



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

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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, 2019.¹ 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 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 swab samples.

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 nasal swabs from individuals who are suspected of COVID-19 by their healthcare provider. 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 Apple® iPhone® 8+ or newer mobile smart device with iOS 13 (or higher). 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 also 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 2019-nCoV RNA. The 2019-nCoV RNA is generally detectable in nasal swabs 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 positive results to the appropriate public health authorities.

Negative results do not preclude 2019-nCoV infection and should not be used as the sole basis for patient management decisions. 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.

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. 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 for presence of human cellular material in the sample and proper assay execution. The RNase P forward primer is conjugated to a small hapten, Digoxigenin (Dig). The RNase P reverse primer is conjugated to HRP.

RNase P serves as the internal control for presence of human cellular material in the sample and proper assay execution. This internal control has been designed to control for 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 25 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.

Materials Required But Not Provided

- Cue Health Monitoring System**

Purchase the Cue Health Monitoring System (REF C0201) from Cue Health Inc. within the Cue Health App, at the online store at www.cuehealth.com, or by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

- Mobile Smart Device**

Apple® iPhone® 8+ or later mobile smart device with iOS 13 or later with Bluetooth and Wi-Fi capability 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.

- Control Swabs**

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. within the Cue Health App, at the online store at www.cuehealth.com, or 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 test has not been FDA cleared or approved.
- This test 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 moderate complexity/high complexity tests and 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 test has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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 nasal

swab samples.

- 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 positive 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.
- Only nasal samples collected with the Cue Sample Wand can be used for the Cue COVID-19 Test.
- 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.

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, 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 Prevention² and the Clinical and Laboratory Standards Institute³.
- Nasal sprays, gels, or cream may not be used before you collect a 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

- Performance of the Cue COVID-19 Test has only been established with Cue Sample Wand nasal swab samples.
- 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.
- Performance has not been established in asymptomatic individuals.
- This assay should not be used within 30 minutes of administering nasal or throat sprays.

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 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) |
|---------------------|----------------------------|

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 shown in the table below. Do not run the Cue COVID-19 Test if you are outside of this temperature condition. This device should not be used outdoors and has not been tested at high temperatures or humidity.

| | |
|-------------------------|----------------------------|
| Operational Temperature | 59°F (15°C) to 86°F (30°C) |
|-------------------------|----------------------------|

Quality Control (QC)

Positive and Negative Controls

Controls must 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 must be stored at 2-8 °C and must remain at room temperature for 10 minutes before use. 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 or shipment of cartridge packs received
- Once for each new operator
- When problems with testing are suspected or identified
- As deemed additionally 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. within the Cue Health App, at the online store at www.cuehealth.com or 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

Only nasal samples collected with the Cue Sample Wand can be used with the Cue Health Monitoring System and the Cue COVID-19 Test Cartridge.

To collect a 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 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 within the Cue Health App), at the online store at www.cuehealth.com, or by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).
- Mobile smart device (Apple® iPhone® 8+ or later mobile smart device with iOS 13 or later) with Bluetooth and Wi-Fi capabilities.
- The Cue Health App installed on your mobile smart device. Download the Cue Health App from Apple App 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 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 iPhone 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 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.

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.

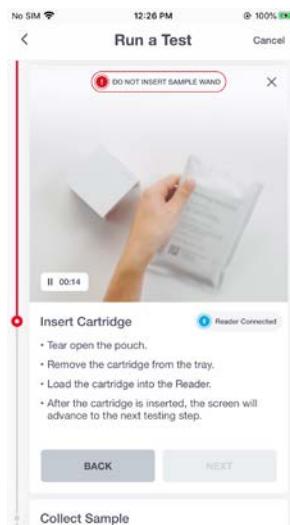


Figure 5-5

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.



