COVID-19

The Cue™ COVID-19 Test for Home and Over The Counter (OTC) Use
Instructions For Use

No Prescription Required

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 for Home and Over The Counter (OTC) Use
Instructions for Use

Introduction

COVID-19 is caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. COVID-19 can present with a mild to severe illness although some people infected with COVID-19 may have no symptoms at all. COVID-19 is contagious and can be spread even before a person shows symptoms of being sick (e.g., fever, coughing, difficulty breathing). Some people may test positive for COVID-19, but not have any symptoms of infection. These people are considered asymptomatic but may still be able to transmit infection to others.

Intended Use

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is a molecular diagnostic test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal (nasal) swab specimens collected with the Cue Sample Wand.

The Cue COVID-19 Test for Home and Over The Counter (OTC) Use is intended for use in adults (self-swabbing) or children ≥2 years of age (swabbed by an adult) with or without symptoms or other epidemiological reasons to suspect COVID-19. It is authorized for nonprescription home use.

This test will give a positive or negative result for COVID-19. The test does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of the SARS-CoV-2 viral RNA. Viral RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral RNA, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results in an asymptomatic individual are presumptive and confirmation with a molecular assay performed in a laboratory, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. It is important to consult your healthcare provider to discuss your results and if additional testing is necessary.

The test is run using the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand nasal swab, and the Cue Health Mobile Application (Cue

Health App) on the compatible mobile smart devices named on the Cue Health website at www.cuehealth.com.

Test results will be reported to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the CDC. Automatic test result reporting will be performed by Cue Health using the Cue Health App and the Cue Health secure cloud server.

When Should the Cue COVID-19 Test for Home and Over The Counter (OTC) Use Be Used?

You should use the test if you believe you have symptoms (e.g., fever, cough, difficulty breathing) of COVID-19. If you do not have symptoms, you should use the test if you have been in close contact with someone who has COVID-19. Another reason to test when you do not have symptoms is if you live in an area or have been to a place where there are many cases of COVID-19.

Adults should test children **≥2 years of age**.

Precautions

General

- This product is an in vitro diagnostic meaning this test is performed outside the body.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization.
- 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 the authorization is revoked sooner.
- All test results must be reported to the appropriate public health authorities. Automatic test result reporting must be performed by Cue Health using the Cue Health App and the Cue Health secure cloud server.
- The Cue COVID-19 Test Cartridge is used 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 anterior nasal samples collected with the Cue Sample Wand can be used for the Cue COVID-19 Test for Home and OTC Use.
- 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.

- Wash your hands with soap and water for at least 20 seconds, rinse, and dry before collecting a nasal sample and after testing.
- The Cue Health Monitoring System must be cleaned and disinfected after each use. See the Cue Health Monitoring System User Manual for instructions.

Cue COVID-19 Test Cartridge and Cue Sample Wand Handling

- Open the Cue COVID-19 Test Cartridge foil pouch when you are ready to test. Do not open the foil pouch more than 30 minutes before you begin a test.
- Do not use scissors or sharp objects to open the foil pouch as damage to the contents can occur.
- The Cue Sample Wand is sterile. Do not use if the packaging is damaged or accidentally opened before use. Open another cartridge foil pouch for a sterile Cue Sample Wand.
- If the Cue COVID-19 Test Cartridge or Sample Wand is dropped, cracked, or found to be damaged when opened, do not use and discard.
- Store and use the Cue COVID-19 Test Cartridge at the temperatures provided in the storage and testing conditions sections below.
- The Cue COVID-19 Test Cartridge will heat up inside the Cartridge Reader for one minute. Insert the Cue Sample Wand with the nasal sample when the Cue Health App screen shows that the cartridge heat cycle is complete. Do not wait longer than 10 minutes after the heat cycle is complete to insert the Cue Sample Wand.
- After the test is complete, remove the Cue COVID-19 Test Cartridge with the Cue Sample Wand still inside and dispose of in general waste.
- Do not open the Cue COVID-19 Test Cartridge.
- Do not remove the Wand from the Cue COVID-19 Test Cartridge.

