



**Mpox (Monkeypox)**

**Cue<sup>®</sup> Mpox (Monkeypox) Molecular Test  
Instructions For Use  
For Professional Use**

**Use with the Cue Health Monitoring System (Reader) and Cue Health App.**

**For use under an Emergency Use Authorization (EUA) only. For prescription use only. For in vitro diagnostic use.**

## **Cue Mpox (Monkeypox) Molecular Test Instructions for Use**

### **Summary and Explanation**

Mpox is a disease caused by the monkeypox virus, which is a double-stranded DNA virus that belongs to the *Orthopoxvirus* genus in the family Poxviridae.<sup>1</sup> Mpox is spread to humans through close contact with an infected person or animal, or with material contaminated with the virus.<sup>2</sup> There are two distinct clades of mpox, clade I (Congo Basin – Central African Region) and clade II (West Africa).<sup>1,2,3</sup> The typical presentation of mpox consists of fever, rash and swollen lymph nodes.<sup>2</sup> Monkeypox virus was first isolated from a 9-month-old boy from the Democratic Republic of the Congo in 1970<sup>4</sup> and since then most mpox cases have been endemic in Central and West Africa.<sup>3,5</sup> Since early May 2022, confirmed cases (clade IIb) have been reported in countries that have not previously reported cases of mpox, and continue to be reported in several endemic countries.<sup>6, 7,8</sup>

The Cue Mpox (Monkeypox) Molecular Test is an in vitro diagnostic test that aids in the detection and diagnosis of monkeypox virus and is based on widely used isothermal nucleic acid amplification technology. The Cue Mpox (Monkeypox) Molecular Test contains primers and probes and internal controls used in molecular tests for the in vitro qualitative detection of monkeypox virus nucleic acid.

The Cue Mpox (Monkeypox) Molecular Test detects monkeypox nucleic acid from samples collected with the Cue Sample Wand directly from skin lesions or by dipping the Cue Sample Wand in previously collected direct skin lesion samples in viral transport media (VTM).

### **Intended Use**

The Cue Mpox (Monkeypox) Molecular Test is an isothermal nucleic acid amplification assay for the qualitative detection of DNA from the monkeypox virus (clade I/II), in human lesion swab specimens (i.e., swabs of acute pustular or vesicular rash) from individuals suspected of mpox by their healthcare provider. The test is run using the Cue Health Monitoring System (Cue Reader), the Cue Mpox (Monkeypox) Molecular Test Cartridge, the Cue Sample Wand, and the Cue Health App on a compatible mobile smart device named on the Cue Health website at [www.cuehealth.com](http://www.cuehealth.com).

Testing 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, 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.

Results are for the identification of monkeypox virus (clade I/II) DNA which is 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 I/II) 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 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 Cue Mpox (Monkeypox) Molecular Test is intended for use by trained operators who are proficient in performing a test using the Cue Health Monitoring System.

The Cue Mpox (Monkeypox) Molecular Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

### **Principles of the Procedure**

The Cue Mpox (Monkeypox) Molecular Test utilizes isothermal nucleic acid amplification technology (NAAT) for the qualitative detection of monkeypox virus nucleic acid. This test detects monkeypox virus nucleic acid using a molecular amplification reaction that is an equivalent alternative amplification method to polymerase chain reaction (PCR). The Cue Mpox (Monkeypox) Molecular Test primers amplify a conserved region found twice (gene name OPG001) within the monkeypox virus genome enabling detection. The Cue Mpox (Monkeypox) Molecular Test forward primers are conjugated to biotin and the reverse primers are conjugated to Horseradish Peroxidase (HRP). RNase P serves as the internal control. The RNase P forward primer is conjugated to a small hapten, Digoxigenin (Dig). The RNase P reverse primer is conjugated to HRP.

The RNase P internal control has been designed to control for presence of human cellular material in the sample and proper assay execution including sample inhibition, amplification, and assay reagent function. If RNase P and monkeypox virus are not detected, the Cue Mpox (Monkeypox) Molecular Test will return an "Invalid" result. In positive samples where target amplification is strong, the internal control is ignored, and the target amplification serves as the control to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust.

When the user inserts the Cue Sample Wand with a skin lesion sample into the Cue Test Cartridge, the test automatically begins. Heating, mixing, amplification, and detection take place within the cartridge. The current flow from the electrodes provides a semi-quantitative nanoampere measurement that is converted to a positive or negative result (based on a pre-determined cutoff). The Cue Mpox (Monkeypox) Molecular Test takes about 25 minutes from Sample Wand insertion to results.

### **Precautions - General**

- This product is an *in vitro* diagnostic test, which means the test is performed outside the body.
- For use under emergency use 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, not from 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. § 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.
- The Cue Mpox (Monkeypox) Molecular Test Cartridge is used with the Cue Reader and Cue Health App.
- The Cue Reader needs to be on a level surface when the Cue Mpox (Monkeypox) Molecular Test Cartridge is inserted and while the test is running. Do not move the Cue Reader while the test is running.
- Only skin lesion swabs from papular (solid, raised with distinct borders), vesicular (fluid trapped under the epidermis), pustular (filled with yellow fluid) or macular (flat) lesions can be used with the Cue Mpox (Monkeypox) Molecular Test.
- Performance of the Cue Mpox (Monkeypox) Molecular Test has only been established for detection of monkeypox virus nucleic acid from samples collected with the Cue Sample Wand directly from skin lesions or by dipping the Cue Sample Wand in previously collected direct skin lesion samples in viral transport media (VTM). The performance of this test with other specimen types or samples has not been evaluated.
- Collection of lesion samples should be performed by healthcare professionals trained to collect lesion samples. Personal protective equipment (PPE) can help protect the skin and mucous membranes of the eyes, nose, and mouth should be worn by the healthcare professional collecting the lesion sample.
- Do not clean the lesion with ethanol or any other disinfectant prior to swabbing.
- Avoid procedures that could generate infectious aerosols.
- Do not use the Cue Mpox (Monkeypox) Molecular Test Cartridge past the Use By date on the Cartridge foil pouch label.
- Do not use the Cue Sample Wand past the Use By date on the Wand label.
- The Cue Health Monitoring System (Cartridge Reader) must be cleaned and disinfected after each use. See the Cue Health Monitoring System User Manual for instructions.
- Do not remove the Wand from the Cue Mpox (Monkeypox) Molecular Test Cartridge during testing or after the test has been performed.

### **Precautions - Cue Mpox (Monkeypox) Molecular Test Cartridge and Cue Sample Wand Handling**

- Open the Cue Mpox (Monkeypox) Molecular Test Cartridge foil pouch when you are ready to test. Do not open the foil pouch more than 30 minutes before you begin a test. If more than 30 minutes have passed since you opened the foil pouch containing the Cartridge, obtain a new Cartridge.
- Do not use scissors or sharp objects to open the foil pouch as damage to the contents can occur.
- The Cue Sample Wand is sterile. Do not use if the packaging is damaged or accidentally opened before use. Open another Cartridge foil pouch for a sterile Cue Sample Wand.
- If the Cue Mpox (Monkeypox) Molecular Test Cartridge or Sample Wand is dropped, cracked, or found to be damaged when opened, do not use. Discard the damaged Cartridge and/or Wand and open another Cartridge foil pouch for a new Cartridge and/or sterile Sample Wand.
- Store and use the Cue Mpox (Monkeypox) Molecular Test Cartridge at the temperatures provided in the storage and testing conditions sections in these instructions for use (15-30°C).
- The Cue Mpox (Monkeypox) Molecular Test Cartridge will heat up inside the Cue Reader for one minute. Insert the Cue Sample Wand with the sample when the Cue Health App screen shows that the Cartridge heat cycle is complete. Do not wait longer than 10 minutes after the heat cycle is complete to insert the Wand.
- After the test is complete, remove the Cue Mpox (Monkeypox) Molecular Test Cartridge with the

Cue Sample Wand still inside and dispose per institutional waste guidelines. Treat all biological specimens, including used Cartridges with Wands, as if capable of transmitting infectious agents.

- Do not attempt to open the Cue Mpox (Monkeypox) Molecular Test Cartridge.
- Do not remove the Wand from the Cue Mpox (Monkeypox) Molecular Test Cartridge after it has been inserted.

### **Precautions – Lesion Swab Collection**

- Specimen collection must occur by trained healthcare personnel.
- Do not clean the lesion with ethanol or any other disinfectant prior to swabbing.
- For best results, swab a lesion that is in one of the following stages: papular (solid and raised with distinct borders), vesicular (a lesion with fluid trapped under the skin), or pustular (a lesion that is filled with yellow fluid). Lesions that look flat, like a rash (macular), may also be swabbed.
- You must insert the Sample Wand with the skin lesion sample into the Cue Mpox (Monkeypox) Molecular Test Cartridge within 5 minutes of collecting the lesion sample.

### **Limitations**

- Detection of monkeypox virus DNA is dependent on the number of copies present in the specimen. Detection of monkeypox nucleic acid may be affected by sample collection methods (e.g., if a specimen is improperly collected, transported, or handled), sample storage, patient factors (e.g., presence, type, and duration of symptoms), and/or stage of infection (e.g., if collected too early or too late in the course of illness), and/or interfering substances.
- The Cue Mpox (Monkeypox) Molecular Test has been evaluated only for use in combination with the following external controls – External Positive Control NATMPXV-ERC and External Negative Control NATSARS(COV2)-NEG (ZeptoMetrix (Buffalo, NY)) using the procedure provided in these instructions for use only. Modifications to this procedure may alter the performance of the test.
- There is a chance that the test may give a negative result even if monkeypox viral DNA is present (false negative). A false negative result can occur when a sample is not collected or handled properly, degradation of the viral DNA during storage, not enough sample was collected, and/or mutations in the monkeypox virus.
- As with any molecular test, mutations within the target regions of the Cue Mpox (Monkeypox) Molecular Test could affect primer and/or probe binding, resulting in failure to detect the presence of viral DNA.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Negative results do not preclude monkeypox virus clade I/II 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.
- Viral nucleic acids may persist in vivo, independent of virus viability. Detection of viral nucleic acids does not imply that the corresponding viruses are infectious or are the causative agents for clinical symptoms.
- There is a chance that the test can give a positive result when monkeypox viral DNA is not actually present (false positive). A false positive result can occur from contamination during specimen handling or preparation, or between patient specimens if the Cartridge Reader is not properly cleaned.
- The performance of this test was established using direct lesion swab specimens collected using the Cue Sample Wand and by using Wands dipped in viral transport media (VTM) containing

previously collected lesion swab specimens only. Assay performance has not been evaluated for use with other collection media and/or specimen types. Use of other collection media and/or specimen types may lead to a false positive, false negative, or invalid result.

- 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 Cue Mpox (Monkeypox) Molecular Test should be interpreted in the context of other available laboratory and clinical data.
- Results from the Cue Mpox (Monkeypox) Molecular Test should be interpreted by a trained professional in conjunction with the patient's history and clinical signs/symptoms and epidemiological risk factors.
- 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 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 I/II.
- This test has not been evaluated for monitoring treatment of monkeypox virus clade I/II infection.
- The impacts of specific vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs on the performance of this test have not been evaluated.
- This test has not been evaluated for screening of blood or blood products for the presence of monkeypox virus clade I/II.

## Conditions of Authorization

The Cue Mpox (Monkeypox) Molecular Test Letter of Authorization along with 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 Cue Mpox (Monkeypox) Molecular Test (referred to in the Letter of Authorization as "Your Product"), the relevant Conditions of Authorization are listed below.

- Authorized laboratories<sup>a</sup> that receive the Cue Mpox (Monkeypox) Molecular Test must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using the Cue Mpox (Monkeypox) Molecular Test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories using the Cue Mpox (Monkeypox) Molecular Test 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 the Cue Mpox (Monkeypox) Molecular Test must use the Cue Mpox (Monkeypox) Molecular Test 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 the Cue Mpox (Monkeypox) Molecular Test are not permitted.

- Authorized laboratories must have a process in place to track adverse events and report to Cue Customer Technical Support 833-283-8378 and to FDA pursuant to 21 CFR Part 803.
- All operators using the Cue Mpx (Monkeypox) Molecular Test must be appropriately trained in performing and interpreting the results of the Cue Mpx (Monkeypox) Molecular Test, use appropriate personal protective equipment when handling the Cue Mpx (Monkeypox) Molecular Test, and use the Cue Mpx (Monkeypox) Molecular Test in accordance with the authorized labeling.
- Cue Health Inc., authorized distributors, and authorized laboratories must collect information on the performance of the Cue Mpx (Monkeypox) Molecular Test and report any significant deviations from the established performance characteristics of the Cue Mpx (Monkeypox) Molecular Test of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA [Reporting@fda.hhs.gov](mailto:Reporting@fda.hhs.gov)). In addition, authorized distributor(s) and authorized laboratories must report to Cue Health Inc. (833.283.8378 or [support@cuehealth.com](mailto:support@cuehealth.com)).
- Cue Health Inc., authorized distributors, and authorized laboratories using the Cue Mpx (Monkeypox) Molecular Test 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.

<sup>a</sup>The letter of authorization refers to “authorized laboratories” as follows: Testing on the Cue Health Monitoring System (Cue Reader) and Cue Cartridge 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, 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.

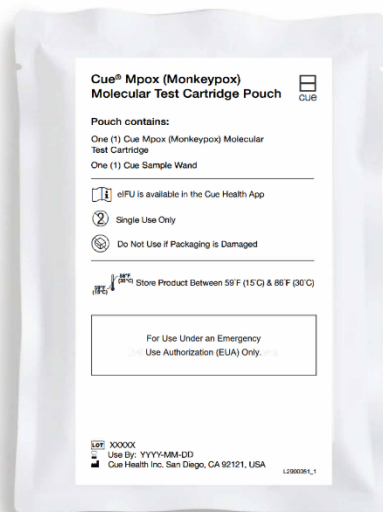
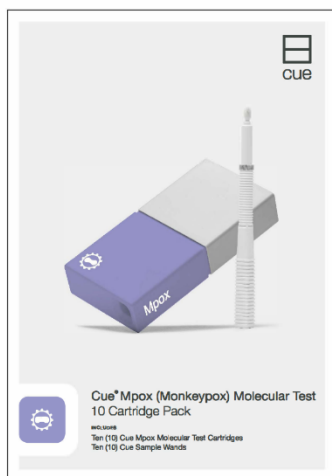
## Materials Provided

- **Cue Mpx (Monkeypox) Molecular Test Cartridge Pack**

Each Cue Mpx (Monkeypox) Molecular Test Cartridge Pack contains one or more foil pouches.

