

# Cue® Health Professional (PRO) COVID-19 Test Helpful Testing Tips

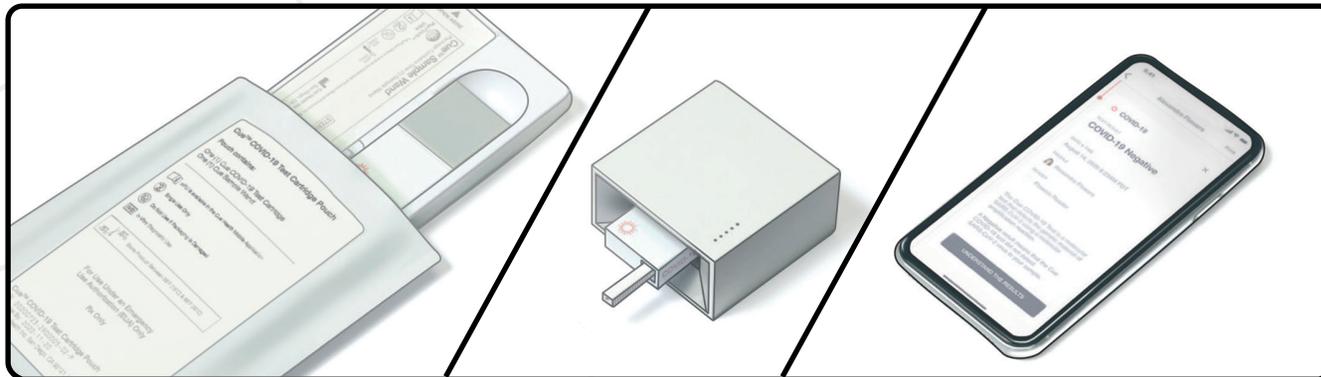


## Cue® Professional (PRO) COVID-19 Test

This document is a supplement to the manufacturer's instructions and is intended to provide helpful testing tips when using the Cue® Integrated Care Platform COVID-19 test. The Cue® platform includes the Cue® Reader, Cue® Cartridge, and Cue® Health App. There are two Cue® COVID-19 tests available--professional (PRO) and over-the-counter (OTC). Check the label on the test kit to confirm test type. Although both tests are functionally the same, customer support is specialized for PRO users (see last slide for reference). This job aid is for the Cue® Professional (PRO) COVID-19 tests that are authorized for use in point-of-care settings (i.e., inpatient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation).

To ensure optimal performance of the Cue® Integrated Care Platform, refer to the package insert or access full instructions for use (IFU) online at [Cue® COVID-9 Test Instructions For Use \(IFU\) \(PDF\)](#).

For more information on the Cue® COVID-19 Test, please view the manufacturer's website at [Diagnostic testing at the speed of life | Cue® \(cuehealth.com\)](#).



\* Use of trade names and commercial sources is for identification only and does not imply endorsement by the Centers for Disease Control and Prevention, the Public Health Service, or the U.S. Department of Health and Human Services.

## Before the Test



Set up a designated testing space in a low traffic area that is free of clutter.

Ensure someone is available to track and meet cartridge kit shipment deliveries so shipments are not left out in temperatures outside of their indications. Check the temperature monitor on the boxes of cartridges to be sure the temperature stayed within range during shipping. Green indicates temperatures were in range and red indicates the temperatures went outside the acceptable range. Do not use the cartridges if the indicator is red.



Store and operate the Cue® COVID-19 cartridge test kits within temperatures of 15–30°C (59–86° F). Do not refrigerate or freeze the kits. The Cue® Health Monitoring System (reader) must be stored between 4–38°C (39–100° F).

Operators must be adequately trained on how to successfully perform testing with this system before beginning specimen collection and processing. Facilities can request practice cartridges through Cue® for staff training. Training and other requests can be submitted to Cue® by contacting customer service at 833-CUE-TEST or emailing support@cuehealth.com. Customer service hours are M–F 5am–7pm PT.

- o Training should include successfully testing one positive and one negative control. For supervisors managing the testing process, additional external control swab packs (REF 2110) that contain three Cue® COVID-19 Test Positive Control Swabs (REF C2111) and three Cue® Test Negative Control Swabs (REF C2112) are available from the manufacturer.

Quality control testing using the Cue® positive and negative control swabs should be performed when

- o Each new lot of cartridge packs is received.
- o Problems with testing are suspected or identified.
- o Required for compliance with internal quality control procedures, with local, state, and/or federal regulations, or accrediting groups.