Figure 5-6-2

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

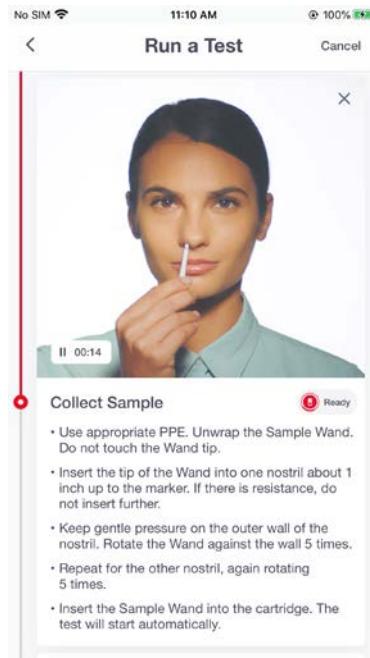


Figure 5-7-1



Figure 5-7-2

REMINDER: It is important to collect the nasal sample at that time 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.

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.

To collect a 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: 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 25 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.

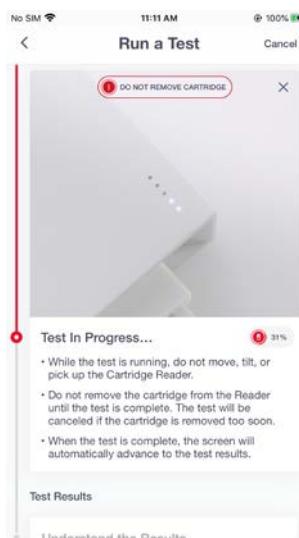


Figure 5-8

Step 5-9: 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 and account profile that was selected before the test started. See Step 6 below for understanding the test results and what each result means.

Step 5-10: 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.

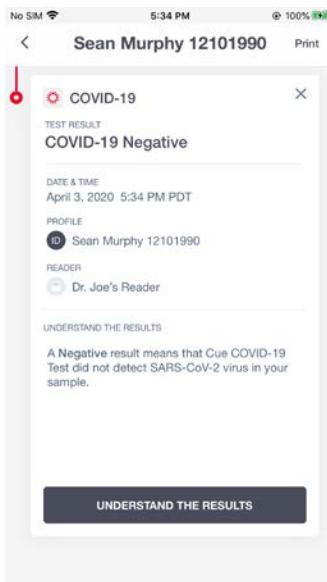


Figure 6-1

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.

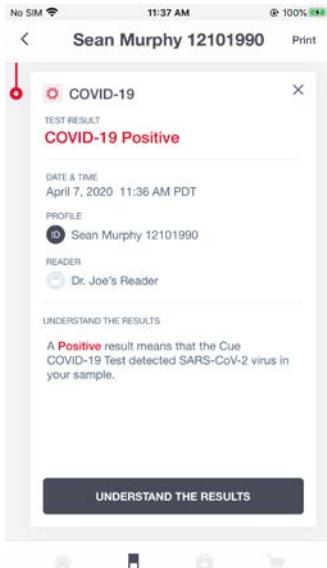


Figure 6-2

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.
- The Cue Cartridge Reader was tilted or moved during processing of the test.

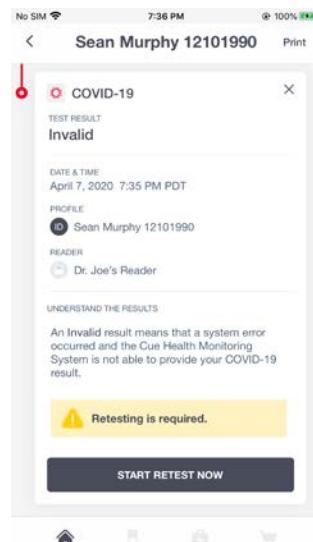


Figure 6-3

If the result is invalid, you will need to run a new test. You must use a new Cue COVID-19 Test Cartridge and a new Cue Sample Wand. The Cue Health App Invalid Result screen will guide you to perform a new test. Follow the instructions in the Cue Health App for retesting.

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 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.