- REF C3090-10 (10 Pack, contains 10 foil pouches with 10 test Cartridges and 10 Sample Wands)

Each foil pouch contains a plastic tray with one (1) single-use Cue Mpx (Monkeypox) Molecular Test Cartridge and one (1) single-use wrapped sterile Cue Sample Wand.



A small pouch called a desiccant is under the Cartridge. This pouch has material inside to protect the Cue Mpox (Monkeypox) Molecular Test Cartridge from damage due to humidity. Throw away the desiccant after the Cartridge is used.

Contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378) if any component is missing or damaged, or if a Cartridge foil pouch is not sealed. You may also contact Cue Health Customer Support to request a physical copy of the Instructions For Use and the Quick Reference Instructions, free of charge.

### Materials Required but Not Provided

- **Cue Health Monitoring System**

Purchase the Cue Health Monitoring System (Cue Reader) (REF C0201) from Cue Health Inc., by contacting Cue Health Customer Support [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378).

- **Mobile Smart Device**

Go to [www.cuehealth.com](http://www.cuehealth.com) for the list of compatible mobile smart devices. BLUETOOTH® wireless technology and Wi-Fi® or cellular capability is required to download the Cue Health App.

- **Cue Health Application installed on the mobile smart device**

Download the Cue Health App from the Apple® App Store® or Google Play™ Store.

- **External Controls**

Controls for the Cue Mpox (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](http://www.zeptometrix.com) or by calling (800) 274-5487.

- Samco Exact Volume Transfer Pipette (Thermo Scientific, Product Number 966NL)
- ARX Sciences Viral Transport Media Collection Kit (Fisher Scientific, Cat # 23-444-014)

### Cue Mpox (Monkeypox) Molecular Test Cartridge Storage Conditions

Store the unopened Cue Mpox (Monkeypox) Molecular Test Cartridge Pack and the foil pouches inside the pack in the temperature range shown in the table below. Do not use a Cartridge that has been stored outside of this temperature condition.

Storage Temperature	59°F (15°C) to 86°F (30°C)
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Do not use a Cartridge beyond the Use By date on the Cartridge foil pouch label.

### Cue Mpox (Monkeypox) Molecular Test Testing Conditions

Run a Cue Mpox (Monkeypox) Molecular Test in the temperature range shown in the table below. Do not run the Cue Mpox (Monkeypox) Molecular Test if you are outside of this temperature condition. Use caution if using this device outdoors as it has not been tested at extreme high or low temperatures or high humidity.

Operational Temperature	59°F (15°C) to 86°F (30°C)
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### Quality Control (QC)

#### External Positive and Negative Controls

External Positive and Negative Controls should show that the Cue Mpox (Monkeypox) Molecular Test is working properly. Controls for the Cue Mpox (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](http://www.zeptometrix.com) or by calling (800) 274-5487. Controls should be stored according to the manufacturer's instructions.

Cue Health recommends that negative and positive controls be run:

- With each new lot of Cartridges 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

### 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.

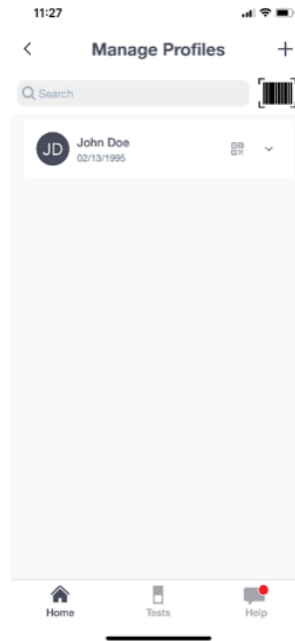
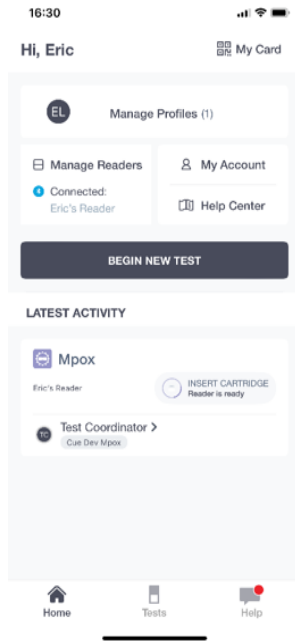
#### Positive Control

Positive Control needs to be diluted using a 300  $\mu$ L Samco Exact Pipette (Product Number 966NL). Pipette 300  $\mu$ L of the Positive Control into 3 mL of Viral Transport Media (VTM) (Fisher Scientific, Cat # 23-444-014). Invert the tube to mix.

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](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378) before testing additional clinical specimens.

## Specimen Collection and Handling

### Direct Skin Lesion Sample Collection

- Specimen collection must occur by trained healthcare personnel.
- Do not clean the lesion with ethanol or any other disinfectant prior to swabbing.
- For best results, swab a lesion that is in one of the following stages: papular (solid and raised with distinct borders), vesicular (a lesion with fluid trapped under the skin), or pustular (a lesion that is filled with yellow fluid). Lesions that look flat, like a rash (macular), may also be swabbed.
- Using the Cue Sample Wand, swab vigorously back and forth on the lesion surface at least 5 times for about 5 seconds.
- Rotate the Cue Sample Wand by one-quarter to one-half turn and swab the same lesion vigorously at least 3 more times.
- Apply firm pressure when swabbing. This may result in discomfort or slight pain, but it is necessary to obtain an adequate sample.
- If the lesion ruptures while swabbing, collect some lesion fluid with the Wand.

### **Previously Collected Skin Lesion Sample in Viral Transport Media**

- The Cue Sample Wand may be dipped into a tube containing a previously collected skin lesion sample in viral transport media (VTM). Instructions for Cue Sample Wand dipping are provided in Step 5-8.
- Lesion swab specimens collected in VTM can be stored refrigerated (2-8°C) up to seven days or at -20°C for up to 30 days before the Cue Sample Wand can be dipped and inserted into the Cartridge for testing.
  - Refer to the CDC Guidelines for Collecting and Handling Specimens for Mpox Testing <https://www.cdc.gov/poxvirus/Mpox/clinicians/prep-collection-specimens.html>

The Cue Sample Wand containing the skin lesion sample must be inserted into the Cartridge within 5 minutes of sample collection.

### **Directions for Running the Cue Mpox (Monkeypox) Molecular Test**

Follow the step-by-step instructions provided below.

#### **Step 1: Obtain Items Required but Not Provided in the Cartridge Pack**

You will need the items below to run the Cue Mpox (Monkeypox) Molecular Test. These items are not included in the Cue Mpox (Monkeypox) Molecular Test Cartridge Pack.

- Cue Health Monitoring System. You can purchase the system from Cue Health Inc., by contacting Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378).
- Go to [www.cuehealth.com](http://www.cuehealth.com) for the list of compatible mobile smart devices. BLUETOOTH wireless technology and Wi-Fi® or cellular capability is required to download the Cue Health App.
- The Cue Health App installed on your mobile smart device. Download the Cue Health App from Apple App Store or Google Play Store.

#### **Step 2: Set Up Your System**

Read the Cue Health Monitoring System Quick Start Guide and the User Manual before you run a Cue Mpox (Monkeypox) Molecular Test. The Quick Start Guide will help you quickly set up your Cue Health Monitoring System (Cue Reader) and get ready to run a test. The User Manual gives you all the information you need to use your Cue Health Monitoring System correctly and safely. The Quick Start Guide or the User Manual will show you step-by-step how to do the following:

1. Unpack and set up the Cue Cartridge Reader.
2. Download the Cue Health App by going to the Apple App Store or Google Play Store and searching for the Cue Health App.
3. Set up your Cue Account in the Cue Health App. Once you have set up a Cue Account, you may create and edit account profiles for persons being tested. All your test data will be saved under your Cue Account in the Cue Health App and on the Cue Health secure cloud server.
4. Pair Cue Reader(s) to your mobile smart device.
5. Connect the Cue Health App to a paired Cue Cartridge Reader to run a Cue Mpox (Monkeypox) Molecular Test.
6. Learn more about your Cue Health Monitoring System and all the above system set-up steps in the Cue Health Monitoring System User Manual.

#### **Step 3: Review All Information**

Review the information provided in this Cue Mpox (Monkeypox) Molecular Test Instructions for Use before running a test. If you do not understand the instructions, do not run a test. Contact Cue Health

Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378) for help.

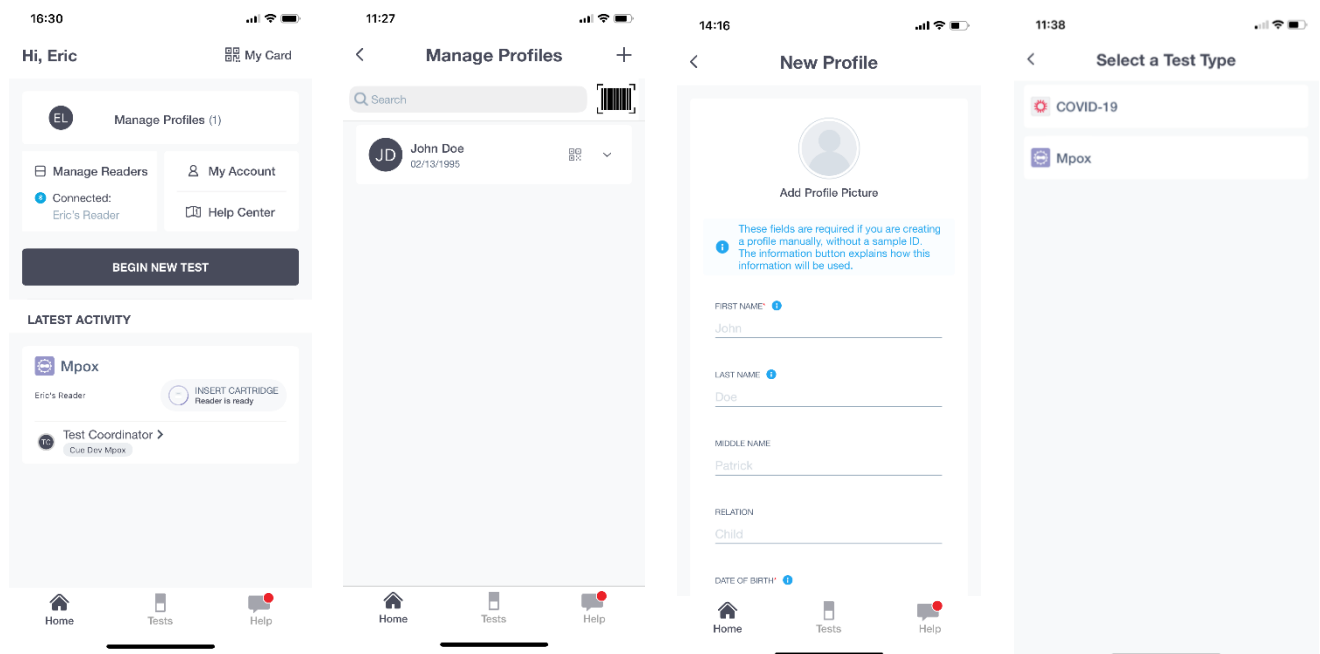
The Cue Health App uses pictures and videos to walk you through, step-by-step, how to collect a skin lesion sample and run a Cue Mpx (Monkeypox) Molecular Test. If you do not follow the instructions, the test may not run as it should, and you may not receive a test result or the test result may not be correct.

#### Step 4: Open the Cue Health App on Your Mobile Smart Device and Follow the On-Screen Instructions

1. The first time you use the Cue Health App you must accept the "Terms of Use and End User License Agreement" and the "Privacy Policy."
2. A Cue Health App update may be required before you run a test. Follow any on-screen instructions for updating the Cue Health App.
3. The first time you use the Cue Health App you will need to tap Create Account. After Creating an Account you may Login.
4. Make sure that the Cue Cartridge Reader you will be using is paired to your mobile smart device. Follow the Cue Health Monitoring System's Quick Start Guide or User Manual and the on-screen instructions to pair the Cue Cartridge Reader to the mobile smart device.
5. Make sure that the Cue Health App is connected to the Cue Cartridge Reader that you will be using for the Cue Mpx (Monkeypox) Molecular Test. Follow the Cue Health Monitoring System User Manual and the on-screen instructions to connect to the Cue Cartridge Reader.
6. Follow the on-screen instructions to run a test. Step 5 below also tells you how to run a test using the Cue Health App.

#### Step 5: Run a Cue Mpx (Monkeypox) Molecular Test

Log into your Cue Account. After logging into your account, tap on Manage Profiles. Choose the person's name or barcode ID being tested or add a new profile. To add a new profile, tap the + sign, type in the person's identification information and SAVE. Tap the barcode icon to scan a patient barcode ID. Tap on the name or patient barcode ID. Then tap "BEGIN NEW TEST" and you will see the screen below to choose to run the Cue Mpx (Monkeypox) Molecular Test.



If prompted, select your organization or select “NOT TESTING FOR AN ORGANIZATION.”

The instructions below are the same step-by-step instructions as shown in the Cue Health App videos and screens.

**REMINDER:** If your mobile smart device loses battery charge while performing the test, the test on the Cue Cartridge Reader will still run to completion. The test result will be saved. The mobile smart device must be charged to see the test result. Make sure your mobile smart device is close to the Cue Reader after a test completes so you can view the result on the screen in the Cue Health App.

