

**PART ONE: Device Set Up and  
External Controls**

For use under Emergency Use Authorization (EUA) only

**IMPORTANT:**

This document does not include the complete Instructions for using The AscencioDx® COVID-19 Test and The AscencioDx Molecular Detector. The complete Instructions for Use (IFU) can be found online at [www.anavasidx.com/documentation](http://www.anavasidx.com/documentation). The Fact Sheet for Healthcare Providers and the Fact Sheet for Patients can also be found at [www.anavasidx.com/documentation](http://www.anavasidx.com/documentation).

**Caution: The AscencioDx COVID-19 Test reaction tube must be kept in its sealed foil pouch until opened for immediate testing and may be open for a maximum of 10 minutes prior to initiating testing on The AscencioDx Molecular Detector.**

Performing the assay outside the time and temperature ranges provided may produce invalid results. Assays not performed within the established time and temperature ranges must be repeated.

**Caution:** Use Standard Precautions and treat all patient samples and used test materials as potentially infectious. Personal protective equipment (PPE), including lab coats, masks, eye protection, and new gloves should be worn at all times when performing patient tests. Disinfect work surfaces and change gloves before each new sample run. Handle and dispose of all used test materials and unused reagents according to your institution’s safety guidelines for hazardous materials, in compliance with applicable government regulations.

Contact Anavasi Diagnostics® Customer Support at 1-888-ANAVASI (1-888-262-8274) if you need a free printed copy or technical support to access the IFU and other documents that are available online. Customer Support may also be reached on the web at [www.anavasidx.com](http://www.anavasidx.com).

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.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.



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15305 NE 95th St. • Redmond, WA 98052  
7005191 QRI 2023-02-08 Rev F Part 1 of 2 Parts  
All prior versions of this document should be discarded.



Please read all instructions carefully before you begin.

**List of Required Materials Needed  
for Running External Controls**

- 1 AscencioDx Molecular Detector
- 1 12-volt power adapter with cable
- 1 Quick Reference Instructions (QRI)
- 1 AscencioDx COVID-19 Test, containing: 1 kit tray, 1 nasal swab, 1 buffer tube, 1 reaction tube in foil pouch, and 1 transfer pipette
- If running positive quality control (QC), test the ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (6 x 1.0 mL), Catalog No. NATSARS (COV2)-ERC1-IVD. This item is available separately. To order, contact ZeptoMetrix either online at [www.zeptometrix.com](http://www.zeptometrix.com) or by telephone at (800) 274-5487. ZeptoMetrix customer service can be reached at [zepto.customerservice@antylia.com](mailto:zepto.customerservice@antylia.com).

**THINGS YOU NEED TO KNOW TO  
BE SUCCESSFUL**

**Do:**

- ✓ **Run negative and positive controls at recommended times (see Quality Control Procedures). Always run negative control first.**
- ✓ Start a new test by pressing the “Select” button.
- ✓ Allow the detector to warm up before starting a test.
- ✓ Run the test within 10 minutes of opening the foil pouch. Only open the foil pouch right after you prepare the sample.
- ✓ When running positive QC, agitate the swab vigorously in the buffer tube to maximize release of sample into the buffer.
- ✓ Pay careful attention to Step 4—getting the correct volume of fluid into the reaction tube is important.
- ✓ Always dispose of used test materials. They could be capable of transmitting infectious agents. Throw them away according to your institution’s biological waste policies.

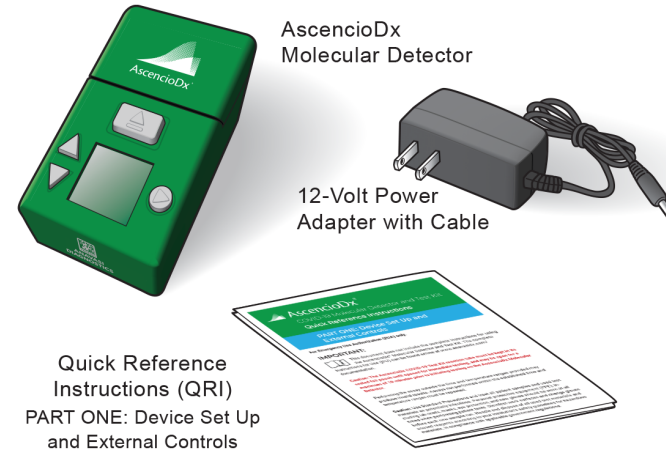
**Don’t:**

- ✗ Do not forget to add buffer fluid to the reaction tube, even when you run controls.
- ✗ Do not run the test if you’ve waited more than 10 minutes after removing the reaction tube from its foil pouch. You need to get a new COVID-19 Test and start over with a fresh sample.
- ✗ Do not squeeze the overflow (lower) bulb of the pipette.
- ✗ Do not pipette solution from the buffer tube into the reaction tube more than once.
- ✗ Do not reuse any leftover buffer solution.
- ✗ Do not unplug or disturb the detector while running a test until it displays a result on the screen.
- ✗ Do not remove the reaction tube from the detector until after you generate and scan a QR code. (After the detector displays your test result, you must press the select button to choose Next Steps and generate a QR code.) If the QR code screen is skipped, you will not be able to return to the QR code.