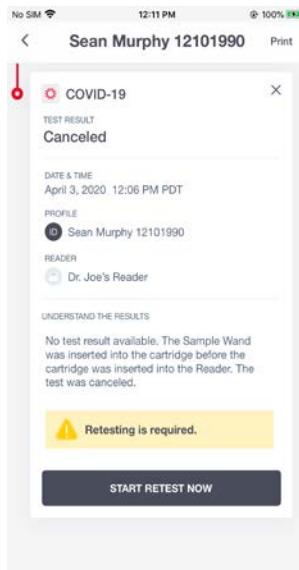


Figure 6-4

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 LABORATORIES AND PATIENT CARE SETTINGS

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/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

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 “laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA),42 U.S.C. §263a, to perform complex, moderate, and waived complexity tests and Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation” as “authorized laboratories”.

- A. Authorized laboratories using the Cue COVID-19 Test will 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. The Letter of Authorization refers to “laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA),42 U.S.C. §263a, to perform complex, moderate, and waived complexity tests” as “authorized laboratories”.
- B. Authorized laboratories using the Cue COVID-19 Test will 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 will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- E. Authorized laboratories will 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 will 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 SARS-CoV-2 cartridge lots by 2 operators on each of 3 days for a total of 36 replicates per dilution. 15 μ L of the RNA dilution was applied to a Cue Sample Wand before testing. The LoD was determined as the lowest concentration with \geq 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/ μ L 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. 15 μ L 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/ μ L 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

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 the Cue COVID-19 Test primers and all sequenced SARS-CoV-2 isolates available in the NCBI public database as of March 31, 2020 and in the GISAID public database as of March 25, 2020.

The Cue COVID-19 Test utilizes a forward, reverse, and probe primer targeting the N (nucleocapsid protein) gene of the SARS-CoV-2 virus. The probe primer imparts greater specificity to the amplification reaction.

Cue COVID-19 Test Reactivity/Inclusivity Evaluation

| Primer | % of 1551 GISAID strains with perfect match | % of 313 NCBI strains with perfect match | % of all analyzed genomes with perfect match |
|---------|---|--|--|
| Forward | 100.00 | 100.00 | 100.00 |
| Reverse | 99.94 | 99.68 | 99.89 |
| Probe | 99.61 | 100.00 | 99.68 |

The forward primer matched 100% to all sequences. The reverse primer matched all but one sequence in the NCIB database and one sequence in the GISAID database. None of these mismatches are predicted to adversely affect primer binding or test performance.

The probe primer showed the same four mismatches to 6 strains originating from pangolins in Guangxi, China. These strains come from a non-human host and were collected in 2017. Since these sequence patterns have not been observed in the genomes of strains collected from humans in 2019 or 2020, these variants are likely not currently circulating among humans and therefore the mismatches would have no adverse effect on test performance.

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</i> (genomic DNA) | 6.90E+04 | genome copies / µl | 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 |
| Human Coronavirus 0C43 | 1.26E+05 | TCID50/mL | 0/3 |
| Human Coronavirus HKU1 RNA | 7.50E+04 | genome copies / µl | 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 | 9.55E+05 | TCID50/mL | 0/3 |

| Organism | Titer | Units of Measurement | Detected/Tested |
|-------------------------|----------|-------------------------|-----------------|
| B | | | |
| 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 re-tested

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 ≥80% sequence homology with the forward primer; 3 viral strains showed ≥80% sequence homology with the reverse primer; and one viral strain showed ≥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 ≥ 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 ≥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 |
| 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 marboxil) | 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 |

| Substance | Concentration | Detected/Tested | |
|-------------|---------------|-----------------------|--|
| | | Negative Nasal Matrix | Positive Nasal Matrix (SARS-CoV-2 RNA present at 3X LoD) |
| Rhinallergy | 20% w/v | 1/9* | 3/3 |

*A fresh dilution was prepared and the potential interferent was re-tested

Clinical Evaluation – Prospective Clinical Study

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 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 Test | |
|-------------------|----------|---|----------|
| | | Positive | Negative |
| Cue COVID-19 Test | Positive | 6 | 3 |
| | Negative | 0 | 35 |

Clinical Evaluation – Retrospective Clinical Samples

The Cue COVID-19 Test was also evaluated with 45 frozen nasopharyngeal swab samples in viral transport media. The samples were de-identified and the study was IRB approved.

