

ANAVASI DIAGNOSTICS®



The AscencioDx® COVID-19 Test and The AscencioDx Molecular Detector

Instructions for Use (IFU)

- For use under Emergency Use Authorization (EUA) only
- For *In Vitro* Diagnostic Use
- For Prescription Use Only
- For use in POC settings operating under a CLIA certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- For qualitative detection only

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For use under Emergency Use Authorization (EUA) only.

For prescription use only.
For point-of-care (POC) use.
For *in vitro* diagnostic use.

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens;

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

INTENDED USE (IU)

The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector is a reverse transcription loop-mediated isothermal amplification (RT-LAMP) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal swab specimens from individuals suspected of COVID-19 by their healthcare providers. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector 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. SARS-CoV-2 RNA is generally detectable in anterior nasal swab 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. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all test results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA certified laboratory that meets requirements to perform high or moderate complexity tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector is intended for use by operators who have received specific training in the use of The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector. The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector consists of a test and a separate molecular detector. The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector analyzes nasal swab samples from individuals who are suspected of infection with SARS-CoV-2 by their healthcare providers. The AscencioDx COVID-19 Test Pack component and the AscencioDx Molecular Detector component together comprise all the materials and equipment needed to fully conduct a single test. Although the AscencioDx COVID-19 Tests are single-use, the AscencioDx Molecular Detector is a re-usable device. Each molecular detector processes one test at a time.

PRINCIPLE OF THE TEST

The AscencioDx COVID-19 Test is a sample-to-answer point-of-care test operated on the AscencioDx Molecular Detector. The test uses RT-LAMP and real-time fluorescence detection to detect SARS-CoV-2 RNA in a nasal swab specimen from patients suspected of COVID-19 by a healthcare provider. All materials needed to run the test are included, and tests can only be used on the AscencioDx Molecular Detector. The operator uses the provided nasal swab to collect a sample from both nostrils of the patient, swirls the nasal swab in the provided buffer tube, uses the transfer pipette to move a small volume of fluid to the reaction tube, and inserts the reaction tube into the detector. The detector heats the reaction tube to amplify the target RNA and detect the fluorescence signals. The detector displays the test result on its screen.

The AscencioDx COVID-19 Test uses RT-LAMP to amplify three regions of the SARS-CoV-2 nucleocapsid gene and an internal amplification control (IAC) from MS2 phage. One fluorescent probe reacts with all three SARS-CoV-2 amplicons to generate green fluorescence, and the second fluorescent probe reacts with the MS2 phage IAC amplicon. The MS2 phage IAC acts as a lysis control, reverse transcription control, and amplification control; MS2 phage is included in the lyophilized reagent mix, so it is present in each test and does not require handling by the operator. Fluorescence signals are detected in real-time by the AscencioDx Molecular Detector, and the SARS-CoV-2 signal or the IAC signal is identified as detected when its fluorescence signal rises sufficiently above its dynamic baseline level. No biotin-streptavidin chemistry is used.

The test is reported as COVID-19 positive if the SARS-CoV-2 fluorescence signal is detected, regardless of the IAC result. The test is reported as COVID-19 negative if the SARS-CoV-2 fluorescence is not detected by the end of the assay time, but the IAC fluorescence is detected. If neither target is detected by the end of the assay time, or the SARS-CoV-2 fluorescence is not detected, but the IAC fluorescence is detected within 18 minutes or less from the beginning of the assay, the test is reported as inconclusive; and if a device fault is detected during the test (e.g., reaction temperature error) the test is reported as a malfunction.

Table 1. Interpreting the Results

SARS-Cov-2	IAC	Result Reported on Screen	Result Meaning
Detected	N/A	"Positive: COVID-19 Virus Detected"	SARS-CoV-2 viral RNA was detected in the sample.
Not Detected	Detected	"Negative: COVID-19 Virus Not Detected"	SARS-CoV-2 viral RNA was not detected in the sample.
Not Detected	Not Detected	"Test Failed: Inconclusive"	The presence or absence of SARS-CoV-2 viral RNA cannot be determined.
N/A	N/A	"Test Failed: Malfunction"	A serious problem has occurred with the device during the test (e.g., heater temperature out of range, failure of LED lights, software errors).

REAGENTS, MATERIALS, AND INSTRUMENTS SUPPLIED

Note: Both the AscencioDx COVID-19 Test Pack component and the AscencioDx Molecular Detector component are needed to conduct a single test. Although they are packaged and sold separately, the contents of both elements are provided here as a comprehensive reference for the entire testing process.

Components Included with the AscencioDx COVID-19 Test Pack:

Table 2: AscencioDx COVID-19 Test Pack Components (Part Number 7005193)

Component	Description	Quantity	Part Number
AscencioDx COVID-19 Test	Boxed test containing all materials needed to test one sample or control.	10	7004946
Quick Reference Instructions (QRI)	Instructional guide containing basic information for running a test.	1	7005191

Table 3: AscencioDx COVID-19 Test Components (Part Number 7004946)

Component	Description	Quantity	Part Number
Nasal Swab	Sterile, packaged anterior nasal swab.	1	7004940
Buffer Tube	Foil pouch containing a screw-top vial of buffer fluid.	1	7005179
Transfer Pipette	Self-metering pipette for moving sample from the buffer tube into the reaction tube.	1	7004941
Reaction Tube Bag Assembly	Foil pouch containing a capped reaction tube containing a dried reagent pellet, along with a disposable desiccant pack.	1	7005133
Kit Tray	Single-use tray to hold the nasal swab, buffer tube, reaction tube, and transfer pipette during test set-up.	1	7005027

Components Required but Not Included:

Table 4: AscencioDx Molecular Detector Components (Part Number 7004895):

Component	Description	Quantity	Part Number
AscencioDx Molecular Detector	Reusable device for use with the AscencioDx COVID-19 Test	1	7004928
Power Supply	12-volt adapter and attached electrical cable for powering the AscencioDx Molecular Detector.	1	7005056
QRI	Quick Reference Instructions	1	7005191

Table 5: External Positive Control Available but Not Provided:

Component	Description	Quantity	Part Number
Positive control	ZeptoMetrix Inc SARS-CoV-2 External Run Control (6 x 1.0 mL). Catalog No. NATSARS(COV2)-ERC1-IVD, available online from www.zeptometrix.com or by telephone at (800) 274-05487.	6	NATSARS(COV2)-ERC1-IVD

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. For use under Emergency Use Authorization (EUA) only.
3. For prescription use only.
4. For use in point-of-care (POC) settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
5. This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
6. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
7. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
8. For use only in 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.
9. Federal Law restricts this product to sale by or on the order of a licensed practitioner.
10. The AscencioDx COVID-19 Test can only be used with the AscencioDx Molecular Detector.
11. Use only the test components provided.
12. All AscencioDx COVID-19 Test components are intended for single use only. Do not use any components for more than one test or retain for any other use. The AscencioDx Molecular Detector is a re-usable device.
13. The performance of this product has only been evaluated for samples indicated in the Intended Use section.
14. Dispose of test components and all sample materials safely according to your institutional policies and in accordance with federal, state, and local regulations.
15. Wash hands thoroughly with soap and water before and after completing the test, as well as after disposing of the test materials at the conclusion of the test.
16. Wear new latex, nitrile, or equivalent gloves when performing the test.

17. Do not remove any test components from packaging until just before use.
18. Proper sample collection and handling are essential for accurate results.
19. Use caution when conducting tests and handling samples. All samples should be treated as potentially infectious.
20. Do not touch the swab's tip or allow it to come into contact with other objects or surfaces when collecting anterior nasal swab samples.
21. Do not use the test or any test components if visible damage is present to packaging and/or contents.
22. Run the test within 10 minutes of opening the foil pouch that contains the reaction tube. If the sample is not tested within this time frame, the sample and all test components should be discarded, and another sample collected and run using a new test.
23. Use only the provided fixed-volume (40 μ L) transfer pipette to transfer the buffer-sample solution from the buffer tube to the reaction tube.
24. Do not transfer more than one sample from the buffer tube to the reaction tube with the transfer pipette.
25. Do not use any solution that gathers in the pipette's overflow area in the lower bulb during the sample transfer process.
26. Do not use leftover buffer solution for additional tests of patient sample or any other patient's test.
27. Test should be performed in an area with adequate ventilation or air purification measures, out of direct sunlight, and free from disturbance.
28. Store the test at 59°F to 77°F (15°C to 25°C) and keep away from moisture and out of direct sunlight.
29. Do not freeze the test.
30. Do not use the test or any test materials beyond their expiration date.

31.       **R_X Only** 

LIMITATIONS

1. The performance of this test system was established using anterior nasal swab specimens only after strict adherence to the instructions provided in the informational package inserts and labeling. Failure to adhere to these guidelines may impair or invalidate test performance.
2. Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets requirements to perform high or moderate complexity tests.
3. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.
4. False negative results may occur if viral levels are insufficient for detection, and/or improperly handled, or if the virus has mutated in all three areas targeted by the test.
5. The AscencioDx COVID-19 Test and the AscencioDx Molecular Detector together comprise a qualitative testing system ("The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector"). As such, it can only evaluate whether the targeted pathogen is present in a sample, not the degree or quantity to which it is present.
6. This test cannot rule out a positive result stemming from co- or distinct infection with another pathogen; nor is it designed to test for pathogens beyond the virus that causes COVID-19.
7. Only a single test from a single patient sample can be run on the AscencioDx Molecular Detector at a time.

8. To ensure accuracy, the test must be run immediately following sample collection.
9. Samples containing blood have been shown to cause inconclusive results; if blood is present on sample, do not use.
10. Performance of the test has not been established in asymptomatic individuals.

Conditions of Authorization for Laboratories

The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector 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>.

However, to assist clinical laboratories using The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector (“your product” in the conditions below), the relevant Conditions of Authorization are listed below:

1. Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and ADL Diagnostics, Inc., dba Anavasi Diagnostics (www.anavasidx.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
7. ADL Diagnostics, Inc., dba Anavasi Diagnostics, authorized distributor(s) and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

* 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 requirements to perform high, moderate, or waived complexity tests. The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector 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.”

QUALITY CONTROL PROCEDURES

External control materials are required to perform a positive Quality Control (QC) test, but they are not included with The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector. The negative QC

test can be performed using only the components of the test itself. Anavasi Diagnostics recommends that you run these quality control (QC) procedures as deemed necessary to conform with your institution's internal QC procedures, local, state and/or federal regulations; and/or accrediting groups. Please note that positive control samples must be purchased separately.

If you do not receive the expected results, please re-read the instructions and repeat the QC using a new QC sample and a new test. If the quality control failure repeats, do not test patient samples. Stop using the device and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com.

Note: To lessen the risk of contamination, the negative control should always be run first. If the controls are not valid, patient samples should not be run on the device.

External Controls

A negative control can help identify environmental contamination (e.g., cross-contamination from the residue of other positive samples when the working area is not routinely cleaned, or operators failing to use new gloves) that may give false positive results. A positive control can help identify problems introduced by failure of the instrument, tests, or operator performance that may give false negative results.

Anavasi Diagnostics recommends that a negative control and a positive control be run:

- When setting up each new device.
- Once for each first-time operator.
- Before using a new lot or shipment of tests.
- When you think there might be a problem with the tests or detector.
- As deemed necessary to conform with internal QC procedures, local, state and/or federal regulations, and/or accrediting groups.

