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

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

Intended Use

The Cue COVID-19 Test is an isothermal nucleic acid amplification assay intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in direct anterior nasal swabs or in previously collected anterior nasal swab specimens in viral transport media from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. The test is run using the Cue Health Monitoring System (Cue Cartridge Reader), the Cue COVID-19 Test Cartridge, the Cue Sample Wand, and the Cue Health App on the compatible mobile smart devices named on the Cue Health website at www.Cuehealth.com. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high, moderate or waived complexity tests. The Cue COVID-19 Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Testing facilities within the United States and its territories are required to report all results to the appropriate public health authorities.

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

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

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

Principles of the Procedure

The Cue COVID-19 Test utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 nucleic acids. This test is a molecular nucleic acid amplification test (NAAT) that detects the genetic material of SARS-CoV-2 using a molecular amplification reaction that is an equivalent alternative amplification method to polymerase chain reaction (PCR). The Cue COVID-19 Test primers amplify the nucleocapsid (N) region of the gene enabling detection. The Cue COVID-19 Test forward primers are conjugated to biotin. Cue COVID-19 Test reverse primers are conjugated to Horseradish Peroxidase (HRP). RNase P serves as the internal control. The RNase P forward primer is conjugated to a small hapten, Digoxigenin (Dig). The RNase P reverse primer is conjugated to HRP.

The RNase P internal control has been designed to control for presence of human cellular material in the sample and proper assay execution including sample inhibition, amplification, and assay reagent function. If RNase P is not detected, the Cue COVID-19 Test will return an "Invalid" result. In positive samples where target amplification is strong, the internal control is ignored and the target amplification serves as the control to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust.

When the user inserts the Cue Sample Wand with nasal sample into the cartridge, the test automatically begins. Heating, mixing, amplification, and detection take place within the cartridge. The current flow from the electrodes provides a semi-quantitative nanoampere measurement that is converted to a positive or negative result (based on a pre-determined cutoff). The Cue COVID-19 Test takes about 20 minutes from Sample Wand insertion to results.

Materials Provided

- Cue COVID-19 Test Cartridge Pack REF C1018
  Contains a foil pouch with a plastic tray. The plastic tray contains one (1) single-use Cue COVID-19 Test Cartridge and one (1) single-use wrapped sterile Cue Sample Wand.

A small pouch called a desiccant is under the cartridge. This pouch has material inside to protect the Cue COVID-19 Test Cartridge from damage due to humidity. Throw away the desiccant after the cartridge is used.

Contact Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378) if any component is missing or damaged or if a cartridge foil pouch is not sealed. You may also contact Cue Health Customer Support to request a physical copy of the Instructions For Use and the Quick Reference Instructions, free of charge.

Materials Required But Not Provided

- **Cue Health Monitoring System**
  Purchase the Cue Health Monitoring System (REF C0201) from Cue Health Inc., by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).
- **Mobile Smart Device**
  Go to www.cuehealth.com for the list of compatible mobile smart devices. BLUETOOTH® wireless technology and Wi-Fi® or cellular capability is required to download the Cue Health App.
- **Cue Health Mobile Application installed on the mobile smart device**
  Download the Cue Health App from the Apple® App Store® or Google Play™ Store.
- **Control Swabs**
  Purchase the Cue COVID-19 External Control Swabs Pack (REF C2110) that contains three Cue COVID-19 Test Positive Control Swabs (REF C2111) and three Cue Test Negative Control Swabs (REF C2112) from Cue Health Inc., by contacting Cue Health Customer Support at support@cuehealth.com or call toll-free at 833.CUE.TEST (833.283.8378).

Precautions - General

- For in vitro diagnostic use.
- This product has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high, moderate or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- This product has been authorized only for the detection of nucleic acid from SARS CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
- Performance of the Cue COVID-19 Test has only been established with Cue Sample Wand

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

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

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

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

Precautions - Used Test Cartridge Disposal

- Used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges. If country or regional regulations do not provide clear direction on proper disposal, used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

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

Precautions - Nasal Sample Collection

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

Limitations

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

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

Cue COVID-19 Test Cartridge Storage Conditions

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

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

Do not use a cartridge beyond the Use By date on the cartridge foil pouch label.