The 45 samples were originally collected from patients suspected of SARS-CoV-2 infection by the healthcare provider. The samples were positive 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 in the clinical sample VTM and immediately inserting into the Cue COVID-19 Test Cartridge.

The Cue COVID-19 Test result was positive for 100% of the 45 samples.

Clinical Evaluation – Contrived Samples

Negative clinical samples and positive contrived clinical samples were prepared for this study. Sixty negative nasal samples were collected from consented healthy volunteers under IRB approval. Positive contrived samples were prepared from 30 of the negative samples by spiking with genomic RNA from SARS-Related Coronavirus 2, Isolate USA-WA1/2020, at the concentrations shown in the table below. Samples were randomized, de-identified, and blinded to the test operator. Sample concentration and test results are shown in the table below. Agreement with expected results was $\geq 95\%$.

Cue COVID-19 Test Clinical Evaluation – Contrived Samples

| Sample Concentration | Detected/Tested | % Agreement |
|----------------------|-----------------|-------------|
| Negative | 0/30 | 100% |
| 1-2X LoD | 19/20 | 95% |
| 5X LoD | 4/4 | 100% |
| 10X LoD | 4/4 | 100% |
| 50X LoD | 2/2 | 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 within the Cue Health Mobile Application, at the online store at www.cuehealth.com, or 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 June 9, 2020)
2. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories. <http://www.cdc.gov/biosafety/publications/> (accessed June 9, 2020)
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 |
|---|---|
| IVD | In Vitro Diagnostic |
|  | Consult Instructions for Use eIFU available on the Cue Health Mobile Application and at www.cuehealth.com |
| SN | Serial Number |
|  | Do not use if seal or packaging is broken or damaged |
|  | Storage temperature range |
| REF | Catalog number |
| CONTROL + | Positive Control |
| CONTROL - | Negative Control |

| SYMBOL | DESCRIPTION |
|---|--------------|
|  | Manufacturer |
|  | Keep dry |
|  | Use By |



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

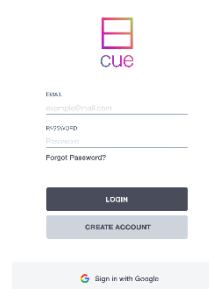
1 SET UP THE CUE HEALTH MONITORING SYSTEM

1.1 Unpack the Cue Cartridge Reader.



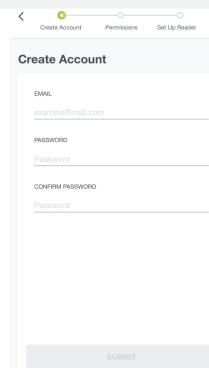
1.2 Download the Cue Health App to your Apple® iPhone® 8+ or later mobile smart device with iOS 13 or later.

The Cue Health App is on the Apple App Store.



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”.



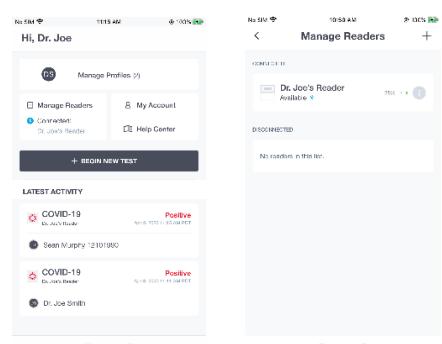
2.2 Follow the on-screen instructions to set up the Cartridge Reader. Connect the Cartridge Reader to power. Pair the Reader to your mobile smart device.



When prompted by the Cue Health App, adjust the mobile 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 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”.

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. 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.

