



COVID-19

**Cue™ COVID-19 Test Instructions For Use**

For Professional Use

**For Use Under an Emergency Use Authorization (EUA) Only**

**Use with the Emergency Use Authorization Only Cue Health Monitoring System and Cue Health Mobile Application**

**IVD**

**For In Vitro Diagnostic Use**

## **Cue COVID-19 Test Instructions for Use**

For Professional Use

### **Summary and Explanation**

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to the World Health Organization (WHO) on December 31, 2019.<sup>1</sup> Chinese authorities identified a novel coronavirus (2019-nCoV) which has resulted in thousands of confirmed human infections in multiple provinces throughout China and exported cases in several Southeast Asian countries and more recently the United States. Cases of severe illness and some deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

The Cue COVID-19 Test is a molecular in vitro diagnostic test that aids in the detection and diagnosis of SARS-CoV-2 and is based on widely used nucleic acid isothermal amplification technology. The Cue COVID-19 Test contains primers and probes and internal controls used in molecular tests for the in vitro qualitative detection of SARS-CoV-2 RNA. The Cue COVID-19 Test detects SARS-CoV-2 nucleic acid in nasal specimens.

### **Intended Use**

The Cue COVID-19 Test is an isothermal nucleic acid amplification assay intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in direct anterior nasal swabs or in previously collected anterior nasal swab specimens in viral transport media from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. The test is run using the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand, and the Cue Health App on the compatible mobile smart devices 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, to perform high, moderate or waived complexity tests. The Cue COVID-19 Test 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 SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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. Testing facilities within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results in an asymptomatic individual are presumptive and confirmation may be performed for patient management, if necessary, with a different molecular test in a laboratory.

The Cue COVID-19 Test is intended for use by operators in a point of care professional environment. No specific operator training is required.

The Cue COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

## Principles of the Procedure

The Cue COVID-19 Test utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 nucleic acids. This test is a molecular nucleic acid amplification test (NAAT) that detects the genetic material of SARS-CoV-2 using a molecular amplification reaction that is an equivalent alternative amplification method to polymerase chain reaction (PCR). The Cue COVID-19 Test primers amplify the nucleocapsid (N) region of the gene enabling detection. The Cue COVID-19 Test forward primers are conjugated to biotin. Cue COVID-19 Test 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 is not detected, the Cue COVID-19 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 nasal sample into the 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 COVID-19 Test takes about 20 minutes from Sample Wand insertion to results.

## Materials Provided

- **Cue COVID-19 Test Cartridge Pack REF C1018**

Contains a foil pouch with a plastic tray. The plastic tray contains one (1) single-use Cue COVID-19 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 COVID-19 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 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 (REF C0201) from Cue Health Inc., by contacting Cue Health Customer Support at 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 and Wi-Fi or cellular capability is required to download the Cue Health App.

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

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

- **Control Swabs**

Purchase the Cue COVID-19 External Control Swabs Pack (REF C2110) that contains three Cue COVID-19 Test Positive Control Swabs (REF C2111) and three Cue Test Negative Control Swabs (REF C2112) from Cue Health Inc., by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

### **Precautions - General**

- For in vitro diagnostic use.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high, moderate or waived complexity tests. This product 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.
- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, 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 diagnostic tests 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.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
- Performance of the Cue COVID-19 Test has only been established with Cue Sample Wand direct

nasal swab samples and by dipping the Cue Sample Wand into a tube containing a nasal specimen in viral transport media.

- Positive results are indicative of the presence of SARS-CoV-2-RNA.
- Synthetic RNA is used to make the Positive Control Swabs. However, control swabs, patient samples, and test cartridges should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- To be used in conjunction with the Cue Cartridge Reader and Cue Health App.
- The Cue Cartridge Reader needs to be on a level surface when the Cue COVID-19 Test Cartridge is inserted and while the test is running. Do not move the Cue Cartridge Reader while the test is running.
- Do not use the Cue COVID-19 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 must be cleaned and disinfected after each use. See the Cue Health Monitoring System User Manual for instructions.
- Do not open the Cue COVID-19 Test Cartridge.
- Do not remove the Wand from the Cue COVID-19 Test Cartridge.

### **Precautions - Cue COVID-19 Test Cartridge and Cue Sample Wand Handling**

- Open the Cue COVID-19 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.
- 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 COVID-19 Test Cartridge or Sample Wand is dropped, cracked, or found to be damaged when opened, do not use and discard.
- Store and use the Cue COVID-19 Test Cartridge at the temperatures provided in the storage and testing conditions sections below.
- The Cue COVID-19 Test Cartridge will heat up inside the Cartridge Reader for one minute. Insert the Cue Sample Wand with the nasal 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 Cue Sample Wand.
- After the test is complete, remove the Cue COVID-19 Test Cartridge with the Cue Sample Wand still inside and dispose of according to the appropriate regulations.

### **Precautions - Used Test Cartridge Disposal**

- 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.

- Also consult your institution's environmental waste personnel on proper disposal of used cartridges, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements different from medical waste disposal. Check state and local regulations as they may differ from federal disposal regulations. Institutions should check the hazardous waste disposal requirements within their respective countries.

### **Precautions - Nasal Sample Collection**

- Treat all biological specimens as if capable of transmitting infectious agents. Wear clean lab coats and gloves. Change gloves between patients.
- Follow safety procedures set by your institution for handling biological specimens.
- Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention<sup>2</sup> and the Clinical and Laboratory Standards Institute<sup>3</sup>.
- Nasal sprays, gels, or cream may not be used before you collect a nasal sample.
- When collecting a direct nasal sample, both nostrils must be swabbed prior to running the test with the Cue Sample Wand nasal sample.
- You must insert the Sample Wand with nasal sample into the Cue COVID-19 Test Cartridge within 5 minutes of collecting the nasal sample.
- The risks of collecting a nasal swab sample include irritation, bleeding, and infection inside the nose where the nasal sample was collected.

### **Limitations**

Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors (e.g., presence of symptoms), and/or stage of infection.

- A false negative result may occur if a sample is improperly collected or handled. False negative results may also occur if inadequate numbers of organisms are present in the sample.
- As with any molecular test, mutations within the target regions of SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Analyte targets (viral nucleic acid) may persist in vivo, independent of virus viability. Detection of analyte targets does not imply that the corresponding viruses are infectious or are the causative agents for clinical symptoms.
- This assay should not be used within 30 minutes of administering nasal or throat sprays.
- The clinical performance has not been established in 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 SARS-CoV-2 and their prevalence, which change over time.

### **Cue COVID-19 Test Cartridge Storage Conditions**

Store the unopened Cue COVID-19 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 COVID-19 Testing Conditions**

Run a Cue COVID-19 Test in the temperature range shown in the table below. Do not run the Cue COVID-19 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)**

**Positive and Negative Controls**

Controls may be used to show that the Cue COVID-19 Test is working properly. The Cue COVID-19 Test Positive Control Swab (REF C2111) and Cue Test Negative Control Swab (REF C2112) are available separately.

The Cue Positive and Negative Control Swabs may be stored at room temperature (15-30 °C / 59-86 °F). Controls are tested using the same procedure as for a patient sample.

Cue Health recommends that a Cue Test Negative Control Swab and a Cue COVID-19 Test Positive Control Swab be run:

- Once for each new lot of cartridge packs received
- When problems with testing are suspected or identified
- Alternatively, as deemed necessary in order to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups

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

Purchase Cue COVID-19 Test Positive Control Swabs and Cue Test Negative Control Swabs from Cue Health Inc., by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

**Specimen Collection and Handling**

The Cue Sample Wand must be used with the Cue Health Monitoring System and the Cue COVID-19 Test Cartridge. To collect a direct nasal swab sample, both nostrils are swabbed with the same Cue Sample Wand. While swabbing in both nostrils do not attempt to scrape or remove excess mucus.

- Insert the tip of the Cue Sample Wand into one nostril about 1 inch or up to the marker on the

Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times.

- Then, insert the same Cue Sample Wand into the other nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times.

The Cue Sample Wand may also be dipped into a tube containing nasal specimens in viral transport media. Instructions for sample dipping are provided in Step 5-8.

The Cue Sample Wand containing the nasal sample must be inserted into the cartridge within 5 minutes of sample collection.

### **Directions for Running the Cue COVID-19 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 COVID-19 Test. These items are not included in the Cue COVID-19 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 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 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 COVID-19 Test. The Quick Start Guide will help you quickly set up your Cue Health Monitoring System 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 Cartridge Reader(s) to your mobile smart device.
5. Connect the Cue Health App to a paired Cue Cartridge Reader to run a Cue COVID-19 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 COVID-19 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 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 nasal sample and run a Cue COVID-19 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 Cartridge Reader that you will be using for the Cue COVID-19 Test. Follow the Cue Health Monitoring System User Manual and the on-screen instructions to connect to the 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 COVID-19 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 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.