Nasal Sample Collection

- Do not use any nasal sprays, gels, or creams before you collect a nasal sample.
- Both nostrils must be swabbed prior to running the test with the Cue Sample Wand nasal swab.
- You must insert the Sample Wand with nasal sample into the Cue COVID-19 Test Cartridge within 5 minutes of collecting the nasal sample.
- You may feel sore or you may bleed a little inside of your nose after collecting your nasal sample. There is a chance that you could develop an infection inside your nose where the nasal sample was collected. Contact your healthcare provider if you think an infection has developed.

Limitations

- It is difficult to determine if persons with no symptoms have COVID-19. Persons who test negative may become positive later. Persons who test too late may have had COVID-19 and are no longer infected on the day of testing.
- There is a chance that the test may give a negative result even if COVID-19 infection is present (false negative). A false negative can occur when the sample was not collected or handled properly, or not enough sample was collected.
- A false negative can also occur if the virus genetic material changes such that the test cannot detect the presence of the virus.
- There is also a chance that the test can give a positive result even if COVID-19 infection is not

present (false positive).

- You should always discuss your test results with your healthcare provider. Do not use this test as the only guide to manage your illness.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants, but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Cue COVID-19 Test Cartridge Pack (REF C1018)

Each Cue COVID-19 Test Cartridge Pack contains one or more foil pouches.

Each foil pouch contains a plastic tray with:

- One (1) single-use Cue COVID-19 Test Cartridge
- 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., by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).
- **Mobile Smart Device with Bluetooth® and Wi-Fi or cellular capability**
  Go to www.cuehealth.com for the list of compatible mobile smart devices.

- **Cue Health Mobile Application installed on the mobile smart device**
  Download the Cue Health App from the Apple App Store or Google Play.

Cue COVID-19 Test Cartridge Storage Conditions

Store the unopened Cue COVID-19 Test Cartridge Pack and the foil pouches inside the pack in the temperature range shown in the table below. Do not use a cartridge that has been stored outside of this temperature condition.

Storage Temperature	59°F (15°C) to 86°F (30°C)

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 for Home and OTC Use in the temperature range shown in the table below. Do not run the test if you are outside of this temperature condition. Use caution if using this device outdoors as it has not been tested at extreme high or low temperatures or high humidity.

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

Directions for Running the Cue COVID-19 Test for Home and OTC Use

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 for Home and OTC Use. These items are not included in the Cue COVID-19 Test Cartridge Pack.

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

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 for Home and OTC Use. The Quick Start Guide will help you quickly set up your Cue Health Monitoring System and get ready to run a test. The User Manual gives you all the information you need to use your Cue Health Monitoring System correctly and safely. The Quick Start Guide or the User Manual will show you step-by-step how to do the following:

1. Unpack and set up the Cue Cartridge Reader.
2. Download the Cue Health App by going to the Apple App Store or Google Play 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 for Home and OTC Use.
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 for Home and OTC Use 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 test. If you do not follow the instructions, the test may not run as it should, and you may not receive a test result, or the test result may not be correct.

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

1. The first time you use the Cue Health App you must accept the "Terms of Use and End User License Agreement" and the "Privacy Policy".
2. A Cue Health App update may be required before you run a test. Follow any on-screen instructions for updating the Cue Health App.
3. The first time you use the Cue Health App you will need to tap Create Account. After Creating an Account, you may Login.
4. Make sure that the Cue Cartridge Reader you will be using is paired to your mobile smart device. Follow the Cue Health Monitoring System's Quick Start Guide or User Manual and the on-screen instructions to pair the Cue Cartridge Reader to the mobile smart device.
5. Make sure that the Cue Health App is connected to the Cartridge Reader that you will be using for the Cue COVID-19 Test for Home and OTC Use. Follow the Cue Health Monitoring System User Manual and the on-screen instructions to connect to that 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 for Home and OTC Use

Log into your Cue Account. After logging into your account, tap on Manage Profiles. Choose the

person's name or you may add a new profile. To add a new profile, tap the + sign to type in a person's identification information and SAVE. Tap on the name, then tap on BEGIN TEST.

REMINDER: Wash your hands with soap and water for at least 20 seconds, rinse, and dry before collecting your or another person's nasal sample and after testing.

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. Limitations are important to understand before you run the test. See the Precautions and Limitations sections in this document.

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 on-screen instructions to pair the Cue Cartridge Reader that will be used for the test 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.