**Step 5-1: View Intended Use**

Read the Intended Use presented to you in the Cue Health App and then you may continue.

**Step 5-2: View Precautions**

Precautions are important to follow to ensure that the test runs correctly. Limitations are important to understand before you run the test. See the Precautions and Limitations sections in this document.

**Wear personal protective equipment when collecting patient samples and when running the Cue Mpox (Monkeypox) Molecular Test.**

Read the precautions presented to you in the Cue Health App and then you may continue.

**Step 5-3: Pair the Cue Health App to the Cue Cartridge Reader(s)**

Connect the Cue Cartridge Reader to power by using the Cue Power Adapter and Cue Charging Cable. Follow the Cue Health App videos and screen instructions to pair the Cartridge Reader that will be used for the test(s) to your mobile smart device. When a paired Cartridge Reader is within BLUETOOTH wireless technology range of the mobile smart device, the Cartridge Reader is “connected” to the Cue Health App. The same instructions are in the Quick Start Guide and the Cue Health Monitoring System User Manual.

**Step 5-4: Gather the Materials to Run the Test**

Place the Cue Reader and a Cue Mpox (Monkeypox) Molecular Test Cartridge foil pouch in front of you. See the Cue Health App video showing these materials that you need to run a test as shown in Figure 5-4.

**REMINDER:** Open the Cue Mpox (Monkeypox) Molecular Test Cartridge foil pouch when you are ready to test. Do not open the foil pouch more than 30 minutes before you begin a test. If more than 30 minutes have passed since you opened the foil pouch containing the Cartridge, obtain a new Cartridge.

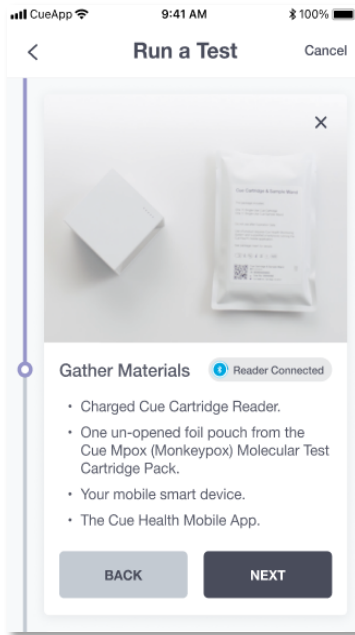


Figure 5-4

**Step 5-5: Prepare the Cue Mpx (Monkeypox) Molecular Test Cartridge and Cue Sample Wand for a Test**

Tear open the top of the Cartridge foil pouch and remove the plastic tray with the Cue Mpx (Monkeypox) Molecular Test Cartridge and sterile Cue Sample Wand. Remove the Cue Mpx (Monkeypox) Molecular Test Cartridge and the wrapped Cue Sample Wand from the tray.

See the Cue Health App video showing how to prepare the Cue Mpx (Monkeypox) Molecular Test Cartridge and Cue Sample Wand for a test as shown in Figure 5-5.

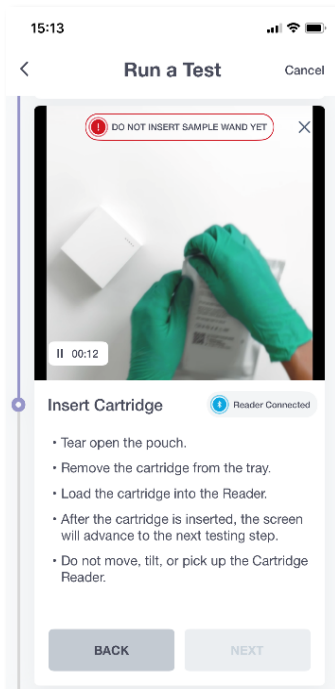


Figure 5-5

## Step 5-6: Insert the Cue Mpox (Monkeypox) Molecular Test Cartridge into the Cue Reader

See the Cue Health App video showing how to insert the test Cartridge into the Cue Reader as shown in Figure 5-6-1.

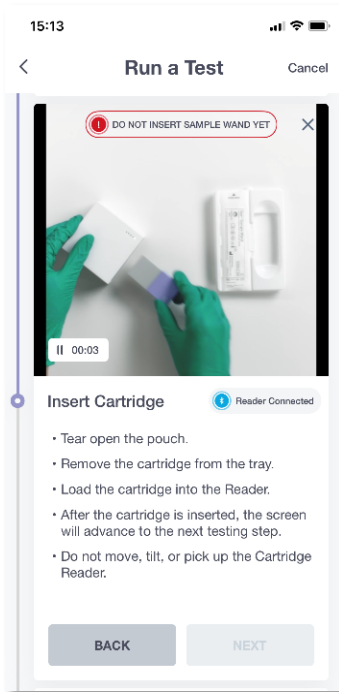


Figure 5-6-1

**REMINDER:** The test Cartridge must be inserted first before the Cue Sample Wand. The test Cartridge must be inserted logo side up.

**REMINDER:** The Cue Reader needs to be on a level surface when the Cue Mpox (Monkeypox) Molecular Test Cartridge is inserted and while the test is running. Do not move the Cue Reader while the test is running.

Support the back of the Cue Reader with one hand and hold the Cue Mpox (Monkeypox) Molecular Test Cartridge in the other hand. Insert the Cartridge (logo side up) into the Cartridge port of the Reader. When you have fully inserted the Cartridge, all five lights on top of the Cue Reader will flash and the Cue Health App screen will progress to the screen entitled "Cartridge Preheating".

**REMINDER:** The test Cartridge must heat up for the full 100% heat cycle before the Cue Sample Wand is inserted into the Cartridge. All of the LED lights on the Reader will flash 5 times when the test Cartridge is ready for the Cue Sample Wand.

When you have inserted the test Cartridge all the way in, the Cartridge will start to heat up to prepare for a test, and you will see the Cue Health App video as shown in Figure 5-6-2. When the test Cartridge has finished heating up, the progress circle will show 100%.

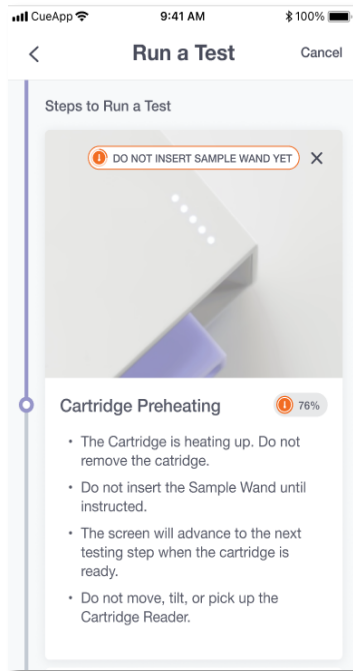


Figure 5-6-2

### **Step 5-7: Collect a Direct Skin Lesion Sample with the Cue Sample Wand and Insert Into the Test Cartridge**

When the test Cartridge heating cycle is completed, the Cue Health App will advance to the Collect Sample screen. You may collect a direct skin lesion sample or you may dip the Cue Sample Wand into a tube containing a previously collected skin lesion sample in viral transport media (VTM).

Open the wrapped Cue Sample Wand on the side labeled "Open Here." Grasp the handle of the Cue Sample Wand and remove it from the wrapping. The Wand is sterile. Make sure the Wand tip does not touch anything. If the Wand accidentally touches any surface or is dropped, use a new Cue Sample Wand.

Proceed to Step 5-8 for instructions on dipping the Cue Sample Wand into a tube containing a previously collected skin lesion sample in viral transport media. Continue below for collecting a direct skin lesion sample.

You will see a video on how to collect a direct skin lesion sample and insert the Cue Sample Wand into the test Cartridge as shown in Figures 5-7-1 and 5-7-2.



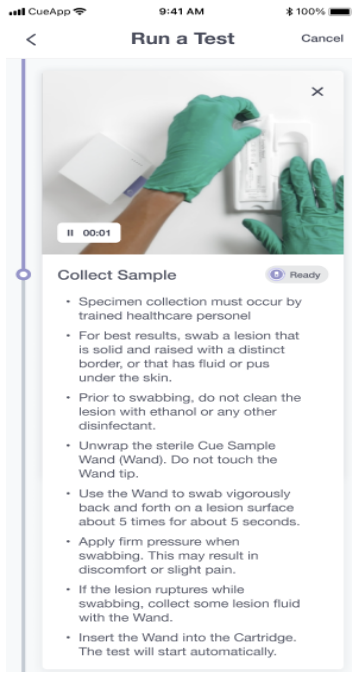


Figure 5-7-1

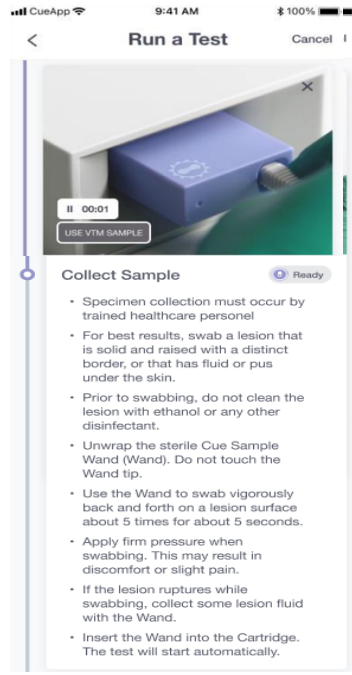


Figure 5-7-2

**REMINDER:** It is important to collect the skin lesion sample at the time of the Collect Sample screen and insert the Cue Sample Wand with the sample into the Cue Mpx (Monkeypox) Molecular Test Cartridge shortly after collecting the skin lesion sample. The Cue Mpx (Monkeypox) Molecular Test Cartridge should not be in the Reader without the inserted Wand for more than 10 minutes after preheating is complete, otherwise the test will automatically cancel. The Cue Health App will display reminders to insert the Cue Sample Wand as shown in Figure 5-7-3.

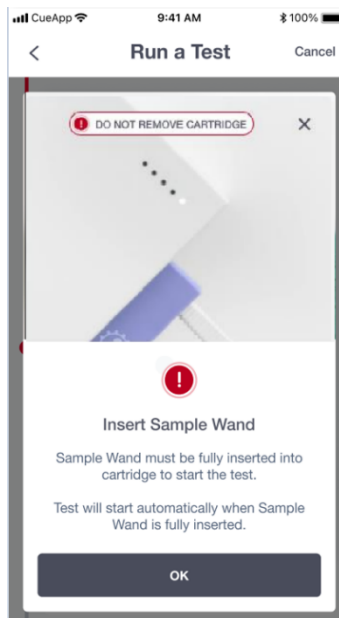


Figure 5-7-3

Follow the Cue Health App instructions below to collect a direct skin lesion swab sample with the Cue Sample Wand.

- Do not clean the lesion with ethanol or any other disinfectant prior to swabbing.
- For best results, swab a lesion that is in one of the following stages: papular (solid and raised with distinct borders), vesicular (a lesion with fluid trapped under the skin), or pustular (a lesion that is filled with yellow fluid). Lesions that look flat, like a rash (macular), may also be swabbed.
- Using the Cue Sample Wand, swab vigorously back and forth on the lesion surface at least 5 times for about 5 seconds.
- Rotate the Cue Sample Wand by one-quarter to one-half turn and swab the same lesion vigorously at least 3 more times.
- Apply firm pressure when swabbing. This may result in discomfort or slight pain, but it is necessary to obtain adequate sample.
- If the lesion ruptures while swabbing, collect some lesion fluid with the Wand.

**REMINDER:** You must insert the Cue Sample Wand with skin lesion sample into the Cue Mpox (Monkeypox) Molecular Test Cartridge within 5 minutes of collecting the skin lesion sample.

Support the back of the Cue Reader with one hand and hold and insert the Cue Sample Wand with skin lesion sample into the port of the Cue Mpox (Monkeypox) Molecular Test Cartridge. Make sure the Wand is inserted all the way in until the Cue Health App progresses to the screen entitled “Test in Progress”. See Step 5-9 and Figure 5-9.

#### **Step 5-8: Sample Dipping**

Skip this step if you have already collected a direct skin lesion sample with the Cue Sample Wand.

Open the wrapped Cue Sample Wand on the side labeled "Open Here." Grasp the handle of the Cue Sample Wand and remove it from the wrapping. The Wand is sterile. Make sure the Wand tip does not touch anything. If the Wand accidentally touches any surface or is dropped, use a new Cue Sample Wand.

Follow the instructions below as shown in the Cue Health App (See Figure 5-8) for dipping the Cue Sample Wand into a tube containing an individual skin lesion swab sample in viral transport media (VTM) and running the sample.

1. To ensure proper mixing, gently invert the capped VTM specimen tube, then hold the cap and gently tap the bottom of the tube on a tabletop 3 times to remove excess sample liquid from the cap.
2. Uncap the tube.
3. Insert the Cue Sample Wand tip into the liquid and swirl the Wand as you rotate around the inner walls of the tube 3 times.
4. 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.
5. 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.
6. 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.

7. Remove the Cue Sample Wand from the tube.
8. Support the back of the Cue Cartridge Reader and insert the Cue Sample Wand with sample into the port of the Cue Mpox (Monkeypox) Molecular Test Cartridge. Make sure the Wand is inserted all the way in until Test in Progress is shown on the Cue Health App screen. See Step 5-9 and Figure 5-9.

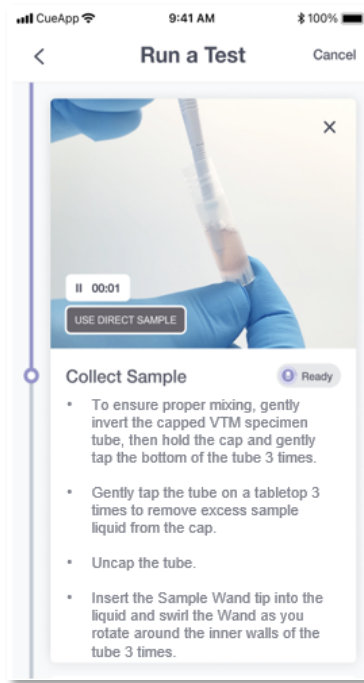


Figure 5-8

**REMINDER:** It is important to collect the Cue Sample Wand lesion sample by dipping into the individual sample tube at the time of the Collect Sample screen in the Cue Health App and inserting the Sample Wand with the lesion sample into the Cue Mpox (Monkeypox) Molecular Test Cartridge immediately. The Cue Mpox (Monkeypox) Molecular Test Cartridge should not be in the Cartridge Reader without the inserted Sample Wand for more than 10 minutes.