**Start Here**

Unpack the AscencioDx Molecular Detector

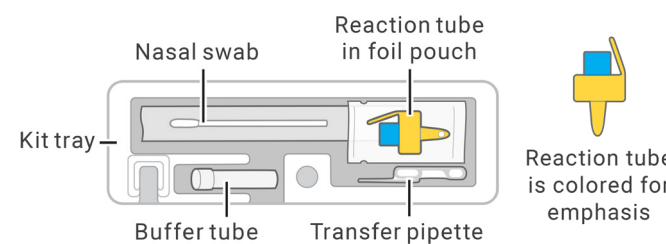
- a. Carefully unpack the box and make sure it contains the following:
  - 1 AscencioDx Molecular Detector
  - 1 12-volt power adapter with cable
  - 1 Quick Reference Instructions (QRI) PART ONE: Device Set Up and External Controls



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

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 where the detector will not be disturbed.

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 latex or nitrile gloves.

**Quality Control Procedures**



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. If you do not receive the expected results, please **re-read the instructions** and repeat the QC using a new test.

If the quality control failure repeats, **do not test patient samples**. Stop using the device and contact Anavasi Customer Support at **1-888-ANAVASI (1-888-262-8274)** or on the web at [www.anavasidx.com](http://www.anavasidx.com). All samples that were run after the last successful control test should be invalidated.

Anavasi recommends that you run a negative and positive control at these times:

- 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 is **Step 2: Prepare the Control Swab**.

- For negative control, **do not** collect any sample during **Step 2: Prepare the Control Swab**. Use the clean swab from the test as your negative control.
- For positive control, use a special External Run Control tube kept in refrigeration for **Step 2: Prepare the Control Swab**. Test the ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (6 x 1.0 mL), Catalog No. NATSARS (COV2)-ERC1-IVD. This item is available separately. To order, contact ZeptoMetrix either online at [www.zeptometrix.com](http://www.zeptometrix.com) or by telephone at (800) 274-5487. ZeptoMetrix customer service can be reached at [zepto.customerservice@antylia.com](mailto:zepto.customerservice@antylia.com).

**Note**

**Always run the negative control first, before the positive control. This helps avoid contamination.**

**Negative Control**

Successfully running the negative control confirms that the detector is operating correctly to detect the absence of the virus that causes COVID-19.

Using a new test, perform **Step 1: Set up the QC Test** through **Step 8: Complete the Test**, except **do not** collect any sample during **Step 2: Prepare the Control Swab**. 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**.

If the test does not produce a **negative** result, the QC has failed. Re-read the QRI and try again with a new test.

**Positive Control**

Successfully running the positive control confirms that the detector is operating correctly to detect the presence of the virus that causes COVID-19.

Test the ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Control (6 x 1.0 mL), Catalog No. NATSARS (COV2)-ERC1-IVD (estimated concentration of 6,250 copies/swab when used as directed as a positive control). This item is available separately. To order, contact ZeptoMetrix either online at [www.zeptometrix.com](http://www.zeptometrix.com) or by telephone at (800) 274-5487. ZeptoMetrix customer service can be reached at [zepto.customerservice@antylia.com](mailto:zepto.customerservice@antylia.com).

**Notes**

- The positive control tube contains enough fluid for 4 positive control tests.
- The positive control must be refrigerated (36–46°F / 2–8°C) when not in use.
- Do not use after the expiration date on the label.
- If the test does not produce a positive result, the QC has failed. Re-read the QRI and try again with a new QC sample and a new test. If the positive control fails a second time, contact Anavasi Customer Support at 1-888-ANAVASI (1-888-262-8274).

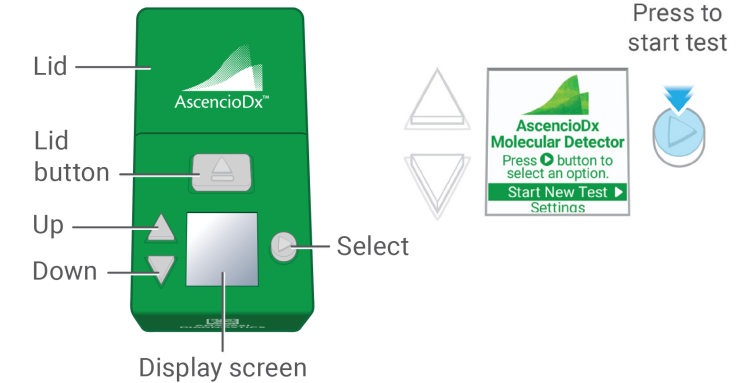
**Instructions**

**1 Set up the QC Test**



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

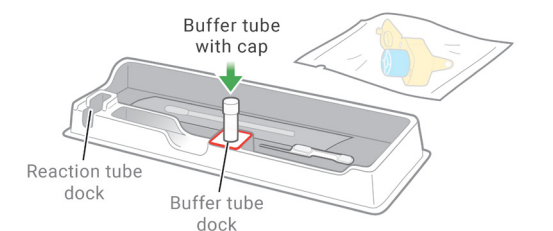
- a. Press the “Select” button to start a new test. (To navigate the screen, use the up and down buttons. To learn more about the settings, refer to the IFU.)



