department immediately for patient evaluation.
- The impacts of specific vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs on the performance of this test have not been evaluated.
- Detection of the Sample Adequacy Control (SAC) indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of monkeypox virus (clade II) and/or non-variola *Orthopoxvirus*. All MPXV and non-variola OPXV-negative specimens must have a positive Sample Adequacy Control result to be identified as valid negatives.

18. Conditions of Authorization for Laboratory and Patient Care Settings

The Cepheid Xpert Mpox Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/monkeypox-emergency-use-authorizations-medical-devices>

To assist clinical laboratories and/or Patient Care Settings using the Xpert Mpox (referred to in the Letter of Authorization as “Your Product”), the relevant Conditions of Authorization are listed below.

- Authorized laboratories^a that receive Xpert Mpox must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using Xpert Mpox must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories using Xpert Mpox must include with test result reports all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using Xpert Mpox must use Xpert Mpox as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials

required to use Xpert Mpox are not permitted.

- Authorized laboratories must have a process in place to track adverse events and report to Cepheid Customer Technical Support 1-888-838 3222 and to FDA pursuant to 21 CFR Part 803.
- All operators using Xpert Mpox must be appropriately trained in performing and interpreting the results of Xpert Mpox, use appropriate personal protective equipment when handling Xpert Mpox, and use Xpert Mpox in accordance with the authorized labeling.
- Cepheid, authorized distributors, and authorized laboratories must collect information on the performance of Xpert Mpox and report any significant deviations from the established performance characteristics of Xpert Mpox of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA Reporting@fda.hhs.gov). In addition, authorized distributor(s) and authorized laboratories report to Cepheid (+1 888 838 3222 or techsupport@cepheid.com).
- Cepheid, authorized distributors, and authorized laboratories using Xpert Mpox must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

^a The letter of authorization refers to “authorized laboratories” as follows: (1) Testing on the GeneXpert Dx and GeneXpert Infinity instruments is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the regulatory requirements to perform high or moderate complexity tests, and (2) Testing on the GeneXpert Xpress (Hub Configuration) instruments is limited to laboratories certified under CLIA that meet requirements to perform high, moderate, or waived complexity tests. Testing is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

19. Performance Characteristics

19.1 Clinical Performance

The performance of the Xpert Mpox test was evaluated using frozen, retrospective clinical lesion swab specimens in either universal transport medium (UTM) or viral transport medium (VTM) collected from patients suspected of mpox. All of the clinical specimens were previously characterized as positive or negative for non-variola *Orthopoxvirus* using an FDA cleared real-time-PCR assay. A total of 31 positive specimens, including four low positive specimens (4/31, 12.9%), and 30 negative specimens were tested on the Xpert Mpox test in a double-blinded fashion in a point of care setting by untrained users.

Positive Percent Agreement (PPA), Negative Percent Agreement (NPA) were determined by comparing the results of the Xpert Mpox test relative to the known results from the FDA cleared real-time-PCR test.

The Xpert Mpox test demonstrated a PPA and NPA of 100.0% and 96.6% for MPXV, respectively (Table 3). The initial non-determinate rate for the Xpert Mpox test was 6.5% (4/61). On repeat testing, all four specimens yielded valid results. The final non-determinate rate for the Xpert Mpox test was 0.0% (0/61).

Table 3. Xpert Mpox Test Performance Results Using Lesion Swab Specimens

		FDA cleared real-time-PCR assay		
		Positive	Negative	Total
Xpert Mpox	Positive	31	1	32
	Negative	0	29	29
	Total	31	30	61
PPA		100% (95% CI: 100%-100%)		
NPA		96.6% (95% CI: 96.6-96.7%)		

19.2 Xpert Mpox Test Performance Around LoD

A total of 20 contrived samples were tested in a blinded fashion by untrained users to evaluate the performance of the Xpert Mpox test near the LoD. At the same point of care site where testing of clinical specimens was conducted, contrived samples were integrated into the workflow along with clinical specimens. The 20 contrived swab samples included 10 monkeypox positive contrived swab samples at $\leq 2x$ LoD and 10 negative samples in a negative clinical buccal swab matrix. Overall agreement with expected results was 100% for monkeypox virus positive and negative samples.

