



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.

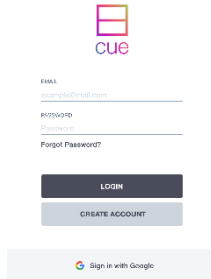
1 SET UP THE CUE HEALTH MONITORING SYSTEM

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.



3.3 Do not use a cartridge past the Use By date on the foil pouch label. Do not use a cartridge that has been stored below 59°F (15°C) or above 86°F (30°C). When you are ready to test, tear open the top of the cartridge foil pouch and remove the plastic tray with the Cue COVID-19 Test Cartridge and Cue Sample Wand. Remove the cartridge from the tray.



Tear pouch



Remove plastic tray



Remove cartridge

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



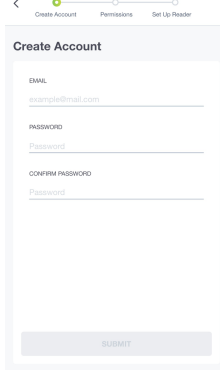
Insert cartridge into Reader



Allow cartridge to heat up

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

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

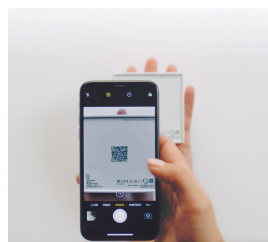


2.2 Follow the on-screen instructions to set up the Cartridge Reader. Connect the Cartridge Reader to power. Pair the Reader to your mobile smart device.

When prompted by the Cue Health App, adjust the mobile 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

When you have inserted the cartridge all the way in, all five lights on top of the Cartridge Reader will flash and the cartridge will pre-heat in preparation for testing. The cartridge must heat up for the full 100% heat cycle before the Sample Wand is inserted into the cartridge.

3.5 Remove the wrapped Sample Wand from the tray. Open the 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

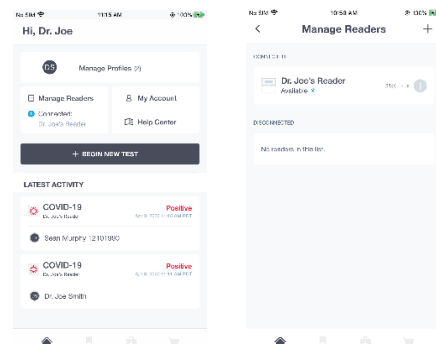
3.6 Do not use a Sample Wand if the wrapper is damaged or opened or if the wand tip touches anything before sample collection. To collect a nasal swab sample insert the tip of the Cue Sample Wand into one nostril about 1 inch or up to the marker on the Wand. If resistance is felt, do not insert any further. 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

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.



3.7 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



For In Vitro Diagnostic Use



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)