Cue COVID-19 Testing Conditions

Run a Cue COVID-19 Test in the temperature range shown in the table below. Do not run the Cue COVID-19 Test if you are outside of this temperature condition. Use caution if using this device outdoors as it has not been tested at extreme high or low temperatures or high humidity.

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

Quality Control (QC)

Positive and Negative Controls

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

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

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

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

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

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

Specimen Collection and Handling

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

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

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

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

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

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

Directions for Running the Cue COVID-19 Test

Follow the step-by-step instructions provided below.

Step 1: Obtain Items Required but Not Provided in the Cartridge Pack

You will need the items below to run the Cue COVID-19 Test. These items are not included in the Cue COVID-19 Test Cartridge Pack.

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

Step 2: Set Up Your System

Read the Cue Health Monitoring System Quick Start Guide and the User Manual before you run a Cue COVID-19 Test. The Quick Start Guide will help you quickly set up your Cue Health Monitoring System and get ready to run a test. The User Manual gives you all the information you need to use your Cue Health Monitoring System correctly and safely. The Quick Start Guide or the User Manual will show you step-by-step how to do the following:

1. Unpack and set up the Cue Cartridge Reader.
2. Download the Cue Health App by going to the Apple App Store or Google Play Store and searching for the Cue Health App.
3. Set up your Cue Account in the Cue Health App. Once you have set up a Cue Account, you may create and edit account profiles for persons being tested. All your test data will be saved under your Cue Account in the Cue Health App and on the Cue Health secure cloud server.
4. Pair Cue Cartridge Reader(s) to your mobile smart device.
5. Connect the Cue Health App to a paired Cue Cartridge Reader to run a Cue COVID-19 Test.

6. Learn more about your Cue Health Monitoring System and all the above system set-up steps in the Cue Health Monitoring System User Manual.

Step 3: Review All Information

Review the information provided in this Cue COVID-19 Test Instructions for Use before running a test. If you do not understand the instructions, do not run a test. Contact Cue Health Customer Support at support@health.com or call toll-free at 833.CUE.TEST (833.283.8378) for help.

The Cue Health App uses pictures and videos to walk you through, step-by-step, how to collect a nasal sample and run a Cue COVID-19 Test. If you do not follow the instructions, the test may not run as it should, and you may not receive a test result or the test result may not be correct.

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

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

Step 5: Run a Cue COVID-19 Test

Log into your Cue Account. After logging into your account, tap on Manage Profiles. Choose the person's name or barcode ID being tested or add a new profile. To add a new profile, tap the + sign to type in a person's identification information and SAVE; or tap the barcode icon to scan a patient barcode ID. Tap on the name or patient barcode ID, then tap on +BEGIN NEW TEST.

If prompted, select your organization or select "NOT TESTING FOR AN ORGANIZATION."

The instructions below are the same step-by-step instructions as shown in the Cue Health App videos and screens.

REMINDER: If your mobile smart device loses battery charge while performing the test, the test on the Cartridge Reader will still run to completion. The test result will be saved. The mobile smart device must be charged to see the test result. Make sure your mobile smart device is close to the Cartridge Reader after a test completes so you can view the result on the screen in the Cue Health App.

Step 5-1: View Intended Use

Read the Intended Use presented to you in the Cue Health App and then you may continue.

Step 5-2: View Precautions

Precautions are important to follow to ensure that the test runs correctly.

Read the Precautions presented to you in the Cue Health App and then you may continue.

Step 5-3: Pair the Cue Health App to the Cue Cartridge Reader(s)

Connect the Cartridge Reader to power. Follow the Cue Health App videos and screen instructions to pair the Cue Cartridge Reader(s) that will be used for the test(s) to your mobile smart device. When a paired Cartridge Reader is within BLUETOOTH wireless technology range of the mobile smart device, the Reader is “connected” to the Cue Health App. The same instructions are in the Quick Start Guide and the Cue Health Monitoring System User Manual.

Step 5-4: Gather the Materials to Run the Test

Place the Cue Cartridge Reader and a Cue COVID-19 Test Cartridge foil pouch in front of you. See the Cue Health App video showing these materials that you need to run a test as shown in Figure 5-4.

> REMINDER: Open the Cue COVID-19 Test Cartridge foil pouch when you are ready to test. Do not open the foil pouch more than 30 minutes before you begin a test.