Complete the instructions for running a test (**Step 1: Set up the QC Test** through **Step 8: Complete the Test**) for both control tests. The **only** step that is different between the negative and positive QC tests is **Step 2: Prepare the Control Swab**.

- **For the negative control: do not** collect any sample during **Step 2: Prepare the Control Swab**. Do not insert a swab into nostrils when running the negative control. Use the clean swab from the kit as your negative control. You will use the clean swab from the test without any nasal sample as the negative control during **Step 3: Prepare the QC sample**. **For the positive control:** Test the ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (6 x 1.0 mL) Inactivated virus along with the swab from The AscencioDx COVID-19 Test.
 - The positive **control** is available online from www.zeptometrix.com or by telephone at (800) 274-5487, Catalog No.: NATSARS (COV2)-ERC1-IVD. The positive control tube contains enough fluid for 4 positive control tests.
 - The positive control must be refrigerated (36-46°F / 2-8°C).
 - Do not use the positive control after the expiration on its label.
- Care should be taken with the positive control sample to prevent its contamination. A new pair of gloves should be worn when handling the positive control sample, and the cap should be removed only for the brief time needed to retrieve the positive control liquid with the swab. The cap should be tightly closed after use, and the tube should be quickly returned to refrigerated storage. In addition, care should be taken to prevent contamination of the testing area or subsequent tests with the positive control sample. After testing controls, operators should put on new gloves before testing patient samples. If the positive control sample is spilled, it should be cleaned immediately with a ≥10% bleach solution, and cleaning materials should be disposed of away from the testing location.

Important: If expected quality control results are not obtained, repeat the failed negative control or positive control using a new test kit or kits. If the failure repeats, do not perform patient sample testing and contact Anavasi Customer Support.

+Table 6 describes the procedure for testing external control swabs.

Table 6: Outline of Instructions for Performing External Controls

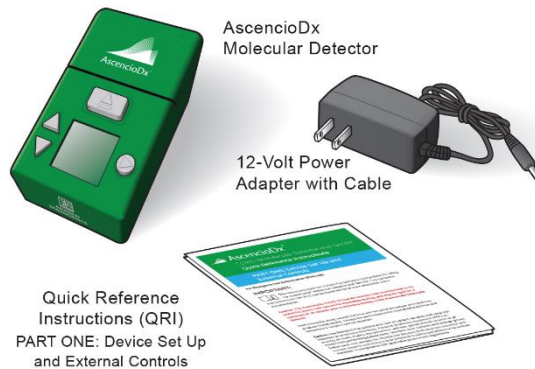
Step	Negative Control	Positive Control
	Prepare the detector and test.	Prepare the detector and test.
1. Set up the QC Test	n/a	Remove the ZeptoMetrix positive template control tube from refrigerated storage, mix by shaking the tube vigorously for 5 seconds, then tap the bottom of the tube against the work surface 3 times to force droplets to the bottom of the tube.
2. Prepare the Control Swab	Open a new AscencioDx COVID-19 Test and open the sterile nasal swab.	Open a new AscencioDx COVID-19 Test and open the sterile nasal swab. Insert the swab from the test into the ZeptoMetrix positive control tube (this step takes the place of collecting a nasal sample; do not insert the swab into nostrils). Rotate the swab around the sides of the positive control tube 10 times, making sure fluid covers the entire spongy part of the swab.
3: Prepare the QC Sample	Use the swab from the test to stir the fluid in the buffer tube; agitate according to instructions in the QRI.	Use this swab immediately to move the positive sample solution into the buffer tube and agitate according to instructions in the QRI.
4: Transfer the QC Sample	Use the pipette to transfer the buffer into the reaction tube and close the reaction tube.	Use the pipette to transfer the buffer into the reaction tube and close the reaction tube.
5: Run the Test	Place the reaction tube in the detector and close the lid to run the test.	Place the reaction tube in the detector and close the lid to run the test.
6: Read Results	Interpret results following instructions in Table 7: External Controls Interpretation.	Interpret results following instructions in Table 7: External Controls Interpretation.
7: Record QC Results	Scan the QR code and record the QC test results according to standard procedures.	Scan the QR code and record the QC test results according to standard procedures.
8: Complete the Test	Remove the reaction tube from the detector and dispose of it and any test materials according to your institution's biological waste policies.	Remove the reaction tube from the detector and dispose of it and any test materials according to your institution's biological waste policies.

Unpack The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector

Carefully unpack The AscencioDx Molecular Detector box and make sure it contains the following:

- 1 AscencioDx Molecular Detector
- 1 12-volt power adapter and cable
- 1 Quick Reference Instructions (QRI), in two parts
 - Part One: Device Set Up and External Controls
 - Part Two: Running the COVID-19 Test

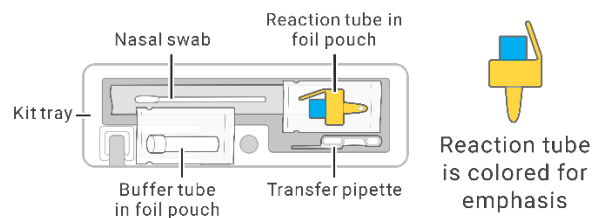
Refer to the **QRI Part One: Device Set Up and External Controls**



Inspect the detector and 12-volt power adapter for any obvious damage prior to use.

To run a test, you will need:

- 1 AscencioDx Molecular Detector
- 1 AscencioDx COVID-19 Test, containing:



Choose a location where the detector can sit undisturbed for 30+ minutes.

In a well-ventilated location, select a clean, level surface out of direct sunlight and near an electrical outlet. To turn on the detector, simply connect the 12-volt power adapter to the power port located on the rear panel of the device and then plug the adapter into the appropriate electrical outlet. (There is no separate power button.)

Wash and dry your hands and put on new latex or nitrile gloves.

Make sure that all the test components are present and free from any obvious damage.

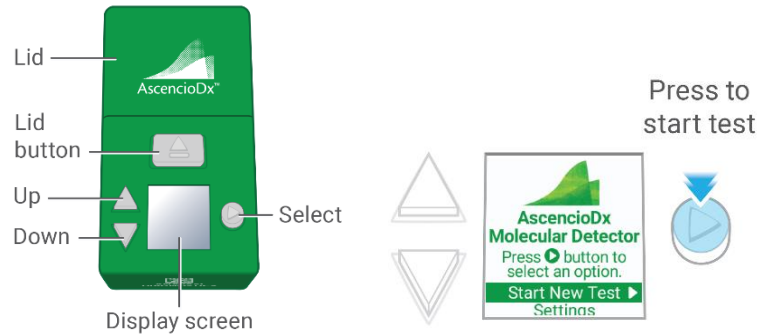
- Buffer tube (in foil pouch)
- Reaction tube (in foil pouch)
- Nasal swab
- Transfer pipette
- Kit Tray

Step 1: Set Up the QC Test



Anavasi recommends that you obtain successful QC results (negative and positive) as previously outlined.

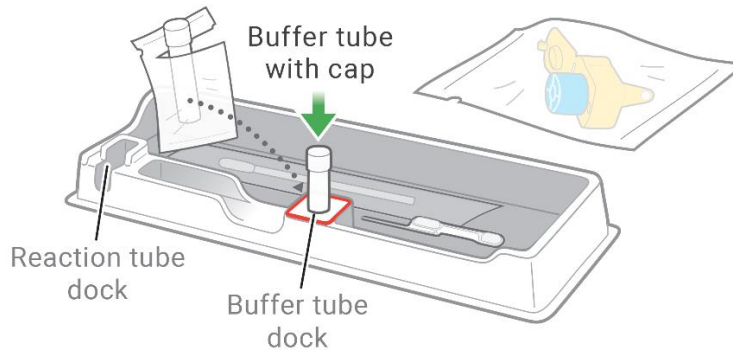
- Press the “Select” button to start a new test. (To navigate the screen, use the up and down buttons. Please note that the screen is not touch-enabled.)



- Wait for the detector to warm up (about a minute). Do not proceed until the detector displays the Prepare Sample Screen.



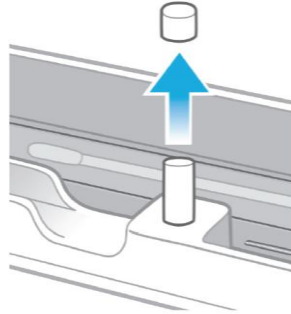
- Open buffer tube pouch and place the buffer tube in the dock in the kit tray.
- Take the transfer pipette out its bag and place it in the tray.



Step 2: Prepare the Control Swab

When you are ready to prepare the QC sample, **remove the cap from the buffer tube.**

Note: Removing the buffer tube cap prematurely increases the risk of contamination and inaccurate test results.



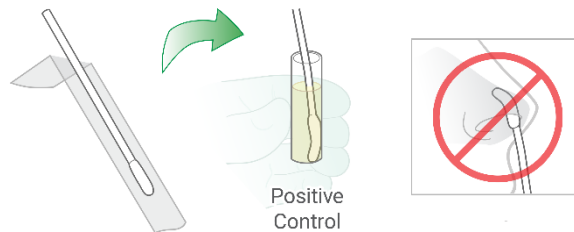
For the negative QC:

Do not collect any sample. Do not insert a swab into nostrils when running the negative control. You will use the clean swab from the test without any nasal sample as the negative control during **Step 3:**

Prepare the QC Sample.

For the positive QC:

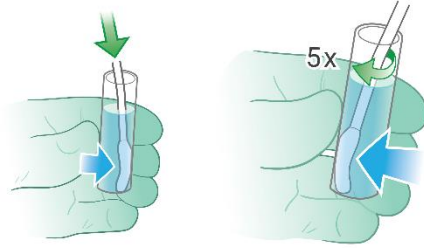
- Retrieve a positive control tube from refrigeration and shake the tube vigorously for 5 seconds. Tap the bottom of the tube against a work surface 3 times to force droplets to the bottom of the tube.
- Open and insert the swab from the test into the positive control tube** (this step takes the place of collecting a nasal sample; do not insert the swab into nostrils).



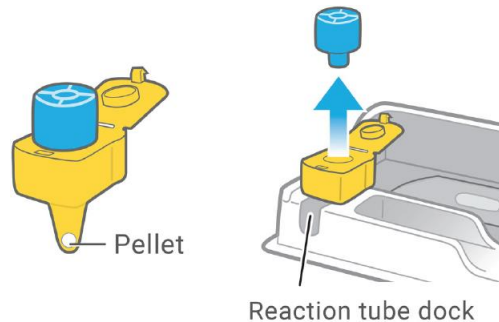
- Rotate the swab around the sides of the positive control tube 10 times, making sure fluid covers the entire spongy part of the swab.
- Use this swab immediately to move the positive sample solution into the buffer tube and agitate it thoroughly as shown in **Step 3: Prepare the QC Sample.**
- Mark the positive control tube with the number of uses. Discard the control tube after 4 positive control tests.
- If the control has been used less than 4 times, return it to refrigerated storage.

Step 3: Prepare the QC Sample

- Pick up the buffer tube and insert the negative or positive QC swab in the buffer tube.
- Press the swab against the tube's side walls as you rotate the swab.
- Squeeze each part of the sponge to get liquid moving in and out of the pores, pumping fluid through the pores to rinse out material that is in the swab.
- Do this vigorously at least five times against the bottom and sides of the tube.