20. Analytical Performance

20.1 Analytical Sensitivity (Limit of Detection)

The Limit of Detection (LoD) is the lowest concentration (genomic copies, GC/mL) per sample that can be reproducibly distinguished from negative samples with 95% confidence or the lowest concentration at which at least 19 of 20 replicates are positive. LoD studies for the Xpert Mpx test were conducted using heat-inactivated monkeypox virus (USA/MA001/2022, Lineage B.1, clade IIb) and vaccinia virus gDNA (Modified Vaccinia Virus Ankara). The concentration of the monkeypox virus stock was 4.23×10^4 GC/mL as determined by digital droplet (dd) PCR. The concentration of vaccinia virus gDNA stock was 1.82×10^7 GC/mL as provided by the manufacturer. The monkeypox virus and vaccinia virus gDNA were serially diluted in pooled negative matrix (PNM), which is made of negative human buccal swab material in universal transport media (UTM-RT Virus Specimen Collection Kit, Copan). Fifty microliters of the spiked PNM was pipetted onto a dry sterile swab, and the wetted swab was then inserted into 3 ml of UTM and tested on the Xpert Mpx test for preliminary LoD and LoD confirmation studies. The confirmed LoD values for both MPXV and OPXV are listed in Table 4.

The LoD for the **MPXV** target of Xpert Mpx test was confirmed to be 2.12×10^1 GC/mL in UTM.

The LoD for the **OPXV** target of Xpert Mpx test was confirmed to be 4.23×10^1 GC/mL for monkeypox virus, and 6.00×10^1 GC/mL for vaccinia virus gDNA in UTM.

Table 4. Xpert Mpx Test Limit of Detection (LoD)

Organism	Xpert Mpx Test Targets (GC/mL)	
	MPXV	OPXV
Inactivated Monkeypox Virus (GC/mL)*	2.12×10^1	4.23×10^1
Vaccinia Virus gDNA (GC/mL)**	-	6.00×10^1

*For an MPXV Clade II detected result based on the Xpert Mpx test interpretation, the LoD of the Xpert Mpx test is 2.12×10^1 GC/mL

**For a non-variola OPXV detected result based on the Xpert Mpx test interpretation, the LoD of the Xpert Mpx test is 6.00×10^1 GC/mL

20.2 Analytical Specificity (Exclusivity)

An *in silico* analysis was performed to evaluate the Xpert Mpx test for analytical specificity (cross-reactivity). Potential cross-reactivity was assessed according to percent homology of the organisms' genomic sequences listed in Table 7 to the primers and probes in the Xpert Mpx test. The Xpert Mpx test contains two monkeypox virus clade II specific targets (MPXV target 1 and target 2), one non-variola *Orthopoxvirus* (OPXV) target, and SPC and SAC internal control targets.

With the exception of variola virus, vaccinia virus, cowpox virus, and ectromelia virus, *in silico* analysis showed that the Xpert Mpx test primers and probe sets do not show $\geq 80\%$ homology to the genomic DNA sequences evaluated of the microorganisms and viruses listed in Table 7. There is potential cross-reactivity of the MPXV target 1 primers and probes with variola, vaccinia and cowpox virus and of MPXV target 2 primers and probes with ectromelia virus sequences as evidenced by the more than 80% sequence identity (Table 5).

Table 5. Organisms with Significant Matches to the Xpert Mpox Test MPXV Target Primers and Probe Sequences

Xpert Mpox test targets	Species	Refseq Accession ID	Forward Primer	Probe	Reverse Primer
MPXV target 1	Variola Virus (smallpox)	NC_001611.1	88% (22/25nt)	92% (23/25nt)	92% (23/25nt)
MPXV target 1	Cowpox virus ^a	NC_003663	100% (25/25nt)	88% (22/25nt)	92% (23/25nt)
MPXV target 1	Camelpox virus ^a	NC_003391	NSM*	92% (23/25nt)	92% (23/25nt)
MPXV target 1	Vaccinia virus ^b	NC_006998	92% (23/25nt)	92% (23/25nt)	92%(23/25nt)
MPXV target 2	Ectromelia virus ^c (mousepox)	NC_004105	92%(23/25nt)	80% (20/25nt)	92% (23/25nt)

*NSM: No significant match

^a Based on the epidemiology of currently circulating orthopoxviruses, and lack of evidence for human-to-human transmission of cowpox and camelpox virus, a false positive result due to cowpox or camelpox infection is unlikely