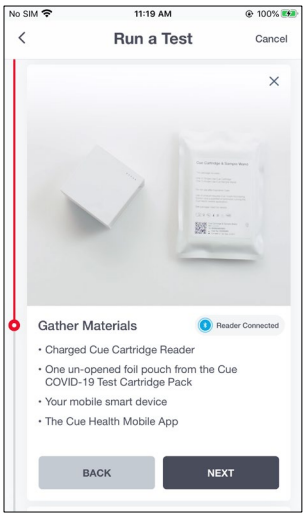

Figure 5-4

Step 5-5: Prepare the Cue COVID-19 Test Cartridge and Cue Sample Wand for a Test

Tear open the top of the cartridge foil pouch and remove the plastic tray with the Cue COVID-19 Test Cartridge and sterile Sample Wand. Remove the Cue COVID-19 Test Cartridge and the wrapped Sample Wand from the tray.

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

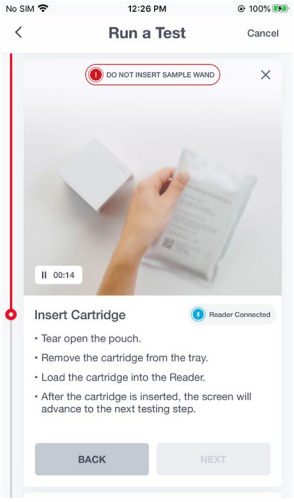

Figure 5-5

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

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

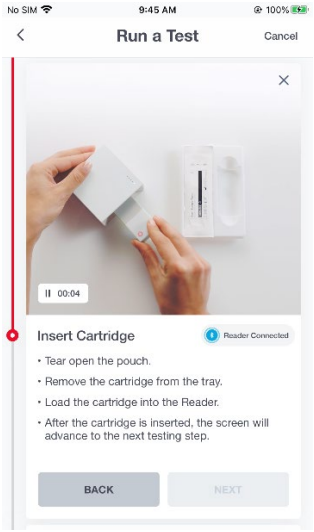

Figure 5-6-1

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

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

Support the back of the Cue Cartridge Reader with one hand and hold the Cue COVID-19 Test Cartridge in the other hand. Insert the cartridge (logo side up) into the Cartridge Port of the Reader. When you have fully inserted the cartridge, all five lights on top of the Cue Cartridge Reader will flash.

REMINDER: The cartridge must heat up for the full 100% heat cycle before the Sample Wand is inserted into the cartridge. All of the LED lights on the Reader will flash 5 times when the cartridge is ready for the Sample Wand.

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

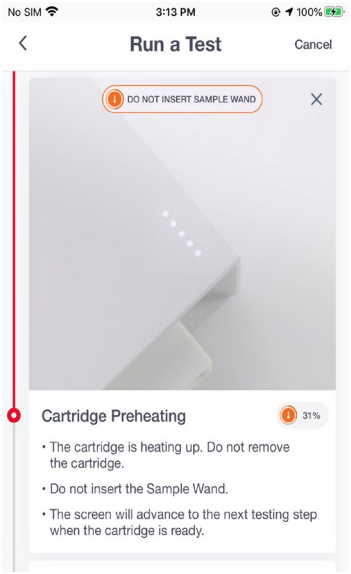

Figure 5-6-2

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

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

Open the wrapped Cue Sample Wand on the side labeled "Open Here." Grasp the handle of the Cue Sample Wand and remove it from the wrapping. The Wand is sterile. Make sure the Wand tip does not touch anything.

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

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

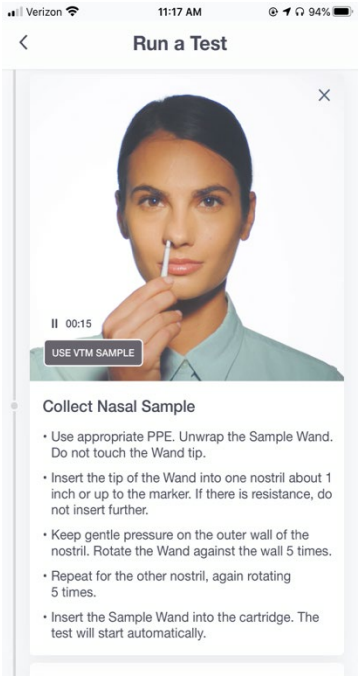

Figure 5-7-1

Figure 5-7-2

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

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

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

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

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

Step 5-8: Sample Dipping

Skip this step if you have already collected a direct nasal sample with the Cue Sample Wand.