### Step 5-9: Test Progress

The test will start as soon as the Cue Sample Wand is fully inserted into the Cue Mpox (Monkeypox) Molecular Test Cartridge. It takes about 25 minutes for the Cue Mpox (Monkeypox) Molecular Test to run. Once the test starts, the Cue Health App will show the test progress as percent completed as shown in Figure 5-9.

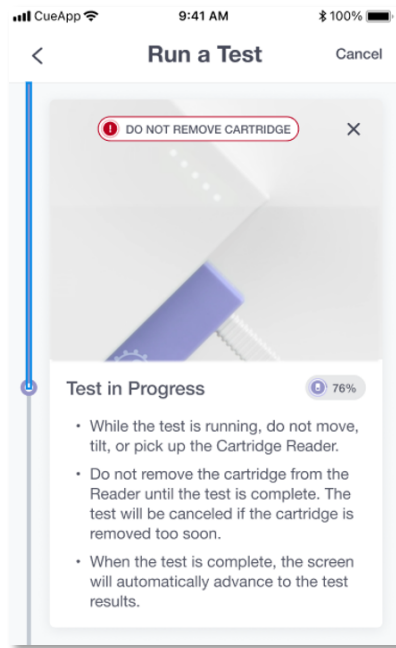


Figure 5-9

### Step 5-10: View the Result

The Cue Health App will show the Cue Mpox (Monkeypox) Molecular Test result when the test is complete. The result is saved in the Cue Account profile that was selected before the test started. See Step 6 below for understanding the test results and what each result means.

### Step 5-11: Remove the Cue Mpox (Monkeypox) Molecular Test Cartridge with the Cue Sample Wand After Testing

Remove the test Cartridge from the Cue Cartridge Reader by holding the Cartridge Reader with one hand and carefully pulling the Cartridge out of the Reader with the other hand. The Sample Wand must not be removed and should remain inside the Cartridge. 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. If country or regional regulations do not provide clear direction on proper disposal, used Cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

## Step 6: Understand the Test Results

The Cue Health App shows the result as Negative, Positive, Invalid, or Canceled.

### Step 6-1: Understanding a Negative Result

A Negative result means that the Cue Mpox (Monkeypox) Molecular Test did not detect monkeypox virus DNA in the sample. It is unlikely that the person you tested has mpox.

- There is a small chance that the test may give a negative result even if the person who was tested has mpox (false negative). A negative result does not rule out mpox 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 mpox. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that mpox is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If mpox is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

- Risks to a patient of a false negative include delayed or lack of supportive treatment; lack of monitoring of infected individuals and their household or other close contacts for symptoms, resulting in increased risk of spread of mpox within the community; and other unintended adverse events.

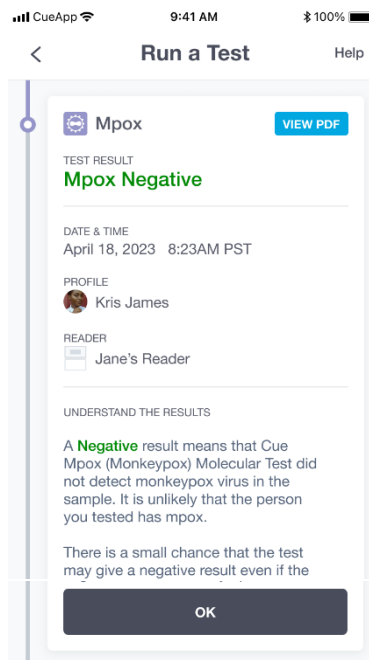


Figure 6-1

Click on back < at the top left of the Cue Health App Screen to return to a screen where you can run a new test.

### Step 6-2: Understanding a Positive Result

A Positive result means that the Cue Mpx (Monkeypox) Molecular Test detected monkeypox virus DNA in the sample. It is likely that the person you tested has mpox.

- There is a small chance that this test can give a positive result even when the person tested does not have mpox (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 mpox.
- A positive result does not mean that the patient's symptoms are from mpox alone. It is possible that another type of illness is contributing to their symptoms.
- Risks to a patient of a false positive includes an unnecessary recommendation for the patient to isolate; unnecessary monitoring of household or other close contacts for symptoms; patient isolation that might limit contact with family or friends and may increase contact with mpox infected patients; limits in the ability to work; delayed diagnosis and treatment of the infection causing the symptoms; unnecessary treatment or therapy; or other unintended adverse effects.

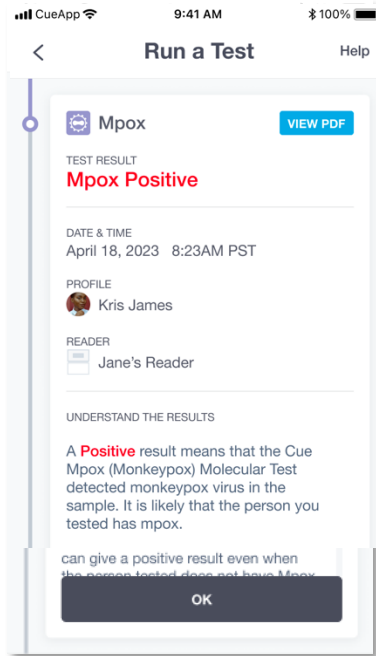


Figure 6-2

Click on back < at the top left of the Cue Health App Screen to return to a screen where you can run a new test.

### Step 6-3: Understanding an Invalid Result

An Invalid result means that you may not have collected enough sample, or a system error occurred, and the Cue Health Monitoring System is not able to provide the result of the test. Retesting is required.

Common causes of invalid results are:

- You did not collect enough sample
- A processing error occurred inside the test Cartridge

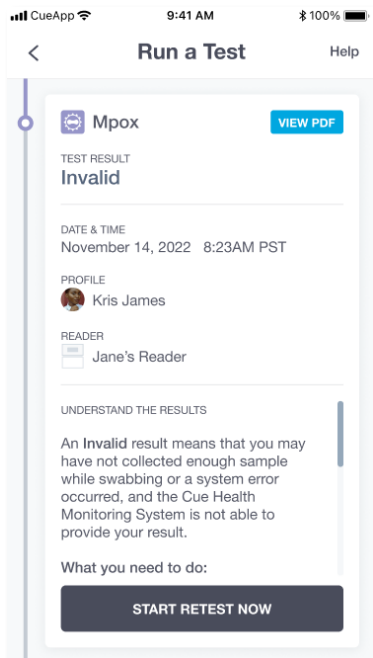


Figure 6-3

If the result is Invalid, retest. Click on START RETEST NOW. You must use a new Cue Mpx (Monkeypox) Molecular Test Cartridge and a new Cue Sample Wand.

#### Step 6-4: Understanding Test Result Canceled

You will see a test result of Canceled if you purposely canceled the test by tapping “Cancel” in the top right corner of the Cue Health App screen, if the system canceled the test due to a mechanical error, or because you did not follow the test instructions correctly.

Examples of when the system will cancel a test include:

- The Cue Cartridge Reader is moved or tilted while the test is running
- The test Cartridge was stored outside of recommended conditions and not equilibrated to the claimed storage range (15-30°C) prior to testing
- The test Cartridge is removed before the test is completed
- The Cue Sample Wand is inserted into the test Cartridge too soon (the Cartridge did not complete preheating) or too late (more than 10 minutes after the test Cartridge completes preheating).

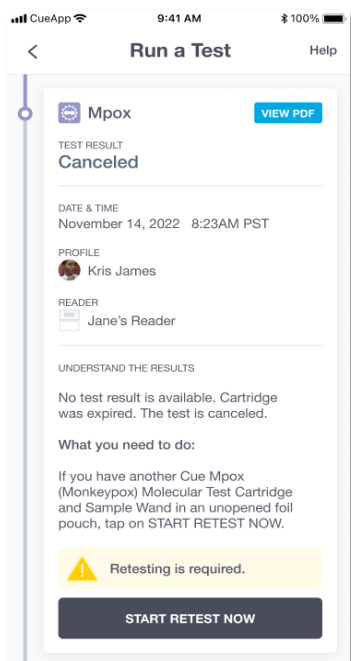


Figure 6-4

If the result is canceled, retest. Click on START RETEST NOW. You must use a new Cue Mpx (Monkeypox) Molecular Test Cartridge and a new Cue Sample Wand.

#### Cleaning and Disinfecting the Cue Cartridge Reader

The Cue Cartridge Reader should be cleaned and disinfected after each use. Wipe down with Clorox® Germicidal Wipes or equivalent (containing 0.55% sodium hypochlorite as the active ingredient). Do not spray any cleaning solution directly onto the Cue Cartridge Reader or into the Cartridge Port. Do not put any part of the Cue Cartridge Reader under water or any other liquid. Do not attempt to clean any internal parts.

#### Disposal of the Used Cue Mpx (Monkeypox) Molecular Test Cartridge

After each test, the Cue Mpx (Monkeypox) Molecular Test Cartridge with the Cue Sample Wand still inside must be removed from the Cue Cartridge Reader. Used test 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. If country or regional regulations do not provide clear direction on proper disposal, used Cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

## Analytical Performance

### Limit of Detection (LoD)

The Limit of Detection (lowest concentration with  $\geq 95\%$  detection) for the Cue Mpox (Monkeypox) Molecular Test was determined with one strain of chemically inactivated monkeypox (ZeptoMetrix; USA/MA001/2022, Cat #NATMPXV-ERC). The concentration of the monkeypox virus stock was 15 copies/ $\mu\text{L}$  as determined by the manufacturer. The monkeypox virus was serially diluted in skin clinical matrix (SCM) which is made of negative skin swabs eluted in Phosphate Buffered Saline (PBS), to obtain four low level concentrations. Ten microliters of each dilution were applied to a dry Cue Sample Wand followed by insertion into the preheated test Cartridges for testing. The dilutions were tested in triplicate using two Cue Mpox (Monkeypox) Molecular Test Cartridge lots on each of three days for a total of 60 replicates per dilution. The confirmed LoD was one (1) genome copy/Sample Wand or 0.1 genome copies/ $\mu\text{L}$  of sample.

### Limit of Detection Confirmation

Material	Claimed LoD Genome Copies/Sample Wand	Claimed LoD Genome Copies/ $\mu\text{L}$ of Sample	Confirmation Positives/Replicates
Inactivated Mpox virus (USA/MA001/2022)	1	0.1	40/40 <sup>1</sup>

<sup>1</sup> Two initial tests were canceled and retested. The repeat testing generated positive results.

### Performance around LoD (Reproducibility)

The performance of the Cue Mpox (Monkeypox) Molecular Test near the LoD was assessed using contrived samples that were tested in a blinded fashion by untrained operators. A total of 36 contrived positive samples consisted of inactivated monkeypox virus (ZeptoMetrix; USA/MA001/2022, Cat #NATMPXV-ERC) prepared at 1.5x LoD in skin clinical matrix (SCM). A total of 36 negative samples were made of SCM only. On each testing day, a trained laboratorian prepared and passed the Sample Wands to the untrained operator to run the test. The study was performed using three internal, simulated POC sites each with four Cartridge Readers. Each panel member was run four times per day per site over three days. Overall agreement with the expected results was 100% for contrived positive and negative samples.

### Evaluation of Performance Around the Assay LoD

Operator	Day	Detected/Total Tested		% Result Agreement
		Negative Sample	Positive Sample	
1	1	0/4	4/4	100%
	2	0/4 <sup>1</sup>	4/4	100%
	3	0/4	4/4	100%
2	1	0/4 <sup>1</sup>	4/4	100%
	2	0/4	4/4 <sup>1</sup>	100%
	3	0/4	4/4	100%
3	1	0/4 <sup>2</sup>	4/4	100%
	2	0/4	4/4	100%
	3	0/4	4/4	100%

<sup>1</sup> One initial canceled test was retested. The repeat testing generated the expected result.

<sup>2</sup> One initial invalid test was retested. The repeat testing generated the expected negative result.



## VTM Matrix Equivalency Study

The LoD of the Cue Mpox (Monkeypox) Molecular Test was confirmed in VTM with natural lesion swab matrix. This study also served to validate the use of skin clinical matrix (SCM), a surrogate for natural lesion swab matrix used in the original LoD study. Contrived specimens were prepared with quantified inactivated monkeypox virus (USA/MA001/2022) in pooled negative skin lesion swab samples collected in VTM at three concentrations relative to the LoD established for the dry Cue Sample Wand (i.e., 1 genome copy/Wand). Wands were prepared by applying 10 µL of inactivated monkeypox virus in pooled VTM lesion swab matrix at different concentrations onto the swab head. The confirmed assay LoD for lesion swab matrix in VTM was 1.5 genome copies/Wand which is similar to the LoD of 1 genome copy/Wand for a dry lesion Cue Sample Wand. This study also demonstrated equivalence between SCM and natural lesion swab matrix containing VTM.

## Analytical Reactivity/Inclusivity

The Cue Mpox (Monkeypox) Molecular Test primers/probe were evaluated *in silico* against all available monkeypox virus strains of the Congo Basin clade (clade I) and the West African clade (clade II) in the NCBI Virus database as of February 2023. Thirty-four monkeypox virus strains of the Congo Basin clade (clade I) and 2056 West African clade (clade II) sequences were used in the analysis. The reverse primer has a single mismatch in the 5<sup>th</sup> position from the 5' end for all clade I monkeypox virus strains that were evaluated. One of the 2056 clade II sequences exhibited a single mismatch in the 9<sup>th</sup> position from the 5' end of the forward primer. The presence of a single mismatch is not predicted to impact test performance. The Cue Mpox (Monkeypox) Molecular Test primers/probe are predicted to be inclusive of all available monkeypox virus strains of the Congo Basin clade (clade I) and the West African clade (clade II) as of February 2023 as shown in the table below.