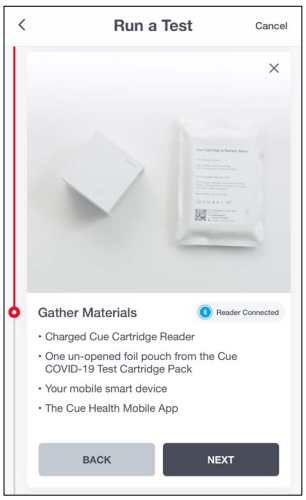

Figure 5-4

Step 5-5: Prepare the Cue COVID-19 Test Cartridge 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.

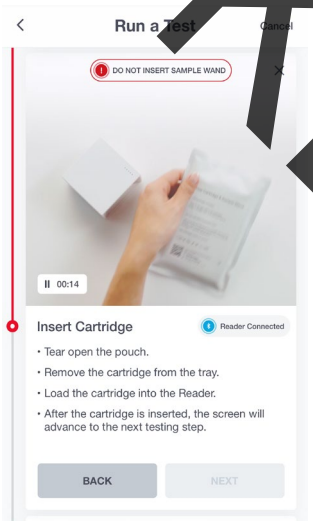

Figure 5-5

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.

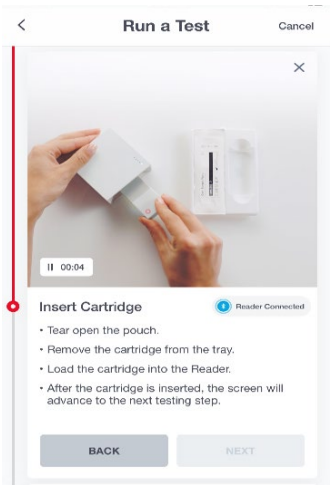

Figure 5-6-1

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.

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

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.

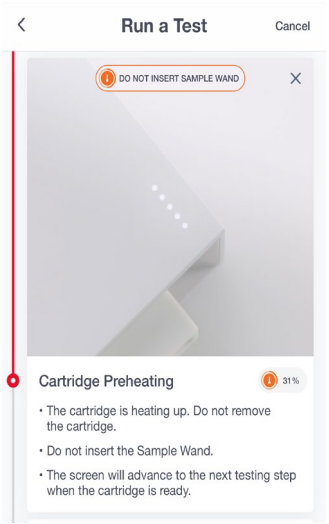

Figure 5-6-2

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.

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.

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.

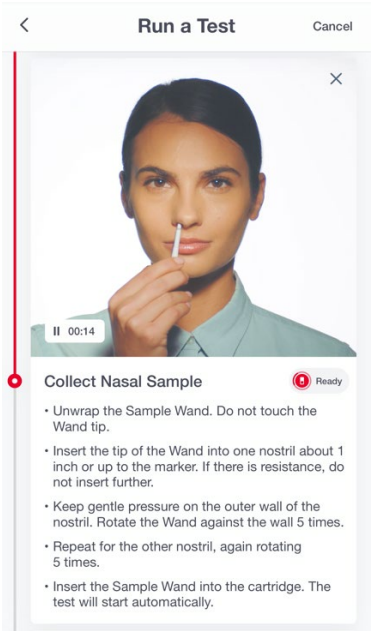

Figure 5-7-1

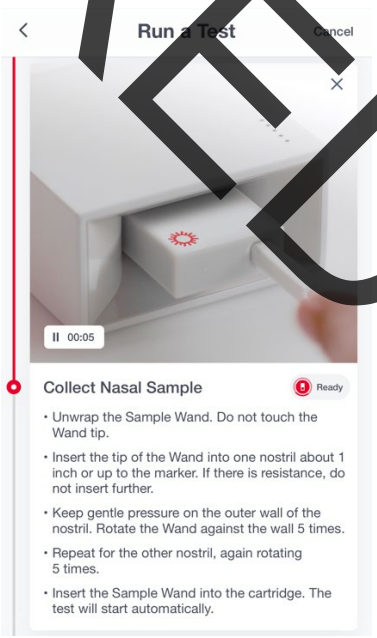

Figure 5-7-2

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

To collect a 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 20 minutes for the 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.