^b *In vitro* testing of vaccinia genomic DNA (gDNA) at a concentration of 1.00 x 10⁶ copies/mL showed no signal with MPXV targets

^c The *in silico* analysis showed sufficient mismatches to the probe sequence of the MPXV target to prevent detection of ectromelia virus

In addition, the OPXV target primer and probe sets have ≥80% homology for variola virus genome. The forward and reverse primers for the Xpert Mpox test OPXV target are exact matches to the locus in the variola genome, however, the probe has three mismatches (Table 6). Though the Xpert Mpox test demonstrated 91% identity to the variola locus, the results of *in vitro* testing with variola DNA conducted by Li, *et al.* demonstrated that testing with a PCR assay using the same non-variola OPXV primers/probe sequences as Xpert Mpox did not provide a positive result when tested against a wide range of variola virus samples⁵.

A ≥80% homology to human genomic DNA was observed for the SAC primers and probe as they are designed to detect human genomic DNA.

Table 6. Percent Homology of Xpert Mpox OPXV Target Primers and Probe with Variola Virus

Species	Refseq Accession ID	Forward Primer	Probe	Reverse Primer
Variola Virus (smallpox)	NC_001611.1	100% (23/23nt)	91% (29/32nt)	100% (28 / 28nt)

Based on the epidemiology of currently circulating orthopoxviruses, a false positive result for the MPXV target (monkeypox virus clade II) due to cowpox or variola virus infection is unlikely. As with any clinical diagnostic test, results should be interpreted in the context of clinical evaluation and current epidemiology. The World Health Organization (WHO) declared smallpox eradicated, therefore the possible variola virus cross-reactivity with the MPXV target 1 primers and probe do not pose any practical risk to the Xpert Mpox test.¹⁰ If variola infection (smallpox) is suspected, the provider is advised to contact the local health department immediately for patient evaluation. The *in silico* analysis showed a two nucleotide deletion in the ectromelia genome sequences compared to the probe sequence of the MPXV target 2. This is predicted to be sufficient to prevent probe binding with the genome of ectromelia virus, avoiding detection of this virus. *In silico* exclusivity analysis results can be found in Table 7.

In vitro testing of vaccinia genomic DNA (gDNA) at a concentration of 1.00 x 10⁶ copies/mL showed no signal with MPXV targets while the OPXV target was positive, as expected.

Table 7. Analytical Specificity of the Xpert Mpox Test**

Species	Refseq Accession ID	MPXV (clade II) target I			MPXV (clade II) target II		
		Forward Primer	Probe	Reverse Primer	Forward Primer	Probe	Reverse Primer
Variola Virus (smallpox)	NC_001611.1	88% (22/25nt)	92% (23/25nt)	92% (23/25nt)	84% (21/25nt)	44% (11/25nt)	NSM
Herpes simplex virus (HSV-1)	NC_001806	NSM	NSM	NSM	NSM	NSM	NSM
Herpes simplex virus (HSV-2)	LS480640.1	NSM	NSM	NSM	NSM	NSM	NSM
Varicella-zoster virus (Chickenpox)	NC_001348.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Staphylococcus aureus</i>	AP017922.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Streptococcus pyogenes</i>	NZ_LS483338.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Pseudomonas aeruginosa</i>	NC_002516.2	NSM	NSM	NSM	NSM	NSM	NSM
<i>Corynebacterium jeikeium</i>	NC_007164.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Escherichia coli</i>	NZ_CP077969.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Bacteroides fragilis</i>	NZ_CP069563.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Neisseria gonorrhoeae</i>	NZ_CP097846.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Mycoplasma pneumoniae</i>	NZ_CP014267.1	NSM	NSM	NSM	NSM	NSM	NSM
Human papilloma virus (HPV)	NC_027779.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Treponema pallidum</i>	NC_016842.1	NSM	NSM	NSM	NSM	NSM	NSM
Molluscum contagiosum virus	MN931752.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Streptococcus mitis</i>	JVJJ01000007.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Staphylococcus epidermidis</i>	JUKL01000001.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Streptococcus agalactiae</i>	NZ_CP012480.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Lactobacillus species (acidophilus)</i>	NZ_CP054559.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Acinetobacter calcoaceticus</i>	NZ_CP020000.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Enterococcus faecalis</i>	NC_021023.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Streptococcus</i> Group C and Group G	AP012976.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Corynebacterium diphtheriae</i>	NZ_CP025209.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Chlamydia trachomatis</i>	NC_000117.1	NSM	NSM	NSM	NSM	NSM	NSM
<i>Mycoplasma genitalium</i>	NC_000908.2	NSM	NSM	NSM	NSM	NSM	NSM