**Percent Match of Primers/Probe to Available Clade I and Clade II Sequences  
as of February 2023**

Primer	# of Sequences Evaluated	# of Sequences with 100% Homology	% of All Analyzed Genomes with Perfect Match
Forward Primer	2150	2149/2150	99.96%
Reverse Primer	2150	2116/2150	98.42%
Probe	2150	2150/2150	100.00%

## Analytical Specificity – Cross-Reactivity *In Silico* Analysis

An *in silico* analysis for possible cross-reactivity with 10 viruses, 2 fungi, and 20 bacteria was conducted by mapping the Cue Mpox (Monkeypox) Molecular Test primers/probe sequences to the genomic sequences of each organism shown below. Of the 97 Cowpox virus BLAST results that were analyzed, 11% exhibited >80% homology to only the monkeypox specific probe, but these sequences are not expected to cross-react since there was no homology to the monkeypox virus primers. Overall, the *in silico* analysis demonstrated that there were no microorganisms for which the reference strain and BLASTn accession IDs showed ≥80% homology with all three oligonucleotide components (forward primer, reverse primer, probe) for the monkeypox virus target.

### Cross-Reactivity *In Silico* Analysis

Organism	Reference Sequence Accession ID	Forward primer results at $\geq 80\%$ homology	Reverse primer results at $\geq 80\%$ homology	Probe results at $\geq 80\%$ homology
<i>Acinetobacter calcoaceticus</i>	NZ_CP020000.1	No	No	No
<i>Bacteriodes fragilis</i>	NZ_CP069563.1	No	No	No
Camelpox virus	NC_003391.1	No	No	No
<i>Candida albicans</i>	NC_032089.1 NC_032090.1 NC_032091.1 NC_032092.1 NC_032094.1 NC_032095.1 NC_032096.1	No	No	No
<i>Chlamydia trachomatis</i>	NC_000117.1	No	No	No
<i>Corynebacterium diphtheriae</i>	NZ_CP025209.1	No	No	No
<i>Corynebacterium jeikeium</i>	NC_007164.1	No	No	No
Cowpox virus	NC_003663.2	No	No	Yes (72-92%)
Ectromelia (mousepox) virus	NC_004105.1	No	No	No
<i>Enterococcus faecalis</i>	NZ_ASDH00000000.1	No	No	No
<i>Escherichia coli</i>	NC_002695.2 NC_000913.3	No	No	No
Herpes Simplex Virus 1	NC_001806.2	No	No	No
Herpes Simplex Virus 2	NC_001798.2	No	No	No
Human Genomic DNA	NC_000001.11 NC_000002.12 NC_000003.12 NC_000004.12 NC_000005.10 NC_000006.12 NC_000007.14 NC_000008.11 NC_000009.12 NC_000010.11 NC_000011.10 NC_000012.12	No	No	No

Organism	Reference Sequence Accession ID	Forward primer results at $\geq 80\%$ homology	Reverse primer results at $\geq 80\%$ homology	Probe results at $\geq 80\%$ homology
	NC_000013.11 NC_000014.9 NC_000015.10 NC_000016.10 NC_000017.11 NC_000018.10 NC_000019.10 NC_000020.11 NC_000021.9 NC_000022.11 NC_000023.11 NC_000024.10 NC_012920.1			
Human papilloma virus (HPV)	NC_027779.1	No	No	No
<i>Lactobacillus acidophilus</i>	NC_021181.2	No	No	No
<i>Lactobacillus jensenii</i>	NZ_CP018809.1	No	No	No
<i>Lactobacillus vaginalis</i>	NZ_CP104399.1	No	No	No
<i>Molluscum contagiosum</i> virus	NC_001731.1	No	No	No
<i>Mycoplasma genitalium</i>	NC_000908.2	No	No	No
<i>Mycoplasma pneumoniae</i>	NZ_LR214945.1	No	No	No
<i>Neisseria gonorrhoeae</i>	NZ_AP023069.1	No	No	No
<i>Pseudomonas aeruginosa</i>	NC_002516.2	No	No	No
<i>Streptococcus pyogenes</i>	NZ_LS483338.1	No	No	No
<i>Streptococcus dysgalactiae</i> subspecies <i>equisimilis</i> (Group C & G)	NZ_AP023394.1	No	No	No
<i>Streptococcus agalactiae</i>	NZ_CP012480.1	No	No	No
<i>Streptococcus mitis</i>	NZ_JYGP00000000.1	No	No	No

Organism	Reference Sequence Accession ID	Forward primer results at ≥80% homology	Reverse primer results at ≥80% homology	Probe results at ≥80% homology
<i>Staphylococcus aureus</i>	NC_007795.1	No	No	No
<i>Staphylococcus epidermidis</i>	NZ_CP035288.1	No	No	No
<i>Treponema pallidum</i>	NC_016842.1	No	No	No
<i>Trichomonas vaginalis</i>	None in Ref Seq Database	No	No	No
<i>Trichophyton rubrum</i>	None in Ref Seq Database	No	No	No
Vaccinia virus	NC_006998.1	No	No	No
Variola virus (smallpox)	NC_001611.1	No	No	No
Varicella-Zoster virus (Chickenpox)	NC_001348.1	No	No	No

### Analytical Specificity – Interfering Substances

Potential assay interference from common endogenous and exogenous substances that could be associated with a lesion swab sample was assessed. Potential interferents were tested at the highest concentration likely to be found in a skin sample. Each interfering substance in negative skin clinical matrix was tested in triplicate. Each interfering substance was also tested in triplicate in the presence of inactivated monkeypox virus (ZeptoMetrix; USA/MA001/2022, Cat #NATMPXV-ERC) at 3x LoD. If any interference was observed, an additional 20 replicates were run. In the case of douche fluid, 20 fresh prepared positive Cue Sample Wands were tested with new test Cartridges from the same Cartridge lot as the initial test and 19/20 replicates generated the expected result. One of the 20 replicates had a canceled test result and upon retesting, generated the expected positive result.

None of the substances tested were found to impact performance of the Cue Mpox (Monkeypox) Molecular Test at the concentrations tested in this study.

### Interfering Substances Evaluation

Substance	Substance Level	Detected/Tested		Interference at Concentration Tested (Yes/No)
		Negative Sample	Positive Sample	
Abreva	7% (w/v)	0/3	3/3*	No
Acyclovir	7 mg/mL	0/3	3/3	No
Albumin	2.2 mg/mL	0/3	3/3	No
Benadryl Cream /Ointment	7% (w/v)	0/3	3/3	No

Substance	Substance Level	Detected/Tested		Interference at Concentration Tested (Yes/No)
		Negative Sample	Positive Sample	
Biotin	3.5 µg/mL	0/3	3/3	No
Blood/EDTA	5% (v/v)	0/3	3/3	No
Carmex	7% (w/v)	0/3	3/3	No
Casein	7 mg/mL	0/3	3/3	No
Cornstarch	2.5 mg/mL	0/3	3/3*	No
Douche	7% (v/v)	0/3	22/23**	No
Feces	0.22% (w/v)	0/3	3/3	No
Female Urine	10% (v/v)	0/3	3/3*	No
Hydrocortisone Cream	7% (w/v)	0/3	3/3	No
KY Jelly	7% (w/v)	0/3	3/3	No
Lanacane	3.5% (w/v)	0/3	3/3	No
Male Urine	10% (v/v)	0/3	3/3	No
Mucin	60 µg/mL	0/3	3/3	No
Neosporin	7% (w/v)	0/3	3/3	No
Seminal Fluid	7% (v/v)	0/3	3/3	No
Vagisil Cream	1% (w/v)	0/3	3/3*	No
Zinc Oxide Ointment	7% (w/v)	0/3	3/3*	No

\*One initial invalid or canceled result was retested. The repeat testing generated the expected result.

\*\*One initial test was negative. Twenty additional samples were tested and one canceled test was retested. The repeat testing generated the expected positive result.

### Clinical Performance

The performance of the Cue Mpox (Monkeypox) Molecular Test was evaluated using 60 deidentified archived clinical lesion swab samples in VTM (30 positive samples and 30 negative samples) collected from patients suspected of mpox. A trained laboratorian prepared Cue Sample Wands by dipping into the archived lesion swab specimens in VTM. Wands were then passed to the untrained user to run the test. Wands were prepared fresh on each day of testing. All of the clinical specimens were acquired from a medical institution with accompanying positive or negative results from an FDA-cleared real-time PCR assay. A total of 30 positive specimens, including four low positive specimens (4/30 = 13.3%) and 30 negative specimens were tested by the Cue Mpox (Monkeypox) Molecular Test in a simulated point of care setting by four untrained operators. Each sample was labeled with a unique study ID, blinding the untrained operator running the test to the expected sample result.

Positive percent agreement (PPA) and negative percent agreement (NPA) were determined by comparing results of the Cue Mpox (Monkeypox) Molecular Test to the known results of the FDA-cleared real-time PCR assay. The PPA and NPA for the Cue Mpox (Monkeypox) Molecular Test were both 100%. Thirty of the 30 known positive samples were positive by the candidate Cue test. One known negative was invalid in the initial Cue test as well as the Cue retest. The internal control and target sensors' values were below the assay thresholds and resulted in an invalid result. The remaining 29 known negative samples were negative by the Cue Mpox (Monkeypox) Molecular Test.

Results are presented below for the 59 evaluable samples with valid results for both the Cue Mpox (Monkeypox) Molecular Test and the comparator method.

## Cue Mpox (Monkeypox) Molecular Test versus FDA-cleared Real-Time PCR Assay

Archived Samples		FDA-cleared real-time PCR assay (Comparator)	
		Positive	Negative
Cue Mpox (Monkeypox)	Positive	30	0
Molecular Test	Negative	0	29

PPA: 100% (95% CI: 88.4% - 100%)

NPA: 100% (95% CI: 88.1% - 100%)

### References

1. World Health Organization. Laboratory Testing for the Monkeypox Virus: Interim Guidance. Geneva, Switzerland: World Health Organization; 23 May 2022.
2. World Health Organization. Clinical Management and Infection Prevention and Control for Monkeypox: Interim Rapid Response Guidance. Geneva, Switzerland: World Health Organization; 10 June 2022.
3. Alakunle E et al. Monkeypox Virus in Nigeria: Infection Biology, Epidemiology, and Evolution. *Viruses*. 2020, 12(11): 1257.
4. Ladnyj ID, Ziegler P, Kima E. A Human Infection Caused by Monkeypox Virus in Basankusu Territory, Democratic Republic of the Congo. *Bull World Health Organ*. 1972; 46(5):593-7.
5. McCollum AM, Damon IK. Human Monkeypox. *Clinical Infectious Diseases*. 2014; 58(2):260-7.
6. Mauldin MR et al. Exportation of Monkeypox Virus from the African Continent. *J Infect Dis*. 2022; 225(8):1367-76.
7. Minhaj FS et al. Monkeypox Outbreak – Nine States, May 2022. US Department of Health and Human Services/Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report*. 2022; 71(23):764-769.
8. Centers for Disease Control and Prevention. 2022 U.S. Monkeypox Outbreak. Available online at: <https://www.cdc.gov/poxvirus/monkeypox/response/2022/index.html>. Last accessed August 23, 2023.
9. Centers for Disease Control and Prevention. Biosafety Laboratory Guidance for Handling and Processing Mpox Specimens. <https://www.cdc.gov/poxvirus/monkeypox/lab-personnel/lab-procedures.html>. Last accessed August 23, 2023.










### Customer Support

If you have questions about this test, contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378).

You can purchase the Cue Health Monitoring System and Cue Mpox (Monkeypox) Molecular Test Cartridge Packs by contacting Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378).

### Symbols Used on the Product Labels

The table below describes the symbols used on the Cue Mpox (Monkeypox) Molecular Test Cartridge Pack, the Cartridge foil pouch, and the Cue Sample Wand.

SYMBOL	DESCRIPTION
	In Vitro Diagnostic
	Consult Instructions for Use eIFU available on the Cue Health Mobile Application and at <a href="http://www.cuehealth.com">www.cuehealth.com</a>
	Serial Number
	Do not use if seal or packaging is broken or damaged
	Storage temperature range
	Catalog number
	Manufacturer
	Keep dry
	Use By

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Wi-Fi® is a registered trademark of Wi-Fi Alliance®.



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Phone: 833.CUE.TEST (833.283.8378)  
Website: [www.cuehealth.com](http://www.cuehealth.com)



## Cue<sup>®</sup> Mpox (Monkeypox) Molecular Test



For In Vitro Diagnostic Use

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



**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](http://www.cuehealth.com). The Cue Health App is available on the Apple<sup>®</sup> App Store<sup>®</sup> and Google Play<sup>™</sup> 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”.