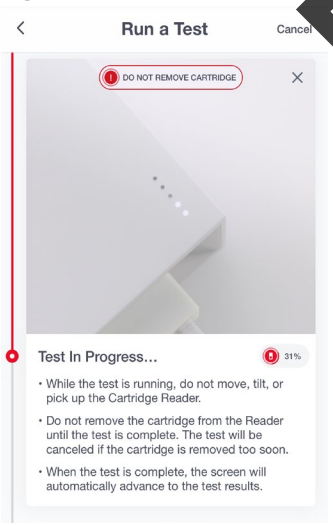

Figure 5-8

Step 5-9: View the Result

The Cue Health App will show the Cue COVID-19 Test for Home and OTC Use result when the test is complete. The result is saved in the Cue Account profile that was selected before the test started. See Step 6 below for understanding the test results and what each result means.

Step 5-10: 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 must not be removed and should still be inside the cartridge. Used cartridges should be considered capable of transmitting infection and require standard precautions. Dispose of the used Cue COVID-19 Test Cartridge with Sample Wand in general waste.

Step 5-11: What to do After Receiving the Cue COVID-19 Test for Home and OTC Use Result

If you have concerns, contact your healthcare provider to discuss your Cue COVID-19 Test for Home and OTC Use results.

If your result is negative, meaning the test did not detect the SARS-CoV-2 virus that causes COVID-19, there is still a chance that you may have COVID-19 or another illness. Your healthcare provider may ask you to take additional medical tests to make a diagnosis.

If your result is positive, meaning the test did detect the SARS-CoV-2 virus that causes COVID-19, there is still a chance that you may not have COVID-19. Your healthcare provider may ask you to take additional medical tests to make a diagnosis.

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 (see Figure 6-1) means the Cue COVID-19 Test for Home and OTC Use did not detect the SARS-CoV-2 virus that causes COVID-19 and it is unlikely that you currently have COVID-19 infection.

- Contact a healthcare provider to discuss your results. Your healthcare provider may ask you to take additional medical tests to make a diagnosis.
- There is a chance that the test may give a negative result even if you have COVID-19 (false negative). A reason for a false negative is that the sample was not collected or handled properly, or not enough sample was collected.

- A false negative can also occur if the virus genetic material changes such that the test cannot detect the presence of the virus.
- Even though you do not have COVID-19, you may still have another type of illness. There are many other viruses that cause similar symptoms to COVID-19 and these may be the cause of your symptoms.
- Tell your healthcare provider if you have symptoms or no symptoms.
- Tell your healthcare provider to view the Cue COVID-19 Test Fact Sheet for Healthcare Professionals at www.cuehealth.com.
- Regardless of the test result, it is important that while you are sick you should practice social distancing and good hygiene.
- If you develop symptoms or your symptoms persist or become more severe, if you are concerned about your health, or if you develop one of the emergency warning signs (www.cdc.gov/coronavirus), then you should seek medical attention immediately.

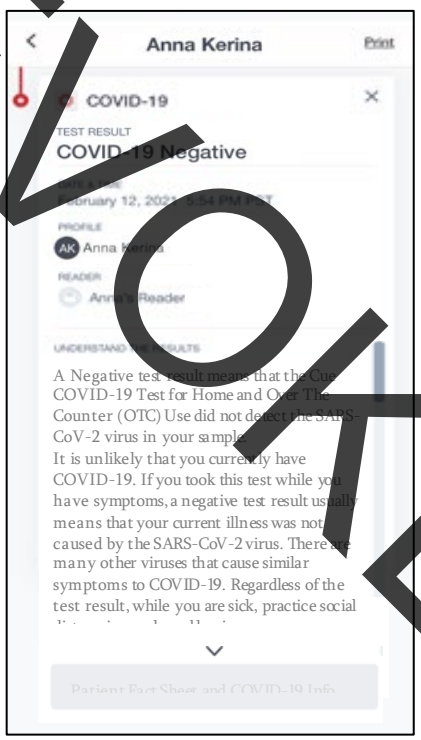

Figure 6-1

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 (see Figure 6-2) means the Cue COVID-19 Test for Home and OTC Use detected the SARS-CoV-2 virus that causes COVID-19 and it is very likely that you currently have COVID-19 infection.