Species	Refseq Accession ID	MPXV (clade II) target I			MPXV (clade II) target II		
		Forward Primer	Probe	Reverse Primer	Forward Primer	Probe	Reverse Primer
Human genome*	Multiple accession numbers	88% (22/25nt) chr 12	NSM	76% (19/25nt)	84% (21/25nt) Chr 18 84% (21/25nt) Chr 6 80% (20/25nt) Chr 13	76% (19/25nt) Chr18 72% (18/25nt) Chr6	84% (21/25nt) Chr 5 80% (20/25nt) Chr 10
<i>Candida albicans</i> *	Multiple accession numbers	NSM	NSM	NSM	NSM	NSM	64% (16/25nt)
<i>Trichophyton rubrum</i> *	Multiple accession numbers	NSM	NSM	NSM	NSM	NSM	NSM
<i>Trichomonas vaginalis</i> *	Multiple accession numbers	68% (17/25nt)	NSM	NSM	NSM	NSM	88% (22/25nt)
Cowpox virus	NC_003663	100% (25/25nt)	88% (22/25nt)	92% (23/25nt)	92% (23/25nt)	76% (19/25)	92% (23/25nt)
Camelpox virus	NC_003391	NSM	92% (23/25nt)	92% (23/25nt)	NSM	76% (19/25)	88% (22/25nt)
Vaccinia virus	NC_006998	92% (23/25nt)	92% (23/25nt)	92% (23/25nt)	NSM	76% (19/25)	96% (24/25nt)
Ectromelia virus (mousepox)	NC_004105	NSM	88% (22/25nt)	NSM	92% (23/25nt)	80 (20/25nt)	92% (23/25nt)

* Multiple Chromosome Organisms

**NSM: No Significant Match was reported by BLAST

20.3 Analytical Reactivity (Inclusivity)

The analytical reactivities of the Xpert Mpx test MPXV and OPXV targets were evaluated *in silico* against sequences from multiple strains of monkeypox virus clade IIa and clade IIb, using comprehensive data sets from NCBI and GISAID (Table 8). According to this analysis, the two MPXV targets and the OPXV target that are present in the Xpert Mpx test are predicted to have 0 to 1 mismatch in the primer and probe sequences with all monkeypox clade II sequences analyzed. As the presence of no more than one mismatch in the primer and probe sequences is not expected to impact test performance, the Xpert Mpx test exhibited 100% inclusivity to monkeypox clade II sequences evaluated.

The analytical reactivity of the Xpert Mpx test OPXV target was evaluated against sequences from monkeypox, vaccinia, cowpox, camelpox and ectromelia viruses (Table 8). Based on the *in silico* analysis, some vaccinia, cowpox and camelpox virus strains have genomic sequences containing two or more mismatches with the OPXV target primers and probe (Table 9), and therefore may not be detected by the test.

Table 8. Sequences Included in Inclusivity Analyses for MPXV and OPXV Targets

Virus	Source	Download Date	Number of unique, non-synthetic sequences analyzed
Monkeypox - clade I	GISAID	10/15/2022	43
Monkeypox - clade IIa	GISAID	10/15/2022	2
Monkeypox - clade IIb	GISAID	10/15/2022	3,057
Monkeypox -unassigned	NCBI	10/15/2022	2,552
Vaccinia	NCBI	10/15/2022	87
Cowpox	NCBI	10/15/2022	9,287
Camelpox	NCBI	10/15/2022	992
Ectromelia	NCBI	10/15/2022	129

Table 9. Percent of Organism-Specific Sequences with Two or More Mismatches with OPXV Target Primers and Probes*

Organism	Oligonucleotide	% of sequences with 2 or more mismatches
Vaccinia virus	OPXV probe	1.2% (1/86)
	OPXV reverse primer	1.2% (1/86)
Cowpox virus**	OPXV probe	56.5% (52/92)
	OPXV reverse primer	7.6% (7/92)
Camelpox virus**	OPXV probe	100.0% (9/9)