- e. Stir the solution with the swab, mixing it well. **Warning:** Failure to stir the solution for a positive QC sample could cause a false negative result.
- f. Safely dispose of the swab according to your institution's biological waste policies.
- g. Remove the reaction tube from its foil pouch. **The test must be initiated within 10 minutes of opening the reaction tube's foil pouch.**
- h. Use the tray to avoid possible cross-contamination.
- i. The reaction tube cap may have come off inside the sealed foil pouch. If so, leave it off. Re-capping the reaction tube could introduce contamination.
- j. Make sure that there is a pellet in the bottom of the reaction tube.
- k. If not, flick or tap the bottom tube to make the pellet fall to the bottom.
- l. Place the reaction tube in the dock in the kit and remove the cap.

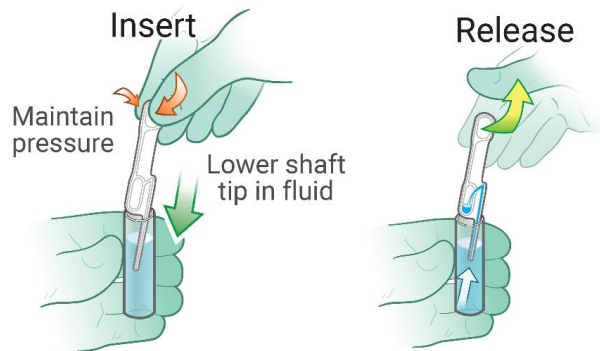
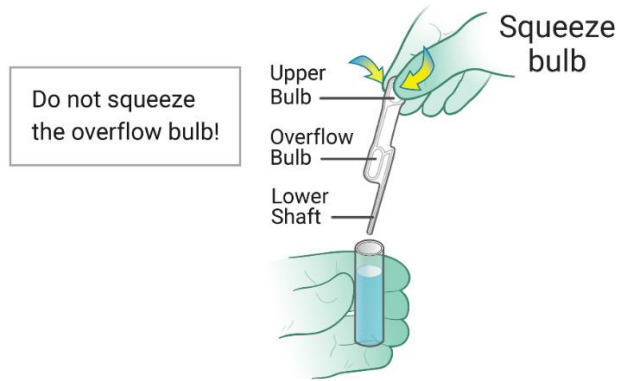


Step 4: Transfer the QC Sample



This is the most important step. Getting the right amount of fluid is critical to getting an accurate result.

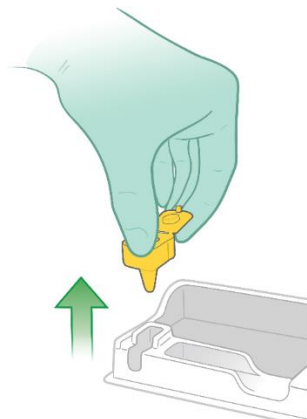
- a. **The transfer pipette is designed to transfer a specific amount of fluid. You should only transfer fluid a single time to get the right amount. In one continuous motion, squeeze the bulb, insert the pipette, and release the bulb.**
 - **Squeeze the upper bulb to expel air.**
 - Maintain pressure on the upper bulb while inserting the lower shaft tip in the buffer tube. Be sure that the shaft tip is in the buffer fluid before releasing the upper bulb.
 - Release the upper bulb to draw in fluid.
 - Do not squeeze the bulb again.
 - Lift the pipette out of the buffer tube.



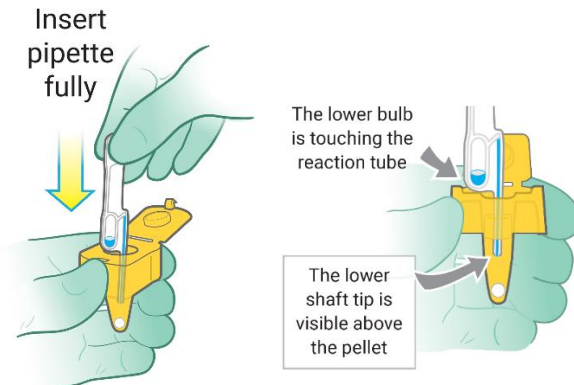
- The lower shaft should be full of liquid with no bubbles, and some fluid should be present in the overflow bulb.



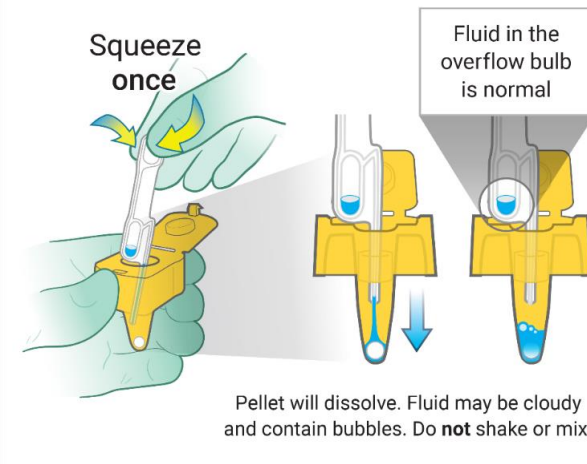
- Make sure you **remove the reaction tube cap**.
- Pick up the reaction tube and place the lower shaft of the pipette into the reaction tube.



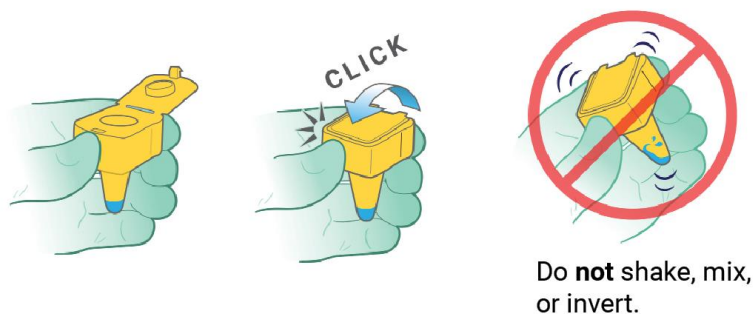
- d. **Fully insert the pipette**, pushing down all the way until the overflow bulb rests on the edge of the reaction tube and the shaft tip is visible above the pellet.



- e. Firmly squeeze the upper bulb once, releasing the solution that is in the shaft. **None of the fluid will come out of the overflow bulb of the pipette.** It is normal for extra fluid to remain in the overflow bulb. **Do not squeeze** the overflow bulb of the pipette or reuse any leftover solution.



- f. Close the lid of the reaction tube. You will hear a soft “click” which means the lid is securely fastened. **Warning: Do not shake, mix, or invert the tube.**



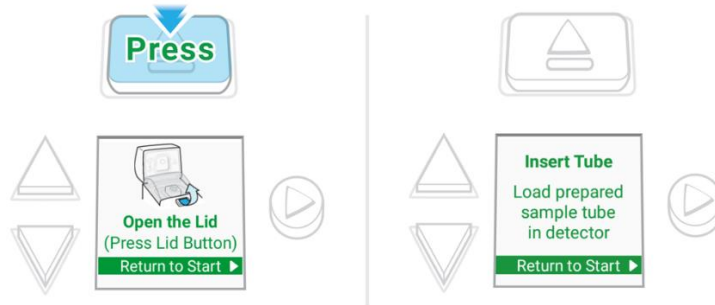
- g. The buffer tube and transfer pipette cannot be reused—put them in the trash. All used test materials could be capable of transmitting infectious agents. Throw them away according to your institution’s biological waste policies.

Note: When using the pipette, none of the fluid will be dispensed from the pipette’s lower bulb overflow area, and additional solution will remain leftover in the buffer tube. **This is expected. Do not squeeze**

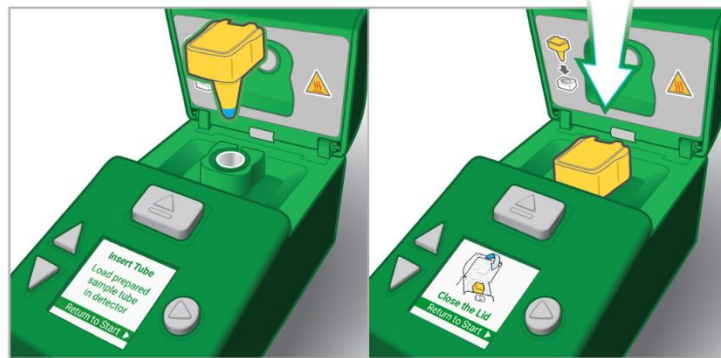
the lower bulb of the pipette or reuse any leftover solution from either implement. The solution transfer is a one-time process.

Step 5: Run the Test

Select “Next” (see **Step 1: Set Up the Test**). The detector should be displaying the Open the Lid Screen.

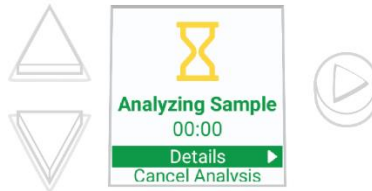


- Open the lid by pressing the lid button. The detector is now ready to receive the reaction tube.
- Gently place the reaction tube into the tube port (it only fits one way).
- Close the lid. Sample analysis will begin automatically.



Notes:

- Do not unplug or disturb the detector until the results are displayed on the screen.
- The detector displays an hourglass icon and timer. This means the sample is being analyzed.



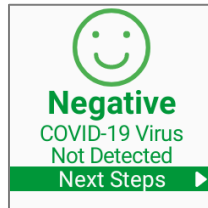
- Test result times vary.
- Do not disturb the Detector until a result has appeared on the Screen.

Step 6: Read Results

When the analysis is finished, the detector displays one of the following four possible results:

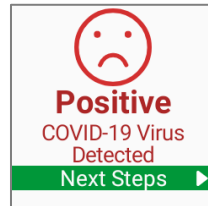
NEGATIVE: COVID-19 VIRUS NOT DETECTED

The virus that causes COVID-19 was NOT detected. A negative result for a negative QC would indicate that the QC was successful. A negative result for a positive QC would indicate that the QC failed.



POSITIVE: COVID-19 VIRUS DETECTED

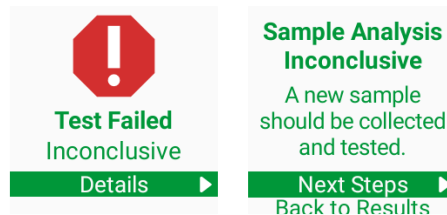
The virus that causes COVID-19 was detected in the sample. A positive result for a negative QC would indicate that the QC failed. A positive result for the positive QC would indicate that the QC was successful.



TEST FAILED: INCONCLUSIVE

There are no clear results about the QC sample. The most likely reason for an inconclusive result is that you did not follow the instructions exactly. Please re-read the instructions and run the QC test again with a new test.

If you repeatedly get inconclusive results, contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com.



TEST FAILED: MALFUNCTION

This means there is a problem with the detector and no clear conclusions can be made about the sample. Do not use this detector anymore.

Contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com.



Step 7: Record QC Results

- Press the “Select” button to choose Next Steps and generate a QR code.
- Scan this code to record the QC test results according to your facility’s standard procedures.



