Fast PCR Mini Respiratory Panel Quick Reference Guide

CLIA Complexity: Waived

Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.

IVD **RX Only**

Operators should read the complete test procedure, including quality control procedures, before performing a test.

Before You Begin

Important: Read the Fast PCR Instrument Quick Reference Guide and the Fast PCR Mini Respiratory Panel Quick Reference Guide prior to running a test.

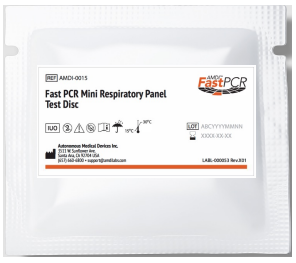
- Expiration Date: Check expiration date on each Fast PCR Test Disc Pouch or outer box before using. DO NOT use any test disc past expiration date printed on the label.
- Do Not use Test Disc if there are any rips or tears in the test disc pouch
- Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.

Prepare Instrument

Verify that the Fast PCR instrument is set up and ready to run selected test. See the Fast PCR Instrument Quick Reference Guide or the Fast PCR Instrument Manual for full instructions.

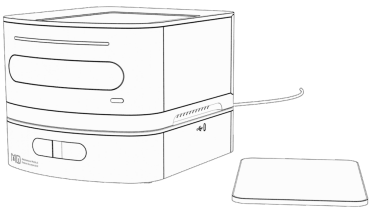
Provided Materials

Fast PCR Test Disc

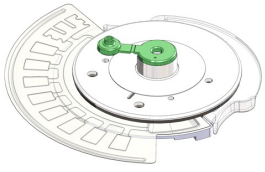


Sample Buffer and Nasal Swab

Fixed Volume Transfer Pipette



Fast PCR Instrument



Test Disc

Quality Control Testing

Quality Control (QC) materials may be purchased directly from AMDI

Positive and Negative Controls are packaged both separately and combined (positive and negative vials) in the AMDI Quality Control kit. If more information is needed, contact Customer Service.

Quality Control (QC) testing should be performed when:

- Training a new Operator
- Receiving a new shipment or lot of AMDI Fast PCR Test Discs
- Receiving a new Fast PCR Base Station

Ensure Quality Control Material is stored appropriately and according to Manufacturer's Instructions.

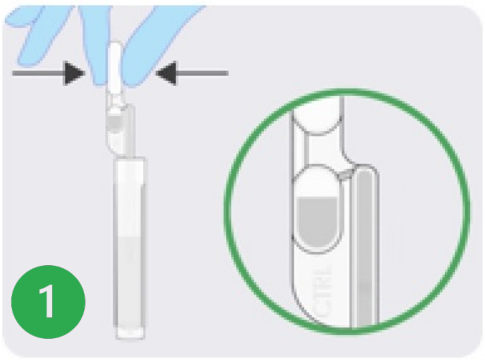
Note: A Negative QC test should be run monthly for each testing location to monitor for potential environmental contamination. Additional negative QC tests should be run if contamination is suspected.

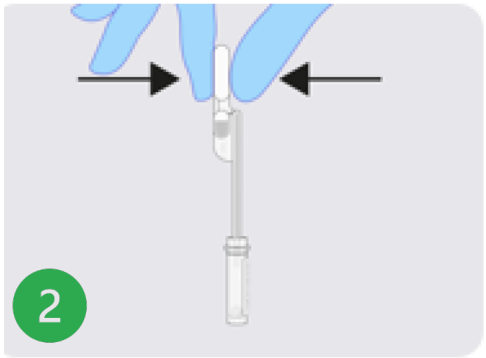
Quality Control Testing Instructions

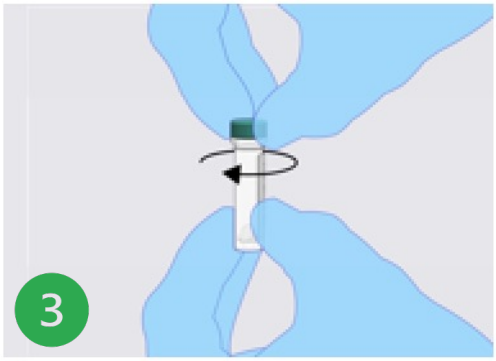
Gather materials needed for testing: (1) Fast PCR Test Disc, (1) 400uL transfer pipette, (1) AMDI Sample Buffer tube, (1) QC vial and (1) QC transfer pipette are needed for each QC test (positive or negative)

1. Draw 600ul from AMDI Sample Buffer tube with the QC transfer pipette.
2. Squeeze the top bulb of the QC transfer pipette to transfer 600ul of sample buffer into the QC vial.