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

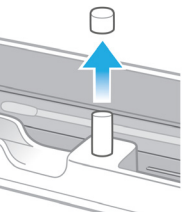


- c. Place the buffer tube in the dock in the kit tray.
- d. Take the transfer pipette out of its bag and place it in the tray.



**2 Prepare the Control Swab**

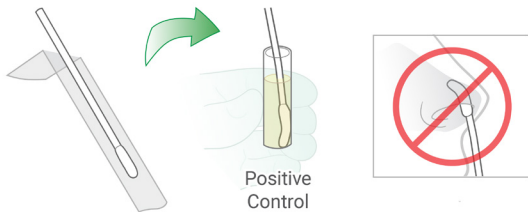
When you are ready to prepare the QC swab, **remove the cap from the buffer tube**.



**For negative QC:**

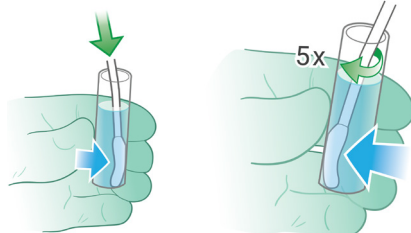
**Do not** collect any sample. Do not insert a swab into nostrils when running the negative control. You will use the clean swab from the test without any nasal sample as the negative control during **Step 3: Prepare the QC Sample**.

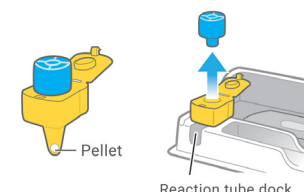
#### For Positive QC:

- 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 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.

### 3 Prepare the QC Sample

- Pick up the buffer tube and insert the negative or positive QC swab into 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.

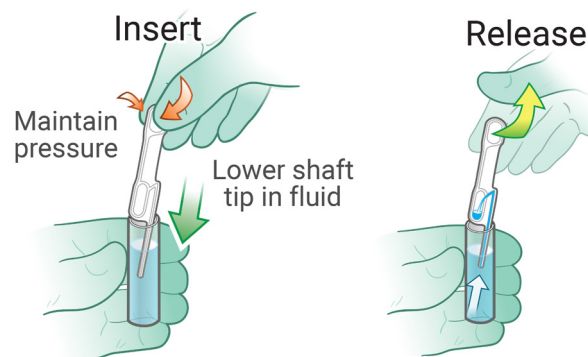
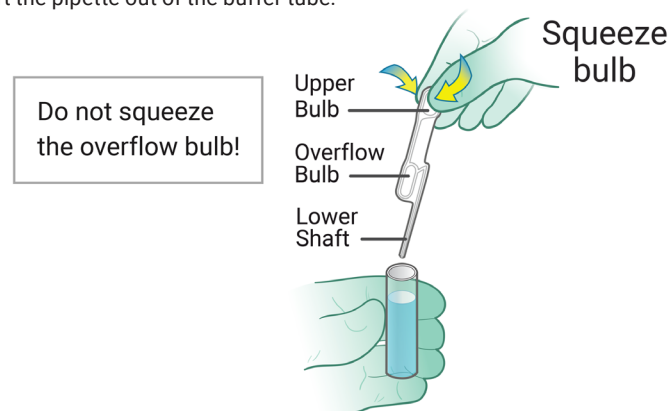


- Stir the solution with the swab, mixing it well.  
**Warning:** Failure to stir the solution could cause a false negative result.
- Safely dispose of the swab according to your institution's biological waste policies.
- Remove the reaction tube from its foil pouch. **The test must be initiated within 10 minutes of opening the 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 until you're ready to use it. Re-capping the reaction tube could introduce contamination.
- Make sure that there is a pellet in the bottom of the reaction tube.
- If not, flick or tap the bottom of tube to make the pellet fall to the bottom.
- Place the reaction tube in the dock in the kit tray and remove the cap.

### 4 Transfer the QC Sample

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

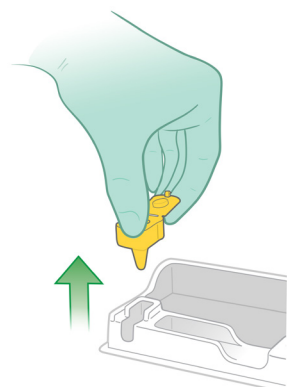
- The transfer pipette is designed to transfer a specific amount of fluid. You should only transfer fluid a single time to get the right amount. In one continuous motion, squeeze the bulb, insert the pipette and release the bulb.**
  - Squeeze the upper bulb to expel air.
  - Maintain pressure on the 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.