Step 8: Complete the Test

After you have recorded the QC test results, follow the instructions on the screen to remove the reaction tube:

- Open the lid.
- Remove the reaction tube and throw it away.
- Close the lid. The detector automatically displays the Main screen.

After successfully completing both negative and positive QC test, you are ready to start a new test or adjust settings.

Table 7 describes interpretation of external controls and the actions to be taken.

Table 7: External Controls Interpretation

Control	Control PASS	Control FAIL	Action if FAIL
Negative Control	The AscencioDx Molecular Detector reports “Negative: COVID-19 Virus Not Detected”	The AscencioDx Molecular Detector reports “Positive: COVID-19 Virus Detected”	Decontaminate the detector and work site with an antiseptic wipe containing a $\geq 10\%$ bleach or equivalent solution, wash your hands and use new gloves before running a new negative control on a new test. <u>Do not spray or soak the detector in any cleaning solution.</u> If the failure repeats, your site may be contaminated and/or your device impaired. Immediately discontinue use of the device and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274), or on the web at www.anavasidx.com .
Negative Control	The AscencioDx Molecular Detector reports “Negative: COVID-19 Virus Not Detected”	The AscencioDx Molecular Detector reports “Test Failed: Inconclusive”	Repeat test using a new test, carefully following test instructions. If failure repeats, the test may be damaged. Run the negative control with the test from a different test lot. If the failure repeats, the device may be damaged. Immediately discontinue use of the device and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274), or on the web at www.anavasidx.com .
Negative Control	The AscencioDx Molecular Detector reports “Negative: COVID-19 Virus Not Detected”	The AscencioDx Molecular Detector reports “Test Failed: Malfunction”	Discontinue use of the detector and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274), or on the web at www.anavasidx.com .
Positive Control	The AscencioDx Molecular Detector reports “Positive: COVID-19 Virus Detected”	The AscencioDx Molecular Detector reports either of the following: <ul style="list-style-type: none"> “Negative: COVID-19 Virus Not Detected” “Test Failed: Inconclusive” 	Repeat test using a new test, carefully following test instructions. If failure repeats, it may mean that the test, the positive control sample, or the device may be damaged. Open a new positive control and repeat the control test using a new test, carefully following test instructions. If the failure repeats, the device may be damaged; immediately discontinue use of the device and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274), or on the web at www.anavasidx.com

Control	Control PASS	Control FAIL	Action if FAIL
Positive Control	The AscencioDx Molecular Detector reports "Positive: COVID-19 Virus Detected"	The AscencioDx Molecular Detector reports "Test Failed: Malfunction"	Discontinue use of the detector and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274), or on the web at www.anavasidx.com .

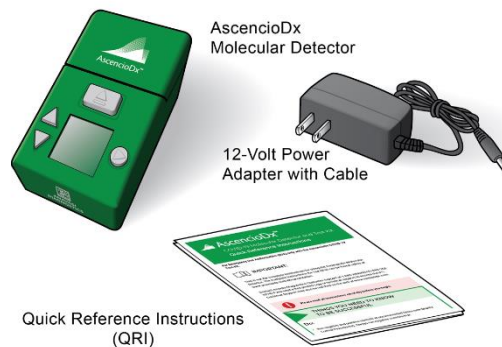
Anavasi Diagnostics Customer Support can be reached by calling 1-888-ANAVASI (262-8274) or through the website at www.anavasidx.com.

TEST PROCEDURE

Unpack The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector

- a. Carefully unpack The AscencioDx Molecular Detector box and make sure it contains the following:
- 1 AscencioDx Molecular Detector
 - 1 12-volt power adapter and cable
 - 1 Quick Reference Instructions (QRI) in two parts
 - Part One: Device Set Up and External Controls
 - Part Two: Running the COVID-19 Test

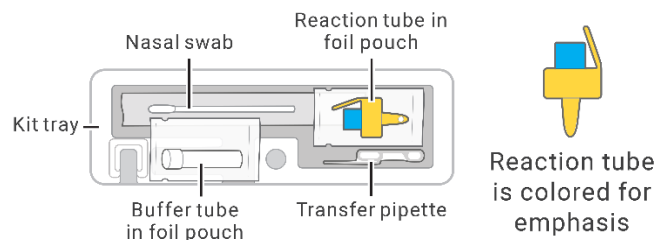
Refer to the **QRI Part Two: Running the COVID-19 Test**



- b. Inspect the detector and 12-volt power adapter for any obvious damage prior to use.

To run a test, you will need:

- 1 AscencioDx Molecular Detector
- 1 AscencioDx COVID-19 Test, containing:



Choose a location where the detector can sit undisturbed for 30+ minutes.

In a well-ventilated location, select a clean, level surface out of direct sunlight and near an electrical outlet. To turn on the detector, simply connect the 12-volt power adapter to the power port located on the rear panel of the device and then plug the adapter into the appropriate electrical outlet. (There is no separate power button.)

Wash and dry your hands and put on new latex or nitrile gloves.

Make sure that all the test components are present and free from any obvious damage.

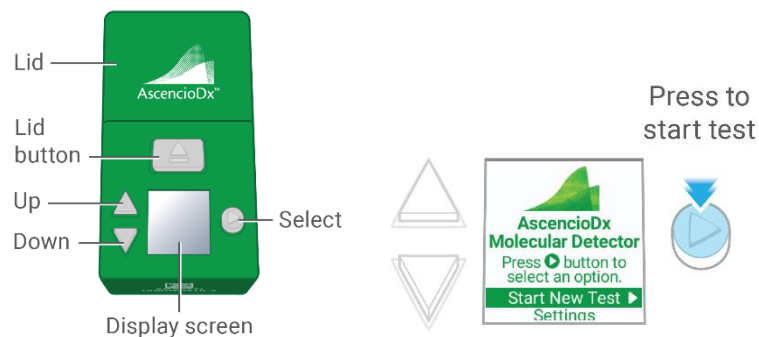
- Buffer tube (in foil pouch)
- Reaction tube (in foil pouch)
- Nasal swab
- Transfer pipette
- Kit Tray

Step 1: Set Up the Test



Anavasi recommends that you obtain successful QC results (negative and positive) as previously outlined.

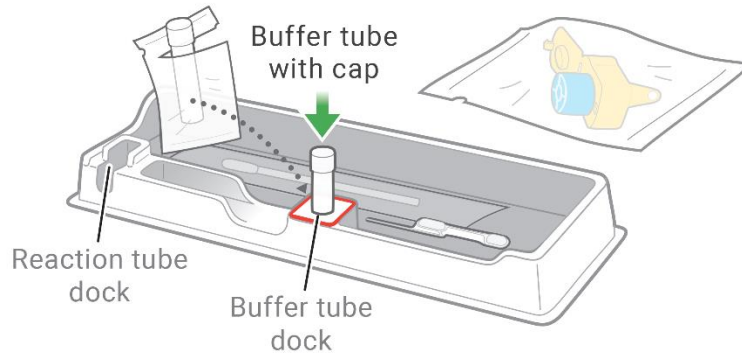
- a. Press the select button to start a new test. (To navigate the screen, use the up and down buttons. Please note that the screen is not touch-enabled.)



- b. Wait for the detector to warm up (about a minute). Do not proceed until the detector displays the Prepare Sample screen.



- c. Open buffer tube pouch and place the buffer tube in the dock in the kit tray.
d. Take the transfer pipette out of its bag and place it in the tray.

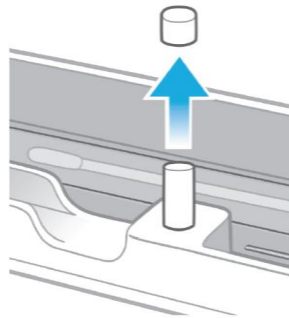


Step 2: Swab Both Nostrils After Nose Is Blown

For this test to work properly, you must swab **both** nostrils and start the test **immediately** after collecting the sample. **If you do not start the test within 10 minutes of collecting the sample, do not run the test. You need to get a new AscencioDx COVID-19 Test and start over with a fresh sample.**

- a. When you are ready to collect the sample, **remove the cap from the buffer tube.**

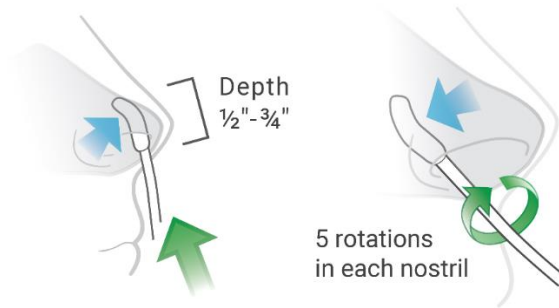
Note: Removing the buffer tube cap prematurely increases the risk of contamination and inaccurate test results.



- b. Ask the patient to blow their nose. This helps the nose produce mucus.

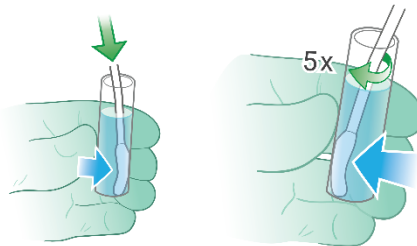


- c. Open the sterile nasal swab and use it to swab the patient's first nostril at a shallow depth of $\frac{1}{2}$ " – $\frac{3}{4}$ ".
- d. Be sure to swab all the way around the inner walls, stretching the nostril and pressing against the inner walls of the nostril for 5 full rotations.
- e. Repeat the swabbing procedure in the patient's other nostril.

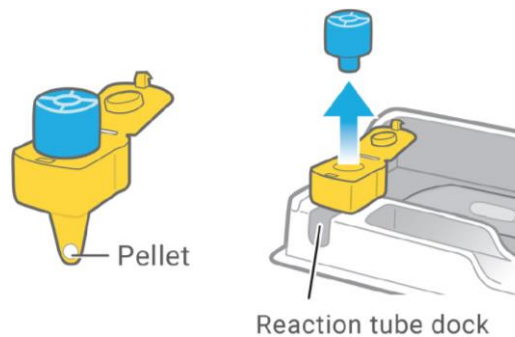


Step 3: Prepare the Sample

- Pick up the buffer tube and insert the swab in the buffer tube.
- Press the swab against the tube's side walls as you rotate the swab.
- Squeeze each part of the sponge to get liquid moving in and out of the pores, pumping fluid through the pores to rinse out material that is in the swab.
- Do this vigorously at least five times against the bottom and sides of the tube.



- Stir the solution with the swab, mixing it well. **Warning: Failure to mix the swab in the buffer can cause a false negative result.**
- Safely dispose of the swab according to your institution's biological waste policies.
- Remove the reaction tube from its foil pouch. **The test must be initiated within 10 minutes of opening the reaction tube's foil pouch.**
- Use the tray to avoid possible cross-contamination.
- The reaction tube cap may have come off inside the sealed foil pouch. If so, leave it off. Re-capping the reaction tube could introduce contamination.
- Make sure there is a pellet in the bottom of the reaction tube.
- If not, flick or tap the bottom of the tube to make the pellet fall to the bottom.
- Place the reaction tube in the dock in the kit tray and remove the cap.