NOTE: Quality Control material must be used within 1 hr of rehydration.

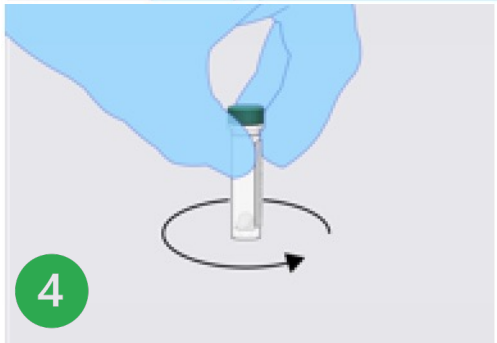






3. Replace the cap on the QC vial.

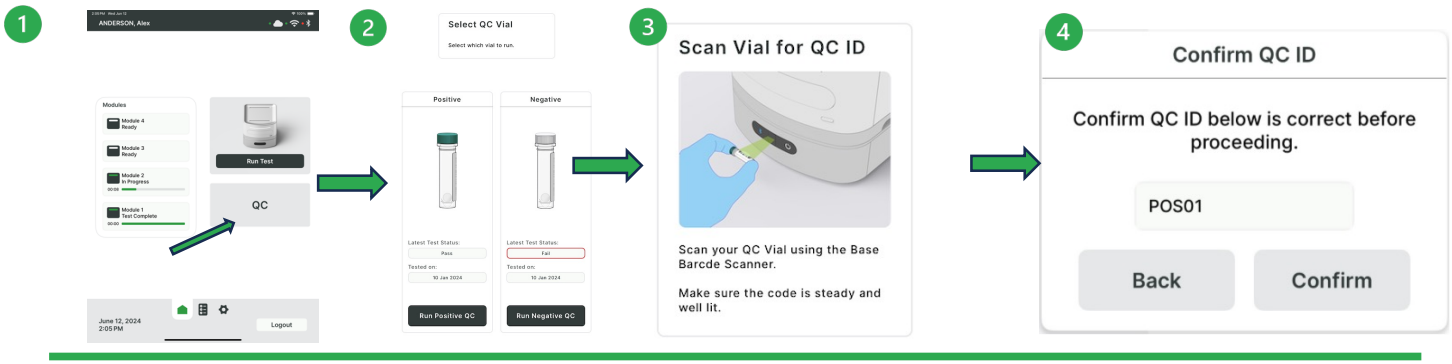
4. Mix the QC sample before testing by swirling/flicking sealed QC vial a minimum of 5 times.



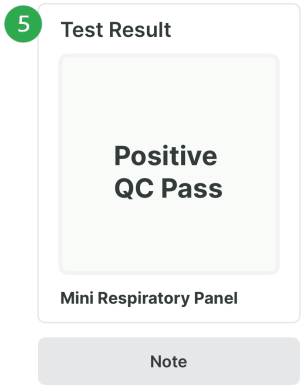
Quality Control Testing Instructions (cont.)

Note: User logs into the system with USER ID and Password set up by the administrator (manually or with USER ID barcode)

1. Press the QC button on the Dashboard.
2. Select Quality Control Vial to run.
3. Scan/Input QC Barcode.
4. Confirm QC vial information is correct.
5. Follow Test Procedure Steps #4 and #5 to complete the Quality Control Procedure for the Quality Control test.



6. Once the Quality Control sample has been run, a result will be provided.
7. If it has passed, then you can move on to the next Quality Control vial by starting a new QC test and picking the alternate vial. If the test has failed, you will need to repeat the procedure by starting a new QC test.