- 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





# Cue® Mpx (Monkeypox) Molecular Test



For In Vitro Diagnostic Use


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

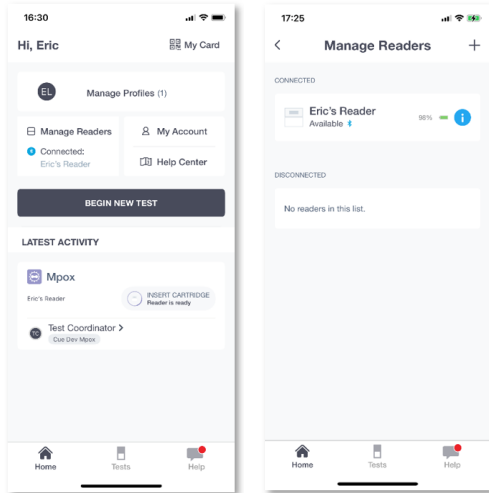


Bottom of the Reader



Find the Reader QR Code

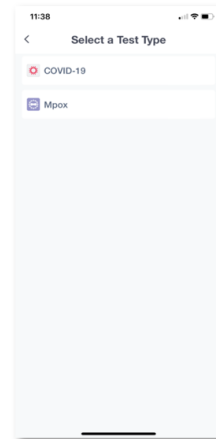
3.3 One or more Cartridge Readers may already be paired to your mobile smart device. Check that the Cartridge Reader you will use for the current test is connected to the Cue Health App. Go to the Dashboard screen by tapping on the home button  at the bottom of the Cue Health App screen. Then tap on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



If prompted, select your organization. View the Cue Mpx 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 Mpx (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**



# Cue<sup>®</sup> Mpox (Monkeypox) Molecular Test



Quick Reference Instructions (QRI) – For Professional Use  
For Use Under an Emergency Use Authorization (EUA) Only  
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For In Vitro Diagnostic Use

**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.**





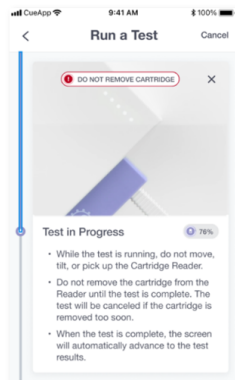
## Cue<sup>®</sup> Mpox (Monkeypox) Molecular Test



Quick Reference Instructions (QRI) – For Professional Use  
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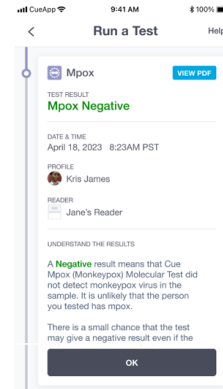
For In Vitro Diagnostic Use

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

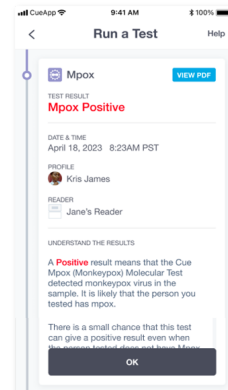


- 4.8 When the test is complete, you will see the result on the Cue Health App screen.

- A Negative result means that the Cue Mpox (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 Mpox (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 Mpox (Monkeypox) Molecular Test Cartridge and a new Cue Sample Wand.

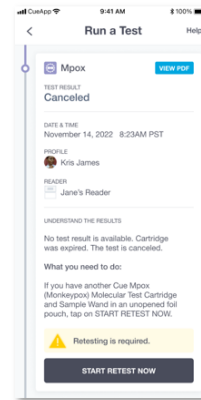
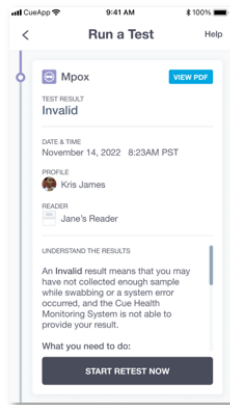


## Cue<sup>®</sup> Mpx (Monkeypox) Molecular Test



Quick Reference Instructions (QRI) – For Professional Use  
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



- 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 Mpx (Monkeypox) Molecular Test Cartridge and a new Cue Sample Wand.

- 4.9 Remove the Cue Mpx (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<sup>®</sup> Germicidal Wipes or equivalent (0.55% sodium hypochlorite).

### 5. Quality Control

External Positive and Negative Controls should be used to show that the Cue Mpx (Monkeypox) Molecular Test is working properly. Controls for the Cue Mpx (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](http://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.



## Cue<sup>®</sup> Mpox (Monkeypox) Molecular Test




For In Vitro Diagnostic Use

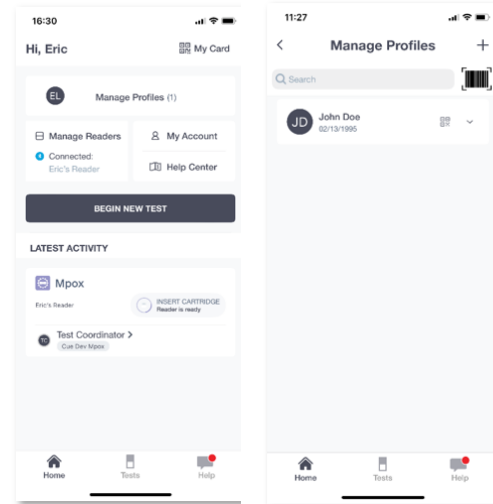
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- **Positive Control**  
Positive Control needs to be diluted using a 300  $\mu$ L Samco Exact Pipette (PN966NL). Pipette 300  $\mu$ L of the Positive Control into 3 mL of Viral Transport Media (VTM). Invert the tube to mix. Cue Health recommends that 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](mailto: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.



## Cue<sup>®</sup> Mpox (Monkeypox) Molecular Test

Quick Reference Instructions (QRI) – For Professional Use  
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

- 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.

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



C3090-10



eIFU available on the Cue Health App

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For Use Under an Emergency Use Authorization (EUA) Only  
For *in vitro* diagnostic use

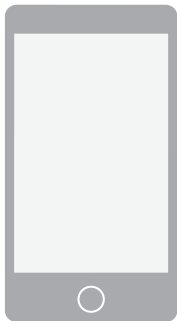


cue

Cue Health Monitoring  
System (Reader)  
[Get Started Here](#)



Cue Health

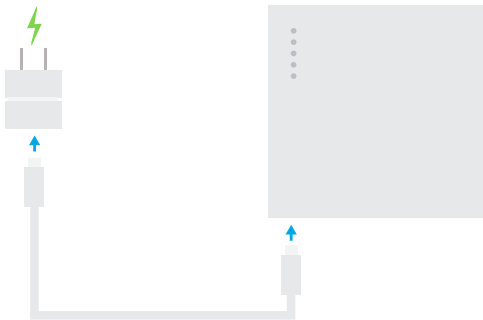


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## Set Up Your Cue® Account

Download the Cue Health App from the Apple App® Store® or Google Play Store™ to your mobile smart device. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible devices. Follow the on-screen instructions to create your account and pair your Cue Health Monitoring System (Reader) to your mobile smart device.

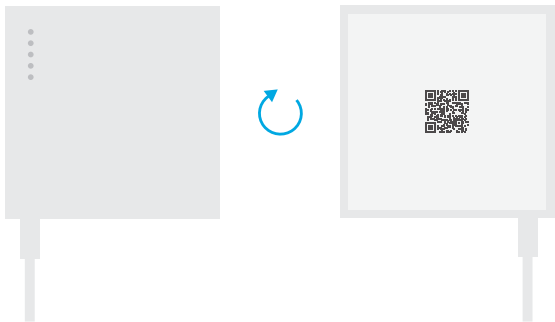




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## Connect Reader to power

When prompted on the Cue Health App, connect your Reader directly to power using the supplied Cue Power Adapter and USB Charging Cable.

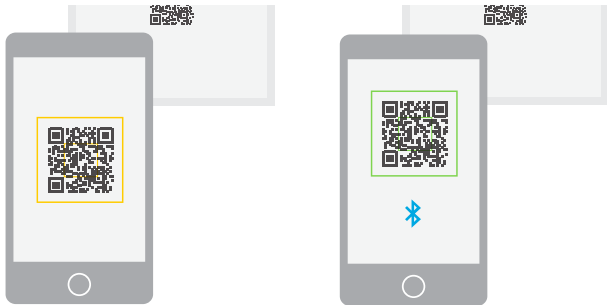


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## Find Reader QR code

Rotate your Reader upside-down so the bottom of the Reader is facing up and the QR code is visible to you.

The QR code is located on the bottom of the Reader.

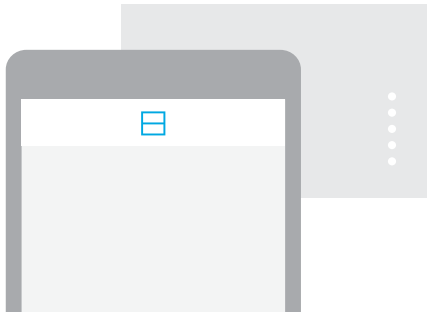


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## Pair Reader to mobile device

When prompted on the Cue Health App, adjust the camera so the QR code is visible on-screen and inside of the capture outline.

When the QR code is recognized, the Reader is paired securely to the mobile smart device.



---

## Cue Reader is ready to use

To begin using the Reader to run tests, open the Cue Health App and follow the on-screen instructions.

---

# Welcome to Cue®

## Welcome

This guide will help you get started using the Cue Health Monitoring System (Reader) and the Cue Health App.

## Get Started

See opposite page for instructions on downloading the Cue Health App, creating your Cue Account, and setting up your Cue Reader.

## Questions

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This product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from SARS-COV-2 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 COVID-19 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.

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

---

# About the Cue Health Monitoring System (Reader)

## **Cue Reader**

Your Reader pairs with the mobile smart device, accepts Cue test-specific Cartridges, and runs tests.



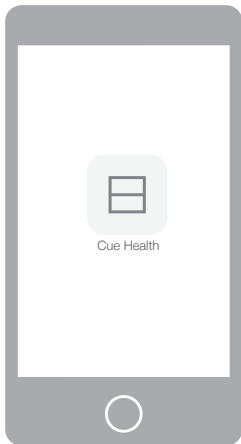
---

# About the Cue Health Monitoring System (Reader)



Your Cue Reader communicates with the Cue Health App using a secure wireless connection to your mobile smart device with **BLUETOOTH®** wireless technology.

A Cue Reader can be used with multiple mobile smart devices, but only one smart device at a time can connect to a Reader to run a test and receive test results.



---

# Charging the Reader

## Charging with USB

Your Cue Reader can be quick-charged directly using a cable through the USB port located on the Reader.

## Charging Wirelessly

Your Cue Reader will wirelessly charge when docked to the optional Wireless Charging Base accessory\*.





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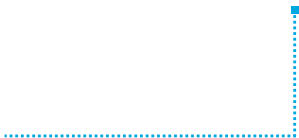
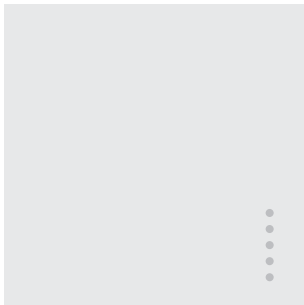
# Indicator Lights

## **Reader lights communicate status**

The Cue Reader features 5 LED indicator lights located on the top of the Cue Reader.

The lights provide quick feedback on the status of the Cue Reader together with the Cue Health App.

The lights display unique patterns to communicate charging status, battery level, prompts for testing actions, test status, and test errors.



---

## Battery Level

When the Reader is connected to power, the lights will sequentially illuminate then flash to indicate the battery charge level.



Lights illuminate sequentially



Battery is 80% charged



Battery is 20% charged

## Prompts for an Action

While running a test or after a test has completed, the indicator lights will sweep from top to bottom or in reverse



Insert Cue Sample Wand with collected specimen into the Cue Test Cartridge



Remove Cue Test Cartridge (with Sample Wand inside) from the Cue Reader

## Alerts

When connecting to the Cue Reader or at the start of a test, the indicator lights will flash in different patterns



Lights flash when connected



Lights flash when the Cue Test Cartridge or the Cue Sample Wand is inserted



Error. See the Cue Health App for details

For Use Under an Emergency Use Authorization (EUA) Only  
For *in vitro* diagnostic use



cue

Cue<sup>®</sup> Health  
Monitoring System  
User Manual

# Cue<sup>®</sup> Health Monitoring System

## User Manual

### **Basic Information**

Please read this User Manual carefully. Contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378 if you have any questions or comments.

### **Cue Health Inc.**

San Diego, CA 92121

[www.cuehealth.com](http://www.cuehealth.com)

# Table of Contents

<b>Chapter 1 - Introduction and User Safety .....</b>	<b>7</b>
Welcome to Cue .....	7
Intended Use .....	7
Before Using a Cue Reader and Cue Test .....	8
Safety Definitions .....	9
Practices Used in This User Manual .....	11
Symbols and Descriptions.....	12
General Precautions.....	14
<b>Chapter 2 - Cue Health Monitoring System</b>	
<b>Overview and Features.....</b>	<b>20</b>
Cue Health Monitoring System Components.....	21
Cue Health Monitoring System Package Contents .....	23
Cue Test Components .....	24
Compatible Mobile Smart Devices .....	26
Cue Health App .....	26

# Table of Contents

## Chapter 3 - Setting Up Your Cue Health

<b>Monitoring System (Reader)</b> .....	<b>28</b>
Identifying Parts of Your Cue Reader .....	28
Your Cue Health App Dashboard .....	31
Cue Reader Indicator Lights.....	32
Downloading and Installing the Cue Health App .....	34
Creating Your Cue Account and User Profile .....	36
Setting Up the Cue Reader .....	39
Account Login .....	43

## Chapter 4 - Running a Test on the Cue

<b>Reader</b> .....	<b>44</b>
Reasons for Incorrect or Invalid Results.....	46
Initiate Test.....	47

## Chapter 5 - Managing Your Cue Health Monitoring

<b>System (Reader)</b> .....	<b>49</b>
Charging your Cue Reader.....	49
Account Settings .....	51

# Table of Contents

Pairing Additional Cue Readers to Your Mobile Smart Device .....	52
Connecting the Cue Reader to the Cue Health App ....	53
Checking the MAC Address of a Connected Cue Reader .....	54
Disconnecting the Cue Reader from the Cue Health App .....	55
Unpairing the Cue Reader from Your Mobile Smart Device .....	56
Managing User Account and Profiles.....	57
Forgot Your Password?.....	58
Printing Your Test Results.....	58
Accessing Product Documentation .....	60
<b>Chapter 6 - Cleaning and Disinfecting .....</b>	<b>61</b>
Cleaning and Disinfecting .....	61

# Table of Contents

<b>Chapter 7 - Troubleshooting .....</b>	<b>63</b>
Error Messages and Recommended Actions .....	64
When to Use the Manual Reset Button .....	66
<b>Chapter 8 - Technical Information and Specifications .....</b>	<b>67</b>
How the Cue Health Monitoring System Works.....	67
Technical Specifications .....	68
Compliance with International Standards .....	70
Disposing of Your Cue Health Monitoring System and Components .....	70
<b>Chapter 9 - Warranty and Supplies .....</b>	<b>71</b>
Manufacturer's One Year Warranty .....	71
Supplies and Accessories .....	71



# Chapter 1

## Introduction and User Safety

### **Welcome to Cue**


The Cue Health Monitoring System (Reader) is a fast and easy-to-use system for performing Cue diagnostic medical tests. Your results are delivered and saved to mobile smart device in minutes. This User Manual will guide you through the proper setup and use of your Cue Reader. Read this manual thoroughly to help you understand the system and its many features.