- You should self-isolate at home per CDC recommendations to stop spreading the virus to others. Consult the CDC recommendations regarding self-isolation at www.cdc.gov/coronavirus.
- Consult your healthcare provider as soon as possible and tell him or her that you tested positive for COVID-19 using the Cue COVID-19 Test for Home and OTC Use.
- Tell your healthcare provider if you have symptoms or no symptoms.
- Tell your healthcare provider to view the Cue COVID-19 Test Fact Sheet for Healthcare Professionals at www.cuehealth.com.
- There is a chance that the test may give a positive result that is wrong (a false positive result).
- There is still a chance of co-infection with another type of illness.
- If you do not have any symptoms, particularly if you live in an area with low numbers of COVID-19 infections and have had no exposure to anyone diagnosed with COVID-19, additional testing to confirm your result may be required.

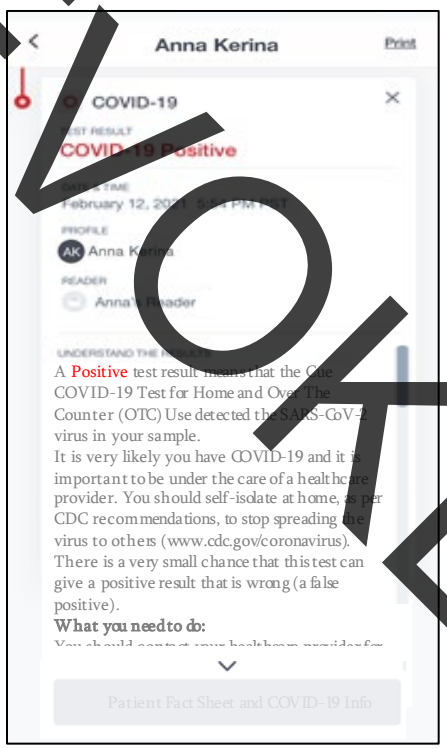

Figure 6-2

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 (see Figure 6-3) means that a system error occurred, and the Cue Health Monitoring System is unable to provide a result. Retesting is required. Common causes of invalid results are:

- You did not collect enough sample

- A processing error occurred inside the cartridge

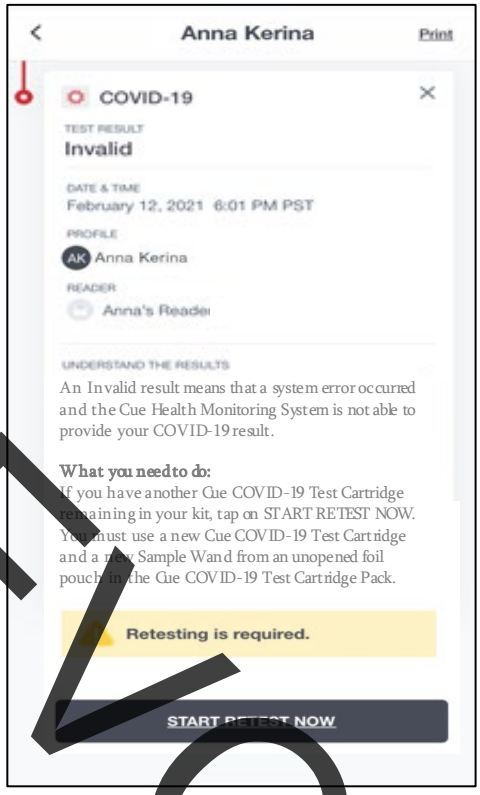

Figure 6-3

If the result is invalid, retest. Click on START RETEST NOW. You must use a new Cue COVID-19 Test Cartridge and a new Sample Wand.

Step 6-4: Understanding Test Result Canceled

You will see a test result of Canceled if you purposely cancel the test by tapping "Cancel" in the top right corner of the Cue Health App screen or if the system cancels the test due to a mechanical error or because you did not follow the test instructions correctly. Examples of when the system will cancel a test include: the Cartridge Reader is moved or tilted while the test is running, the test cartridge is removed before the test is completed, the Sample Wand is inserted into the cartridge too soon or too late.