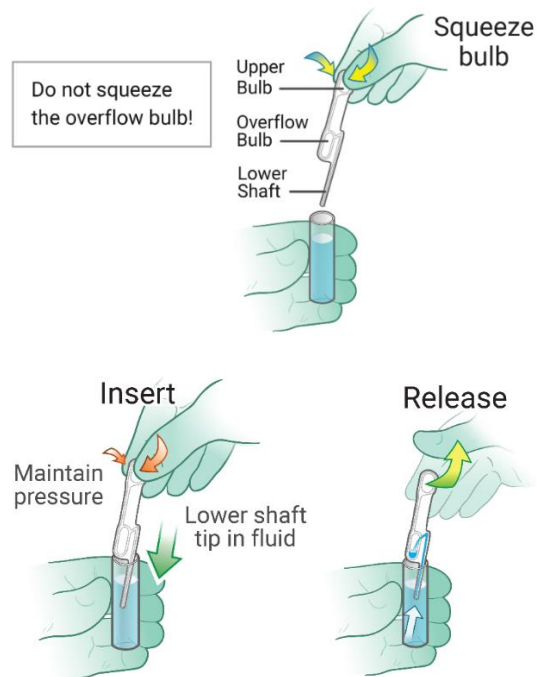
Step 4: Transfer the Sample



This is the most important step. Getting the right amount of fluid is critical to getting an accurate result.

a. **The transfer pipette is designed to transfer a specific amount of fluid. You should only transfer fluid a single time to get the right amount. In one continuous motion, squeeze the bulb, insert the pipette, and release the bulb.**

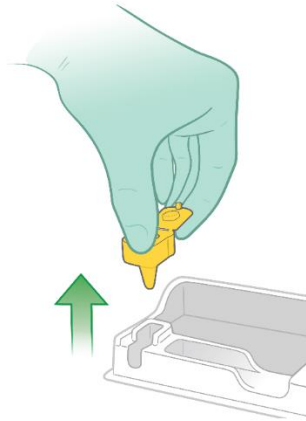
- **Squeeze the upper bulb to expel air.**
- Maintain pressure on the upper bulb while inserting the lower shaft tip in the buffer tube. Be sure that the shaft tip is in the buffer fluid before releasing the upper bulb.
- Release the upper bulb to draw in fluid.
- Do not squeeze the bulb again.
- Lift the pipette out of the buffer tube.



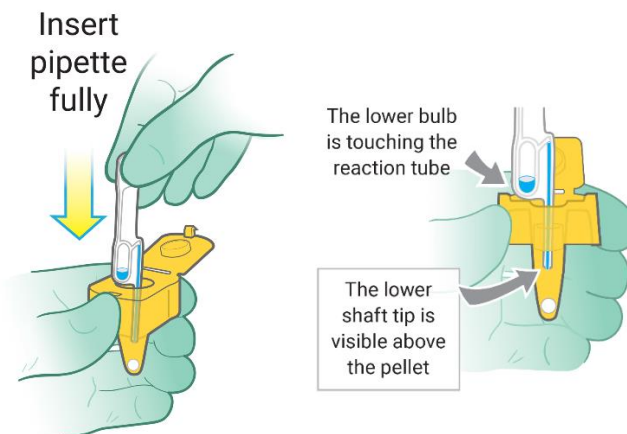
- The lower shaft should be full of liquid with no bubbles, and some fluid should be present in the overflow bulb.



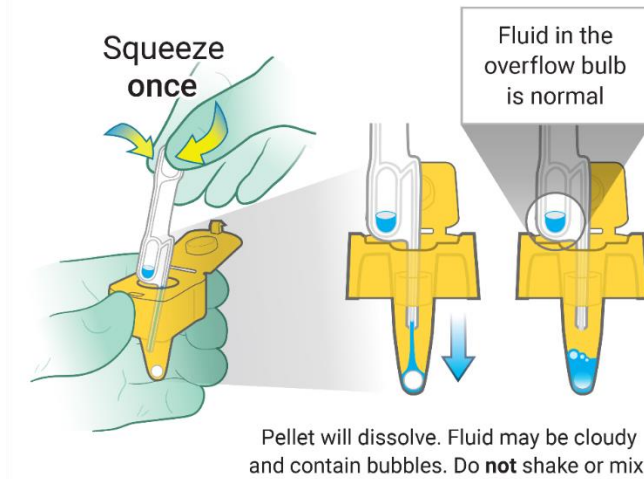
- Make sure you **remove the reaction tube cap**.
- Pick up the reaction tube and place the lower shaft of the pipette into the reaction tube.



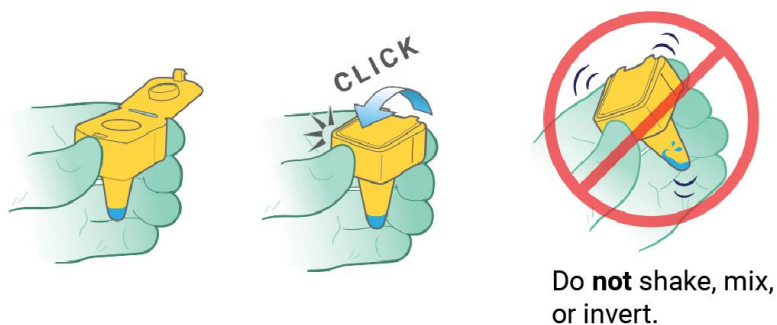
- Fully insert the pipette**, pushing down all the way until the overflow bulb rests on the edge of the reaction tube and the shaft tip is visible above the pellet.



- e. Firmly squeeze the upper bulb once, releasing the solution that is in the shaft. **None of the fluid will come out of the overflow bulb of the pipette.** It is normal for extra fluid to remain in the overflow bulb. **Do not squeeze** the overflow bulb of the pipette or reuse any leftover solution.



- f. Close the lid of the reaction tube. You will hear a soft “click” which means the lid is securely fastened. **Warning: Do not shake, mix, or invert the tube.**



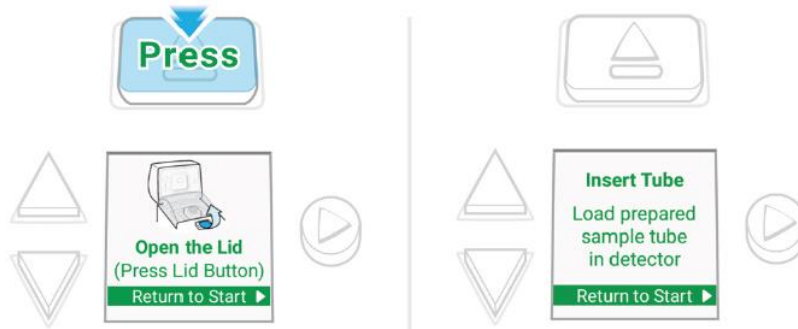
- g. The buffer tube and transfer pipette cannot be reused—put them in the trash. All used test materials could be capable of transmitting infectious agents. Throw them away according to your institution’s biological waste policies.

Note: When using the pipette, none of the fluid will be dispensed from the pipette’s lower bulb overflow area, and additional solution will remain leftover in the buffer tube. **This is expected. Do not squeeze the lower bulb of the pipette or reuse any leftover solution from either implement. The solution transfer is a one-time process.**

Step 5: Run the Test

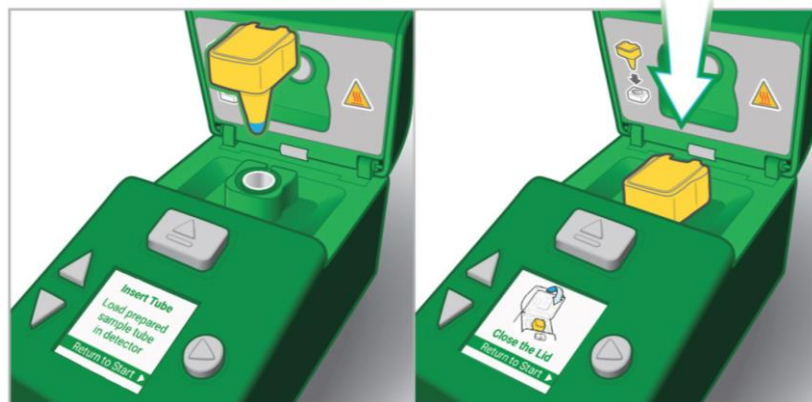
Select “Next” (see **Step 1: Set Up the Test**). The detector should be displaying the Open the Lid screen.

a. Open the lid by pressing the lid button. The detector is now ready to receive the reaction tube.



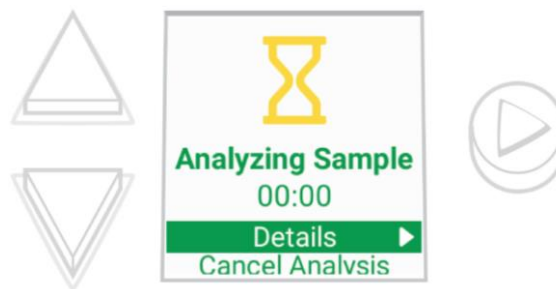
b. Gently place the reaction tube into the tube port (it only fits one way).

c. Close the lid. Sample analysis will begin automatically.

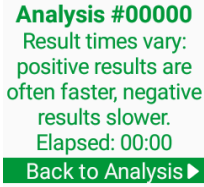


Notes:

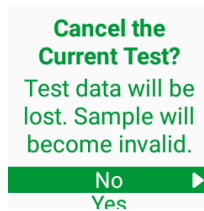
- Do not unplug or disturb the detector until the results are displayed on the screen.
- The detector displays an hourglass icon and timer. This means the sample is being analyzed.



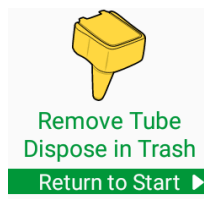
- Test result times vary.
- All COVID-19 positive and negative results may be reported to public health authorities either through the detector's QR code reporting feature or your institution's own procedures.
- If you select Details while the test is running you will see the screen that explains that test results often take about 30 minutes to process, but they can be faster. Do not disturb the Detector until a result has appeared on the Screen.



- The Analysis Details screen shows the analysis run number currently in progress. Analysis run numbers, along with the device serial number give each sample a unique identifier. Each detector assigns analysis run numbers in sequential order and never repeats, so if a user notes down the serial number of the detector and the run number, they will be able to refer back to the data produced for a specific sample. This, along with scanning the QR code, is important when troubleshooting samples.
- If you select Cancel Analysis while the test is running, an option to confirm cancellation and accept the loss of test data and the validity of the sample will be given:



- Selecting “No” here returns the detector to the Analyzing Sample screen with the running timer—thus continuing the sample analysis without interruption—while selecting “Yes” irrevocably terminates the test. The screen will instruct you to remove the reaction tube and discard it. All used test materials could be capable of transmitting infectious agents. Throw them away according to your institution’s biological waste policies.



Step 6: Read Results

When the analysis is finished, the detector displays one of the following four possible results:

NEGATIVE: COVID-19 VIRUS NOT DETECTED

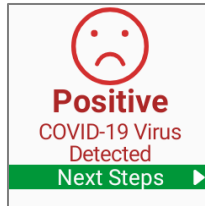
The virus that causes COVID-19 was NOT detected. If the patient has symptoms, a negative result could mean that their illness was caused by something other than the COVID-19 virus.



POSITIVE: COVID-19 VIRUS DETECTED

The virus that causes COVID-19 was detected in the sample.