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 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 Cartridge 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.

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 Cartridge Reader to power. Follow the Cue Health App videos and screen instructions to pair the Cue Cartridge Reader(s) that will be used for the test(s) to your mobile smart device. When a paired Cartridge Reader is within Bluetooth® range of the mobile smart device, the 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 Cartridge Reader and a Cue COVID-19 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 COVID-19 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.

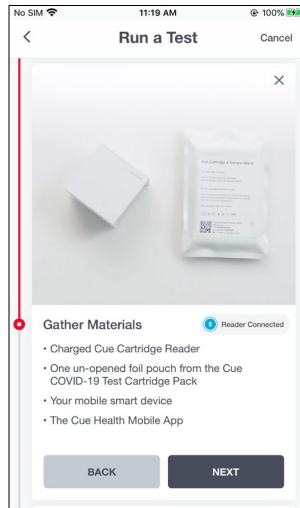


Figure 5-4

**Step 5-5: Prepare the Cue COVID-19 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 COVID-19 Test Cartridge and sterile Sample Wand. Remove the Cue COVID-19 Test Cartridge and the wrapped Sample Wand from the tray.

See the Cue Health App video showing how to prepare the Cue COVID-19 Test Cartridge and Cue Sample Wand for a test as shown in Figure 5-5.

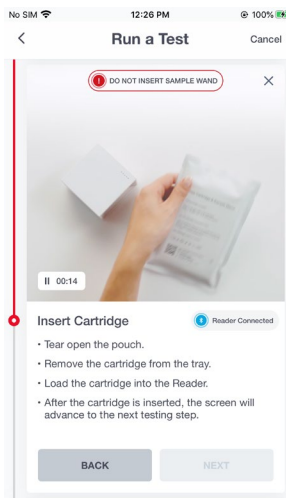


Figure 5-5

**Step 5-6: Insert the Cue COVID-19 Test Cartridge into the Cue Cartridge Reader**

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

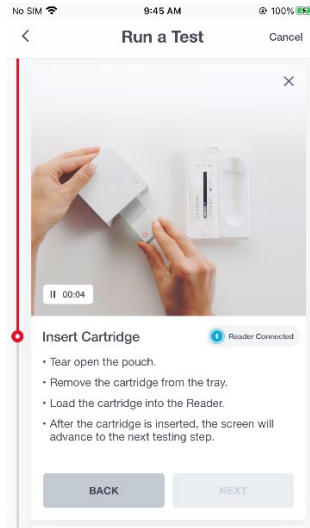


Figure 5-6-1

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

**REMINDER:** The Cue Cartridge Reader needs to be on a level surface when the Cue COVID-19 Test Cartridge is inserted and while the test is running. Do not move the Cue Cartridge Reader while the test is running.

Support the back of the Cue Cartridge Reader with one hand and hold the Cue COVID-19 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 Cartridge Reader will flash.

**REMINDER:** 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.

When you have inserted the 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 cartridge has finished heating up, the progress circle will show 100%.

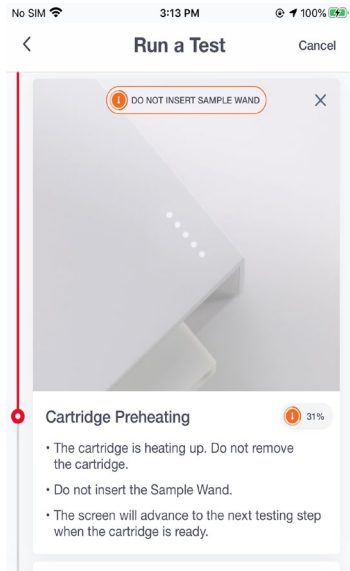


Figure 5-6-2

**Step 5-7: Collect a Nasal Specimen with the Cue Sample Wand and Insert Into the Cartridge**

When the cartridge heating cycle is completed, the Cue Health App will advance to the Collect Sample screen. You may collect a direct nasal sample or you may dip the Cue Sample Wand into a tube containing a nasal specimen in viral transport media.

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.

Proceed to Step 5-8 for instructions on dipping. Continue below for collecting a direct nasal sample.

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

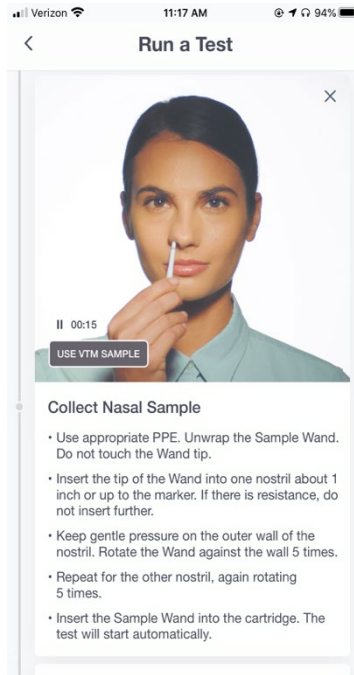


Figure 5-7-1

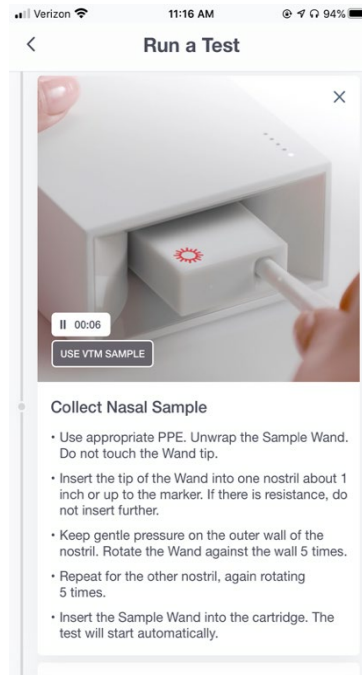


Figure 5-7-2

**REMINDER:** It is important to collect the nasal sample at the time of the Collect Nasal Sample screen and insert the Cue Sample Wand with the nasal sample into the Cue COVID-19 Test Cartridge shortly after collecting the nasal sample. The Cue COVID-19 Test Cartridge should not be in the Cartridge Reader without the inserted Sample Wand for more than 10 minutes.

To collect a direct nasal swab sample, both nostrils are swabbed with the same Cue Sample Wand. While swabbing in both nostrils do not attempt to scrape or remove excess mucus.

- Insert the tip of the Cue Sample Wand into one nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times.
- Then, insert the same Cue Sample Wand into the other nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times.

**REMINDER:** You must insert the Sample Wand with nasal sample into the Cue COVID-19 Test Cartridge within 5 minutes of collecting the nasal sample.

Support the back of the Cue Cartridge Reader and insert the Cue Sample Wand with nasal sample into the port of the Cue COVID-19 Test Cartridge. Make sure the Wand is inserted all the way in until Test in Progress is shown on the Cue Health App screen.

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

Skip this step if you have already collected a direct nasal 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.

Follow these instructions for dipping the Cue Sample Wand into a tube containing an individual nasal specimen in viral transport media (VTM).

- Use the appropriate PPE.
- Gently invert the capped VTM specimen tube to ensure proper mixing.
- Uncap the VTM specimen tube and insert the Sample Wand tip into the tube tilting the VTM tube, if necessary, until the Sample Wand tip comes in contact with liquid. The Sample Wand flocked tip will absorb the sample.
- Carefully remove the Cue Sample Wand from the VTM specimen tube.
- Support the back of the Cue Cartridge Reader and insert the Cue Sample Wand with the nasal specimen into the port of the Cue COVID-19 Test Cartridge. Make sure the Wand is inserted all the way in until Test in Progress is shown on the Cue Health App screen.

**REMINDER:** It is important to collect the Cue Sample Wand nasal specimen by dipping into the individual sample tube at the time of the Collect VTM Sample screen in the Cue Health App and insert the Sample Wand with the nasal specimen into the Cue COVID-19 Test Cartridge promptly. The Cue COVID-19 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 inserted into the Cue COVID-19 Test Cartridge. It takes about 20 minutes for the Cue COVID-19 Test to run. Once the test starts, the Cue Health App will show the test progress as percent completed as shown in Figure 5-8.