* Only the primers and probes with two or more mismatches listed

**Cowpox and Camelpox viruses are not currently circulating in humans; further these viruses are not known to transmit from human-to-human

20.4 Interfering Substances Study

The assay uses a well-established nucleic acid extraction method; therefore, interference from common endogenous substances is not expected. This is further supported by the results of an Interfering Substances study in which potentially interfering substances that may be present in a skin swab were evaluated for potential to impact the performance of the Xpert Mpx test. Positive and negative samples were prepared in pooled negative matrix (PNM), which is made of negative human buccal swab material in UTM, and tested in the presence of potentially interfering substances. Negative matrix samples (n=3) were tested to determine the impact of such substances in the performance of the sample processing control (SPC) and sample adequacy control (SAC). In addition, positive samples, containing monkeypox virus at 3X LoD (n = 3), were tested to determine the impact of such substances in the detection of monkeypox virus. The evaluated substances are listed in Table 10, with active ingredients and concentrations tested shown. None of the substances tested were found to impact performance of the test at the concentrations tested in study.

Table 10. Potentially Interfering Substances Tested in the Xpert Mpx Test

Substance/Class	Description/Active Ingredient	Concentration Tested
Control	Pooled negative matrix	100% (v/v)
Abrevea	Behenyl alcohol	7% (w/v)
Acyclovir	Antiviral medication	7 mg/mL
Albumin	Protein	≥ 2.2 mg/mL
Blood/EDTA	Blood (human)	5% (v/v)
Mucin	Purified Mucin protein (Bovine or porcine submaxillary gland)	60 µg/mL
Hydrocortisone cream	Cortisol hormone	5% (w/v)
Benadryl cream/ointment	Diphenhydramine (antihistamine)	5% (w/v)
Carmex	Camphor, white petrolatum	7% (w/v)
Casein	Milk protein	7 mg/mL
Lanacane	Benzocaine	3.5% (w/v)
KY Jelly	Glycerol (glycerine) and Hydroxyethylcellulose	7% (w/v)
Douche	Benzalkonium chloride	7% (w/v)
Neosporin	Bacitracin, neomycin, and polymixin b	5% (w/v)
Female urine	Female urine, human	10% (v/v)
Male urine	Male urine, human	10% (v/v)
Feces	Feces, human	0.22% (w/v)
Seminal fluid	Seminal fluid, human	7% (v/v)
Zinc Oxide ointment	Zinc oxide	7% (w/v)
Vagisil cream	Benzocaine and resorcinol	1% (w/v)
Cornstarch	Cornstarch	2.5 mg/mL

21. References

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2. World Health Organization. Monkeypox: experts give virus variants new names. <https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names>. Published online August 12, 2022. Accessed January 17, 2023
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4. U.S. Department of Health & Human Services. Determination that a Public Health Emergency Exists. Published August 4, 2022. Accessed January 15, 2023. <https://aspr.hhs.gov/legal/PHE/Pages/monkeypox-4Aug22.aspx>
5. Li, Y, Olson VA, Laue, T, Laker, MT, et al. Detection of monkeypox virus with real-time PCR assays. J Clin Virol. 2006; 36(3):194-203.
6. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories (refer to latest edition). <http://www.cdc.gov/biosafety/publications/>
7. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).
8. REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on the classification labeling and packaging of substances and mixtures amending and repealing, List of Precautionary Statements, Directives 67/548/EEC and 1999/45/EC (amending Regulation (EC) No 1907/2007).
9. Occupational Safety and Health Standards, Hazard Communication, Toxic and Hazard Substances (March 26, 2012) (29 C.F.R., pt. 1910, subpt. Z).
10. World Health Organization. Smallpox Overview. https://www.who.int/health-topics/smallpox#tab=tab_1. Accessed January 15, 2023

22. Cepheid Headquarters Locations

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23. Technical Assistance
















Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Lot number
- Serial number of the instrument
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag Number

US

Telephone: + 1 888 838 3222
Email: techsupport@cepheid.com

24. Table of Symbols

Symbol	Meaning
	Catalog number
	<i>In vitro</i> diagnostic medical device
	Do not reuse
	Batch code
	Consult instructions for use
	Manufacturer
	Country of Manufacture
	Contains sufficient for <n> tests
	Control
	Expiration date
	Temperature limitation
	Biological risks
	Caution
	Warning
	For prescription use only



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For use under Emergency Use Authorization (EUA) Only

25. Revision History

Description of Changes: Initial Release of 302-9630

Purpose: Initial Release of Instructions for Use

Section	Description of Change
Throughout	Initial Release

Xpert[®] Mpox and the GeneXpert[®] Xpress System (HUB configuration)



For use under the Emergency Use Authorization (EUA) only.