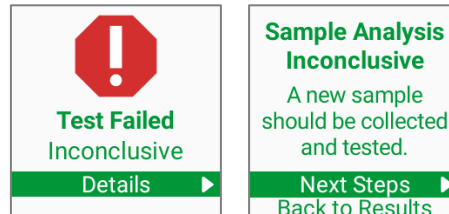
Note: a positive result does not rule out the possibility of co-infection with another pathogen.



TEST FAILED: INCONCLUSIVE

There are no clear results about the sample. The most likely reason for an inconclusive result is that you did not follow the instructions exactly. Please re-read the instructions and begin again with a new test and a fresh sample.

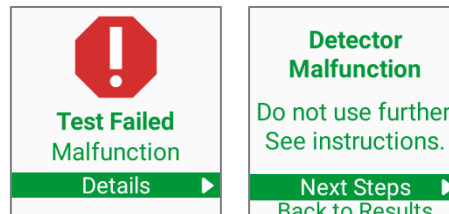
If you repeatedly get inconclusive results, contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com.



TEST FAILED: MALFUNCTION

This means there is a problem with the detector and no clear conclusions can be made about the sample. Do not use this detector anymore.

Contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com.



Step 7: Report Results

- Press the "Select" button to choose Next Steps and generate a QR code.
- Scan this code to notify public health authorities of the result through the Anavasi Diagnostics secure website.



Notes:

- Test results can be reported to public health authorities by your institution's normal reporting procedures or by using the QR code to link to the Anavasi Diagnostics secure reporting system.
- When using the QR code that is displayed by the detector, the operator can scan the screen with a smart phone or with a barcode reader connected to a host computer. Scanning the QR code provides the Anavasi Diagnostics secure reporting website with access to the encoded test result along with the device's unique identifier.
- Patient information will be entered in either case by healthcare providers. No patient information is ever stored in The AscencioDx Molecular Detector.

Step 8: Complete the Test

After you have recorded the test results, follow the instructions on the screen to remove the reaction tube:

- a. Open the lid.
- b. Remove the reaction tube and throw it away.
- c. Close the lid. The detector automatically displays the Main screen.
- d. You can now start a new test or adjust settings.



All used test kit materials could be capable of transmitting infectious agents. Throw them away according to your institution's biological waste policies.

Notes:

- Leave the detector plugged in. Unplugging the detector more than necessary will introduce wear on the power connections. If a new test is not initiated, the detector will enter Sleep Mode—a low-power state from which it can be awakened by pressing any button.
- Dispose of the remaining test materials in accordance with your institution's biological waste disposal policies.
- Because the reaction tube is sealed, there is no requirement to clean the detector between tests. Periodic cleaning instructions can be found in the next section.

Operating and Maintaining The AscencioDx Molecular Detector

Main Screen:

The detector will automatically power up after it is plugged into an appropriate power outlet. The successful start screen, called the Main Screen, will display The AscencioDx logo and options to Start New Test or adjust Settings.



Navigating Menu Screens:

The area at the bottom of each screen in any given display is the menu. The menu is navigated by the up and down buttons to the left of the screen and the select button to the right of the screen.

There is a thin line above the menu text lines that permanently separates the menu from the area above. As the menu is navigated with the up and down buttons, the menu scrolls so that the selected item is fully visible. If the menu is not empty, then exactly one menu item is always highlighted. The selected item is illuminated by a green strip on the Screen and contains a right-facing, triangular 'play' icon at its right side. This is the item that will be actuated if the select button is pressed.

Settings:

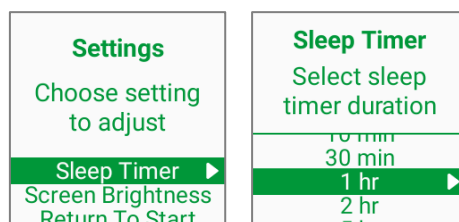
There are two settings that can be adjusted on the detector by selecting the settings option from the main screen: Sleep Timer and Screen Brightness.

Sleep Timer:

Whenever the detector is not analyzing a sample or responding to user inputs, an internal timer is activated to track the amount of time since the last user input. If the timer expires, the detector enters sleep mode, a low-power state.

When in sleep mode, the screen is dimmed by a reduction in the backlighting and the internal heating system cools; but the detector remains fully responsive to potential user inputs. Sleep mode is exited whenever there is a new user input—e.g., when any button on the detector is pressed, the lid is opened or closed, or a reaction tube is removed from or inserted into the device. From sleep mode, any such input will only wake the detector. To execute a new action, the user must further navigate through the options that appear on the screen.

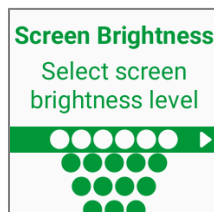
The duration of the sleep timer, which governs sleep mode, can be set by the user through the settings by selecting the sleep timer option.



The possible durations available are: 30 s(econds), 1 min(ute), 2 min, 5 min, 10 min, 30 min, 1 hr (hour), 2 hr, 5 hr, and Off. The default sleep timer duration is 1 hr. On entering this setting, the current sleep timer duration is given as the selected option. To select a new setting, simply use the up and down buttons to navigate to the preferred option and then press the select button, saving the new sleep timer setting.

Screen Brightness:

When Screen Brightness is selected under settings, a screen depicting a range of brightness levels will appear.



There are six total levels of screen brightness available, represented by six (maximum brightness) to one (minimum brightness) colored circles. While the default is set to maximum brightness, the screen

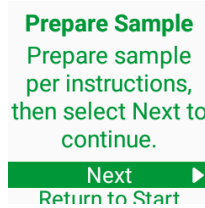
brightness will instantly adjust based on the level selected by the user through the up and down buttons. Once a preferred level of brightness has been selected, it can be set for the detector by pressing the select button.

Detector Warming:

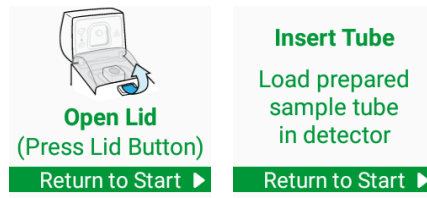
After being plugged in or returning from sleep mode, the detector must go through a warmup process and reach a baseline temperature before it is ready to start a new test. This process takes less than a minute and is depicted by the Detector Warming screen.



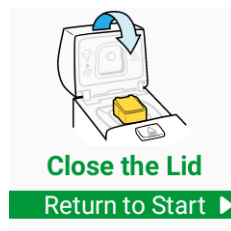
When the detector senses that the internal well block heater is within tolerance of its setpoint, it will transition to the Prepare Sample screen. Select Next to advance to next screen.



After the Prepare Sample screen, the detector will transition to the Open Lid screen. Press the lid button after you have prepared the sample and the detector will transition to the Insert Tube screen—at which point the reaction tube can be inserted.

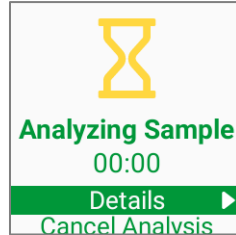


If the reaction tube is inserted, the detector will indicate the lid should be closed. Once the lid is closed, sample analysis will automatically begin.

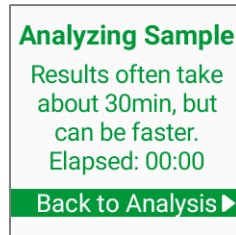


Analyzing Sample:

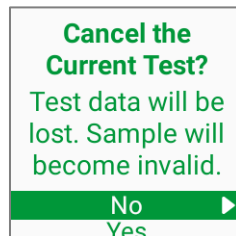
When the detector is analyzing a sample, the screen shows a mm:ss counter that *counts up* from the time at which sample analysis started. The timer counts up rather than down because the duration of the test will vary from sample to sample. Most tests will be completed in approximately 30 minutes.



The Menu in the analyzing sample screen contains two items: Details and Cancel Analysis. Selecting the details option will display the following screen, which provides basic information regarding the duration range for processing a result.



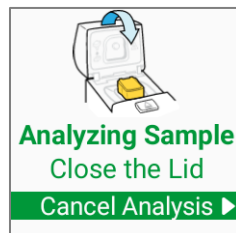
Selecting Cancel Analysis transitions to this confirmation screen, with the option to select Yes or No for finalizing the test cancellation.



Allowing the sample analysis to resume will let the Detector continue to run until it reaches one of the four possible analysis results: **COVID-19 Positive**, **COVID-19 Negative**, **Test Failed: Inconclusive**, and **Test Failed: Malfunction**.


Problems with Sample Analysis:

If the lid should inadvertently or deliberately be open during sample analysis, the detector will show this screen:



When the lid is opened during analysis, the detector automatically initiates a timer to track how long the lid has been open. Table 8 represents the possible outcomes:

Table 8: Lid Opens During Sample Analysis

Event	New Detector Screen State	Test Outcome	Next Action
Lid Closed	 Analyzing Sample 00:00 Details ► Cancel Analysis	Sample analysis is resumed.	Wait until sample analysis is complete.
Tube Removed	Analysis Canceled Tube removed, sample is invalid. Start a new test with fresh sample Return to Start ►	Sample analysis is canceled, and sample is now invalid.	Return to the main screen and start a new test if desired.
Timer Expired	Analysis Canceled Lid open too long, sample is invalid. Start a new test with fresh sample Remove Tube ►	Sample analysis is canceled, and sample is now invalid.	Remove and discard the reaction tube. Close the lid. Return to the main screen and start a new test if desired.

Maintenance & Cleaning:

The AscencioDx Molecular Detector has no power button, and it is recommended that it be left plugged in continuously to reduce wear on the power connections. The detector will go into a low-power sleep mode whenever it is not in use beyond the time set in the sleep mode timer. The detector can be brought back to full power from sleep mode at any time by pressing any button or opening/closing the lid.

The sealed reaction tube used in the detector and proper handling procedures help safeguard the detector from contamination, it is still recommended to clean the surface of the device (including the area beneath the lid) at the end of each day of testing with an antiseptic wipe. Anavasi Diagnostics recommends running the external QC controls on a regular schedule (as discussed in the Quality Control section) to help ensure that the detector continues to work properly.



Important: To reduce the risk of electrical shock and prevent damage to the Detector, unplug it before cleaning and never spray or soak it in any liquids.

Troubleshooting:

Problems with the Test or Test Process:

If any parts of the COVID-19 Test are damaged, leaking, missing, or the test itself is beyond its expiration date, the components should not be used.


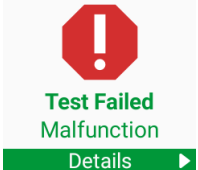
When using the transfer pipette to transfer the sample-buffer solution from the buffer tube to the reaction tube, please follow directions carefully and note that liquid will remain in the overflow area of the lower bulb. Only the liquid drawn into the shaft of the pipette—which has a fixed volume at 40 µL—is needed to run the test. Adding more or less sample-buffer solution to the reaction tube could impair the accuracy of the test results.

Problems with the Detector:

If the detector fails to turn on after being plugged into an appropriate electrical outlet via the 12-volt power adapter, first check the connections to make sure they are tight. If this does not solve the problem, plug the detector into a different outlet. Should the detector still fail to turn on, contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com to report the issue.