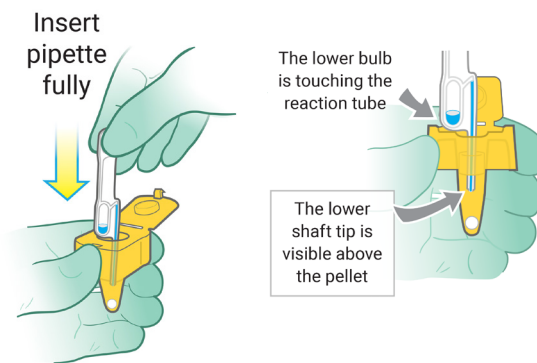
- The lower shaft should be full of liquid with no bubbles, and some fluid should be present in the overflow bulb.



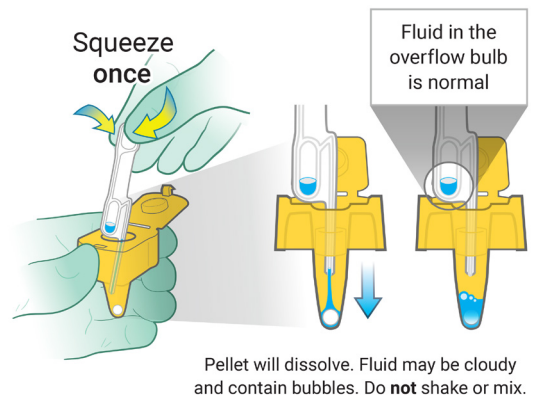
- Make sure you **removed the reaction tube cap.**
- Pick up the reaction tube and place the lower shaft of the pipette into the reaction tube.



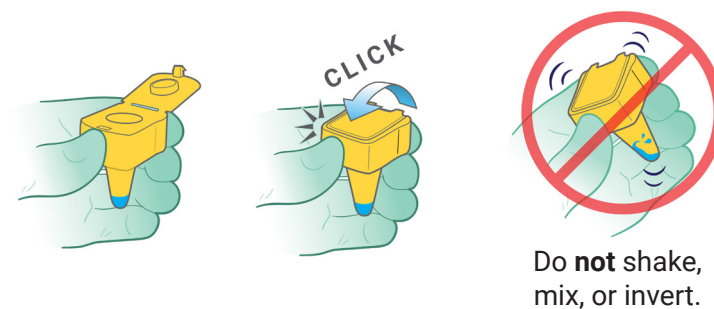
- Fully insert the pipette**, pushing down all the way until the overflow bulb rests on the edge of the reaction tube and the shaft tip is visible above the pellet.



- 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 solution to remain in the overflow bulb. **Do not squeeze the overflow bulb of the pipette or reuse any leftover solution.**



- Close the lid of the reaction tube. You will hear a soft "click" which means the lid is securely fastened.

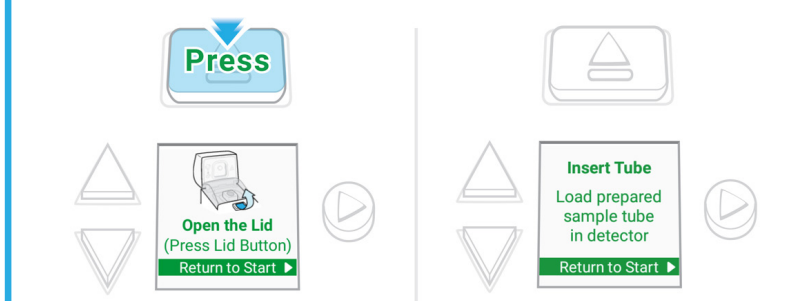


- The buffer tube and transfer pipette cannot be used again—put them in the trash.

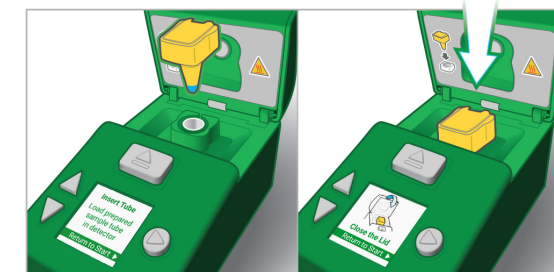
### 5 Run the Test

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 sample.

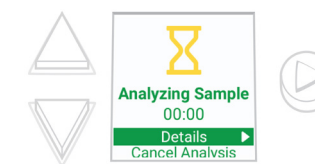


- Gently place the reaction tube into the tube port (it only fits one way).
- Close the lid. Sample analysis will begin automatically.



#### Notes

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



- Test result times vary.

### 6 Read Results

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

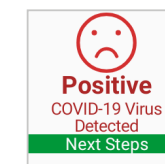
**NEGATIVE: COVID-19 VIRUS NOT DETECTED**

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**

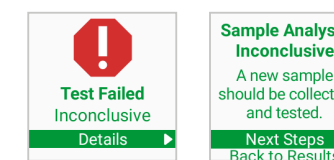
The virus that causes COVID-19 was detected in the sample. A positive result for a negative QC would indicate that the QC failed. A positive result for the positive QC would indicate that the QC was successful.