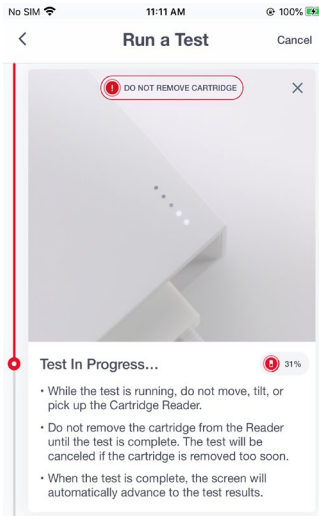


Figure 5-8

### Step 5-10: View the Result

The Cue Health App will show the Cue COVID-19 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 COVID-19 Test Cartridge with Sample Wand After Testing

Remove the 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 should still be 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 Cue COVID-19 Test did not detect SARS-CoV-2 virus in the sample.

- A negative test result for this test means that SARS-CoV-2 RNA was not present in the sample above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19. Negative results should be treated as presumptive and, if inconsistent with clinical



signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests.

- 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 COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 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 COVID-19 within the community, or other unintended adverse events.

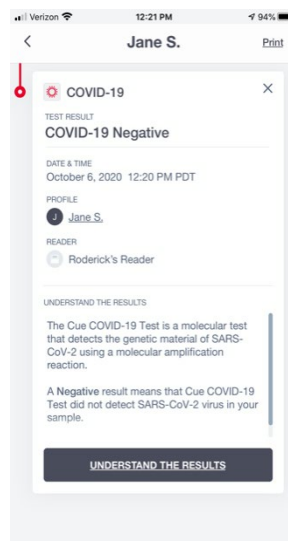


Figure 6-1

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 COVID-19 Test detected SARS-CoV-2 virus in the sample.

- When diagnostic testing is 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 COVID-19.
- Risks to patients of false positives include: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient

isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

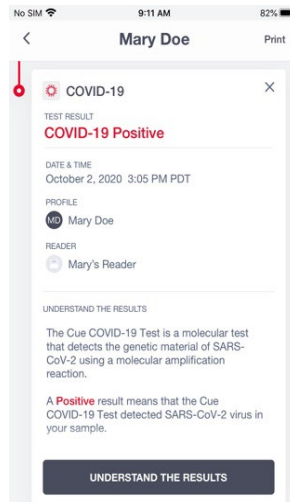


Figure 6-2

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 a system error occurred and the Cue Health Monitoring System is unable to provide the SARS-CoV-2 result. Retesting is required. Common causes of invalid results are:

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

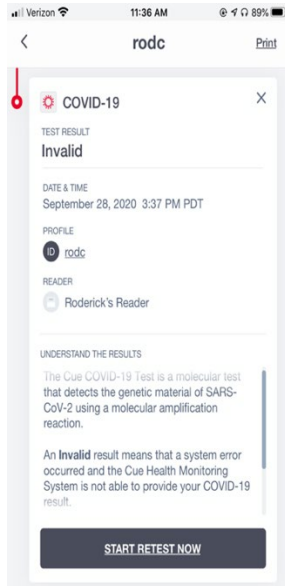


Figure 6-3

If the result is invalid, retest. Click on **START RETEST NOW**. You must use a new Cue COVID-19 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 cancel the test by tapping “Cancel” in the top right corner of the Cue Health App screen or if the system cancels 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 Cartridge Reader is moved or tilted while the test is running, the test cartridge is removed before the test is completed, the Sample Wand is inserted into the cartridge too soon or too late. If the result is canceled, retest. Click on **START RETEST NOW**. You must use a new Cue COVID-19 Test Cartridge and a new Sample Wand.

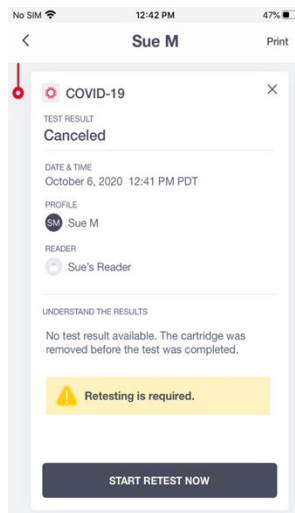


Figure 6-4

## **Disposal of the Used Cue COVID-19 Test Cartridge**

After each test, the Cue COVID-19 Test Cartridge with the Sample Wand still inside must be removed from the Cue Cartridge Reader. 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.

## **CONDITIONS OF AUTHORIZATION FOR AUTHORIZED LABORATORIES**

The Cue COVID-19 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>

To assist clinical laboratories using the Cue COVID-19 Test, the relevant Conditions of Authorization are listed below, and are required to be met by authorized laboratories performing the test. Please note the Letter of Authorization refers to "authorized laboratories" as "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test 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."

- A. Authorized laboratories using the Cue COVID-19 Test must include with result reports of the Cue COVID-19 Test all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- B. Authorized laboratories using the Cue COVID-19 Test must perform the Cue COVID-19 Test as outlined in the Cue COVID-19 Test Instructions for Use. Deviations from the authorized procedures, including authorized clinical sample types and authorized control materials required to perform the Cue COVID-19 Test, are not permitted.
- C. Authorized laboratories that receive the Cue COVID-19 Test must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- D. Authorized laboratories using the Cue COVID-19 Test must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories must collect information on the performance of the test and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Cue Health Inc. Technical Support (support@cuehealth.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they have become aware.
- F. All operators using the Cue COVID-19 Test must be able to perform and interpret the

test results, use appropriate personal protective equipment, and use the product in accordance with the authorized labeling.

- G. Cue Health, distributors, and authorized laboratories using the Cue COVID-19 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.

### Cue COVID-19 Test Performance

#### Limit of Detection – Viral Genomic RNA

Limit of Detection (LoD) testing was performed with genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020. The RNA was diluted in clinical nasal matrix to obtain 4 low level concentrations. The dilutions were tested in triplicate in 2 Cue COVID-19 Test cartridge lots by 2 operators on each of 3 days for a total of 36 replicates per dilution. 15 µL of the RNA dilution was applied to a Cue Sample Wand before testing. The LoD was determined as the lowest concentration with ≥ 95% detection.

The LoD was confirmed with 20/20 replicates testing positive.

#### Cue COVID-19 Test Limit of Detection Confirmation

Material	Claimed LoD Genome Copies/Sample Wand	Claimed LoD Genome Copies/µL of Sample	Confirmation Positives/Replicates
SARS-CoV-2 viral genomic RNA	20	1.3	20/20

The claimed Limit of Detection is 20 genome copies/Sample Wand

#### Limit of Detection – Live SARS-CoV-2 Virus

Samples containing live SARS-CoV-2 virus were tested at 20 virions, 40 virions, 60 virions, 100 virions and 1000 virions, which is 1x, 2x, 3x, 5x, and 50x LoD relative to the Cue COVID-19 LoD of 20 copies of SARS-CoV-2 genomic RNA per wand. 15µL of live virus diluted in clinical nasal matrix was applied to a Cue Sample Wand before testing in the Cue COVID-19 Test.

Samples at 20 virions (20 replicates) and 1000 virions (5 replicates) were also tested in the EUA CDC 2019–Novel Coronavirus (2019–nCoV) RT-PCR Diagnostic Test.

Live virus diluted in clinical nasal matrix was added to 1 mL of VTM and tested in the CDC 2019–Novel Coronavirus (2019–nCoV) Real-Time RT-PCR Diagnostic test.

Virions/ Sample Wand	Virions/ μL of Sample	Cue COVID-19 Detected/Tested	Cue COVID-19 % Detected	CDC RT-PCR Detected/Tested	CDC RT-PCR % Detected
20	1.3	15/20	75%	7/20	35%
40	2.7	18/20	90%	Not tested	N/A
60	4.0	5/5	100%	Not tested	N/A
100	6.7	9/9	100%	Not tested	N/A
1000	66.7	5/5	100%	5/5	100%

During the study, any samples with invalid results, cancelled tests, or suspected sample addition errors were replaced.

### Analytical Reactivity/Inclusivity

The Cue COVID-19 Test utilizes a forward and reverse primer and a probe targeting the N (nucleocapsid protein) gene of the SARS-CoV-2 virus. The probe imparts greater specificity to the amplification reaction. Due to the limited availability of SARS-CoV-2 isolates for inclusivity testing, *in silico* analysis was used to evaluate the extent of homology between each of the test primers/probe and sequenced SARS-CoV-2 isolates available in public databases.

The original *in silico* analysis utilized sequences available early in the pandemic from the NCBI public database (<https://www.ncbi.nlm.nih.gov/labs/virus/vssi/#/>, data downloaded March 2020) and the GISAID public database (<https://www.gisaid.org/>, data downloaded April 2020). The results from this analysis are summarized in the table below. The forward primer matched 100% to all sequences. The reverse primer matched all but one sequence in the NCBI database and one sequence in the GISAID database. A few sequences from the GISAID database showed mismatches to the probe, but these strains were all collected pre-pandemic from non-human hosts.