The user should be trained in the procedure. The test is only for human lesion swab specimens collected in UTM or VTM.

Wear the appropriate protective attire for your safety when handling patient samples.

Clean testing surfaces according to your institution's policy. For assistance, call Cepheid Technical Support at (888) 838-3222.

Before you begin

- Read through this 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 Mpox are 15–30 °C, 20–80% relative humidity.

Storage and Handling

- Wear gloves. Change gloves between processing each sample.
- Store the Xpert Mpox cartridges at 2–28 °C.
- DO NOT use a cartridge beyond its expiration date.

1 Patient Specimen Collection

Swab specimens must be collected in UTM/VTM by trained personnel.

2 Starting the System

A Starting the Instrument

- 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 and touch arrow next to the password field.
- Allow 30 seconds for the software to load.

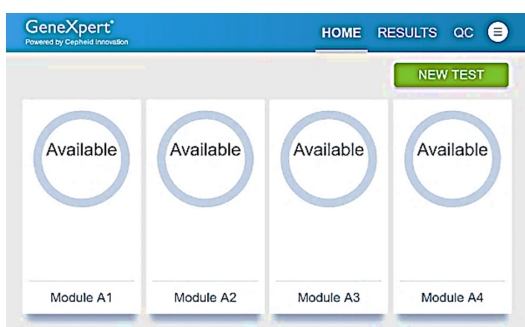
B Enter UserID and Password

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

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



C Home Screen Displays



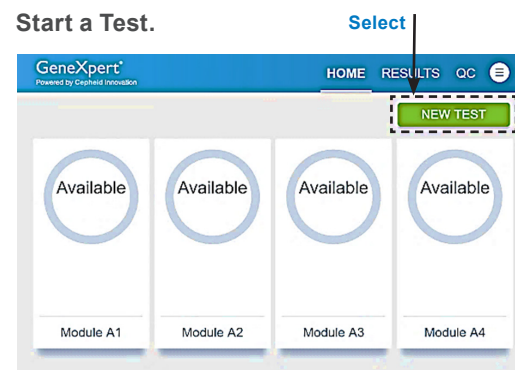
3 Testing a Patient Specimen

WARNINGS

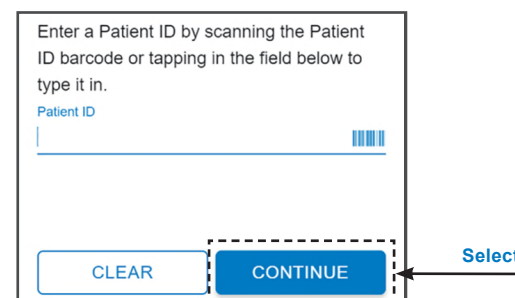
- **DO NOT** use a cartridge that is wet or has leaked.
- **DO NOT** use a cartridge that has been dropped.
- **DO NOT** open a cartridge lid until you are ready to perform testing.
- **DO NOT** shake or tilt the cartridge after adding the sample.
- **DO NOT** reuse disposable pipettes or cartridges.
- **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.

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

A Start a Test.

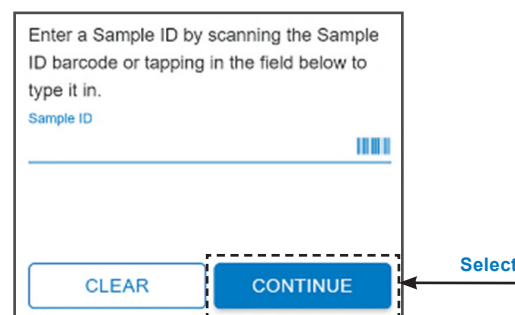


B



C Review and confirm patient information as it can not be altered after submission.

D



E Review and confirm sample information as it can not be altered after submission.