#### 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 QC sample and a new test.

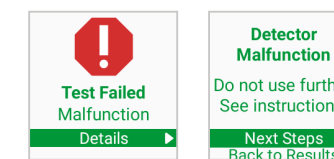
If you repeatedly get inconclusive results, contact Anavasi Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at [www.anavasidx.com](http://www.anavasidx.com).



#### TEST FAILED: MALFUNCTION

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

Contact Anavasi Customer Support at 1-888-ANAVASI (1-888-262-8274) or on the web at [www.anavasidx.com](http://www.anavasidx.com).



### 7 Record QC Results

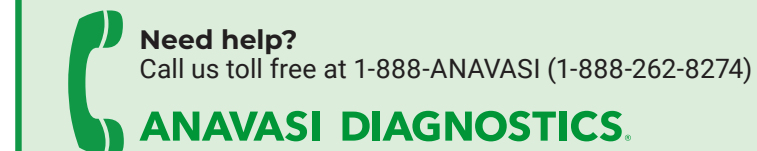
- Press the "Select" button to choose Next Steps and generate a QR code.
- Scan this code to record the QC test results according to your facility's standard procedures.



### 8 Complete the Test

After you have recorded the QC test results, follow the instructions on the screen to remove the 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 tests, you are ready to start a new test or adjust settings.



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Performing the assay outside the time and temperature ranges provided may produce invalid results. Assays not performed within the established time and temperature ranges must be repeated.

**Caution:** Use Standard Precautions and treat all patient samples and used test materials as potentially infectious. Personal protective equipment (PPE), including lab coats, masks, eye protection, and new gloves should be worn at all times when performing patient tests. Disinfect work surfaces and change gloves before each new sample run. Handle and dispose of all used test materials and unused reagents according to your institution's safety guidelines for hazardous materials, in compliance with applicable government regulations.

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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.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Please read all instructions carefully before you begin.

**List of Required Materials**

- 1 AscencioDx Molecular Detector
- 1 12-volt power adapter with cable
- 1 Quick Reference Instructions (QRI)
- 1 AscencioDx COVID-19 Test, containing: 1 kit tray, 1 nasal swab, 1 buffer tube, 1 reaction tube in foil pouch, and 1 transfer pipette

**THINGS YOU NEED TO KNOW TO BE SUCCESSFUL**

**Do:**

- ✓ Run negative and positive controls at recommended times (see Quality Control Procedures in **PART ONE: Set Up and External Controls**).
- ✓ Start a new test by pressing the "Select" button.
- ✓ Allow the detector to warm up before starting a test.
- ✓ Run the test within 10 minutes of opening the foil pouch. Only open the foil pouch right before you are ready to use the test.
- ✓ Swab both nostrils.
- ✓ Agitate the swab vigorously in the buffer tube to maximize release of sample into the buffer.
- ✓ Pay careful attention to Step 4—getting the correct volume of fluid in the reaction tube is important.
- ✓ Always dispose of used test materials. They could be capable of transmitting infectious agents. Throw them away according to your institution's biological waste policies.

**Don't:**

- ✗ Do not forget to add buffer fluid to the reaction tube.
- ✗ Do not run the test if you've waited more than 10 minutes after removing the reaction tube from its foil pouch. You need to get a new COVID-19 Test and start over with a fresh sample.
- ✗ Do not squeeze the overflow (lower) bulb of the pipette.
- ✗ Do not pipette solution from the buffer tube into the reaction tube more than once.
- ✗ Do not reuse any leftover buffer solution.
- ✗ Do not unplug or disturb the detector while running a test until it displays a result on the screen.
- ✗ Do not remove the reaction tube from the detector until after you generate and scan a QR code. (After the detector displays your test result, you must press the select button to choose Next Steps and generate a QR code.) If the QR code screen is skipped, you will not be able to return to the QR code.

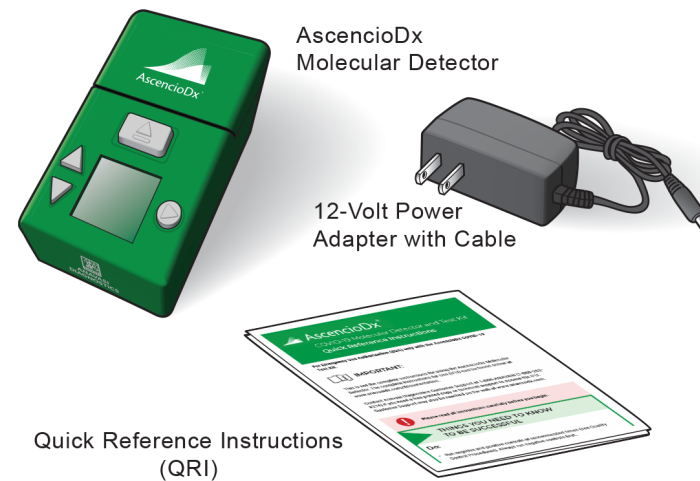
**Instructions**

**Start Here**

Unpack the AscencioDx Molecular Detector

a. Carefully unpack the box and make sure it contains the following:

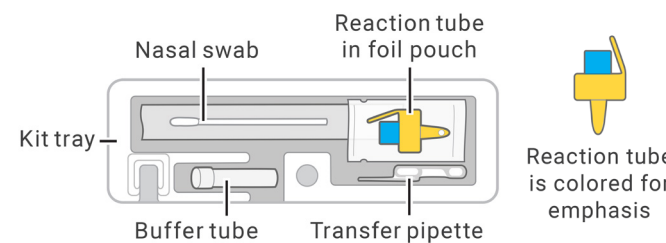
- 1 AscencioDx Molecular Detector
- 1 12-volt power adapter with cable
- 1 Quick Reference Instructions (QRI)



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

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 where the detector will not be disturbed.

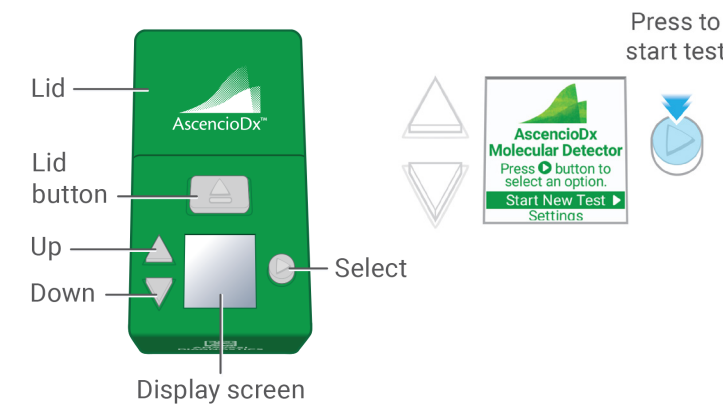
To turn on the detector, simply connect the 12-volt power adapter to the power port located on the rear panel of the device and then plug the adapter into the appropriate electrical outlet. (There is no separate power button.)

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

**1 Set up the Test**

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

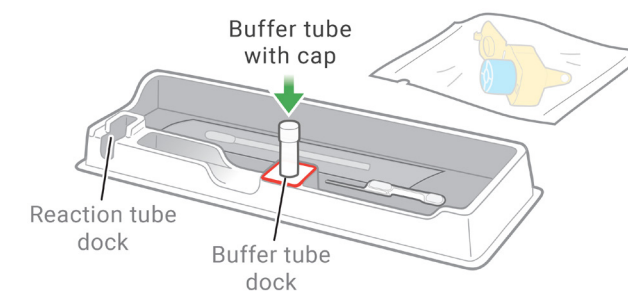
a. Press the "Select" button to start a new test. (To navigate the screen, use the up and down buttons. To learn more about the settings, refer to the IFU.)



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



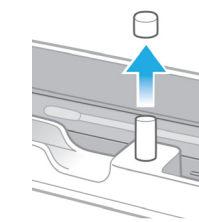
c. Place the buffer tube in the dock in the kit tray.  
d. Take the transfer pipette out of its bag and place it in the tray.



**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 COVID-19 Test and start over with a fresh sample.**

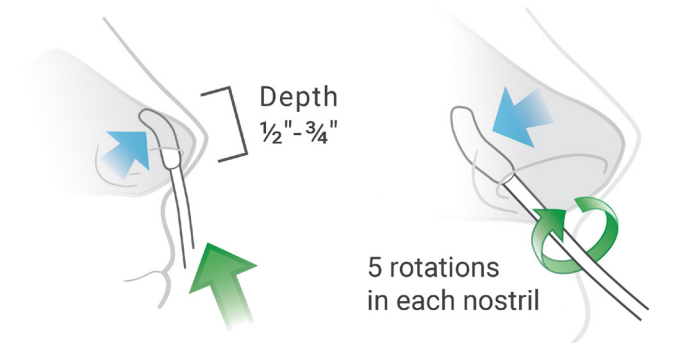
a. When you are ready to collect the sample, **remove the cap from the buffer tube.**



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

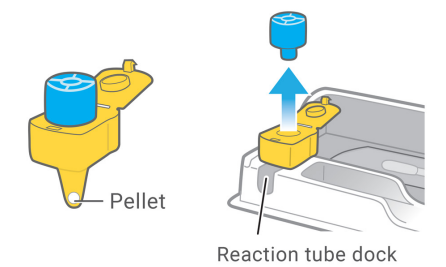
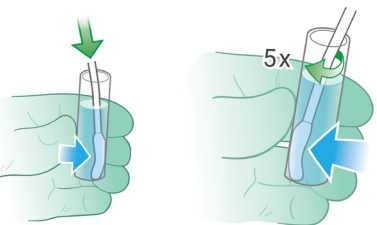


c. Open the sterile nasal swab, and use it to swab the patient's first nostril at a shallow depth of 1/2"-3/4".  
d. Be sure to swab all the way around the inner walls, stretching the nostril and pressing against the inner walls of the nostril for 5 full rotations.  
e. Repeat the swabbing procedure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



**3 Prepare the Sample**

- a. Pick up the buffer tube and insert the swab in the buffer tube.
- b. Press the swab against the tube's side walls as you rotate the swab.
- c. 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.
- d. 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 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 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 of tube to make the pellet fall to the bottom.
- l. Place the reaction tube in the dock in the kit tray and remove the cap.