### Reactivity/Inclusivity Evaluation (March/April 2020)

Primer	% of 1551 GISAID strains with perfect match	% of 313 NCBI strains with perfect match	% of all analyzed genomes with perfect match
Forward	100.0	100.0	100.0
Reverse	99.9	99.7	99.9
Probe	99.6	100.0	99.7

An updated analysis was performed in December 2020. Sequence data was obtained from the GISAID database, where the sample collection was specified as occurring between November 5 and December 14, 2020. Sequences were filtered to select for completeness and high coverage. Because of the high number of resulting sequences (19319) obtained with these query parameters, a random subset of 2000 sequences was chosen for the downstream analysis.

After performing alignment via Clustal Omega (<https://www.ebi.ac.uk/Tools/msa/clustalo/>), sequences were visualized in Geneious (v. 9.0.5) and mismatch occurrences were analyzed. In all cases, mismatch occurrence reflected a single base mismatch. There are no sequences that exhibited a mismatch to more than one primer/probe. The results are summarized below.

**Reactivity/Inclusivity Evaluation (Worldwide, November 5 - December 14, 2020)**

Primer	# of GISAID strains with perfect match	# of GISAID strains containing mismatch	% of GISAID strains with perfect match
Forward	1998	2	99.9 %
Reverse	1988	12	99.4 %
Probe	1971	28*	98.6 %

\*One strain had an ambiguous result due to a degenerate base call, thus it was not included in the analysis for the probe.

A similar analysis was performed, but with the sample location restricted to North America, and with samples collected between October 15 and December 1, 2020. The resulting sequences were aligned and then analyzed within Geneious software (v. 9.0.5) to determine the number of sequences that contained mismatches to each of the primers/probe. Results are summarized in the table below. In all cases, mismatch occurrence reflected a single base mismatch. Only 3/2087 samples (0.14%) showed a mismatch in sequence to more than one primer/probe. Overall, the analysis indicates a very high level of conservation of the targeted genomic locus within the North American population.

**Reactivity/Inclusivity Evaluation  
(North America, October 15 – December 1, 2020)**

Primer	# of GISAID strains with perfect match	# of GISAID strains containing mismatch	% of GISAID strains with perfect match
Forward	2079	8	99.6 %
Reverse	2081	6	99.7 %
Probe	2074	12*	99.4 %

\*One strain had an ambiguous result due to a degenerate base call, thus it was not included in the analysis for the probe.

An analysis was also performed to examine several emergent viral variants of special interest: the UK variant B.1.1.7, the South African variant B.1.351, and the Brazilian variant P.1.

The GISAID query for the B.1.1.7 variant resulted in a set of 721 strain sequences. Those sequences were downloaded and examined within Geneious Prime software (v. 2021.0.1). The results are summarized below. For each primer/probe, greater than 99.0% of the sequences are a perfect match.

**Reactivity/Inclusivity Analysis of B.1.1.7 Variant Strains  
(Worldwide, February 5 - February 15, 2021)**

Primer	# of GISAID strains with perfect match	# of GISAID strains containing mismatch	% of GISAID strains with perfect match
Forward	717	4	99.4%
Reverse	714	7	99.0%
Probe	719	1*	99.9%

\*One strain had an ambiguous result due to a degenerate base call, thus it was not included in the analysis for this probe.

The GISAID query for the B.1.351 variant resulted in a set of 676 strain sequences. Those sequences were downloaded and examined within Geneious Prime software (v. 2021.0.1). The results are summarized below. For each primer/probe, at least 99.7% of the sequences are a perfect match.

**Reactivity/Inclusivity Analysis of B.1.351 Variant Strains  
(Worldwide – all available sequences as of February 15, 2021)**

Primer	# of GISAID strains with perfect match	# of GISAID strains containing mismatch	% of GISAID strains with perfect match
Forward	676	0	100.0%
Reverse	676	0	100.0%
Probe	674	2	99.7%

The GISAID query for the P.1 variant resulted in a set of 358 strain sequences. Those sequences were downloaded and examined within Geneious Prime software (v. 2021.0.1). The results are summarized below. For each primer/probe, at least 98.5% of the sequences are a perfect match.



**Reactivity/Inclusivity Analysis of P.1 Variant Strains  
(Worldwide – all available sequences as of February 23, 2021)**

Primer	# of GISAID strains with perfect match	# of GSAID strains containing mismatch	% of GISAID strains with perfect match
Forward	357	1	99.7%
Reverse	351	5*	98.6%
Probe	348	5**	98.9%

\*Two strains had an ambiguous result due to “N” base calls, and were thus not included in the analysis for this primer.

\*\* Five strains had an ambiguous result due to “N” base calls, and were thus not included in the analysis for this primer.

**Analytical Specificity – Cross-Reactivity**

A study was performed testing 31 potentially cross-reacting organisms with the Cue COVID-19 Test. Each organism was diluted in clinical nasal matrix and tested in triplicate. The organisms, concentrations, and test results are shown in the table below. None of the 31 organisms cross-reacted in the Cue COVID-19 Test at the concentrations tested.

**Cue COVID-19 Test Cross-Reactivity Evaluation**

Organism	Titer	Units of Measurement	Detected/Tested
<i>Chlamydia pneumoniae</i>	1.47E+07	CFU/mL	0/3
<i>Haemophilus influenzae</i>	7.87E+07	CFU/mL	0/3
<i>Legionella pneumophila</i>	6.82E+08	CFU/mL	0/3
<i>Mycobacterium tuberculosis (genomic DNA)</i>	6.90E+04	genome copies / $\mu$ l	0/3
<i>Streptococcus pneumonia</i>	4.73E+07	CFU/mL	0/3
<i>Streptococcus pyogenes</i>	4.30E+08	CFU/mL	0/3
<i>Bordetella pertussis</i>	1.17E+09	CFU/mL	0/3
<i>Mycoplasma pneumoniae</i>	2.47E+06	CFU/mL	0/3
<i>P.jiroveci-S.cerevisiae Recombinant</i>	1.56E+07	CFU/mL	0/3
<i>Pseudomonas aeruginosa</i>	6.14E+07	CFU/mL	0/3
<i>Staphylococcus epidermidis</i>	1.17E+09	CFU/mL	1/9*
<i>Streptococcus salivarius</i>	1.79E+08	CFU/mL	0/3
Human Coronavirus 229E	1.26E+05	TCID50/mL	0/3

Organism	Titer	Units of Measurement	Detected/Tested
Human Coronavirus OC43	1.26E+05	TCID50/mL	0/3
Human Coronavirus HKU1 RNA	7.50E+04	genome copies / $\mu$ l	0/3
Human Coronavirus NL63	1.10E+04	TCID50/mL	0/3
SARS Coronavirus (Inactivated)	10 fold dilution of stock with Ct values from 25-28	Ct value	1/3
MERS-Coronavirus (Inactivated)	4.17E+04	TCID50/mL	0/3
Adenovirus Type 1	3.39E+06	TCID50/mL	2/9*
Human Metapneumovirus	1.70E+04	TCID50/mL	0/3
Parainfluenza 1	4.17E+04	TCID50/mL	0/3
Parainfluenza 2	4.17E+04	TCID50/mL	0/3
Parainfluenza 3	8.51E+06	TCID50/mL	0/3
Parainfluenza 4	1.60E+03	TCID50/mL	0/3
Influenza A/New York/18/09 (Inactivated)	1.15E+06	TCID50/mL	0/3
Influenza B/Indiana/17/2017	1.00E+07	TCID50/mL	0/3
Enterovirus Type 70	5.00E+05	TCID50/mL	0/3
Respiratory Syncytial Virus B	9.55E+05	TCID50/mL	0/3
Rhinovirus type 1A	1.51E+05	TCID50/mL	1/10*
Pooled human nasal wash	10%	percent of total volume	0/3
Candida albicans	5.02E+07	CFU/mL	0/3

\*A fresh dilution was prepared and the potential cross-reactant was retested.

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

An in silico analysis for possible cross-reactions with all of the 31 organisms in the table above was also conducted by mapping the Cue COVID-19 Test target nucleic acid sequences to the organism's genome sequences. The analysis of the non-influenza viruses utilized the NCBI virus search tool. The analysis of the influenza viruses utilized an influenza research database. Twelve viral strains showed  $\geq 80\%$  sequence homology with the forward primer; 3 viral strains showed  $\geq 80\%$  sequence homology with the reverse primer; and one viral strain showed  $\geq 80\%$  sequence homology with the probe primer. Of all the viruses analyzed, only SARS-CoV-1 strain showed sequence homology to more than one Cue COVID-19 Test primer at the  $\geq 80\%$  sequence homology level. For the in silico analysis of microbial organisms a Blast tool using the NCBI database was utilized.