3.3 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



Insert cartridge into Reader



Allow cartridge to heat up

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 wand from the tray. Open the Sample Wand wrapper on the side labeled “Open Here”. Grasp the handle of the Sample Wand and remove it from the wrapping.



Open Sample Wand wrapper



Remove Sample Wand from wrapper

3.6 Do not use a Sample Wand if the wrapper is damaged or opened or if the wand tip touches anything before sample collection. To collect a nasal swab sample 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 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

3.7 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 nasal sample. The cartridge should not be in the Reader without the Sample Wand for more than 10 minutes. Make sure the Wand is inserted all the way in until Test in Progress is shown on the Cue Health App screen.



Insert Sample Wand

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.

3.9 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 re-testing. 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 coinfection with other viruses. An Invalid or Canceled result means that a system error occurred and there is no test result. Re-test 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 (0.55% sodium hypochlorite).



Specimen Collection and Handling

Cue Sample Wand Nasal Sample

To collect a 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.

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 2-8°C and must remain at room temperature for 10 minutes before use. 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
- Once for each new operator
- When problems with testing are suspected or identified
- As deemed additionally 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 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. within the Cue Health App, at the online store at www.cuehealth.com, or by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

Precautions

- This test has not been FDA cleared or approved.
- This test 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 moderate complexity/high complexity tests and 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 test has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
- This test 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or 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

IVD

For In Vitro Diagnostic Use

REF

C1018



eIFU available on the Cue Health Mobile Application

Rx Only

Manufacturer:



cue
 Cue Health Inc.
 San Diego, CA 92121
 USA

Cue Health Inc., Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378)

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



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 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

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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® 8+ or later with iOS 13 or later.

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 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 |
|----------------------------|--|
| Bold | 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 |
| <i>Bold Italics</i> | 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.
- This product 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 moderate complexity/high complexity tests and 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.
- 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 Act, 21 U.S.C §360bbb-3(b)(1), unless the authorization is terminated or 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 8+ or later device. The iPhone 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 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 |
|-------------------------|---|--|
| Cue Test Cartridge Pack | 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. |  Cue COVID-19 Test Cartridge  Cue Sample Wand |

Compatible Mobile Smart Devices

The Cue Health Monitoring System may be used with iPhone 8+ or later models. The operating system on the iPhone 8+ or above must be iOS 13 or later.

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

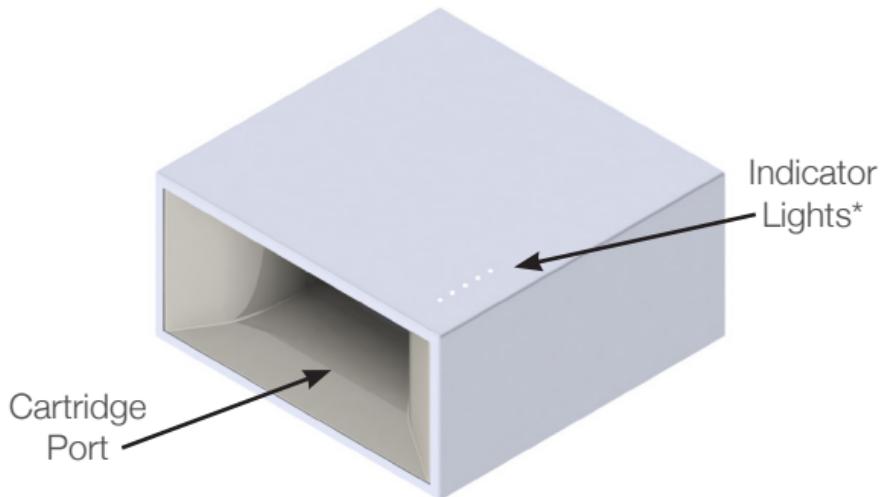
| Component | Description | Image |
|----------------------------|---|---|
| Cue Wireless Charging Base | The Cue Cartridge Reader may be charged wirelessly using the Cue Wireless Charging Base. The Cue Cartridge Reader is secured by magnets when charging on top of the Cue Wireless Charging Base. |  |