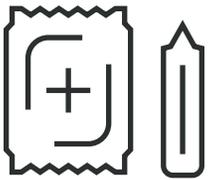


## Before the Test (continued)



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.

Disinfect the device and surrounding area according to the manufacturer's instructions (solution containing at least 0.55% sodium hypochlorite) after every test run. Using a disinfectant wipe, wipe around the outside of the device and the opening. Avoid inserting the wipe into the reader.



Only Cue® sample wands provided with the kit are approved for use with the test. Do not use other swabs for sample collection. Prior to use, make sure to visually inspect the unopened pouch and sample wand for obvious signs of damage or improper seals. If any damage is identified, discard the wand. Do not use a sample wand if the wand tip touches anything before sample collection.

Treat all samples as though they contain infectious material.



It is important to wear appropriate personal protective equipment (gloves, gown, respirator, eye protection) during sample collection and when performing the test. Gloves should be changed between specimens to avoid potential contamination. Discard used gloves in a biohazardous waste container.

Acceptable specimens include direct nasal swabs obtained by collection from both nostrils or previously collected nasal swab specimens in Viral Transport Media (VTM). The VTM collection process should be validated separately if it is a new process for the laboratory.

If patients are self-collecting their nasal specimen, have them wash their hands before and after sample collection.



Open the app on your smart device and follow the on-screen instructions. After completing the initial prompts, log into your facility's Cue® account and add a new profile or barcode ID for the specimen being tested. Make sure to add and keep the Cue® Health app on your smart device (phone/tablet) up to date with all updates. The Cue® Health mobile application can be downloaded from the Apple® App Store® or Google Play™ store. Go to [www.cuehealth.com](http://www.cuehealth.com) for the list of compatible mobile smart devices. Bluetooth® wireless technology and WiFi® or cellular capability is required to download the Cue® Health App.

## During the Test



Make sure that the Cue® Cartridge Reader you will be using is paired to your mobile smart device using Bluetooth®. 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. For app troubleshooting details, check out the Troubleshooting the Cue® Health App section at the end of this job aid.



Leave the cartridge in its pouch until just before use. Do not use the cartridge if the cartridge or pouch are open, damaged, expired, or you have opened the cartridge foil pouch more than 30 minutes before you begin a test.



Make sure the Cue® sample wand is inserted into the patient's nose up to the line designated on the sample wand.

The cartridge reader must be on a stable, flat surface during its entire run. If it is bumped, shaken, or moved at all during its run, the test will continue for the full 20 minutes but may give an invalid result.

Insert the cartridge into the Cue® reader, logo side up. All five lights on top of the reader will flash when the cartridge is fully inserted into the reader and the cartridge will start to heat up. If the cartridge is removed before the test run is complete, you must start the test over.



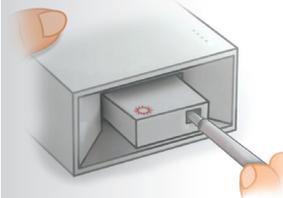
It is very important to keep the smart device close to the cartridge reader (within 8 feet). Consider placing the phone/tablet near the reader during the entire run to make sure you do not accidentally walk away from the Cue® reader with the phone/tablet.

Let the cartridge heat up completely (approximately one minute) before inserting the sample wand. When the cartridge has finished heating up, the progress circle will show 100% and the light will illuminate indicating that it's ready for the wand. Inserting the sample wand too early could lead to an invalid result. Do not wait longer than 10 minutes after the heat cycle is complete to insert the sample wand.



For direct nasal swab samples, insert the sample wand into the heated cartridge reader within 5 minutes of collecting the nasal sample.

Use two hands to secure the Cue® Health Monitoring System. Brace the back of the device with one hand while inserting the wand with the other hand until "Test in Progress" is shown on the Cue® Health App. When the wand has been inserted, 5 lights will flash to indicate that the reaction is proceeding. Not inserting the wand correctly could produce an invalid result. It is important not to insert the sample wand too far into the device, but to make sure it is inserted far enough. If the cartridge is removed before the test run is complete, you must start the test over.



The test automatically begins once the sample wand is inserted into the heated cartridge.

## After the Test

The Cue® Health app will show the Cue® COVID-19 test result as Negative, Positive, Invalid, or Canceled when the test is complete. The result is saved in the Cue® account profile that was selected before the test started.