3 Testing a Patient Specimen (continued)

F Scan Cartridge Barcode.



G Confirm test information by touching Confirm.

H Watch video & touch CONTINUE when complete.

I Mix the Sample:

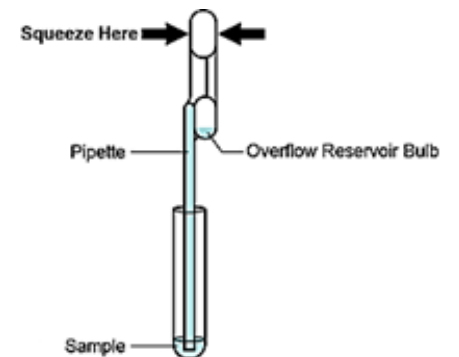
- Check that the specimen tube cap is closed.
- Mix the specimen by rapidly inverting the specimen transport tube 5 times. Open the cap on the specimen transport tube.
- Open the cartridge lid.



Note: Samples can be stored at room temperature (15-30 °C) for up to 48 hours in viral transport medium (VTM/UTM) until testing is performed. Alternatively, samples in VTM/UTM can be stored refrigerated (2-8 °C) up to seven days until testing is performed.

J Fill Pipette with Sample.

- Remove the transfer pipette from wrapper.
- Squeeze the top bulb of the pipette **completely until the bulb is fully flat** and then 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 to fill the pipette with sample before removing it from the tube. It is okay if the liquid goes into the overflow reservoir. Check that the pipette does not contain air bubbles.



K Transfer Sample to Cartridge.

- Place the pipette tip into the large opening of the cartridge (Sample Chamber). Squeeze the top bulb of the pipette **completely until the two sides of the bulb touch** to empty the contents of the pipette into the large opening (Sample Chamber).
- 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)

L Load Cartridge Into Module.

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



M 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** if performing a new test.
- To log out, touch the **USER MENU** icon then select **LOGOUT**.



4 How To Start Another Test While a Test is Running

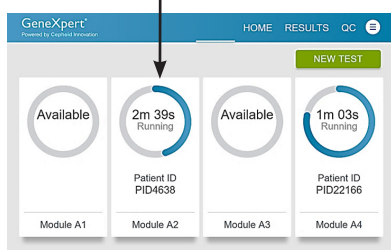
- Touch the **HOME** button on the Test Running screen.
- The **HOME** screen will display the module status and the **NEW TEST** button.
- You can now perform the same steps in **Section 3. Testing a Patient Specimen** to perform a new test. Change gloves between processing each sample.

5 How to View Status of Tests In Progress and Completed Tests

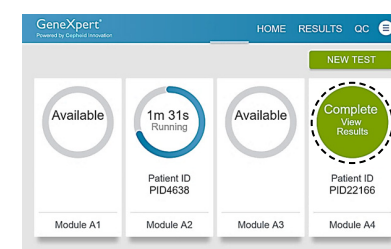
A Touch HOME button.

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.

Warning:

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;

This product has been authorized only for the detection of nucleic acid from monkeypox virus or other non-variola orthopoxviruses, not from any other virus or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of infection with the monkeypox virus, including in vitro diagnostics that detect and/or diagnose infection with non-variola *Orthopoxvirus*, under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

6 How to Run External Controls – Positive and Negative Controls

The following external controls are recommended for use with the Xpert Mpx test:

- ZeptoMetrix Catalog # NATMPXVPOS-6C (positive external controls)
- ZeptoMetrix Catalog # NATMPXVNEG-6C (negative external controls)

External controls should be run:

- Each time a new shipment of Xpert Mpx 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.

To prepare the controls:

IMPORTANT: Change Gloves and clean workstation between and after running the controls.

Dilution of the Positive Control is necessary to confirm the performance of the test.

Run the Positive Control first, followed by the Negative Control.

Positive Control (NATMPXVPOS-6C) must be diluted prior to use as follows (Steps 1-3):

1. Label a 3 ml VTM tube "Diluted Positive Control". Uncap the tube.
2. Using an exact volume transfer pipette provided in the kit, add one draw (300 ul) of the (undiluted) Positive Control material to the VTM tube.
3. Recap the tube tightly and mix by inverting the tube 5 times. Proceed to Step 4.