Only one microbial organism showed  $\geq 80\%$  sequence homology to more than one of the three Cue COVID-19 Test primers.

The Cue COVID-19 Test, designed for the specific detection of SARS-CoV-2 virus, showed no significant combined homologies with the potential cross-reactants analyzed in silico that would predict potential Cue COVID-19 Test false results.

### Analytical Specificity – Interfering Substances

A study was performed to assess substances with the potential to interfere with the performance of the Cue COVID-19 Test. Potential interferents were tested at the highest concentration likely to be found in a nasal sample. Each interfering substance in negative clinical nasal matrix was tested in triplicate. Each interfering substance was also tested in triplicate in the presence of genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020, at 3X LoD.

The substances, concentrations, and test results are shown in the table below. None of the substances interfered in the Cue COVID-19 Test at the concentrations tested.

### Cue COVID-19 Test Interfering Substances Evaluation

Substance	Concentration	Detected/Tested	
		Negative Nasal Matrix	Positive Nasal Matrix (SARS-CoV-2 RNA present at 3X LoD)
Afrin	20% (v/v)	0/3	3/3
Saline Nasal Spray	20% (v/v)	1/9*	3/3
Zicam Allergy Relief	15% (v/v)	0/3	3/3
Chloroseptic Max	20% (v/v)	0/3	3/3
Neo-Synephrine	20% (v/v)	0/3	3/3
Mucin	0.5% (w/v)	0/3	3/3
Zanamivir (Relenza)	0.3 mg/ml	0/3	3/3
Mupirocin	10 mg/ml	0/3	3/3
Tamiflu (Oseltamivir phosphate)	0.01mg/ml	0/3	3/3
Budesonide	0.05 mg/ml	0/3	3/3

Substance	Concentration	Detected/Tested	
		Negative Nasal Matrix	Positive Nasal Matrix (SARS-CoV-2 RNA present at 3X LoD)
Flunisolide	0.04 mg/ml	0/3	3/3
Dexamethasone	0.5 mg/ml	0/3	3/3
Beclomethasone	0.068 mg/mL	0/3	3/3
Biotin	3.5 ug/mL	0/3	3/3
Xofluza (baloxavir marboixil)	0.01mg/ml	0/3	3/3
Nasacort/Triamcinolone	0.04 mg/ml	0/3	3/3
Flonase/Fluticasone	0.04 mg/ml	0/3	3/3
Mometasone	0.04 mg/ml	0/3	3/3
Tobramycin	2.5mg/ml	0/3	3/3
Whole Blood	1% (v/v)	0/3	3/3
Chloroseptic (solid)	20% w/v	1/9*	3/3
Galphimia Glauca	20% w/v	0/3	3/3
Rhinallergy	20% w/v	1/9*	3/3

\*A fresh dilution was prepared and the potential interferent was retested.

### **Clinical Evaluation – Prospective Clinical Study in Emergency Departments**

A prospective clinical study was conducted in 2 emergency departments (ED) located in an epicenter for the COVID-19 outbreak in the US. The study was IRB approved.

Patients presenting at either of two EDs with signs and/or symptoms of COVID-19 as determined by the healthcare provider were tested using the Cue COVID-19 Test at point of care. Testing was performed by untrained operators with no prior laboratory training or experience.

The Cue COVID-19 Test results were compared to the results from the healthcare institution's standard of care EUA PCR test for SARS-CoV-2. There was 100% agreement for positive cases and 92% agreement for negative cases.

		Institutional Standard of Care EUA SARS-CoV-2 PCR Test	
		Positive	Negative
Cue COVID-19 Test	Positive	6	3
	Negative	0	35

**Clinical Evaluation – Prospective Clinical Study in a Drive-Thru Testing Center**

A prospective clinical study was conducted at a mid-western community drive-thru specimen collection and testing center. The study was IRB approved.

Adult outpatients were referred for testing after nurse triage based upon symptoms, exposures, or other criteria for COVID-19 testing. Patients with positive results for SARS-CoV-2 were both symptomatic and asymptomatic.

Patients were tested using the Cue COVID-19 Test at the point of care, drive-thru setting. Testing was performed by untrained operators with no prior laboratory training or experience.

The Cue COVID-19 Test results were compared to the results from the healthcare institution’s standard of care EUA PCR test for SARS-CoV-2. There was 92% agreement for positive cases and 98% agreement for negative cases.

		Institutional Standard of Care EUA SARS-CoV-2 PCR Test	
		Positive	Negative
Cue COVID-19 Test	Positive	22	4
	Negative	2*	239

\*One patient did not have a tie-breaker SARS-CoV-2 test result available. Positive percent agreement would be 22/23 (96%) excluding that patient.

**Clinical Evaluation – Retrospective Clinical Samples and Sample Dipping**

The Cue COVID-19 Test was also evaluated with 76 frozen nasal specimens in viral transport media. The samples were de-identified and the study was IRB approved.

The 76 samples were originally collected from patients suspected of SARS-CoV-2 infection by the healthcare provider. The samples were positive or negative by the healthcare institution’s standard of care EUA test for SARS-CoV-2.

The thawed sample was applied by dipping the Cue Sample Wand into the clinical sample VTM and immediately inserting into the Cue COVID-19 Test Cartridge.

There was 100% positive (60/60) and negative (16/16) agreement of the Cue COVID-19 Test result with the institutional EUA.

### **Clinical Evaluation – Prospective Clinical Study with Lay Users**

Cue Health conducted prospective studies at 4 urgent care locations and at 2 Cue Health locations to evaluate use of the Cue COVID-19 Test by lay users in a simulated home use environment. All subjects successfully followed the instructions in the Cue Health App to run the Cue COVID-19 Test, start to finish without any assistance.

Adult lay users ( $\geq 18$  years of age) self-collected or collected from their child ( $< 18$  years of age) a Cue Sample Wand nasal swab and ran the test.

Adult and child subjects were enrolled in an “all comers” style at the urgent care sites. Adult subjects at the Cue Health locations were enrolled to enrich inclusion of asymptomatic positive subjects by including subjects who were known positive for COVID-19. Among the total 286 subjects, 276 were adult  $\geq 18$  years of age self-swabbing and self-testing in the Cue COVID-19 Test and 10 were children  $< 18$  years of age where their parent collected the nasal sample and ran the Cue test. Thirteen (13) samples could not be included as there was no comparator assay result or Cue result available. Among the 10 unavailable Cue test results, 7 tests were cancelled, and 3 tests had invalid results. The 7 cancelled tests were 5 cartridge flow errors, 1 tilt threshold exceeded, and 1 user accidentally cancelled the test while in progress.

The rate of invalid or cancelled test results observed in this prospective clinical study was 3.7% (10/273).

Demographics for the 273 subjects included in the performance analyses are presented below.

Age Range	N	%
<14	6	2.2%
14-23	66	24.2%
24-64	181	66.3%
>65	18	6.6%
N/A	2	0.7%

Sex	N	%
Male	133	48.7%
Female	139	50.9%
Unknown	1	0.4%

There were 38 subjects with positive results, 233 subjects with negative results, and 2 subjects with inconclusive results by the FDA Emergency Use Authorized (EUA) molecular comparator method. Among the subjects, 10 subjects were asymptomatic positive, 123 subjects were asymptomatic negative, and 1 subject was asymptomatic inconclusive by the comparator.

All Data		FDA EUA Molecular Comparator		
		Positive	Negative	Inconclusive
Cue COVID-19 Test	Positive	37	2	2*
	Negative	1	231	0

\*The 2 inconclusive samples by the comparator tested positive by the Cue COVID-19 Test.

Positive Percent Agreement (PPA): 97.4% (95% CI: 86.5% - 99.5%)

Negative Percent Agreement (NPA): 99.1% (95% CI 96.9% - 99.8%)

Symptomatic Individuals		FDA EUA Molecular Comparator		
		Positive	Negative	Inconclusive
Cue COVID-19 Test	Positive	27	2	1*
	Negative	1	108	108

\*The 1 inconclusive sample by the comparator tested positive by the Cue COVID-19 Test

PPA: 96.4% (95% CI: 82.3% - 99.4%)

NPA: 98.2% (95% CI: 93.6% - 99.5%)

Asymptomatic Individuals		FDA EUA Molecular Comparator		
		Positive	Negative	Inconclusive
Cue COVID-19 Test	Positive	10	0	1*
	Negative	0	123	0

\*The 1 inconclusive sample by the comparator tested positive by the Cue COVID-19 Test.