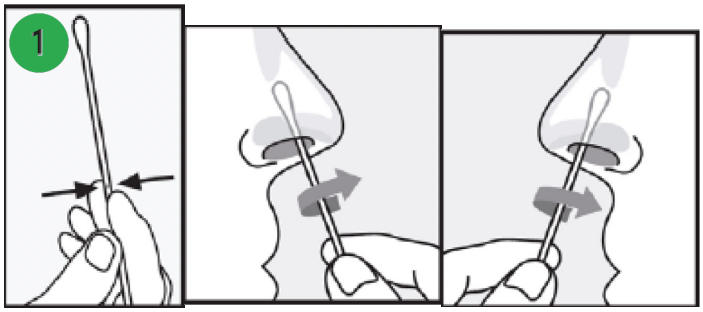
QC Results	Explanation	Action
Pass	A Positive QC Test or Negative QC Test have Pass Results	Report the Results.
Fail	A Positive QC Test has Negative Results	Retest the Positive QC material once. If the failure persists, contact Customer Service for further instruction.
Fail	A Negative QC Test has positive results	If contamination is suspected, clean the area and retest a new Negative QC vial. If failure persists, contact Customer Service for further instruction.

Test Procedure

Step 1: Collect Nasal (Anterior Nares, AN) Swab Sample

WARNING: DO NOT PRE-WET SWAB – use only one swab for both nares

1. Collect: Hold the swab towards the end of the shaft. Insert the swab 1-2 cm into one of the anterior nares. Rotate the swab against the nasal mucosa at least 4 times for about 15 seconds and withdraw. Repeat the other anterior nares using the same swab.

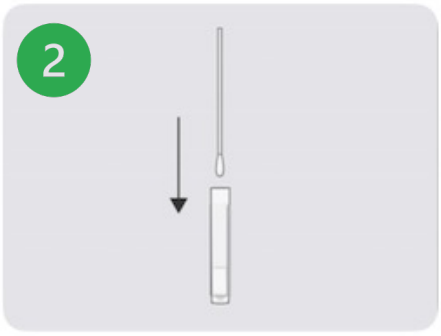


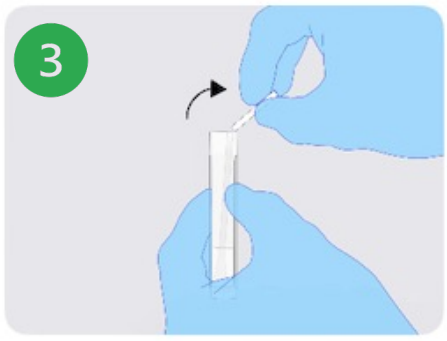
Do not let the swab touch any surface before placing it into the collection tube.

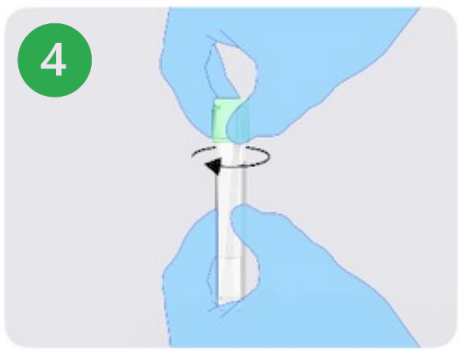
2. Uncap: Remove the cap from the AMDI Sample Buffer tube and lower the swab specimen into the tube, tip first.

3. Break: Carefully leverage the swab against the tube rim to break the swab shaft to fit into tube.

4. Close: Tightly re-cap the collection tube properly without the shaft interfering with the thread on the rim to prevent the AMDI Sample Buffer from leaking.