Negative Control (NATMPXVNEG-6C) is ready to use directly. No additional preparation steps are necessary. Proceed to Step 4.

4. Open the Cartridge Lid.



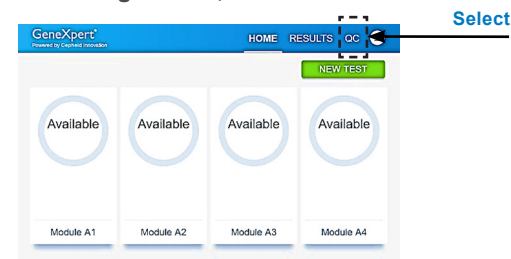
5. Using a new exact volume transfer pipette provided in the kit, add one draw (300 ul) of the diluted Positive Control or the Negative Control material into the cartridge.



6. Close the cartridge lid and proceed to the next step (6A).

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

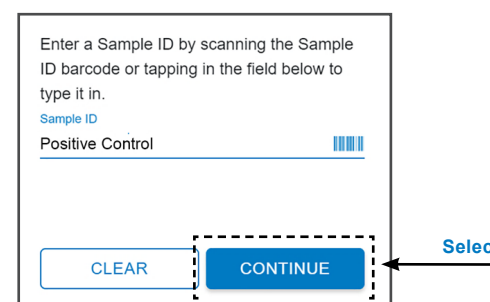
A On the Home screen or the Test Running screen, touch QC.



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 Review and confirm sample information by touching CONTINUE.

E Scan Cartridge Barcode.



F Review and confirm Test Information by touching CONTINUE.

G To run the Negative Control, begin at step 6A.

H Load the cartridge in the module.

Note: Change gloves and clean the workstation between and after running the controls.

Note: The positive external control should provide a "MPXV Clade II Detected" result. If a different result is obtained, repeat the positive external control run with a new positive control dilution.

The negative external control should provide a "MPXV Clade II NOT DETECTED, Non-variola OPXV NOT DETECTED" result. If a different result is obtained, repeat the external control run.

Note: If repeated control runs do not produce the expected results, contact Cepheid Technical Support.

7 Possible Results

Possible Test Results	Interpretation
MPXV Clade II DETECTED	Monkeypox virus Clade II DNA DETECTED* This specimen is POSITIVE for monkeypox virus clade II.
Non-variola OPXV DETECTED	Non-Variola <i>Orthopoxvirus</i> Viral DNA DETECTED*† This specimen is POSITIVE for non-variola <i>Orthopoxvirus</i> DNA. Low levels of monkeypox viral DNA in a specimen may on rare occasions, result in monkeypox virus clade II DNA Not Detected and non-variola <i>Orthopoxvirus</i> DNA Detected. This result may occur in the case of low monkeypox viral DNA concentrations at levels near or below the limit of detection, or may indicate another <i>Orthopoxvirus</i> infection although no other known orthopoxviruses are currently circulating in the United States.
MPXV Clade II NOT DETECTED Non-variola OPXV NOT DETECTED	Monkeypox Clade II Viral DNA and Non-Variola <i>Orthopoxvirus</i> Viral DNA not detected*† This specimen is NEGATIVE for monkeypox virus clade II.
NO RESULT - REPEAT TEST	If the result is NO RESULT – REPEAT TEST, repeat the test with a new cartridge. If the retest result is NO RESULT – REPEAT TEST, collect new specimen and REPEAT TEST.
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.

* Laboratories should notify appropriate Federal, State, or local public health agencies of the test results in accordance with applicable laws.

† If clinically indicated, consider collecting another specimen.

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English (US)

Xpert® Mpox (EUA) Documentation and ADF
For use under Emergency Use Authorization (EUA) only

This is not the full Instructions for Use. Access to the Xpert® Mpox full Instructions for Use (IFU), EUA documentation and Assay Definition File (ADF) is available online at https://www.cepheid.com/en_US/tests/Critical-Infectious-Diseases/Xpert-Mpox. Under the Xpert Mpox Product Resources section on the webpage, select the Xpert Mpox EUA item you wish to view. A new tab on your internet browser will open to allow access to the Xpert Mpox EUA item selected.

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Please contact +1 (888) 838-3222 if you require a printed copy free of charge or need technical support to access the package insert.

Rx only. *In Vitro* Diagnostic Use Only.