PPA: 100% (95% CI: 72.2% - 100%)

NPA: 100% (95% CI: 97.0% - 100%)

### Customer Support

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






You can purchase the Cue Health Monitoring System and Cue COVID-19 Test Cartridge Packs by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

## References







1. Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/index.html> (accessed March 23, 2021)
2. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories. <http://www.cdc.gov/biosafety/publications/> (accessed March 23, 2021)
3. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).

## Symbols Used on the Product Labels

The table below describes the symbols used on the Cue COVID-19 Test Cartridge Pack, the cartridge foil pouch, the Cue Sample Wand, the Cue COVID-19 Test Positive Control Swab, and the Cue Test Negative Control Swab.

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



SYMBOL	DESCRIPTION
	Catalog number
	Positive Control
	Negative Control
	Manufacturer
	Keep dry
	Use By



 Cue Health Inc.  
 San Diego, CA 92121 USA  
 Email: [support@cuehealth.com](mailto:support@cuehealth.com)  
 Phone: 833.CUE.TEST (833.283.8378)  
 Website: [www.cuehealth.com](http://www.cuehealth.com)



These are not the complete instructions for use. Go to the Cue Health App to see the Cue Health Monitoring System User Manual and the Cue COVID-19 Test Instructions for Use.

### 1 SET UP THE CUE HEALTH MONITORING SYSTEM

1.1 Unpack the Cue Cartridge Reader.



1.2 Download the Cue Health App to a compatible mobile smart device named on the Cue Health website at www.cuehealth.com.

The Cue Health App is available on the Apple® App Store® and Google Play™ Store.



3.3 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). When you are ready to test, tear open the top of the cartridge foil pouch and remove the plastic tray with the Cue COVID-19 Test Cartridge and Cue Sample Wand. Remove the cartridge from the tray.



Tear pouch



Remove plastic tray



Remove cartridge

3.4 Insert the cartridge into the Cartridge Reader. Support the back of the Cartridge Reader with one hand and hold the cartridge in the other hand. Insert the cartridge into the port of the Cartridge Reader.



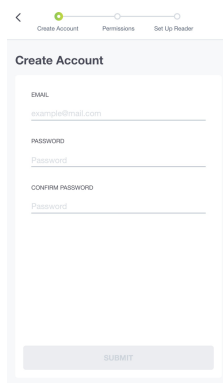
Insert cartridge into Reader



Allow cartridge to heat up

### 2 OPEN THE CUE HEALTH APP & FOLLOW THE ON-SCREEN INSTRUCTIONS

2.1 Set up your Cue Account. Follow the on-screen instructions for "Create Account."



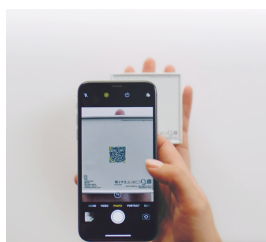
2.2 Follow the on-screen instructions to set up the Cartridge Reader. Connect the Cartridge Reader to power. Pair the Reader to your mobile smart device.

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.



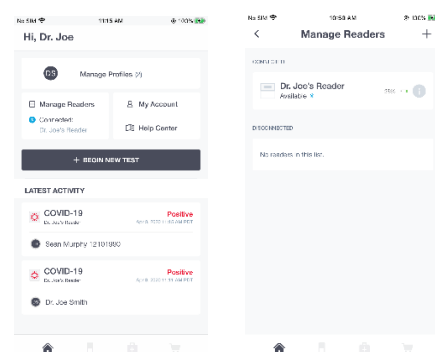
Bottom of Reader



Find the Reader QR code

2.3 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.



2.4 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."

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.

3.5 Remove the wrapped Sample Wand from the tray. Open the Wand wrapper on the side labeled "Open Here." Grasp the handle of the wand and remove it from the wrapping. Do not use a Sample Wand if the wrapper is damaged or opened or if the Wand tip touches anything before sample collection.



Open Sample Wand wrapper



Remove Sample Wand from wrapper

3.6a Cue Sample Wand Direct Nasal Swab: To collect a direct nasal swab sample, insert the tip of the Sample Wand into one nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times. Then, insert the same Sample Wand into the other nostril and follow the same collection instruction as for the first nostril. Do not try to remove excess mucus. Sample collection is demonstrated in a video in the Cue Health App.



Collect nasal sample

3.6b Alternate Sample Type Using a Previously Collected Traditional Nasal Specimen in VTM: To collect a VTM sample, gently invert the capped VTM tube to ensure mixing. Uncap the tube and insert the Cue Sample Wand tip into the tube, tilting the tube until the Wand tip comes in contact with liquid. The Sample Wand flocked tip will absorb the sample. Remove the Sample Wand from the VTM tube.



Insert Sample Wand

3.7 When the Cue Health App screen shows that the cartridge is "Ready", insert the Sample Wand into the cartridge. Insert the Sample Wand within 5 minutes after collecting the sample until Test in Progress is shown on the Cue Health App screen.

3.8 The Cue Health App will show the test progress. The Cue COVID-19 Test takes about 20 minutes to run. Do not move the Cartridge Reader while the test is running.

### 3 FOLLOW THE CUE HEALTH APP TO RUN A CUE COVID-19 TEST

3.1 Tap "+ BEGIN NEW TEST." View the Cue COVID-19 Test Intended Use. If prompted, select your organization. Also view the Precautions of the test.

3.2 Place the Cue Cartridge Reader and a Cue COVID-19 Test Cartridge foil pouch in front of you. Make sure the Reader is charged or connected to power. The Reader needs to be on a level surface when the cartridge is inserted and while the test is running. Do not move the Reader while the test is running. Do not use a cartridge if the foil pouch is damaged.



3.9 When the test is complete, you will see the result on the Cue Health App screen. You will also see information to help you understand a Negative or Positive result. If the result is Invalid or Canceled you will see instructions for retesting. A Negative result means that the Cue COVID-19 Test did not detect SARS-CoV-2 virus in the sample. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. A negative result does not rule out co-infections with other pathogens. A Positive result means that the Cue COVID-19 Test detected SARS-CoV-2 virus in the sample. Positive results do not rule out bacterial infection or co-infection with other viruses. An Invalid or Canceled result means that a system error occurred and there is no test result. Retest using a new Cue COVID-19 Test Cartridge and new Cue Sample Wand. Refer to the Cue COVID-19 Test Instructions for Use for more information on understanding test results.



**3.10** Remove the Cue COVID-19 Test Cartridge from the Cartridge Reader after you see the result. Dispose of the used Cue COVID-19 Test Cartridge with Sample Wand according to your institution’s environmental waste procedures for proper disposal of used cartridges. The Reader should be cleaned/disinfected after each use. Wipe with Clorox® Germicidal Wipes or equivalent (0.55% sodium hypochlorite).

### Specimen Collection and Handling

#### Cue Sample Wand Direct Nasal Swab Sample

To collect a direct nasal swab sample, both nostrils are swabbed with the same Cue Sample Wand. While swabbing in both nostrils do not attempt to scrape or remove excess mucus.

- Insert the tip of the Cue Sample Wand into one nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times.
- Then, insert the same Cue Sample Wand into the other nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. Keep gentle pressure on the outer wall of the nostril and rotate the Wand against the wall 5 times.

#### Alternative Sample Type Using a Previously Collected Traditional Nasal Specimen in Viral Transport Media (VTM)

Obtain a previously collected traditional nasal specimen in VTM collected in accordance with institutional or manufacturer’s instructions.

- Gently invert the capped VTM specimen tube to ensure proper mixing.
- Uncap the VTM specimen tube and insert the Sample Wand tip into the tube tilting the VTM tube, if necessary, until the Sample Wand tip comes in contact with liquid. The Sample Wand flocked tip will absorb the sample.
- Carefully remove the Cue Sample Wand from the VTM specimen tube.

### Quality Control (QC)

Controls may be used to show that the Cue COVID-19 Test is working properly. The Cue COVID-19 Test Positive Control Swab (REF C2111) and Cue Test Negative Control Swab (REF C2112) are available separately.

Control Swabs are stored at room temperature (15-30 °C / 59-86 °F). Control Swabs are tested using the same procedure as for a patient sample.

Cue Health recommends that a Cue Test Negative Control Swab and a Cue COVID-19 Test Positive Control Swab be run:

- Once for each new lot or shipment of cartridge packs received
- When problems with testing are suspected or identified
- Alternatively, as deemed necessary in order to conform with your internal quality control procedures, with local, state and/or federal regulations, or accrediting groups

If correct control results are not obtained, repeat the test using a new Control Swab, 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.

Purchase the Cue COVID-19 External Control Swabs Pack (REF 2110) that contains three Cue COVID-19 Test Positive Control Swabs (REF C2111) and three Cue Test Negative Control Swabs (REF C2112) 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).

### Precautions

- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This product 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.
- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, 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.

