



Cue[®] MpoX (Monkeypox) Molecular Test

Quick Reference Instructions (QRI) – For Professional Use
For Rx Use Only
For Use Under an Emergency Use Authorization (EUA) Only
Use with the Cue Health Monitoring System and Cue Health App



For In Vitro Diagnostic Use



These are not the complete instructions for use.

Lesion specimens must be collected by trained personnel.

For more information, go to the Cue Health App to see the Cue Health Monitoring System User Manual and the Cue MpoX (Monkeypox) Molecular Test Instructions for Use.

1. REMINDERS

- Read this entire Quick Reference Instructions before beginning a test.
- Do not use a cartridge that is damaged or has been dropped.
- Do not move or tilt the Cartridge Reader while the test is running.
- Do not use a cartridge that has been removed from its foil pouch (and testing has not begun) for over 30 minutes.
- Make sure the Cartridge Reader is connected to a power supply or has at least a 10% battery level before beginning a test.
- Change gloves between processing each sample.
- Make sure to follow the cleaning procedure for the Cartridge Reader after testing each clinical specimen.

2. SET UP THE CUE MONITORING SYSTEM

2.1 Unpack the Cue Cartridge Reader



2.2 Download the Cue Health App to a compatible mobile smart device named on the Cue Health website at www.cuehealth.com. The Cue Health App is available on the Apple[®] App Store[®] and Google Play[™] Store.

3. OPEN YOUR CUE ACCOUNT. FOLLOW THE ON-SCREEN INSTRUCTIONS

3.1 Set up your Cue Account. Follow the on-screen instructions for “Create Account”.

The screenshot shows a mobile app interface for creating an account. At the top, there are three tabs: 'Create Account' (selected), 'Permissions', and 'Set Up Reader'. Below the tabs is the title 'Create Account'. There are three input fields: 'EMAIL' with the placeholder 'example@email.com', 'PASSWORD', and 'CONFIRM PASSWORD'. Each field has a small eye icon to toggle visibility. At the bottom of the form is a 'SUBMIT' button.

3.2 Follow the on-screen instructions to set up the Cartridge Reader. Connect the Cartridge Reader to power. Pair the Reader to your mobile smart device. When prompted by the Cue Health App, adjust the mobile smart device camera so the QR code is visible on-screen and inside of the capture outline. When the QR code is recognized, the Cartridge Reader is securely paired. If the QR code does not scan quickly, make sure the Cartridge Reader is connected to power.



Cue Health
Smart Health Platform



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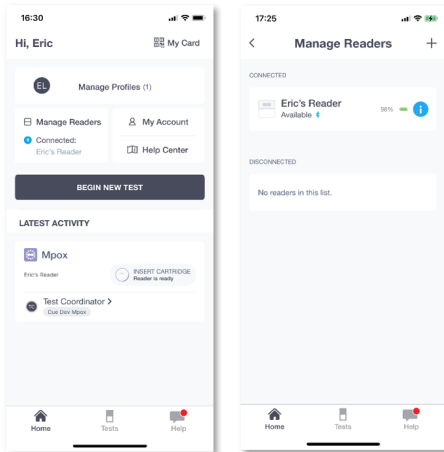


Bottom of the Reader



Find the Reader QR Code

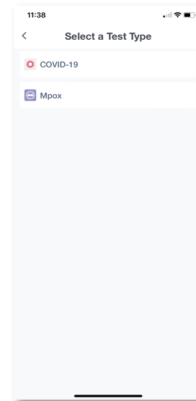
- 3.3 One or more Cartridge Readers may already be paired to your mobile smart device. Check that the Cartridge Reader you will use for the current test is connected to the Cue Health App. Go to the Dashboard screen by tapping on the home button  at the bottom of the Cue Health App screen. Then tap on “Manage Readers”. Connect to the Cartridge Reader that you want to use for the current test by tapping on the name of the Cartridge Reader.



- 3.3 Tap on "Manage Profiles" on the Dashboard screen. Choose the profile for the patient being tested or add a new profile. To add a new profile, tap the + sign to type in a person's identification information and SAVE, or tap the barcode icon to scan a patient barcode ID. Tap on the name or patient barcode ID, then tap on “BEGIN NEW TEST”.

4. FOLLOW THE CUE HEALTH APP TO RUN A CUE MPOX TEST

- 4.1 Tap “BEGIN NEW TEST” and you will see the screen below to choose to run the Cue MpoX test.



If prompted, select your organization. View the Cue MpoX test Intended Use. Also view the Precautions of the test.

- 4.2 **The recommended environmental operating conditions for this test is 59°F (15°C) or above 86°F (30°C), ambient humidity.** Place the Cue Cartridge Reader and a Cue MpoX (Monkeypox) Molecular Test Cartridge foil pouch in front of you. **Make sure the Cartridge Reader is connected to a power supply or has at least a 10% battery level before beginning a test. The Reader needs to be on a level surface when the cartridge is inserted and while the test is running. Do not move or tilt the Cartridge Reader while the test is running.**



Do not use a cartridge if the foil pouch is damaged. Do not use a cartridge past the Use By date on the foil pouch label. Do not use a cartridge that has been stored below 59°F (15°C) or above 86°F (30°C). Do not use a



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cartridge that has been removed from its foil pouch (and testing has not begun) for over 30 minutes.