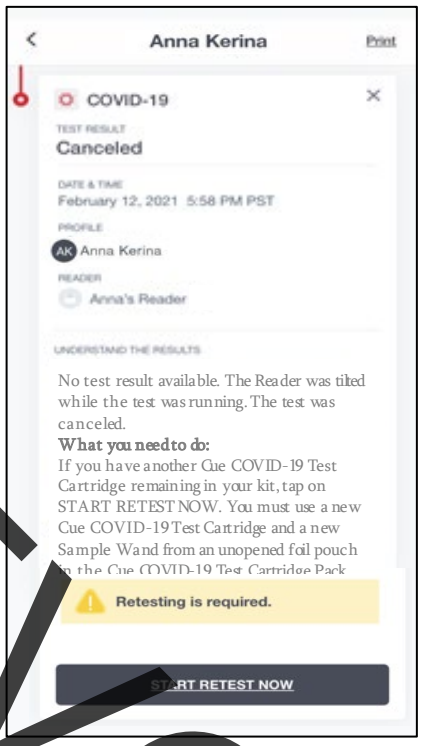

Figure 6-4

If the result is canceled, retest. Click on START RETEST NOW. You must use a new Cue COVID-19 Test Cartridge and a new Sample Wand.

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 and disposed of in general waste.

Cue COVID-19 Test for Home and OTC Use Performance

Limit of Detection – Viral Genomic RNA

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

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

Limit of Detection Confirmation

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

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

Limit of Detection – Live SARS-CoV-2 Virus

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

Samples at 20 virions (20 replicates) and 1000 virions (5 replicates) were also tested in the EUA CDC 2019-Novel Coronavirus (2019-nCoV) RT-PCR Diagnostic Test.
Live virus diluted in clinical nasal matrix was added to 1 mL of VTM and tested in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic test.

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

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

Analytical Reactivity/Inclusivity

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

The original *in silico* analysis utilized sequences available early in the pandemic from the NCBI public database (https://www.ncbi.nlm.nih.gov/labs/virus/vssi/#/, *data downloaded March 2020*) and the GISAID public database (https://www.gisaid.org/, *data downloaded April 2020*). The results from this analysis are summarized in the table below. The

forward primer matched 100% to all sequences. The reverse primer matched all but one sequence in the NCBI database and one sequence in the GISAID database. A few sequences from the GISAID database showed mismatches to the probe, but these strains were all collected pre-pandemic from non-human hosts.

Reactivity/Inclusivity Evaluation (March/April 2020)

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

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

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

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

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

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

A similar analysis was performed, but with the sample location restricted to North America, and with samples collected between October 15 and December 1, 2020. The resulting sequences were aligned and then analyzed within Geneious software (v. 9.0.5) to determine the number of sequences that contained mismatches to each of the

primers/probe. Results are summarized in the table below. In all cases, mismatch occurrence reflected a single base mismatch. Only 3/2087 samples (0.14%) showed a mismatch in sequence to more than one primer/probe. Overall, the analysis indicates a very high level of conservation of the targeted genomic locus within the North American population.

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

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

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

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

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

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

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

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

The GISAID query for the B.1.351 variant resulted in a set of 676 strain sequences. Those sequences were downloaded and examined within Geneious Prime software (v. 2021.0.1).

The results are summarized below. For each primer/probe, at least 99.7% of the sequences are a perfect match.

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

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

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

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

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

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

Analytical Specificity – Cross-Reactivity

A study was performed testing 31 potentially cross-reacting organisms with the Cue COVID-19 Test for Home and OTC Use. 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 test at the concentrations tested.

Cross-Reactivity Evaluation

Organism	Titer	Units of Measurement	Detected/Tested
Chlamydia pneumoniae	1.47E+07	CFU/mL	0/3
Haemophilus influenzae	7.87E+07	CFU/mL	0/3
Legionella pneumophila	6.82E+08	CFU/mL	0/3
Mycobacterium tuberculosis (genomic DNA)	6.90E+04	genome copies / µl	0/3
Streptococcus pneumonia	4.73E+07	CFU/mL	0/3
Streptococcus pyogenes	4.30E+08	CFU/mL	0/3
Bordetella pertussis	1.17E+09	CFU/mL	0/3
Mycoplasma pneumoniae	2.47E+06	CFU/mL	0/3
P.jiroveci-S.cerevisiae Recombinant	1.56E+07	CFU/mL	0/3
Pseudomonas aeruginosa	6.14E+07	CFU/mL	0/3
Staphylococcus epidermidis	1.17E+09	CFU/mL	1/9*
Streptococcus salivarius	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 B	9.55E+05	TCID50/mL	0/3