Open the wrapped Cue Sample Wand on the side labeled "Open Here." Grasp the handle of the Cue Sample Wand and remove it from the wrapping. The Wand is sterile. Make sure the Wand tip does not touch anything.

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

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

  REMINDER: It is important to collect the Cue Sample Wand nasal specimen by dipping into the individual sample tube at the time of the Collect VTM Sample screen in the Cue Health App and insert the Sample Wand with the nasal specimen into the Cue COVID-19 Test Cartridge promptly. The Cue COVID-19 Test Cartridge should not be in the Cartridge Reader without the inserted Sample Wand for more than 10 minutes.

Step 5-9: Test Progress

The test will start as soon as the Cue Sample Wand is inserted into the Cue COVID-19 Test Cartridge. It takes about 20 minutes for the Cue COVID-19 Test to run. Once the test starts, the Cue Health App will show the test progress as percent completed as shown in Figure 5-8.

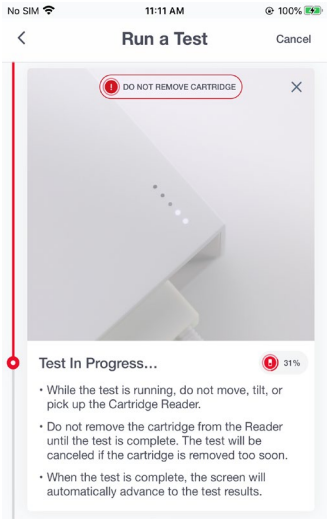

Figure 5-8

Step 5-10: View the Result

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

Step 5-11: Remove the Cue COVID-19 Test Cartridge with Sample Wand After Testing

Remove the cartridge from the Cue Cartridge Reader by holding the Cartridge Reader with one hand and carefully pulling the cartridge out of the Reader with the other hand. The Sample Wand should still be inside the cartridge. Used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges. If country or regional regulations do not provide clear direction on proper disposal, used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

Step 6: Understand the Test Results

The Cue Health App shows the result as Negative, Positive, Invalid, or Canceled.

Step 6-1: Understanding a Negative result

A Negative result means that Cue COVID-19 Test did not detect SARS-CoV-2 virus in the sample.

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

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

- When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.
- Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

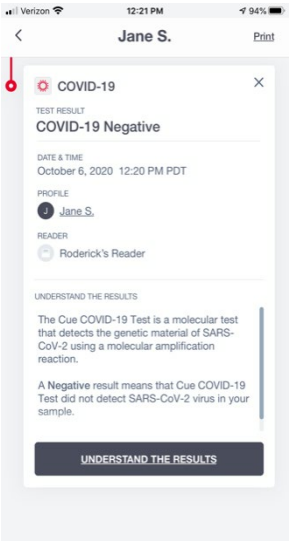

Figure 6-1

Click on back < at the top left of the Cue Health App Screen to return to a screen where you can run a new test.

Step 6-2: Understanding a Positive Result

A Positive result means that the Cue COVID-19 Test detected SARS-CoV-2 virus in the sample.

- When diagnostic testing is positive, the possibility of a false positive result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19.
- Risks to patients of false positives include: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient

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

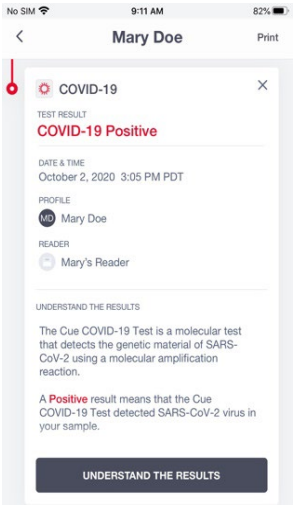

Figure 6-2

Click on back < at the top left of the Cue Health App Screen to return to a screen where you can run a new test.