Change gloves between processing each sample; put on a clean pair of gloves before opening the cartridge foil pouch.

- 4.3 When you are ready to test, tear open the top of the cartridge foil pouch and remove the plastic tray with the Cue Mpox (Monkeypox) Molecular Test Cartridge and Cue Sample Wand. Remove the cartridge from the tray.



Tear Pouch



Remove Plastic Tray



Remove Cartridge

- 4.4 Insert the cartridge logo side up into the port of the Cartridge Reader. Support the back of the Cartridge Reader with one hand and hold the cartridge in the other hand. When you have inserted the cartridge all the way in, all five lights on top of the Cartridge Reader will flash and the cartridge will pre-heat in preparation for testing. The cartridge must heat up for the full 100% heat cycle before the Sample Wand is inserted into the cartridge. All of the LED lights on the Reader will flash 5 times when the cartridge is ready for the Sample Wand.



Insert Cartridge into Reader



Allow the Cartridge to heat up

- 4.5 Collect the lesion swab sample **or** dip the Cue Sample Wand into a previously collected skin lesion sample in VTM.

When using a previously collected skin lesion sample in VTM: Gently invert the capped VTM tube to ensure mixing. Tap the tube on a tabletop 3 times to remove excess sample liquid from the cap. Uncap the tube. Insert the Sample Wand tip into the liquid and swirl the Wand as you rotate around the inner walls of the tube 3 times. Lift the Wand tip above the liquid level and swirl the Wand tip 3 times against the inside of the tube to dispel air bubbles. Place the Wand tip back into the sample liquid and again swirl the Wand as you rotate around the inner walls of the tube 3 more times. Lift the Wand tip above the liquid level and again swirl the Wand tip three times against the inside of the tube to dispel air bubbles. Remove the Sample Wand from the tube.



- 4.6 When the Cue Health App screen shows that the cartridge is “Ready”, support the back of the Cartridge Reader while inserting the Cue Sample Wand with the lesion sample into the port of the test cartridge. Insert the Sample Wand within 5 minutes after collecting the sample until Test in Progress is shown on the Cue Health App screen. A dipped Cue Sample Wand into a previously collected skin lesion swab sample in VTM should be immediately inserted into the test Cartridge.

Do not move or tilt the Cartridge Reader while the test is running.





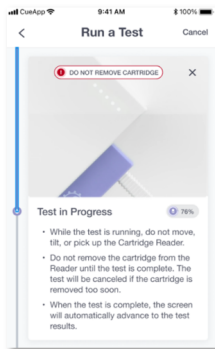
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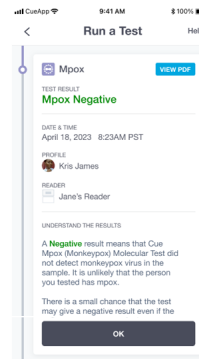
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- 4.7 Once the test starts, the Cue Health App will show the test progress. The Cue Mpxx (Monkeypox) Molecular Test takes about 25 minutes to run. Do not move the Cartridge Reader while the test is running.

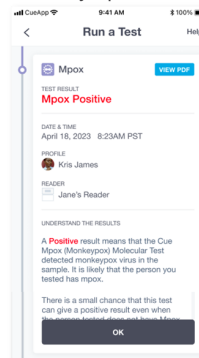


- 4.8 When the test is complete, you will see the result on the Cue Health App screen.

- A Negative result means that the Cue Mpxx (Monkeypox) Molecular Test did not detect monkeypox viral DNA in the sample, and it is unlikely that the person you tested has monkeypox virus infection. There is a small chance that the test may give a Negative result even if the person who was tested has monkeypox virus infection (false negative). A Negative result does not rule out monkeypox virus infection and should not be used as the sole basis for treatment or patient management decisions. When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with monkeypox virus infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that monkeypox virus infection is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If monkeypox virus infection is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.



- A Positive result means that the Cue Mpxx (Monkeypox) Molecular Test detected monkeypox viral DNA in the sample. There is a small chance that this test can give a positive result even when the person tested does not have monkeypox virus infection (false positive). The possibility of a false positive result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with monkeypox virus infection. A positive result does not mean that the patient's symptoms are from monkeypox virus alone. It is possible that another type of illness is contributing to their symptoms.



- An Invalid result means that you may not have collected enough sample or a system processing error occurred, and the Cue Health Monitoring System is not able to provide the result of the test. Retesting is required. You must use a new Cue Mpxx (Monkeypox) Molecular Test Cartridge and a new Cue Sample Wand.