Chapter 3

Setting Up Your Cue Health Monitoring System

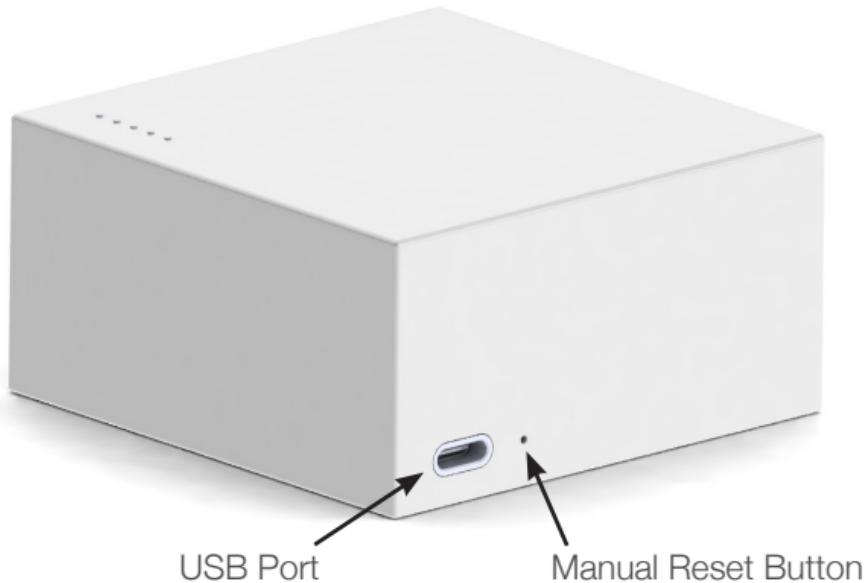
Identifying Parts of Your Cue Cartridge Reader

The Top and Front of Your Cue Cartridge Reader

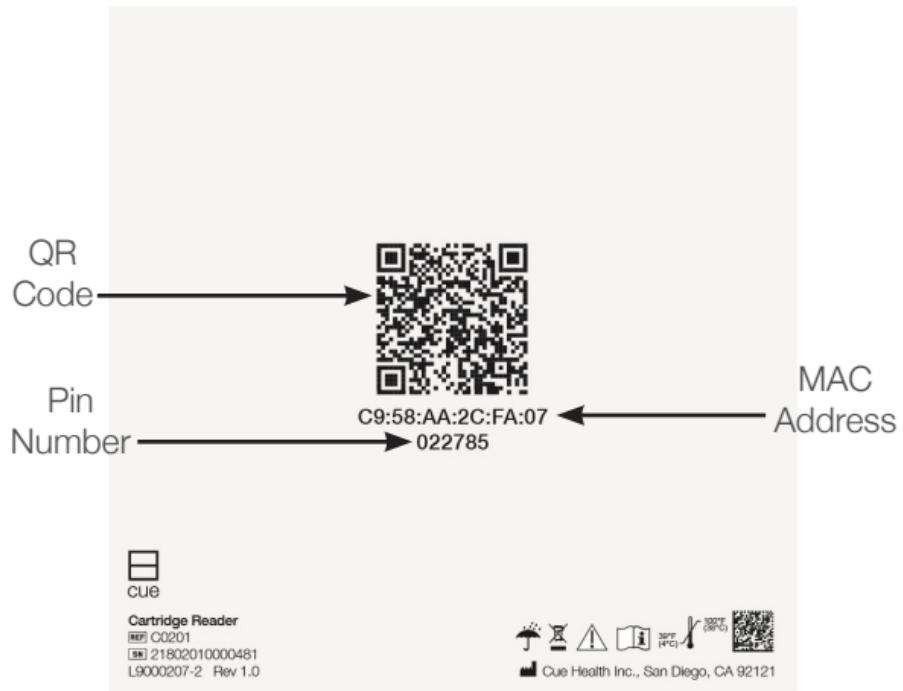


*See “Cue Cartridge Reader Indicator Lights” in Chapter 3 for information on the meaning of the indicator light patterns.