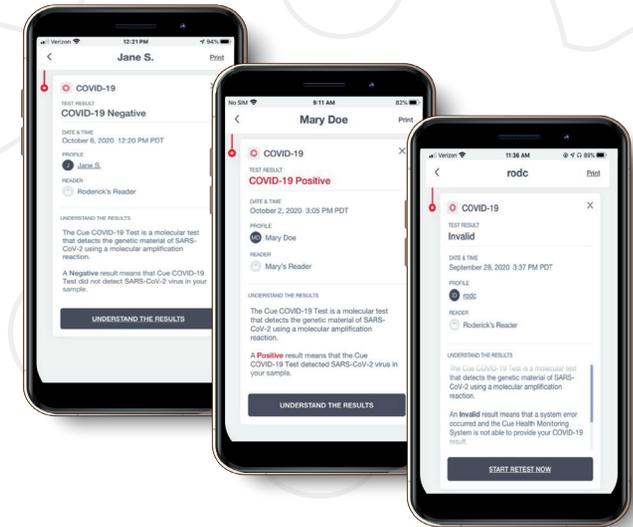
After the test is complete, remove the test cartridge with the sample wand still inside. Do not reuse the wand or the cartridge.

Do not remove the wand from the cartridge after the run completes or open the cartridge at any time. Doing so could contaminate all areas of the room.

Safely dispose of used cartridges in a biohazardous waste container. If you do not know where to dispose of biohazard waste, contact your local health department partners.

Avoid cross-contamination between specimens by disinfecting the surfaces of the cartridge reader following the manufacturer's instructions (solution containing at least 0.55% sodium hypochlorite) before processing another specimen. Do not decontaminate the inside of the reader.

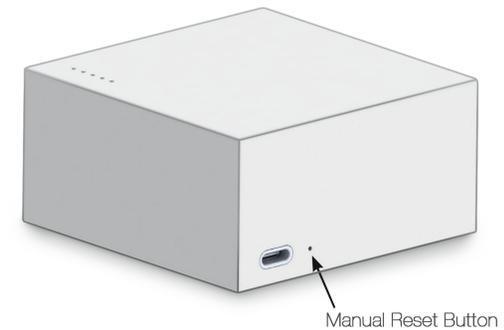
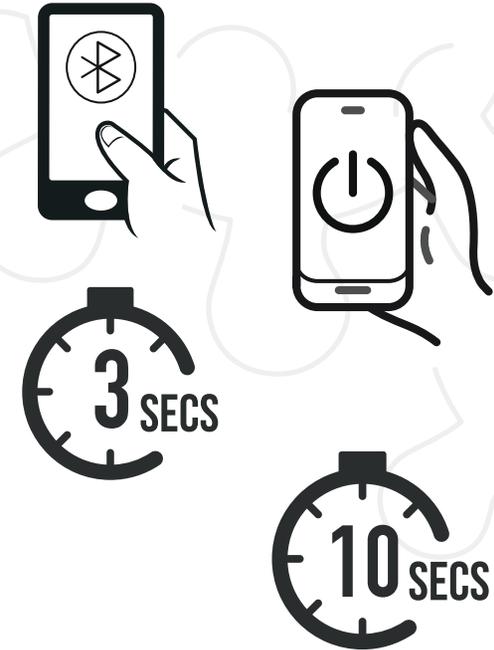
Repeat the test if the result for a given sample is invalid or canceled. You must use a new Cue® COVID-19 test cartridge and new sample wand.



## Troubleshooting the Cue® Integrated Care Platform

If there are problems with pairing your smart device and a Cue® device, try the following troubleshooting steps:

- o Turn off Bluetooth® on the smart device and then turn it back on.
- o If that does not work, turn off your smart device and turn it back on or uninstall and reinstall the app if there are other app issues.
- o You can completely reset the pairing between the smart device and the Cue device by pressing the small button on the back of the Cue® device for 3 seconds. If the reader has fallen asleep after the factory reset, plug it in or perform a soft reset again to 'wake up' the reader.
- o If you need to do a full factory reset of the Cue® device, you can press the small button on the back of the Cue® device for at least 10 seconds. If the reader has fallen asleep after the factory reset, plug it in or perform a soft reset again to 'wake up' the reader.
- o For product assistance, contact Cue® customer support at 833-CUE-TEST. Find FAQs, videos, and product documentation at:  
<https://cuehealth.com/help-and-support/faqs/>



This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.