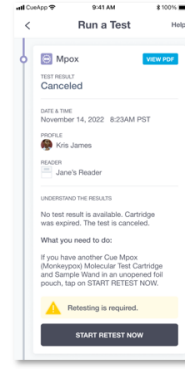
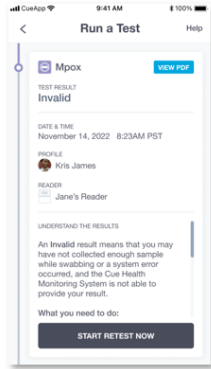


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- You will see a test result of Canceled if you purposely canceled the test or if the system canceled the test due to a mechanical error or a damaged/defective test Cartridge was used. The system will cancel a test because you did not follow the test instructions correctly, for example, if the Reader is moved or tilted while the test is running, if the test cartridge is removed before the test is completed, when the Wand is inserted into the cartridge too soon (the Cartridge did not complete preheating) or too late (more than 10 minutes after the test Cartridge completes preheating), if the test Cartridge has expired, or if the test Cartridge was previously used. The system will also cancel the test when the system detects that the test Cartridge was stored outside of recommended conditions and not equilibrated to the claimed storage range (15-30°C) prior to testing.

Retesting is required. You must use a new Cue Mpxx (Monkeypox) Molecular Test Cartridge and a new Cue Sample Wand.

- Remove the Cue Mpxx (Monkeypox) Molecular Test Cartridge from the Cartridge Reader after you see the result. Dispose of the used test cartridge with Sample Wand according to your institution's environmental waste procedures for proper disposal of used test cartridges.

Make sure to clean the Cartridge Reader after testing each clinical specimen. The Reader should be cleaned/disinfected after each use. Wipe with Clorox[®] Germicidal Wipes or equivalent (0.55% sodium hypochlorite).

5. Quality Control

External Positive and Negative Controls should be used to show that the Cue Mpxx (Monkeypox) Molecular Test is working properly. Controls for the Cue Mpxx (Monkeypox) Molecular Test are available from ZeptoMetrix. Catalog number NATMPXV-ERC (Positive Control) and Catalog number NATSARS(COV2)-NEG (Negative Control) at www.zeptometrix.com or by calling (800) 274-5487. Controls should be stored according to the manufacturer's instructions.

Preparation of the Controls for Use

Follow the manufacturer's instructions for mixing the controls.

- Negative Control
Negative Control is supplied ready to use and does not need further processing before use.



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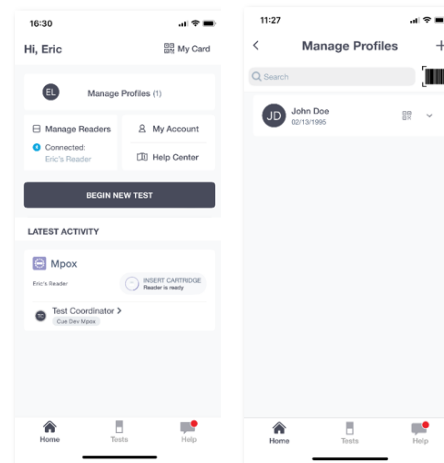
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- **Positive Control**
Positive Control needs to be diluted using a 300 µL Samco Exact Pipette (PN966NL). Pipette 300 µL of the Positive Control into 3 mL of Viral Transport Media (VTM). Invert the tube to mix. Cue Health recommends that a negative and a positive control be run:
 - Once for each new lot of cartridge packs received.
 - When problems with testing are suspected or identified.
 - As deemed necessary in order to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

The instructions for dipping into the Negative Control vial and the diluted Positive Control vial are: (1) insert the Sample Wand tip into the liquid and swirl the Wand as you rotate around the inner walls of the vial 3 times; (2) lift the Wand tip above the liquid level and swirl the Wand tip 3 times against the inside of the vial to dispel air bubbles; (3) place the Wand tip back into the liquid and again swirl the Wand as you rotate around the inner walls of the vial 3 more times; (4) remove the Sample Wand from the vial.



Tap on "Manage Profiles", then tap on the barcode icon  on the Dashboard screen and add a sample ID for both the Negative and Positive Control. Dip a new Cue Sample Wand into the Negative Control and test that Sample Wand in a new Cue Mpox (Monkeypox) Molecular Test Cartridge. Dip a new Cue Sample Wand into the Positive Control and test that Sample Wand in a new Cue Mpox (Monkeypox) Molecular Test Cartridge. The expected result for the Negative Control is "Negative" and the expected result for a Positive Control is "Positive".



If correct control results are not obtained, repeat the testing using a control sample on a new Cue Sample Wand and a new test cartridge. If the control testing continues to fail, do not perform additional clinical specimen tests or report results. Contact Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378) before testing additional clinical specimens.

6. Precautions

- 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.



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IVD

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- This product has been authorized only for the detection of nucleic acid from monkeypox virus, not for any other viruses 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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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IVD

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REF

C3090-10



eIFU available on the Cue Health App

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