### **Intended Use**

The Cue Reader is an in vitro diagnostic medical device for use with Cue tests and the Cue Health App installed on a mobile smart device. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible devices.

## **Before Using a Cue Reader and Cue Test**

Review the Quick Start Guide and this User Manual before you run a test using the Cue Reader. The Quick Start Guide will help you quickly set up your Cue Reader and get ready to run a test. This User Manual gives you all the information you need to use your Cue Reader correctly and safely.

 ***It is important that you follow the instructions in this User Manual. If you do not use the system correctly, you may get an incorrect or invalid result, the system may cancel your test, or you may damage the system. Do not use the system if you cannot follow the instructions.***

If you have any questions, please contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378.

## **Safety Definitions**

This User Manual includes three types of important messages. They are Warnings, Cautions, and Notes. It is important that you pay close attention to these messages to make sure you use the Cue Health Monitoring System correctly and safely.



### **Warning**

A Warning message tells you what you need to do to prevent injury or damage to health.

Follow the instructions given when you see a Warning message. Do not proceed if you do not fully understand the actions to take after seeing a Warning message.



## **Caution**


A Caution message tells you what you need to do to prevent damage to your Cue Health Monitoring System (Reader). Do not proceed if you do not fully understand the actions to take after seeing a Caution message.



## **Note**

A Note gives you more information to help you understand the instructions.

## Practices Used in This User Manual

Procedure steps in this User Manual are easy to find. They begin with a  symbol, followed by a short description of the action you should take.







Procedure steps are numbered and should be completed in the order given.





A system response to a completed procedure step appears in italics below the procedure step.

Words in:	Description
<b>Bold</b>	Names of menus and buttons
<i>Italics</i>	System response that occurs after the user presses an icon or completes a step that appears in the Cue Health App
<b><i>Bold Italics</i></b>	Important information

## Symbols and Descriptions

The table below describes the symbols used on the Cue Health Monitoring System packaging and on the system parts.

Symbol	Description
	Consult User Manual
	Serial Number
	Do not use if seal or packaging is broken or damaged
	Storage temperature range
	Humidity storage range
	Catalog number

Symbol	Description
	Manufacturer
	Keep dry
	Electrical and Electronic Equipment Waste: Discard product at separate collection facility for recovery and recycling.
	Caution: User should consult the test's Instructions for Use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be printed on the medical device itself.

## General Precautions

The Cue Health Monitoring System (Reader) may not work correctly if the package or the system parts are damaged.

- Do not use the Cue Reader if the package seals are broken.
- Do not use the Cue Reader if any part is damaged.
- Do not run a test if the room temperature is outside of the testing conditions stated in the Cue test Instructions for Use. Testing in room temperatures that are too high or too low may cause an incorrect or invalid result.
- Do not run a Cue diagnostic test at altitudes higher than 8530 feet (2600 meters). Testing at altitudes that are too high may cause an incorrect or invalid result.
- Do not leave the Cue Reader in temperatures below 39°F (4°C) or above 100°F (38°C).
- If you make changes to any of the parts of your Cue Reader or use any components that did not come with the Reader, you may harm yourself or the device. You will also void your warranty.
- Place your Cue Reader on a stable, flat, and level surface while running a test. Do not move or tilt the Reader while



a test is in progress.

- Do not bend or damage the Cue Charging Cable or Cue Power Adaptor (plug), or pull the cable excessively when disconnecting it from the Reader or the plug. Do not use a damaged power cable, plug, or loose electrical sockets. These actions could cause electric shock or fire.
- The Cue Reader includes a built-in, rechargeable lithium-ion polymer battery. Avoid exposing your Reader to very cold or very hot temperatures, or to high external pressure, and do not place or store your Reader near or in heaters, microwave ovens, or stoves. The battery could overheat and cause a fire.
- Do not use your Reader near flammable liquids, and never dispose of the Reader in a fire. The Reader could explode or cause a fire.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the

instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received,

including interference that may cause undesired operation.

- Electronic wireless devices or networks that are in use nearby, such as a cordless or cell phone (excluding your mobile device that is paired to the Reader) or a garage door opener, could prevent or delay communications between your Cue Reader and your mobile smart device and interfere with your Cue test.
- Do not use your Cue Reader or the Cue Health App where the use of cell phones or other electronic devices is restricted or prohibited, such as in aircraft or in hospitals. Your Cue devices must not cause harmful interference.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.

When used with the “Cue COVID-19 Test” or the “Cue COVID-19 Test for Home and Over The Counter (OTC) Use” EUA products

- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens; and

- 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 COVID-19 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.

When used with the “Cue Mpox (Monkeypox) Molecular Test” EUA product

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

## Chapter 2




# Cue Health Monitoring System Overview and Features

The Cue Health Monitoring System (Reader) comes as three parts. These parts are the Cue Reader, the Cue Power Adapter, and the Cue Charging Cable.

The Cue Reader is used with test-specific Cue cartridges and sample collection devices (Cue Sample Wand). The Cue Reader connects to the Cue Health App installed on your mobile smart device. The mobile smart device is the primary display for the test system.

## **Cue Health Monitoring System Components**

Each Cue Health Monitoring System part (component) is described in the table on the next page.

Component	Description	Image
<p>Cue Reader (C0201)</p>	<p>The Cue Reader communicates with the Cue Health App and a Cue Test Cartridge to run a test on a sample.</p>	
<p>Cue Power Adapter (C0011)</p>	<p>The Cue Power Adapter plugs into standard wall power. The Cue Charging Cable plugs into the Cue Power Adapter.</p>	
<p>Cue Charging Cable (C0020 or C0021)</p>	<p>The Cue Charging Cable connects the Power Adapter to the Reader.</p>	



## **Cue Health Monitoring System Package Contents**




Make sure that your package contains the following parts (components):

- One (1) Cue Reader
- One (1) Cue Power Adapter
- One (1) Cue Charging Cable
- User Manual
- Quick Start Guide

Contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378 if you do not have all of these parts. Also, contact Cue Health Customer Support if a part is damaged.

## **Cue Test Components**

The table on the next page describes the parts (components) of Cue tests, for example, the Cue COVID-19 Test, which detects SARS-CoV-2 virus, or the Cue Mpox (Monkeypox) Molecular Test, which detects monkeypox virus (or other non-variola orthopoxviruses). Cue tests are sold separately and can be purchased in multiple packs. Tests can be used only once, and they must be used before the Use By date printed on the packaging.

Component	Description	Image
<p>Cue Test Cartridge Pack</p>	<p>A Cue Test Cartridge Pack comes with a Cue test cartridge (Cue COVID-19 Test or Cue COVID-19 Test for Home and Over The Counter (OTC) Use or Cue Mpox (Monkeypox) Molecular Test), a Cue Sample Wand for collecting a sample, and Instructions for Use. The Instructions for Use tell you how to use the Cue Cartridge Reader, the Cue Health App, and the Cue test cartridge to run a test on the sample.</p>	 <p>Cue COVID-19 Test Cartridge</p>  <p>Cue Mpox (Monkeypox) Molecular Test Cartridge</p>  <p>Cue Sample Wand</p>

## **Compatible Mobile Smart Devices**

The Cue Health Monitoring System must be used with a mobile smart device downloaded with the Cue Health App. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible devices.

## **Cue Health App**

The Cue Health App is required to run a Cue test on the Cue Reader. Download the Cue Health App from the Apple® App Store® or Google Play™ Store.

The Cue Health App displays test results from the Cue Health Monitoring System. The Cue Health App must be open to see test results.

If the mobile smart device loses power while the Cue test is running, the Cue Reader will still complete the test. The result will not be displayed until the mobile smart device is charged or connected to power, however. Bring the charged mobile smart device close to the Cue Reader and open the Cue Health App to see the test result.

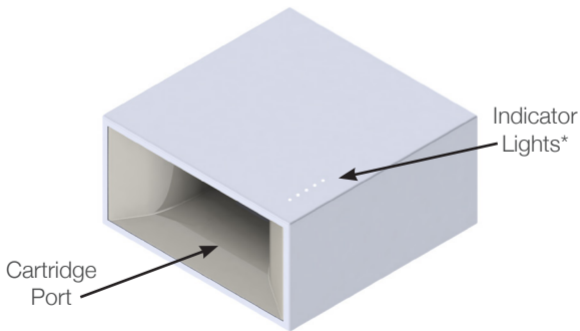
The Cue Health App securely stores test results and communicates results to authorized individuals.

## Chapter 3

# Setting Up Your Cue Health Monitoring System (Reader)

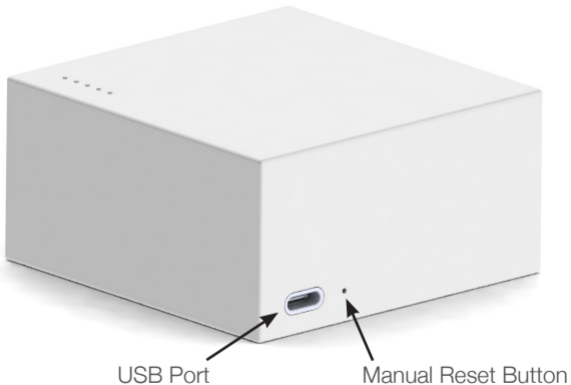
### Identifying Parts of Your Cue Reader

#### The Top and Front of Your Cue Reader



\*See “Cue Reader Indicator Lights” in Chapter 3 for information on the meaning of the indicator light patterns.

## The Back of Your Cue Reader



# The Bottom of Your Cue Reader



Cartridge Reader

REF: C0201

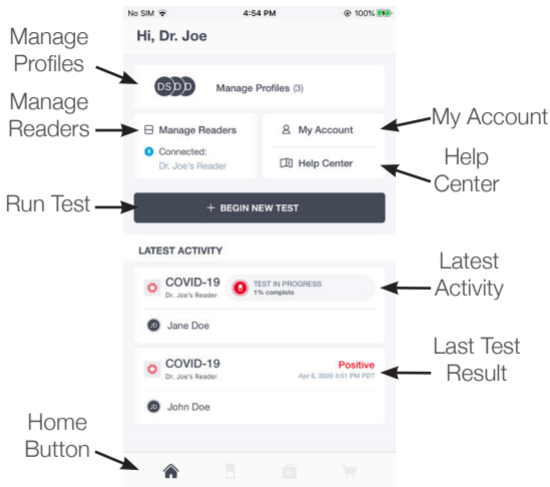
S/N: 21802010000481

L9000207-2 Rev 1.0





# Your Cue Health App Dashboard



Press the Home Button  on the Cue Health App screen to see with your Cue Dashboard.

## Cue Reader Indicator Lights

### Status Indicators

You will see different light patterns on top of the Reader. The light patterns will tell you when the Reader is connected to the Cue Health App. The light patterns will also tell you when a cartridge is inserted, and when there is an error.



Lights Flash when connected



Lights Flash when the Cue Cartridge or the Cue Sample Wand is inserted



Error, see Cue Health App for details

## Prompts for Action

You will see these light patterns on top of the Reader after you insert a Cue Cartridge into the Cartridge Port.



Insert Sample Wand with collected specimen into the Cue Cartridge



Remove Cue Cartridge (with Sample Wand inside) from the Cue Reader

## Downloading and Installing the Cue Health App

You can download and install the Cue Health App to your mobile smart device from the Apple App Store or Google Play Store. The Cue Health App is downloaded and installed the same way as other apps on your mobile smart device. The Cue Health App is free of charge.



Cue Health

 Downloading the Cue Health App from the Apple App Store or Google Play Store requires internet connectivity.

 Download the Cue Health App:

1. Turn on your mobile smart device.
2. Confirm your mobile smart device has internet connectivity.

3. Launch the Apple App Store or Google Play Store app.
4. Search for the “Cue Health App” by Cue Health Inc. and tap on the Cue Health App icon.
5. Tap Install.
6. Enter your App password information as required.

*The application downloads. Once installed, the Cue Health App icon appears on your mobile smart device home screen.*




The Cue Health App needs to be installed on each mobile smart device that will be paired with the Cue Reader.



Cue Health App updates must be downloaded from the Apple App Store or Google Play Store when a new version is available.

## Creating Your Cue Account and User Profile

 *Your test results will be saved to your Cue Account and in a secured cloud storage.*

 To create your Cue Account and User Profile:

1. Launch the “**Cue Health App**” on your mobile smart device.

*The “Login” screen will be displayed by the Cue Health App.*

2. Tap on “**Create Account**”.
3. Input your email and create a password on the “Create Account” screen. Continue following the on-screen instructions. You must accept the End User License Agreement and Privacy Policy to continue.


*After you have created your account, the Cue Health App will display the “Profile Information” screen.*

4. At the “Profile Information” screen, input the requested information in each field.
5. Tap on “**SUBMIT**” and follow the on-screen instructions.

*After you have created your profile, the Cue Health App will display the “Permissions” screen.*

6. Follow the Cue Health App on-screen instructions to progress through the “Permissions” screens.

*After you have progressed through the “Permissions” screens, the Cue Health App will display the “Set Up the Cue Cartridge Reader” screen.*

 *Multiple user profiles can be created under one Cue Account. The primary Cue Account holder will have access to all user profiles and test results under the same Cue Account.*




## Setting Up the Cue Reader

 To set up your Cue Cartridge Reader:

*After you set up your user profile(s), the Cue Health App will display the “Set Up the Cartridge Reader” screen.*

1. Place the Cue Reader on a stable, flat, and level surface.
2. Connect the Cue Charging Cable to the Cue Power Adapter and plug the Power Adapter into wall power.
3. Follow the Cue Health App Instructions.