For Use Under an Emergency Use Authorization (EUA) Only  
Use with the Emergency Use Authorization Only Cue™ Health Monitoring System and Cue™ Health Mobile Application



For In Vitro Diagnostic Use



C1018



eIFU available on the Cue Health Mobile Application

### Rx Only



CUE  
Cue Health Inc.  
San Diego, CA92121  
USA

Cue Health Inc., Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at 833.CUE.TEST (833.283.8378)  
Contact Cue Health Customer Support to request a physical copy of the Instructions For Use and the Quick Reference Instructions, free of charge.

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



cue

User Manual

# Cue™ 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)

Cue™ is a trademark of Cue Health Inc.

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# Chapter 1

## Introduction and User Safety

### **Welcome to Cue**

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


### **Intended Use**

The Cue Health Monitoring System is an in vitro diagnostic medical device for use with test-specific Cue Cartridge(s) and the Cue Health Mobile Application (Cue Health App) installed on a mobile smart device such as the Apple® iPhone® or iPad. Go to [www.cuehealth.com](http://www.cuehealth.com) for a list of compatible mobile smart devices.

## **Before Testing with the Cue Health Monitoring System**

Review the Quick Start Guide and this User Manual before you run a test using the Cue Health Monitoring System.

The Quick Start Guide will help you quickly set up your system and get ready to run a test. This User Manual gives you all the information you need to use your system 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 possible risk of injury or damage to your 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. Do not proceed if you do not fully understand the actions to take after seeing a Caution message.



## **Note**

A Note is used to give you more information to make the instructions clearer.

## 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 to be performed.







Procedure steps are numbered and should be performed in that order.





When there is a system response to the procedure step performed, it 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 as a result of pressing an icon or an action command in the Cue Health App
<b><i>Bold Italics</i></b>	Used to emphasize 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: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.



## General Precautions

The Cue Health Monitoring System may not work correctly if there is damage to the package or the system parts.

- Do not use the Cue Health Monitoring System if the package seals are broken.
- Do not use Cue Health Monitoring System if any part is damaged.
- Do not run a test if the room temperature is outside of the testing conditions stated in the test-specific Cue Cartridge Instructions for Use. Testing in room temperatures that are too high or too low may cause an incorrect or invalid result.
- Do not use the Cue Health Monitoring System in 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 Health Monitoring System 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 Health Monitoring system or use any parts that did not come with the system, you may harm yourself and the system. You will also void your warranty.

- The Cartridge Reader should be placed on a stable, flat, and level surface while running a test. Do not move or tilt the Reader while a test is in progress.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.
- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, 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.

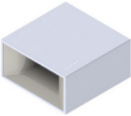


## Chapter 2

# Cue Health Monitoring System Overview and Features

The Cue Health Monitoring System include three parts. These parts include the Cue Cartridge Reader, the Cue Power Adapter, and the Cue Charging Cable. The Cue Wireless Charging Base is available as an optional part (accessory). The Cue Health Monitoring System is used with test-specific Cue Cartridges and sample collection devices (Cue Sample Wand). The Cue Cartridge Reader connects to the Cue Health App installed on your Apple iPhone or iPad. 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
Cue Cartridge Reader	The Cue Cartridge Reader communicates with the Cue Health App and the test-specific Cue Cartridges to run a test on a sample.	
Cue Power Adapter	The Cue Power Adapter plugs into standard wall power. The Cue Charging Cable plugs into the Cue Power Adapter.	
Cue Charging Cable	The Cue Charging Cable connects the Power Adapter to the Cartridge Reader.	

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



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

- One (1) Cue Cartridge 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 Cartridge Pack**

The table on the next page describes Cue Test Cartridge Packs. Cue Test Cartridge Packs are available for different tests including a test for SARS-CoV-2 virus (COVID-19). Cue Test Cartridge Packs are sold separately and must be used before the Use By date printed on the cartridge pack label.

Component	Description	Image
<p>Cue Test Cartridge Pack</p>	<p>A Cue Test Cartridge Pack comes with a Cue test cartridge, 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 cartridge to run a test on the sample.</p>	 <p>Cue COVID-19 Test Cartridge</p>  <p>Cue Sample Wand</p>



## **Compatible Mobile Smart Devices**

The Cue Health Monitoring System may be used with certain iPhone and iPad models. 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 the Cue Health Monitoring System. Download the Cue Health App from the Apple App 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, the test on the Cue Health Monitoring System will still run to completion. The result will not be displayed until the mobile smart device is charged. Bring the charged mobile smart device close to the Cue Cartridge Reader and open the Cue Health App to see the test result.

The Cue Health App also stores test results and communicates with the internet and the secured cloud storage.

### Accessories Available Separately

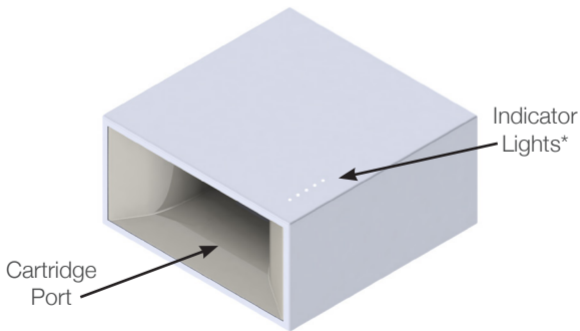
Component	Description	Image
Cue Wireless Charging Base	The Cue Cartridge Reader may be charged wirelessly using the Cue Wireless Charging Base. The Cue Cartridge Reader is secured by magnets when charging on top of the Cue Wireless Charging Base.	 A white, rectangular wireless charging base with a square charging pad on top and a small port on the side.

## Chapter 3

# Setting Up Your Cue Health Monitoring System

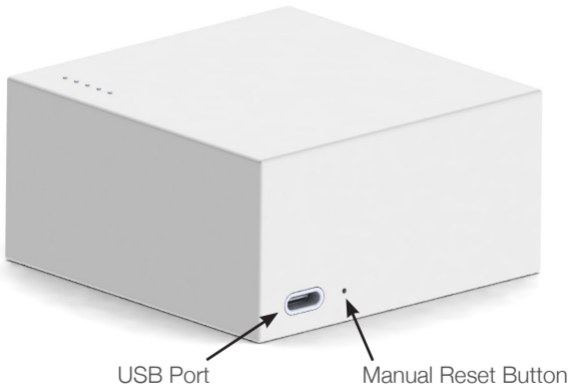
### Identifying Parts of Your Cue Cartridge Reader

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



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

## The Back of Your Cue Cartridge Reader



# The Bottom of Your Cue Cartridge Reader



Cartridge Reader

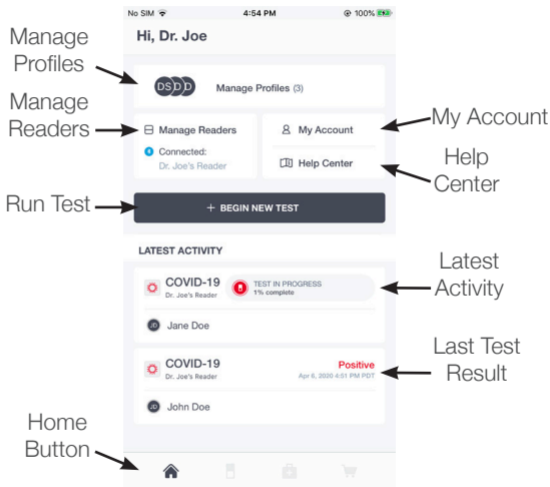
REF: C0201

SN: 21802010000481

L9000207-2 Rev 1.0



# Your Cue Health App Dashboard



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

## Cue Cartridge 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 an 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 Cartridge 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. 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 App 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 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 Store 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.

 Cue Health App updates must be downloaded from the Cue Health App 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.


*At the completion of account creation, the “Profile Information” screen will be displayed by the Cue Health App.*

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

*At the completion of profile creation, the “Permissions” screen will be displayed by the Cue Health App.*

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

*After progressing through the “Permissions” screens, the “Set Up the Cue Cartridge Reader” screen will be displayed by the Cue Health App.*

 *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 Cartridge Reader

☒ To Set Up your Cue Cartridge Reader:

*After creating a Cue Account, the “Set Up the Cartridge Reader” screen will be displayed by the Cue Health App.*

1. Place the Cue Cartridge Reader on top of 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 use Cue-supplied Charging Cable and Power Adapter.*

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

*When the Cue Cartridge 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 Cartridge Reader is by disconnecting and reconnecting the Cue Charging Cable. You can also wake the Reader by placing it on top of the Cue Wireless Charging Base. Make sure the Cue Wireless Charging Base is connected to wall power.