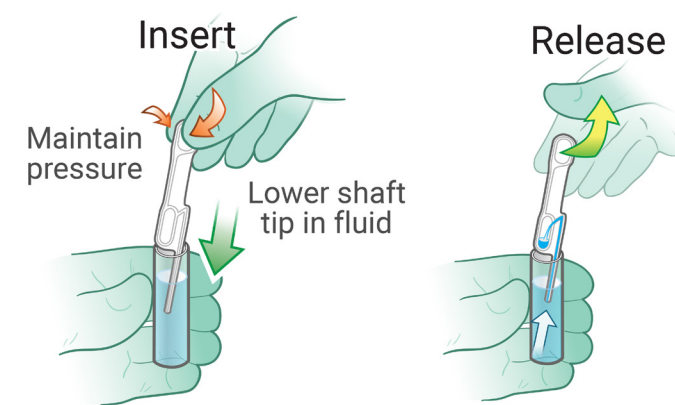
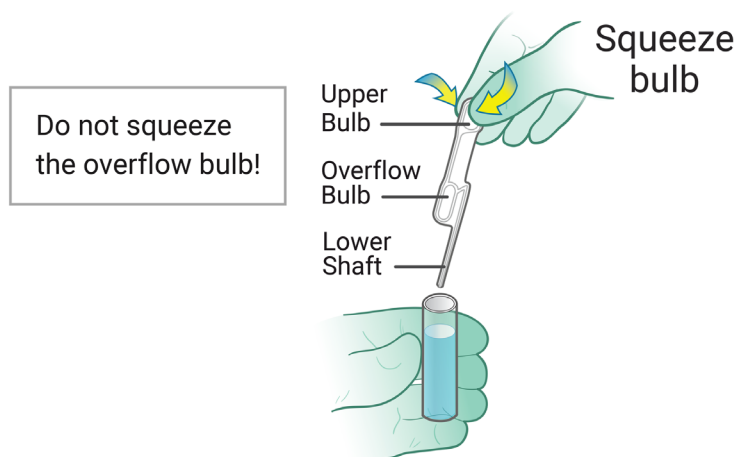


## 4 Transfer the Sample

**!** 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.

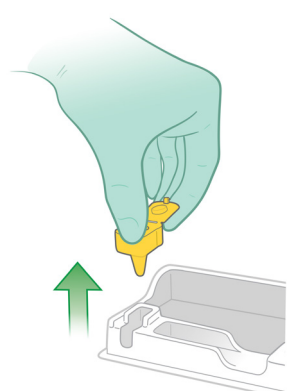
- › Squeeze the upper bulb to expel air.
- › Maintain pressure on the upper bulb while inserting the lower shaft tip in the buffer tube. Be sure that the shaft tip is in the buffer fluid before releasing the upper bulb.
- › Release the upper bulb to draw in fluid.
- › Do not squeeze the bulb again.
-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



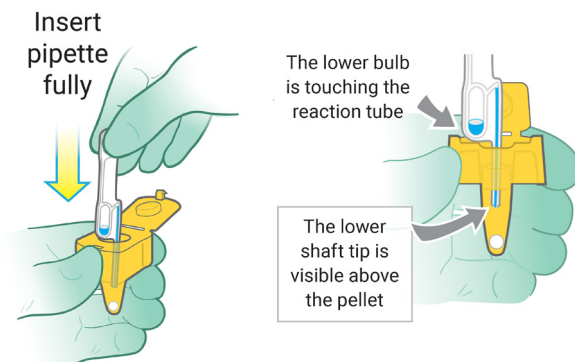
- › The lower shaft should be full of liquid with no bubbles, and some fluid should be present in the overflow bulb.



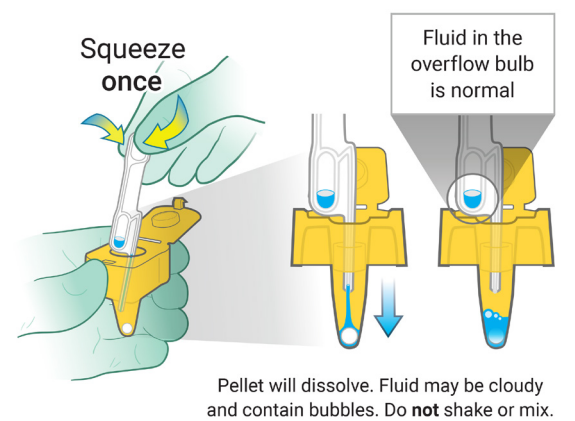
- b. Make sure you removed the reaction tube cap.
- c. Pick up the reaction tube and place the lower shaft of the pipette into the reaction tube.