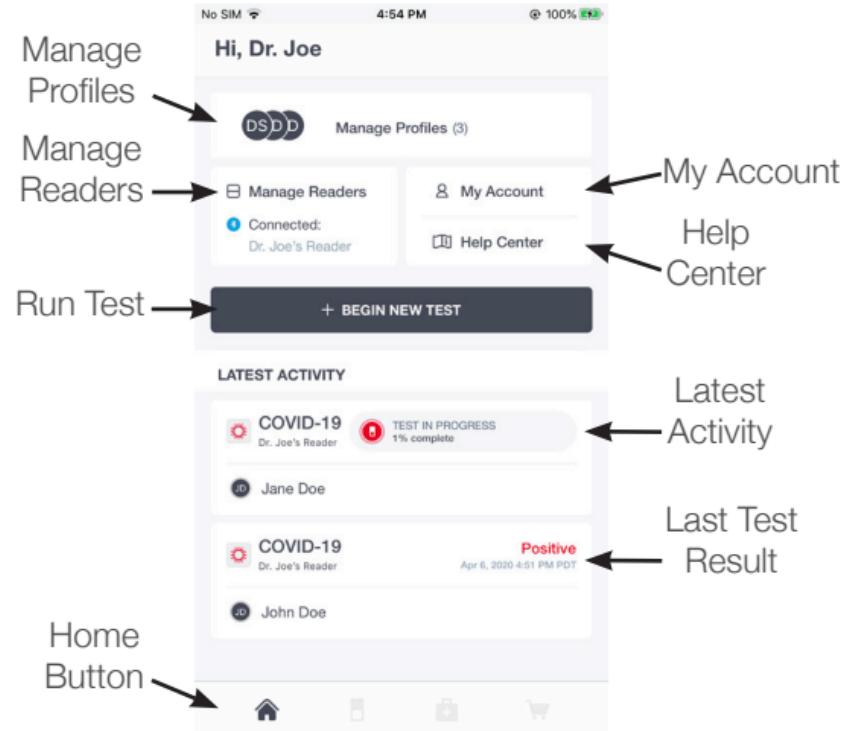
The Back of Your Cue Cartridge Reader



The Bottom of Your Cue Cartridge Reader



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

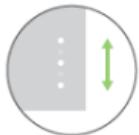
You will see different light patterns on top of the Reader. The light patterns will tell you when the Reader is connected to the Cue Health App. The light patterns will also tell you when a cartridge is inserted, and when there is an error.



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 iPhone 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 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

 *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 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 an iPhone 8+ (or later) 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.