Organism	Titer	Units of Measurement	Detected/Tested
Rhinovirus type 1A	1.51E+05	TCID50/mL	1/10*
Pooled human nasal wash	10%	percent of total volume	0/3
Candida albicans	5.02E+07	CFU/mL	0/3

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

Analytical Specificity – Cross-Reactivity In Silico Analysis

An *in silico* analysis for possible cross-reactions with all of the 31 organisms in the table above was also conducted by mapping the Cue COVID-19 Test for Home and OTC Use primer/probe sequences to the organism's genome sequences. For each viral organism, an alignment of strains was generated to serve as the basis for the analysis. Adenovirus was an exception, as only a single reference sequence was used.

Twelve viruses contained strains exhibiting ≥80% sequence homology with the forward primer; three viruses contained strains exhibiting ≥80% sequence homology with the reverse primer; and one virus (SARS-CoV-1) contained strains with ≥80% sequence homology with the probe. Of all the viruses analyzed, only SARS-CoV-1 showed sequence homology to more than one test primer/probe at the ≥ 80% sequence homology level.

For the *in silico* analysis of the microbial organisms, NCBI's blastn tool was used to search for primer sequence homology among the listed microbes. Only one microbial organism showed ≥80% sequence homology to more than one of the three test primers/probe.

With the exception of SARS-CoV-1, the Cue COVID-19 Test for Home and OTC Use, 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 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 for Home and OTC Use. 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 for Home and OTC Use at the concentrations tested.

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 marboixil)	0.01mg/ml	0/3	3/3
Nasacort/Triamcinolone	0.04 mg/ml	0/3	3/3
Flonase/Fluticasone	0.04 mg/ml	0/3	3/3
Mometasone	0.04 mg/ml	0/3	3/3
Tobramycin	2.5mg/ml	0/3	3/3

Substance	Concentration	Detected/Tested	
		Negative Nasal Matrix	Positive Nasal Matrix (SARS-CoV-2 RNA present at 3X LoD)
Whole Blood	1% (v/v)	0/3	3/3
Chloroseptic (solid)	20% w/v	1/9*	3/3
Galphimia Glauca	20% w/v	0/3	3/3
Rhinallergy	20% w/v	1/9*	3/3

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

Clinical Performance

Prospective Clinical Study with Lay Users

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

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

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

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

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

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

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

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

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

*The 2 inconclusive samples by the comparator tested positive by the Cue COVID-19 Test for Home and OTC Use.

Positive Percent Agreement (PPA): 97.4% (95% CI: 86.5% - 99.5%)
Negative Percent Agreement (NPA): 99.1% (95% CI: 96.9% - 99.8%)

Symptomatic Individuals		FDA EUA Molecular Comparator		
		Positive	Negative	Inconclusive
Cue COVID-19 Test for Home and OTC Use	Positive	27	2	1*
	Negative	1	108	0

*The 1 inconclusive sample by the comparator tested positive by the Cue COVID-19 Test for Home and OTC Use.

PPA: 96.4% (95% CI: 82.3% - 99.4%)
NPA: 98.2% (95% CI: 93.6% - 99.5%)

Asymptomatic Individuals		FDA EUA Molecular Comparator		
		Positive	Negative	Inconclusive
Cue COVID-19 Test for Home and OTC Use	Positive	10	0	1*
	Negative	0	123	0

*The 1 inconclusive sample by the comparator tested positive by the Cue COVID-19 Test for Home and OTC Use.

PPA: 100% (95% CI: 72.2% - 100%)
NPA: 100% (95% CI: 97.0% - 100%)

Customer Support

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

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

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, and the Cue Sample Wand.

SYMBOL	DESCRIPTION
	In Vitro Diagnostic
	Consult Instructions for Use eIFU available on the Cue Health Mobile Application and at www.cuehealth.com
	Serial Number
	Do not use if seal or packaging is broken or damaged

SYMBOL	DESCRIPTION
	Storage temperature range
	Catalog number
	Manufacturer
	Keep dry
	Use By

cue

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