Table 9 lists the possible error messages that might appear on the detector during operation, a description of that state, and the actions that should be taken:

Table 9: Error Messages on Detector

Error	Screen	Description	Action
Lid Open Too Long	<p>Analysis Canceled Lid open too long, sample is invalid. Start a new test with fresh sample</p> <p>Remove Tube ▶</p>	If the detector lid is either inadvertently or deliberately opened during sample analysis for too long (as determined by a timer in the device), the sample analysis will be automatically canceled, and the sample invalidated.	Remove and discard reaction tube, close the lid, move through prompts to start a new test. Then collect a fresh sample with a new test and run another test.
Tube Removed	<p>Analysis Canceled Tube removed, sample is invalid. Start a new test with fresh sample</p> <p>Return to Start ▶</p>	If at any point during sample analysis, the reaction tube is removed or becomes dislodged from the tube port, the sample analysis will be automatically canceled, and the sample invalidated.	Remove and discard reaction tube, close the lid, move through prompts to start a new test. Then collect a fresh sample with a new test and run another test.
Test Failed: Inconclusive		No definitive conclusions can be made about the sample. An inconclusive test may have occurred if the sample could not be read by the detector because of interfering substances in the sample, an expired or damaged test, a problem with the detector, incorrect procedures by the operator, or some other problem.	First try conducting another test with a fresh sample from a new test. If problems persist, contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com .
Test Failed: Malfunction		No definitive conclusions can be made about the sample as a result of a detector error.	Immediately discontinue use of the detector and contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at www.anavasidx.com .

Safety Information:

The AscencioDx Molecular Detector is designed to provide the highest levels of safety and reliability, but it must be used in accordance with the specifications of these Instructions for Use (IFU). **Failure to follow these procedures may compromise the detector and/or pose a health risk to others.**



To reduce the risk of electrical shock:

- Unplug the detector prior to cleaning.
- Do not immerse, spray, or otherwise expose the detector to liquids.
- Do not attempt to disassemble the detector.
- Plug the detector into a safe and approved electrical outlet using the provided 12-volt power adapter.



To reduce the risk of burns to skin:

- During or after a test, use caution when touching any area on, around, or beneath the detector's lid, which could become hot.
- Do not attempt to remove the reaction tube until instructed by the guidance on the detector's screen. A brief cool-down period must first take place before the reaction tube is completely safe to handle.

To reduce the risk of erroneous result:

- Ensure operators are thoroughly familiar with all instructional documentation for The AscencioDx COVID-19 Test and The AscencioDx Molecular Detector.
- Discontinue use of the detector whenever a malfunction or other uncorrectable error is reported.
- Use only undamaged AscencioDx COVID-19 Tests that have not passed their expiration date.

To reduce the risk of environmental contamination:

- Clean the detector according to the guidelines detailed in this Instructions for Use document.
- Clean the detector prior to return or disposal.
- Only dispose of the detector according to applicable federal, state, and local requirements governing electronic medical waste. If unsure of these requirements, contact a certified waste expert for disposal information or contact Anavasi Diagnostics Customer Support for further guidance.

To reduce the risk of biohazard:

- Dispose of used samples and test materials in accordance with federal, state, and local requirements.
- Treat all samples and used test materials as potential biohazards.
- Clean the detector according to the guidelines detailed in this Instructions for Use document.
- Dispose of the detector according to applicable federal, state, and local requirements governing electronic medical waste. If unsure of these requirements, contact a certified waste expert for disposal information or contact Anavasi Diagnostics Customer Support for further guidance.
- Use new nitrile, latex, or equivalent gloves when handling samples or test materials and while operating the detector.

Important: Failure to follow any of the preceding safety guidelines will invalidate the product's warranty.

Technical Information and Specifications of The AscencioDx Molecular Detector

The AscencioDx Molecular Detector works by heating and illuminating the sample contained in the reaction tube to amplify the target COVID-19 viral RNA and then detecting the resultant fluorescence signals. Once a signal meets a certain threshold, the detector displays the test results on its screen.

Table 10: Technical Specifications of The AscencioDx Molecular Detector

Overall Device Dimensions	112 x 64 x 58 mm
Total Device Weight	132 grams
Device Power Supply	12VDC 1A
Device Display Screen	1.3", 240px x 240px Color TFT LCD Screen
Operating Humidity Range	5% to 90% RH non-condensing
Operating Temperature Range	15° to 40° C

Warranty and Disposal

The AscencioDx Molecular Detector is backed by a **1-year limited warranty** from Anavasi Diagnostics. Should the device fail within this time because of a defect with its materials or manufacture, Anavasi Diagnostics agrees to replace the defective part(s) or offer a refund if the device is unsalvageable. This warranty only covers the original owner of the device and only those defects which can reasonably be proven to be the result of manufacturer error. If a device fails or is not working properly, please contact Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274). Customer support may also be reached by going to www.anavasidx.com.

The AscencioDx Molecular Detector is an electronic medical device which may be contaminated with infectious substances after use. It should be cleaned according to the procedures described in this document before careful disposal. Disposal of the device should follow all federal, state, and local regulations for electronic and biological waste.

PERFORMANCE EVALUATION

Clinical Evaluation

The ability of untrained operators to successfully perform The AscencioDx COVID-19 Test in a POC setting was evaluated in a multi-center study. Patient samples were prospectively collected and tested in four sites in the U.S. Enrolled subjects who provided informed consent (or informed assent, as appropriate) were individuals ≥ 2 years old who were suspected of COVID-19 by their healthcare providers due to symptoms associated with COVID-19 or recent exposure. The IRB-approved study protocol stipulated that subjects were invited to enroll after they received the standard-of-care COVID-19 test provided by the clinical study site. After informed consent and enrollment, two study-specific anterior nasal swabs were taken from each participant: one each for the subject test and the comparator (reference) test (a highly sensitive EUA-authorized RT-PCR test). The anterior nasal swabs were collected using the cross-over approach so that each swab was the “first swab” in one of the subject’s nostrils. Subjects were enrolled beginning October 25, 2022, and enrollment concluded on November 22, 2022. A total of 225 participants who were qualified to participate in the study enrolled at the four point of care sites (e.g., urgent care facilities). Out of those 225 participants, 216 samples were included in the final dataset. Six samples were excluded due to inconclusive subject test results, and two other samples were excluded due to subject test device malfunction. One participant enrolled but failed screening following informed consent. The positive percent agreement (PPA) for The AscencioDx COVID-19 Test was 89.2% (95% CI = 75.3% to 95.7%) and negative percent agreement (NPA) was 96.1% (95% CI = 92.1% to 98.1%) (Table 11). False negative results were on samples with low virus levels near or below the LoD of the reference PCR test.

Table 11. The AscencioDx COVID-19 Test Clinical Performance

	High Sensitivity Molecular FDA EUA-Authorized Test		
	Positive	Negative	Total
The AscencioDx COVID-19 Test Positive	33	7**	40
The AscencioDx COVID-19 Test Negative	4*	172	176

Total	37	179	216
Positive Percent Agreement (PPA) = 33/37 = 89.2% (95% CI = 75.3% to 95.7%)			
Negative Percent Agreement (NPA) = 172/179 = 96.1% (95% CI = 92.1% to 98.1%)			

*One false negative specimen gave a “presumptive positive” result on the reference test (negative for SARS-CoV-2 but positive for the pan-Sarbecovirus at Ct=36.06) and was not detected on a second highly sensitive PCR test in agreement with The AscencioDx COVID-19 Test result. The remaining three false negative specimens had very low viral loads as indicated by their Ct values near or below the reference test LoD.

**All 7 specimens tested negative on a second EUA-authorized molecular test.

Performance around the Limit of Detection (LoD)

To demonstrate the performance of The AscencioDx COVID-19 Test around the limit of detection (LoD) when conducted by minimally trained operators, low positive (~2x LoD) and negative swab samples were tested at the point of care testing sites (e.g., urgent care facilities) by the same test operators running the clinical study described above. At least 3 positive and 3 negative swab samples were presented to each test operator in a blinded fashion. The results are summarized below.

Table 12. Performance Around the LoD Study Testing Results

Target Concentration	Number Concordant/ Number Tested	% Agreement [95% CI]
Positive (2xLoD)	40/40*	100% (91.2% - 100%)
Negative	39/40	97.5% (87.1% - 99.6%)

*One contrived positive sample had a result of “malfunction” and was replaced with a new contrived positive sample.

Analytical Sensitivity (LoD)

LoD was established by preparing a 2-fold dilution series using fifty microliters (50µL) of nasal matrix diluted 1:1 in saline spiked with quantified UV-inactivated SARS-CoV-2 virus (ZeptoMetrix product 0810587UV) and processed according to the Quick Reference Instructions (QRI). The preliminary LoD was the lowest concentration tested that resulted in three out of three positive replicates. Following identification of the preliminary LoD, an additional 20 replicates of the preliminary LoD concentration (2344 copies/swab) and the concentration above the preliminary LoD concentration (4688 copies/swab) were tested. The LoD was confirmed to be 4688 copies/swab (Table 13).

Table 13. LoD Study Results

SARS-CoV-2 Added to Swab (copies/swab)	SARS-CoV-2 Detected/Tested	Detection Rate
4688	3/3	100.0%
2344	3/3	100.0%
1172	1/3	33.33%
4688 (confirmatory)	19/20	95.0%
2344	15/20	75.0%

Analytical Reactivity (Inclusivity)

To reduce likelihood of false negative results due to virus mutations, the assay includes three N gene sub-assays that all report as a single output; a positive test result can be generated by any combination of these three sub-assays. Our determination is that our current primer designs maintain high aggregate coverage across all identified VOI, VOC, VOHC, and VBM groupings, as well as against recently submitted sequences. Anavasi Diagnostics in-house analysis for coverage showed all VBM as of December 1, 2022, and Omicron sub-lineages to have 100% aggregate coverage and a minimum of 98% coverage in aggregate assay when allowing 1 mismatch in primer regions.

Table 14: Anavasi Diagnostics in-house analysis: assay coverage vs total Omicron and Omicron sub lineages

	Lineage and descendants	Aggregate (1 mismatch)*
Omicron BA.1	BA.1	99.98%

Omicron BA.2	BA.2 (including BN.1)	100.00%
Omicron BA.4	BA.4 (including BA.4.6)	100.00%
Omicron BA.5	BA.5 (including BF.7 and BQ.1.1)	99.83%
Omicron XBB	XBB	100.00%
Omicron other	other omicron lineages	100.00%
Total Omicron	Including BA.1, BA.2, BA.4, BA.5, XBB and others	99.99%

Based on 59,468 Complete High Coverage GISAID sequences collected in the USA with 942 sequences excluded for length or quality.

*1 mismatch allowed per primer region for this aggregate coverage column

Table 15: Anavasi Diagnostics in-house analysis: assay coverage vs VBM

	Lineage and descendants	Aggregate (1 mismatch)*
Alpha ¹	B.1.1.7 + Q	100.00%
Beta ²	B.1.351	100.00%
Delta ³	B.1.617.2 + AY	100.00%
Gamma ⁴	P.1	100.00%
Epsilon ⁵	B.1.427 + B.1.429	100.00%
Eta ⁶	B.1.525	100.00%
Kappa ⁷	B.1.617.1	100.00%
Iota ⁸	B.1.526	100.00%
Mu ⁹	B.1.621, B.1.621.1	100.00%
Zeta ¹⁰	P.2	100.00%

Based on 64,375 Complete High Coverage GISAID sequences collected with 321 sequences excluded for length or quality.