5. In the “Set Up the Cartridge Reader” screen in the Cue Health App, tap on “**SCAN NOW**” to begin pairing the Cartridge Reader to the mobile smart device.
6. Turn your Cue Cartridge 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 Cartridge 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 reading the QR code. The side with the lights on top of the Reader is top-side up.*




 “Pairing” a Cartridge Reader is scanning the QR Code found on the bottom of the Reader. When a “Paired” Cartridge Reader is within Bluetooth® range of the 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 to manually enter the Cartridge 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 Cartridge Reader can pair with multiple mobile smart devices.

 One mobile smart device can pair with multiple Cue Cartridge Readers.

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

 Multiple Cue Cartridge 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 Cartridge Reader

Carefully read this chapter. It is important that you read and follow the test-specific instructions for Use found inside the Test Cartridge Pack box, 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 Cartridge Reader should be placed 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 Cartridge Reader battery is too low to complete a test. Connect the Reader to power when needed.



If your mobile smart device loses battery charge, 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 Cartridge 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.

Some reasons for incorrect or invalid results are:

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

## 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 Cartridge Reader will automatically go into standby mode.*

**ⓘ** *If two or more Cartridge 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

## Cue Health Monitoring System Management

### **Charging the Cue Cartridge Reader**

 To Charge your Cue Cartridge Reader:

1. Plug the Cue Power Adapter into wall power.
2. Connect 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 Cartridge Reader to start charging.
4. You may also charge the Cue Cartridge Reader by placing it on top of the Cue Wireless Charging Base. Make sure the Cue Wireless Charging Base is connected to power.

*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 Cartridge Readers to Your Mobile Smart Device


 To Pair Additional Cue Cartridge 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 your mobile smart device Bluetooth is enabled.
4. Tap on “+”.
5. Follow on-screen instructions to pair the additional Cue Cartridge Reader.

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

## Connecting the Cue Cartridge Reader to the Cue Health App


 To Connect a Paired Cue Cartridge Reader to the Cue Health App:



 A Cue Cartridge Reader that is “Paired” to your mobile smart device can disconnect if the Cartridge Reader is out of Bluetooth range 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 Cartridge Readers, tap on the one you would like to connect to.

*The indicator lights will flash when the Cue Cartridge Reader is connected to the Cue Health App.*

## Checking the MAC Address of a Connected Cue Cartridge 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 Cartridge 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 Cartridge Reader from the Cue Health App

 To Disconnect the Cue Health App from connected Cue Cartridge 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 Cartridge Readers, tap on the  next to the one you would like to disconnect.
4. Look at the MAC address on the bottom of the Cartridge 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**”.

*Cue Cartridge Reader is now disconnected from the Cue Health App.*



## Unpairing the Cue Cartridge Reader from Your Mobile Smart Device


 To Unpair the Cue Cartridge 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 Cartridge Readers, tap on the  next to the Reader you would like to unpair.
4. Tap on “**FORGET THIS READER**”.


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

## Managing User Account and Profiles

 To Manage User Account:


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**” 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 “Dashboard” screen 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 on Print 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 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 “Dashboard” screen 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.

### **Cleaning and Disinfecting**


The Cue Health Monitoring System should be cleaned and disinfected after each use. Wipe down with Clorox® Germicidal Wipes 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 Health Monitoring System 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 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 Cartridge 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 Cartridge Reader to power. Use the Cue Health Monitoring System components/ 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 Cartridge. Take a new sample using a new test-specific Cue Sample Wand and use a new test-specific Cue 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 Cartridge 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. 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 detects test-specific targets using electrochemical biosensor technology.

## Technical Specifications

### Cue Cartridge Reader Specifications

Power Supply	Input: 100-240V~, 50/60Hz, 0.2A Output: 5VDC, 1.5A, 7.5W
Dimensions	(3.0 in x 3.0 in x 1.5 in) (74 mm x 74 mm x 37 mm)
Weight	5.3 oz (150 g)
Display	Cue Health App on 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)



For test-specific Cue Cartridge technical specifications, refer to the test-specific Instructions for Use.

### **Compliance with International Standards**

The Cue Health Monitoring System will be tested 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.







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



Get Started Here

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# Welcome to Cue

## Welcome

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

## Questions

Dial (833) CUE-TEST · (833) 283-8378

This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, 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.



Cue Health

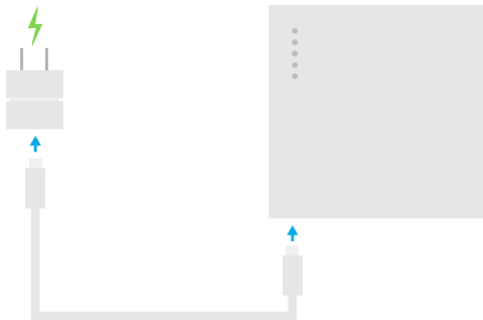


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## Set Up Your Cue Account

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

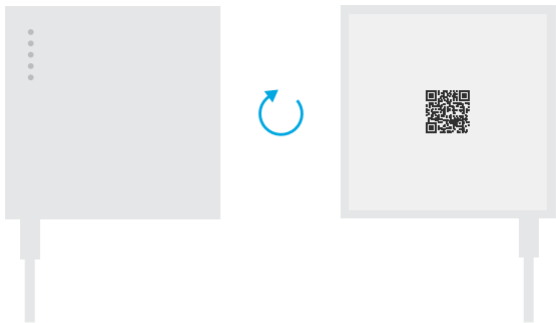




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## Connect Cartridge Reader to power

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

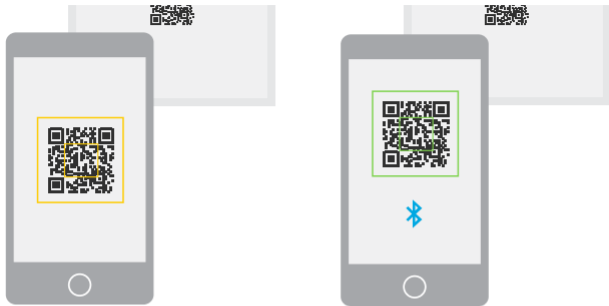


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## Find Cartridge Reader QR code

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

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



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## Pair Cartridge 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 Cartridge Reader is paired securely to the mobile smart device.



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## Cue Cartridge Reader is ready to use

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

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# About the Cue Health Monitoring System

## **Cue Cartridge Reader**

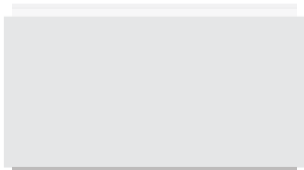
Your Reader pairs with the mobile smart device, accepts Cue test-specific Cartridges, and runs tests.



## **Wireless Charging Base\***

Light-ring illuminates when Cartridge Reader is docked and charging.

\*The Wireless Charging Base is sold separately as an accessory to the Cue Health Monitoring System.



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# About the Cue Health Monitoring System



Your Cue Cartridge Reader communicates with the Cue Health App using a secure wireless Bluetooth® connection.

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



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# Charging the Cartridge Reader

## Charging with USB

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

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



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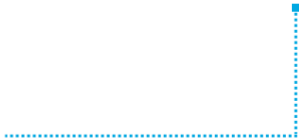
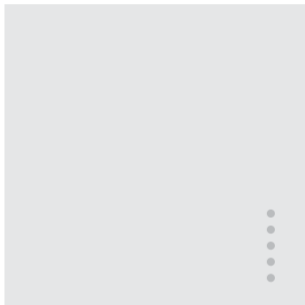
# Indicator Lights

## **Cartridge Reader lights communicate status**

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

The lights provide quick feedback on the status of the Cue Cartridge 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.





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## Battery Level

When the Cartridge 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 Sample Wand with collected specimen into the Cue Cartridge



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

## Alerts

When connecting to the Cue Cartridge 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 Cartridge or the Cue Sample Wand is inserted.



Error, see the Cue Health App for details

## For Professional Use

The Cue COVID-19 Test Cartridge Pack is used with the Cue Health Monitoring System and the Cue Health Mobile Application for the qualitative detection of nucleic acid from SARS-CoV-2 virus.

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**REF** C1020

**LOT**



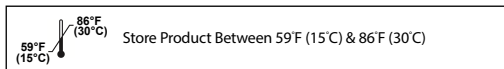
Use By:

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For Use Under an Emergency Use Authorization (EUA) Only

Rx Only

**IVD**



## Questions?

Contact Cue Customer Support at [support@cuehealth.com](mailto:support@cuehealth.com) or call toll-free at (833) CUE-TEST · (833) 283-8378 for questions and to request a physical copy of the Instructions For Use and the Quick Reference Instructions, free of charge.