Step 6-3: Understanding an Invalid Result

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

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

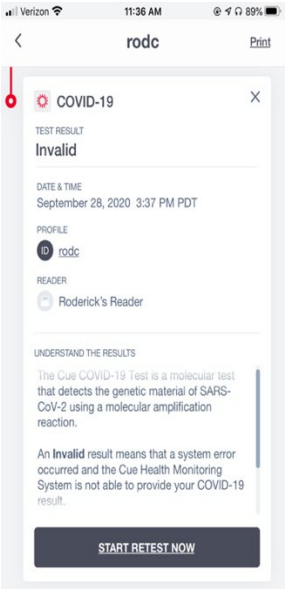

Figure 6-3

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

Step 6-4: Understanding Test Result Canceled

You will see a test result of Canceled if you purposely cancel the test by tapping "Cancel" in the top right corner of the Cue Health App screen or if the system cancels the test due to a mechanical error or because you did not follow the test instructions correctly. Examples of when the system will cancel a test include: the Cartridge Reader is moved or tilted while the test is running, the test cartridge is removed before the test is completed, the Sample Wand is inserted into the cartridge too soon or too late. If the result is canceled, retest. Click on START RETEST NOW. You must use a new Cue COVID-19 Test Cartridge and a new Sample Wand.

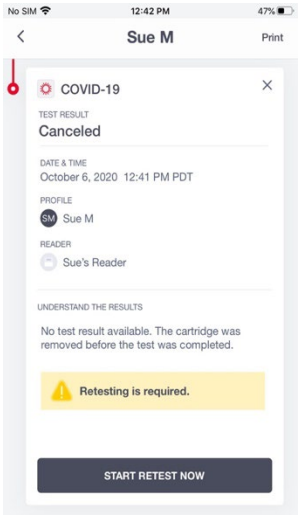

Figure 6-4

Disposal of the Used Cue COVID-19 Test Cartridge

After each test, the Cue COVID-19 Test Cartridge with the Sample Wand still inside must be removed from the Cue Cartridge Reader. Used cartridges should be considered capable of transmitting infectious agents requiring standard precautions. Follow your institution's environmental waste procedures for proper disposal of used cartridges. If country or regional regulations do not provide clear direction on proper disposal, used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

CONDITIONS OF AUTHORIZATION FOR AUTHORIZED LABORATORIES

The Cue COVID-19 Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients and authorized labeling are available on the FDA website:
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas
To assist clinical laboratories using the Cue COVID-19 Test, the relevant Conditions of Authorization are listed below, and are required to be met by authorized laboratories performing the test. Please note the Letter of Authorization refers to "authorized laboratories" as "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation."

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

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

G. Cue Health, distributors, and authorized laboratories using the Cue COVID-19 Test must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Cue COVID-19 Test Performance

Limit of Detection – Viral Genomic RNA

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

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

Cue COVID-19 Test Limit of Detection Confirmation

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

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

Limit of Detection – Live SARS-CoV-2 Virus

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

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

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

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

Analytical Reactivity/Inclusivity

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

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

Reactivity/Inclusivity Evaluation (March/April 2020)

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

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

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

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

Primer	# of GISAID strains with perfect match	# of 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. 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
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

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

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

Analytical Specificity – Cross-Reactivity In Silico Analysis

An in silico analysis for possible cross-reactions with all of the 31 organisms in the table above was also conducted by mapping the Cue COVID-19 Test target nucleic acid sequences to the organism's genome sequences. The analysis of the non-influenza viruses utilized the NCBI virus search tool. The analysis of the influenza viruses utilized an influenza research database. Twelve viral strains showed ≥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

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

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

Clinical Evaluation – Prospective Clinical Study in Emergency Departments

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

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

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

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

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

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

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

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

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

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

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

Clinical Evaluation – Retrospective Clinical Samples and Sample Dipping

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

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

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

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

Clinical Evaluation – Prospective Clinical Study with Lay Users

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

Adult lay users (≥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 and 10 were children <18 years of age where their parent collected the nasal sample and ran the Cue test. Thirteen (13) samples could not be included as there was no comparator assay result or Cue result available. Among the 10 unavailable Cue test results, 7 tests were cancelled, and 3 tests had invalid results. The 7 cancelled tests were 5 cartridge flow errors, 1 tilt threshold exceeded, and 1 user accidentally cancelled the test while in progress.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Customer Support

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

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

References

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

Symbols Used on the Product Labels

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

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

SYMBOL	DESCRIPTION
CONTROL +	Positive Control
CONTROL −	Negative Control
	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