 ***Only the Cue-supplied Charging Cable and Power Adapter.***


4. Wake the Cue Reader by connecting it to the Cue Charging Cable.

*When the Cue Reader is connected to power, the lights on top of the Reader will illuminate one-by-one. The lights will then flash to show charge level. The Reader is now ready for pairing with a mobile smart device.*





Another way to wake the Cue Reader is by disconnecting and reconnecting the Cue Charging Cable.

5. In the “Set Up the Cartridge Reader” screen in the Cue Health App, tap on “**SCAN NOW**” to begin pairing the Reader to the mobile smart device.
6. Turn your Cue Reader upside-down so the bottom of the Cue Cartridge Reader is facing up. You will see the serial number and QR code.
7. Move the mobile smart device until you can see the QR code inside of the focus square on the camera screen.


 If the QR code does not scan quickly, make sure the Cartridge Reader is connected to power.

*When the QR code is recognized, the Cue Health App will display a message that says, “Reader Authorized Successfully”. This means that the Cue Reader is paired securely to the mobile smart device. The Cue Dashboard will then be displayed on the screen. Make sure to turn the Cartridge Reader over to top-side up after you have scanned the QR code. The side with the lights on top of the Reader is top-side up.*


 “Pairing” a Reader is scanning the QR Code found on the bottom of the Reader. When a “paired” Reader is within range of the BLUETOOTH® wireless technology of your smart mobile device, the Reader is “connected” to the Cue Health App on the smart mobile device.


 If the camera scan of the Reader QR code does not work, the Cue Health App will let you manually enter the Reader MAC address and Pin Number. The MAC address

and Pin are on the bottom of the Reader. See “Identifying Parts of Your Cue Cartridge Reader” in Chapter 3 for how to find the MAC address and Pin Number.

 One Cue Reader can pair with multiple mobile smart devices.

 One mobile smart device can pair with multiple Cue Readers.

 When you choose a paired Cue Reader to run a test, that Reader is connected to the Cue Health App. One Cue Reader can only connect with the Cue Health App on one mobile smart device at one time.

 Multiple Cue Readers can be connected to the Cue Health App on one mobile smart device at one time.

## Account Login

If you already have a Cue Account, you can log in directly. If you do not have a Cue Account, see “Creating Your Cue Account and User Profile” in Chapter 3 for instructions on how to set up a Cue Account.

 To Log In:

1. Launch the “**Cue Health App**” on your mobile smart device.

*The “Login” screen will be displayed by the Cue Health App.*


2. Input your Email and Cue Account password.
3. Tap on “**LOGIN**”.


*The “Dashboard” screen will be displayed by the Cue Health App after login.*


## Chapter 4

### Running a Test on the Cue Reader

Carefully read this chapter. It is important that you read and follow the test-specific Instructions for Use available electronically in the Help Center of the Cue Health App, or at [www.cuehealth.com](http://www.cuehealth.com).

 ***If you do not follow all of the instructions you may get an incorrect or invalid result.***

 ***The Reader should be on a stable, flat, and level surface while running a test. Do not move or tilt the Reader while a test is in progress.***

 The Cue Health App will tell you if the Reader battery is too low to complete a test. Connect the Reader to power when needed.



If your mobile smart device loses power, the test on the Cartridge Reader will still run to completion. The test result will be saved. The mobile smart device must be charged to see the test result. Make sure your mobile smart device is close to the Reader after a test completes so you can view your result on the screen in the Cue Health App.

## **Reasons for Incorrect or Invalid Results**

Always follow the directions in this User Manual when you store, handle, and operate the Cue Health Monitoring System (Reader).

Some reasons for incorrect or invalid results are:

- Storing or operating the Cue Reader in temperatures that are too low or too high. See “Technical Specifications” in Chapter 8 for more details.
- Storing or operating the Cue Reader at altitudes that are too high. See “Technical Specifications” in Chapter 8 for more details.
- Dropping the Cue Reader.
- Using a damaged Cue Reader.



## Initiate Test

 To initiate a test:

1. Launch the **Cue Health App** on your mobile smart device.



Cue Health

*The “Login” screen is displayed by the Cue Health App after launch.*

2. Log into your Cue Account.

*The “Dashboard” screen is displayed by the Cue Health App after successful account login.*

3. On the “Dashboard” screen, tap on “**+ BEGIN NEW TEST**”.

4. Follow on-screen instructions to run a test.

*After the test is complete, the Reader will automatically go into standby mode.*

**ⓘ** *If two or more Readers are paired, you must identify the Reader you want to use by its MAC address. See “Checking the MAC Address of a Connected Cue Cartridge Reader” in Chapter 5 for more details.*

## Chapter 5

# Managing Your Cue Health Monitoring System (Reader)

### **Charging your Cue Reader**

Your Cue Reader has a built-in, rechargeable lithium-ion polymer battery. By charging your Reader's battery, you don't need a separate power source to take a Cue test.

 To charge your Cue Cartridge Reader:

1. Plug the Cue Power Adapter into wall power.
2. Connect the Cue Charging Cable to the USB port of the Cue Power Adapter.
3. Connect the other end of the Cue Charging Cable to the USB port of the Cue Reader to start charging.

*When you connect or disconnect the Cue Charging Cable, the lights on the Reader will light up one-by-one (sequentially) and then flash to tell you the charge level.*



Lights illuminate sequentially




Battery is 80% charged




Battery is 20% charged

\*Green indicates flashing light


## Account Settings

 To access your account settings:

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**My Account**”.
3. Tap on “**Settings**”.
4. Within the “**Settings**” menu, you can:
  - Allow Notifications
  - Allow Location Services
  - Enable Camera Access
  - Auto - Reconnect
  - Change Password
  - Delete Account

## Pairing Additional Cue Readers to Your Mobile Smart Device


 To pair additional Cue Readers to your mobile smart device:


1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. Confirm that the BLUETOOTH wireless technology of your mobile smart device is enabled.
4. Tap on “+”.
5. Follow on-screen instructions to pair the additional Cue Reader.

*The Cue Reader is now paired to the mobile smart device.*


## Connecting the Cue Reader to the Cue Health App



 To connect a paired Cue Reader to the Cue Health App:

 A Cue Reader that is “Paired” to your mobile smart device can disconnect if the Reader is out of range of the BLUETOOTH wireless technology of the mobile smart device.

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**DISCONNECTED**” Cue Readers, tap on the one you would like to connect to.  
*The indicator lights will flash when the Cue Reader is connected to the Cue Health App.*

## Checking the MAC Address of a Connected Cue Reader

 To check the MAC address of the connected Reader on the Cue Health App:

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**CONNECTED**” Cue Readers, tap on the  next to the one you would like to check.



*The MAC address will be displayed on the “Reader Information” screen.*

4. Compare the MAC address printed on the bottom of the Cartridge Reader to the MAC address displayed on the “Reader Information” screen.





## Disconnecting the Cue Reader from the Cue Health App

 To Disconnect the Cue Health App from connected Cue Readers:

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**CONNECTED**” Cue Readers, tap on the  next to the one you would like to disconnect.
4. Look at the MAC address on the bottom of the Reader. Confirm the MAC address on the screen matches the MAC address on the bottom of the Reader you want to disconnect.
5. Tap on “**DISCONNECT**”.  
*The Cue Reader is now disconnected from the Cue*

## Unpairing the Cue Reader from Your Mobile Smart Device


 To Unpair the Cue Reader from your mobile smart device:

1. When logged into your Cue Account, access the “Dashboard” screen by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Readers**”.
3. From the list of “**CONNECTED**” and “**DISCONNECTED**” Cue Readers, tap on the  next to the Reader you would like to unpair.
4. Tap on “**FORGET THIS READER**”.


*The Cue Reader is now unpaired from the mobile smart device.*

## Managing User Account and Profiles

 To manage your user account:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on “**My Account**” for more options.


 To manage profiles:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Profiles**”.
3. Tap on the profile of interest and tap on “**VIEW**” for more options.

*The “Test History” and “Medication History” of the*

*profile can be viewed on the screen.*


## **Forgot Your Password?**

 To retrieve your password:


1. Launch the **Cue Health App** on your mobile smart device.
2. Tap on “**Forgot Password?**”
3. Follow the on-screen instructions.


## **Printing Your Test Results**


 To print your test results:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on “**Manage Profiles**”.
3. Tap on the profile of interest and tap on “**VIEW**”.

*The “Test History” and “Medication History” of the profile can be accessed on the screen.*


4. From the “**TEST HISTORY**” list, tap on the test result of interest.
5. Tap the button at the top right corner of the screen. Then tap on “**PRINT**” at the bottom of the results display screen and choose the printer icon . Then tap Print at the top right of the screen.

 Printing test results from the Cue Health App requires that a printer be connected to (or paired with) the mobile smart device.

 If you print results in public places, you could be sharing your personal information.

## Accessing Product Documentation

 To access product documentation:

1. When logged into your Cue Account, access the Cue Dashboard by tapping on the home button  at the bottom of the screen.
2. Tap on “**Help Center**” for options.


# Chapter 6

## Cleaning and Disinfecting


This section provides cleaning and disinfecting information for your Cue Health Monitoring System (Reader).


### **Cleaning and Disinfecting**


The Cue Reader should be cleaned and disinfected after each use. Wipe down with Clorox® Germicidal Wipes or equivalent (containing 0.55% sodium hypochlorite as the active ingredient).

 Do not spray any cleaning solution directly onto the Cue Reader or into the cartridge port.

 Do not put any part of the Cue Reader under water or any other liquid.

 Do not attempt to clean any internal parts.

 If part of your device becomes wet, wipe off all moisture and allow sufficient time for drying before use.

 Only Clorox Germicidal Wipes or equivalent should be used. Other products have not been tested and should not be used. Follow manufacturer's instruction for handling and storage of wipes.



# Chapter 7

## Troubleshooting

In this chapter, you will learn about symbols and error messages displayed by the Cue Health App.

Pay attention to all symbols, messages, and indicator lights when you use the system. They give you important information to help you use the system correctly and safely.

If you have questions, contact Cue Health Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378.

## Error Messages and Recommended Actions

Certain messages displayed by the Cue Health App indicate an error. An error message requires your attention and action.

The following table lists the Error Message and the Recommended Action.

Error Message	Recommended Action
App displays “Tilt Warning”	Position the Cue Reader on top of a stable, flat, and level surface.
App displays “The battery on your cartridge reader is too low to run a test”	Connect the Cue Reader to power. Use the Cue Health Monitoring System components or accessories.

Error Message	Recommended Action
App displays “Testing Error” or “Cartridge Error”	Follow on-screen instructions.
App displays “Test Has Been Canceled”	Remove and dispose of the Cue Test Cartridge. Take a new sample using a new test-specific Cue Sample Wand and use a new test-specific Cue Test Cartridge to repeat the test. See the Cue Health App on-screen instructions for additional details.

## **When to Use the Manual Reset Button**

If the Reader is not responding as described in this User Manual you must reset the Reader. Press and hold the Manual Reset Button for one second using the end of a small wire, such as a paperclip. Do not hold the Manual Reset Button for more than 3 seconds.

 Pressing the Manual Reset Button for 10 seconds will bring the Reader back to the out-of-the box settings. Wake the Reader by connecting it to power.

# Chapter 8

## Technical Information and Specifications

This section provides technical information on your Cue Health Monitoring System.

### **How the Cue Health Monitoring System Works**

The Cue Health Monitoring System (Reader) detects test-specific targets using electrochemical biosensor technology.

## Technical Specifications

### Cue Reader Specifications

Dimensions	(2.9 in x 2.9 in x 1.5 in) (74 mm x 74 mm x 37 mm)
Weight	5.29 oz (150 g)
Power Supply	Input: 100-240V~, 50/60Hz, 0.2A Output: 5VDC, 1.5A, 7.5W  Battery 1 (one) pre-installed, non-serviceable, 1400mAh rechargeable lithium polymer battery, 3.85v (5V input voltage)
Display	Cue Health App on a mobile smart device screen
Operational Temperature	59°F (15°C) to 95°F (35°C)
Operational Humidity	10% to 100%

Operational Altitude	0 ft (0 m) to 8530 ft (2600 m)
Storage Temperature	39°F (4°C) to 100°F (38°C)
Storage Humidity	10% to 100%
Storage Altitude	< 8530 ft (2600 m)
FCC ID	2A3QA-001



For technical specifications of Cue diagnostic tests, refer to the test-specific Instructions for Use. All product documentation can be found at the Help Center on the Cue Health App or on the Cue website at [www.CueHealth.com/help-and-support/product-documentation/](http://www.CueHealth.com/help-and-support/product-documentation/).

## **Compliance with International Standards**

The Cue Health Monitoring System complies to the following standards:

- UL 61010-1. 3rd Edition.
- UL 61010-2-101. 2nd Edition.
- FCC Part 15B
- ICES-003
- IEC/EN 61326 Class B
- FCC Part 15.247
- UL 60950-1
- UL 62368-1

## **Disposing of Your Cue Health Monitoring System and Components**

Dispose of used products according to regulations applicable in your country. For information about the correct method of disposal, contact your local authorities.



# Chapter 9

## Warranty and Supplies

### **Manufacturer's One Year Warranty**

Cue Health Inc. warrants your new Cue Health Monitoring System will be free from defects in materials and workmanship for a period of one (1) year from the date of the original purchase. If during this time the Cue Health Monitoring System does not work properly because of a defect in materials or workmanship, Cue Health Inc. agrees to replace free of charge any and all parts proven to be defective and subject to warranty. This warranty only applies to the original purchaser of the Cue Health Monitoring System.

### **Supplies and Accessories**

Cue Health Monitoring System supplies and accessories are available by calling toll-free at (833) CUE-TEST • (833) 283-8378.



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