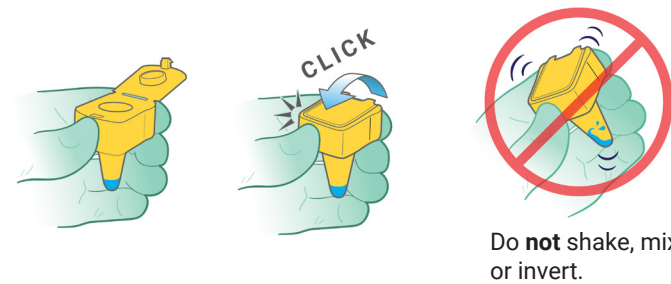
- d. Fully insert the pipette, pushing down all the way until the overflow bulb rests on the edge of the reaction tube and the shaft tip is visible above the pellet.



- 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 solution 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.

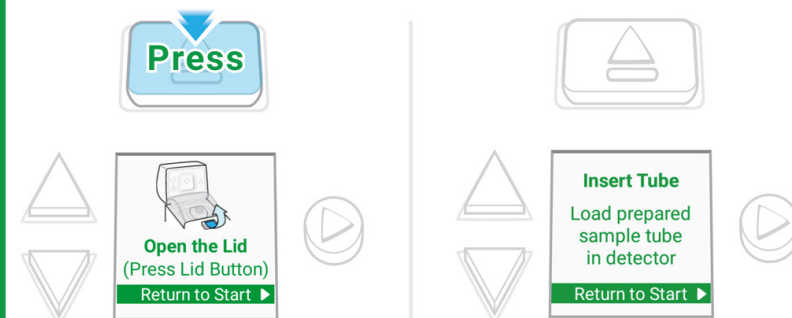


- g. The buffer tube and transfer pipette cannot be used again—put them in the trash.

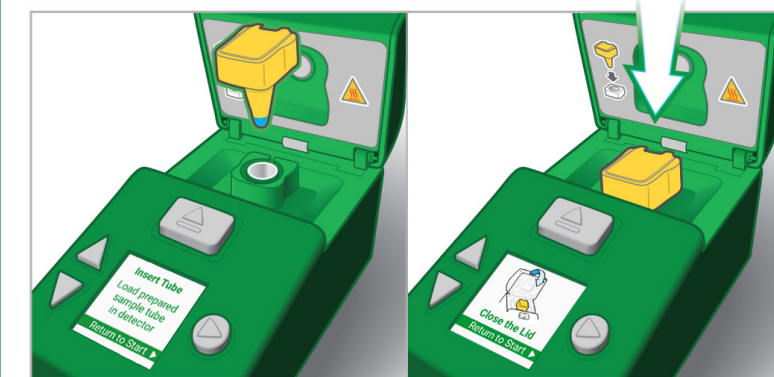
## 5 Run the Test

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 sample.

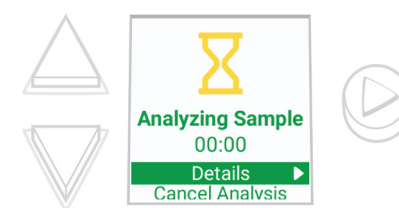


- b. Gently place the reaction tube into the tube port (it only fits one way).
- c. Close the lid. Sample analysis will begin automatically.



### Notes

- › Do not unplug or disturb the detector until the results display 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 must be reported to public health authorities either through the detector's QR code reporting feature or your institution's own procedures.

## 6 Read Results

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

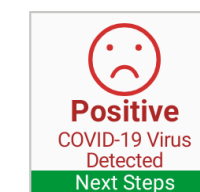
**NEGATIVE: COVID-19 VIRUS NOT DETECTED**

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.



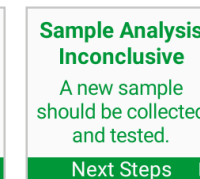
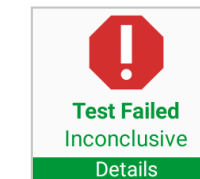
**POSITIVE: COVID-19 VIRUS DETECTED**

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



**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.

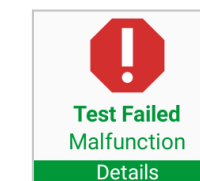


If you repeatedly get inconclusive results, contact Anavasi Customer Support at 1-888-ANAVASI (1-888- 262-8274) or on the web at [www.anavasidx.com](http://www.anavasidx.com).

**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 Customer Support at 1-888-ANAVASI (1-888- 262-8274) or on the web at [www.anavasidx.com](http://www.anavasidx.com).



## 7 Report Results

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



## 8 Complete the Test

After you have recorded the test results, follow the instructions on the screen to remove the 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 materials could be capable of transmitting infectious agents. Throw them away according to your institution's biological waste policies.

**Need help?**  
Call us toll free at 1-888-ANAVASI  
(1-888-262-8274)

**ANAVASI DIAGNOSTICS**