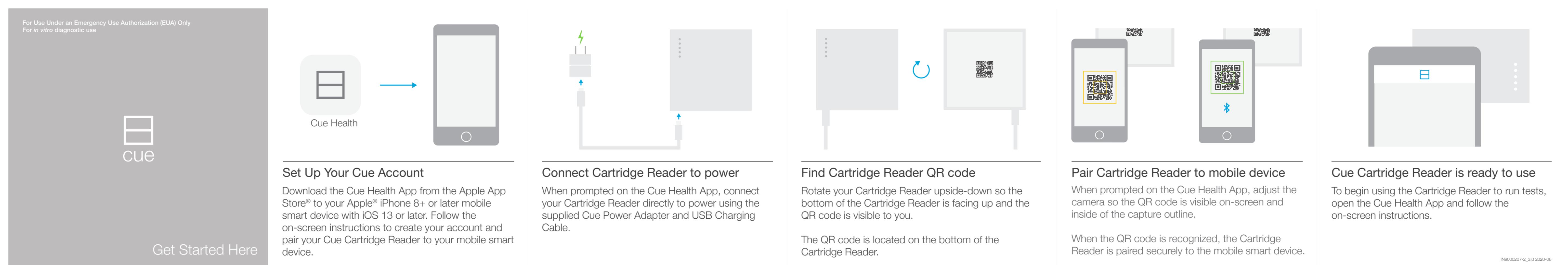
Supplies and Accessories

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

Notes

Notes

IN9000207-1_4.0



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

About the Cue Health Monitoring System

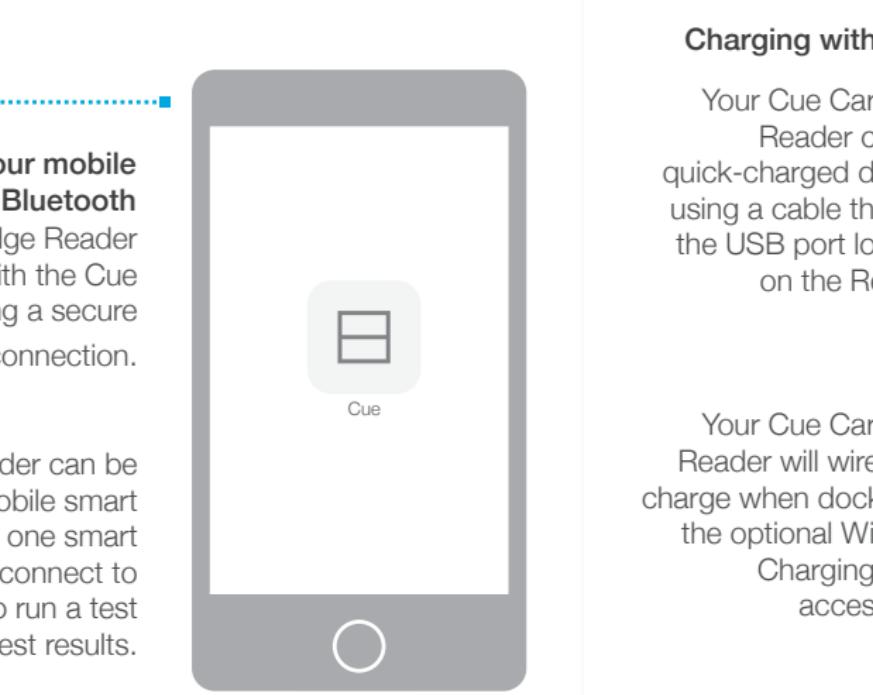
Cue Cartridge Reader

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.

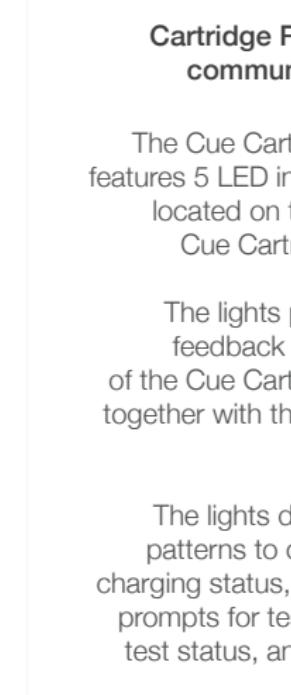
*The Wireless Charging Base is sold separately as an accessory to the Cue Health Monitoring System.



Pairs wirelessly to your mobile smart device with Bluetooth

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.



Cartridge Reader lights communicate status

Your Cue Cartridge Reader can be quick-charged directly

using a cable through the USB port located on the Reader.

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

Alerts

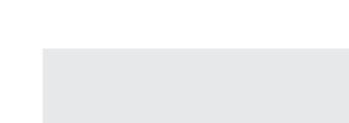
When connecting to the Cue Cartridge Reader or at the start of a test,

the indicator lights will flash in different patterns

Charging status, battery level, prompts for testing actions, test status, and test errors.

Battery Level

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



Charging with USB

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

communications with the Cue Health App using a secure wireless Bluetooth® connection.

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

Alerts

When connecting to the Cue Cartridge Reader or at the start of a test,

the indicator lights will flash in different patterns

Charging status, battery level, prompts for testing actions, test status, and test errors.

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

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

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

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