*1 mismatch allowed per primer region for this aggregate coverage column

¹ Based on 9,551 included Complete High Coverage GISAID sequences collected in the USA on or after 2021-06-17 submitted prior to 2022-12-01 and classified as VBM Alpha.

² Based on 2,076 included Complete High Coverage GISAID sequences collected in the USA submitted prior to 2022-12-01 and classified as VBM Beta.

³ Based on 9,625 included Complete High Coverage GISAID sequences collected in the USA on or after 2021-12-28 submitted prior to 2022-12-01 and classified as VBM Delta.

⁴ Based on 9,818 included Complete High Coverage GISAID sequences collected in the USA on or after 2021-05-08 submitted prior to 2022-12-01 and classified as VBM Gamma.

⁵ Based on 9,537 included Complete High Coverage GISAID sequences collected in the USA on or after 2021-03-25 submitted prior to 2022-12-01 and classified as VBM Epsilon (lineage B.1.427 + B.1.429).

⁶ Based on 2,875 included Complete High Coverage GISAID sequences collected Globally submitted prior to 2022-12-01 and classified as VBM Eta (lineage B.1.525).

⁷ Based on 5,265 included Complete High Coverage GISAID sequences collected Globally submitted prior to 2022-12-01 and classified as VBM Kappa (lineage B.1.617.1).

⁸ Based on 9,922 included Complete High Coverage GISAID sequences collected in the USA on or after 2021-04-14 submitted prior to 2022-12-01 and classified as VBM Iota (lineage B.1.526).

⁹ Based on 2,794 included Complete High Coverage GISAID sequences collected in the USA submitted prior to 2022-12-01 and classified as VBM Mu.

¹⁰ Based on 1,089 included Complete High Coverage GISAID sequences collected in the USA submitted prior to 2022-12-01 and classified as VBM Zeta (lineage P.2).

Analytical Specificity (Cross Reactivity)

In silico analysis

NCBI BLAST was used to evaluate primer sequences and probe sequences for homology with organisms that may be present in a respiratory tract specimen. Primer or probe sequences that showed >80% homology in the three SARS-CoV-2 sub-assays (each with 8 primers), the IAC assay (with 7 primers), or the UDP probes are indicated in Table 14. In all cases, non-specific amplification is not expected because the homology would not be sufficient to create the structural arrangement needed for LAMP amplification. Nevertheless, organisms were wet-tested to confirm no cross-reactivity (Table 16).

Table 16: In Silico Cross-reactivity Analysis (Analytical Specificity)*

Organism/Primer	NC1 primer set >80%	NC5 primer set >80%	NC3 primer set >80%	IAC primer set >80%	UDP Probes >80%
Human [§]	(4/8)	(3/8)	(4/8)	(5/7)	None

Organism/Primer	NC1 primer set >80%	NC5 primer set >80%	NC3 primer set >80%	IAC primer set >80%	UDP Probes >80%
Human coronavirus 229E	None	None	None	None	None
Human coronavirus OC43	None	None	None	None	None
Human coronavirus HKU1	None	None	None	None	None
Human coronavirus NL63	None	None	None	None	None
SARS-CoV-1 [#]	(6/8)	(8/8)	(4/8)	None	None
MERS-coronavirus	None	None	None	None	None
Adenovirus (e.g., C1 Ad. 71) (Adenoviridae, all)	None	None	None	None	None
Human Metapneumovirus (hMPV)	None	None	None	None	None
Parainfluenza virus 1-4 (paraphyletic group)	None	None	None	None	None
Influenza A	None	None	None	None	None
Influenza B	None	None	None	None	None
Enterovirus (e.g., EV68)	None	None	None	None	None
Respiratory syncytial virus	None	None	None	None	None
Rhinovirus	None	None	None	None	None
<i>Chlamydia pneumoniae</i> [§]	None	None	(1/8)	None	None
<i>Haemophilus influenzae</i>	None	None	None	None	None
<i>Legionella pneumophila</i> [§]	None	None	(1/8)	(1/7)	None
<i>Streptococcus pneumoniae</i> [§]	(1/8)	(2/8)	(1/8)	(1/7)	None
<i>Streptococcus pyogenes</i> [§]	None	(1/8)	None	None	None
<i>Bordetella pertussis</i> [§]	None	(1/8)	None	(1/7)	None
<i>Mycoplasma pneumoniae</i>	None	None	None	None	None
<i>Candida albicans</i> [§]	(1/8)	(1/8)	None	(2/7)	None
<i>Pseudomonas aeruginosa</i> [§]	None	None	None	(1/7)	None
<i>Staphylococcus epidermidis</i>	None	None	None	None	None
<i>Streptococcus salivarius</i> [§]	(2/6)	(2/8)	(1/8)	None	None

*Table entries show number of primers with >80% homology/total primers in the sub-assay

[#]Analysis performed using (taxid:228407) for SARS-CoV-2 assays, (taxid:694009 excl 2697049) for IAC, (SARS coronavirus, all) for probes.

[§]Indicated homology is not expected to lead to non-specific amplification. Organisms were tested in The AscencioDx COVID-19 Test and showed no cross-reactivity (Table 15).

Wet-Testing

Potential cross-reactive organisms were tested in negative nasal matrix at the final concentrations in the reaction shown in Table 17 on The AscencioDx COVID-19 Test according to the QRI. The AscencioDx COVID-19 Test showed no cross-reactivity with any organisms tested.

Table 17. Cross-reactivity Wet-Testing Results (Analytical Specificity)

Organism	Final Concentration Tested	Detected / Tested	Cross-Reactive
Human coronavirus 229E	1.00E5 TCID50/mL	0/3	No
Human coronavirus OC43	1.00E5 TCID50/mL	0/3	No
Human coronavirus HKU1	1.00E5 genome copies/mL	0/3	No
Human coronavirus NL63	1.00E5 genome copies/mL	0/3	No
SARS-coronavirus	1.00E5 genome copies/mL	0/3	No
MERS-coronavirus	1.00E5 genome copies/mL	0/3	No
Adenovirus 5, strain Adenoid 75	1.00E5 particles/mL	0/3	No
Human Metapneumovirus (hMPV)	1.00E5 genome copies/mL	0/3	No
Parainfluenza virus 1	1.00E5 TCID50/mL	0/3	No
Parainfluenza virus 2, strain Greer	1.00E5 genome copies/mL	0/3	No
Parainfluenza virus 3, strain C 243	1.00E5 genome copies/mL	0/3	No
Parainfluenza virus 4b, strain CH 19503	1.00E5 TCID50/mL	0/3	No
Influenza A H1N1, A/PR/8/34	1.00E5 genome copies/mL	0/3	No
Influenza A H3N2, A/Hong Kong/8/68	1.00E5 genome copies/mL	0/3	No
Influenza B/Wisconsin/1/2010	1.00E5 genome copies/mL	0/3	No
Enterovirus 71, Strain BrCr	1.00E5 genome copies/mL	0/3	No
Respiratory Syncytial Virus A2	1.00E5 genome copies/mL	0/3	No
Rhinovirus 2, Strain HGP	1.00E5 genome copies/mL	0/3	No
Rhinovirus 17, Strain 33342	1.00E5 genome copies/mL	0/3	No

Organism	Final Concentration Tested	Detected / Tested	Cross-Reactive
<i>Chlamydia pneumoniae</i> , strain AR-39	1.00E6 genome copies/mL	0/3	No
<i>Haemophilus influenzae</i> , strain Type B: Eagan	1.00E6 CFU/mL	0/3	No
<i>Legionella pneumophila</i> , strain Philadelphia	1.00E6 CFU/mL	0/3	No
<i>Mycobacterium tuberculosis</i> , strain H37Rv	1.00E6 genome copies/mL	0/3	No
<i>Streptococcus pneumoniae</i> , Strain Z022, Serotype 19F	1.00E6 CFU/mL	0/3	No
<i>Streptococcus pyogenes</i> , Strain Z018, Serotype M58	1.00E6 CFU/mL	0/3	No
<i>Bordetella pertussis</i>	1.00E6 genome copies/mL	0/3	No
<i>Mycoplasma pneumoniae</i> , Strain M129-B7	1.00E6 genome copies/mL	0/3	No
Pooled human nasal wash	10% v/v	0/3	No
<i>Candida albicans</i> , Strain Z006	1.00E6 genome copies/mL	0/3	No
<i>Pseudomonas aeruginosa</i> , Strain R. Hugh 813	1.00E6 genome copies/mL	0/3	No
<i>Staphylococcus epidermidis</i> , Strain MSSE: HER 1292	1.00E6 CFU/mL	0/3	No
<i>Streptococcus salivarius</i> , Strain Z127	1.00E6 CFU/mL	0/3	No

Interfering Substances

The AscencioDx COVID-19 Test was evaluated in the presence of endogenous and exogenous substances for cross-reactivity and interference with detection of SARS-CoV-2. Substances were diluted in negative nasal matrix to create interference samples. For the cross-reactivity evaluation, interference samples were tested without SARS-CoV-2 virus. For interference testing, SARS-CoV-2 virus was added to create interference samples at a concentration of 3X LoD. The AscencioDx COVID-19 Test did not cross-react with endogenous or exogenous substances, and those substances did not interfere with detection of SARS-CoV-2 (Table 18).

Table 18. Interfering Substances Evaluated

Substance	Concentration on Swab	Results without SARS-CoV-2	Results with SARS-CoV-2	Interfering Result
Human Genomic DNA	10 ng/μL	0/3	3/3	No
Mucin	2% w/v	0/3	3/3	No
Whole Blood	2.5% v/v	0/3	3/3	No
Afrin	20% v/v	0/3	3/3	No
Throat lozenges	20% w/v	0/3	3/3	No
Cough Syrup	5% v/v	0/3	3/3	No
Chewing Tobacco (snuff)	30 μg/mL	0/3	3/3	No
Flonase/ Fluticasone	40 μg/mL	0/3	3/3	No
Homeopathic allergy relief	20% w/v	0/3	3/3	No
Mupirocin	10 mg/mL	0/3	3/3	No
Nasal Allergy Spray (Triamcinolone acetonide)	1.25% v/v	0/3	3/3	No
NeilMed Nasogel	1.25% v/v	0/3	3/3	No
Neo-Synephrine	20% v/v	0/3	3/3	No
Saline Spray	20% v/v	0/3	3/3	No
Zicam	15% v/v	0/3	3/3	No

TECHNICAL ASSISTANCE

If you have any questions regarding the use of these products or if you want to report a problem with the test system, please call Anavasi Diagnostics Customer Support at 1-888-ANAVASI (1-888-262-8274). Customer Support can also be reached by going to www.anavasidx.com.


















 Manufactured for Anavasi Diagnostics • 15305 NE 95th St., Redmond, WA 98052 • www.anavasidx.com

TABLE OF SYMBOLS USED ON PACKAGING AND INSERTS

Symbol	Symbol Description
	Manufacturer
	Catalog number
	Serial number
	Batch code
	Use by date
	In vitro diagnostic medical device
	Consult instructions for use
	Caution: Read all warnings and precautions in instructions for use
	Test storage temperature range
	Keep dry
	Caution: Hot surface
	Do not reuse
	Prescription only
	Do not use if package/seal has been broken
	Keep out of sunlight
	Total number of tests that can be performed with IVD device