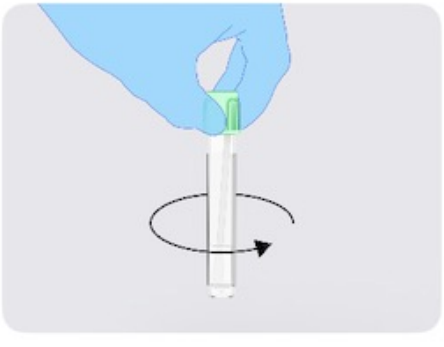






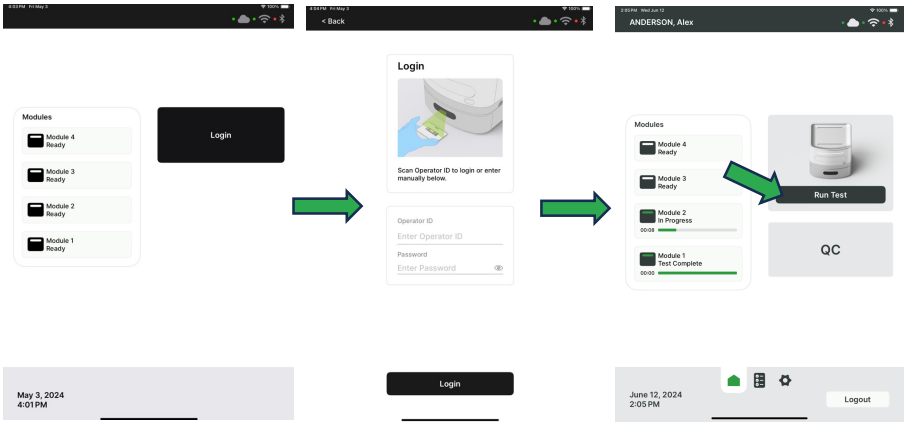
Step 2: Prepare the Sample

Mix patient sample (AN swab in AMDI Sample Buffer) before testing by swirling/flicking sealed transport medium tube a minimum of 5 times.



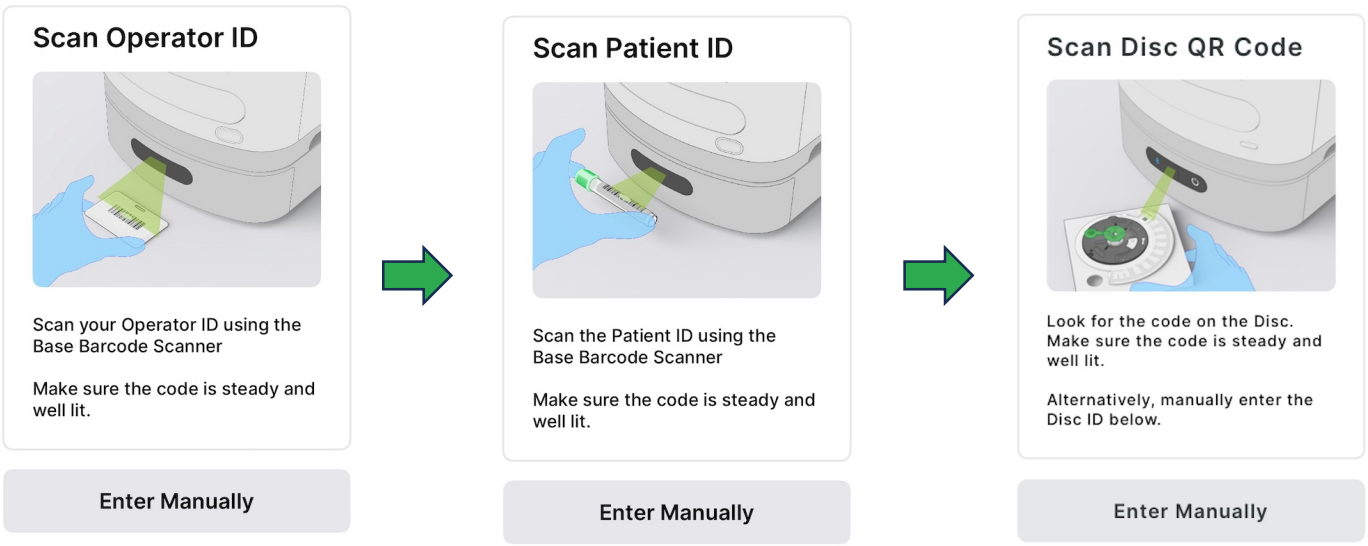
Step 3: Log into System and Initiate the Test

1. Log into the system with Operator ID and Password set up by the administrator (manually or with Operator ID barcode).
2. Press Run Test and follow instructions on screen.



3. Scan (or enter manually) Operator ID barcode to ensure each test run is associated to the specific Operator running the test.
4. Scan (or enter manually) Patient ID barcode.
5. Remove Test Disc from pouch and Scan (or enter manually) Test Disc ID barcode to associate it with Patient ID.

Note: Test Disc should only be removed from pouch immediately before using.



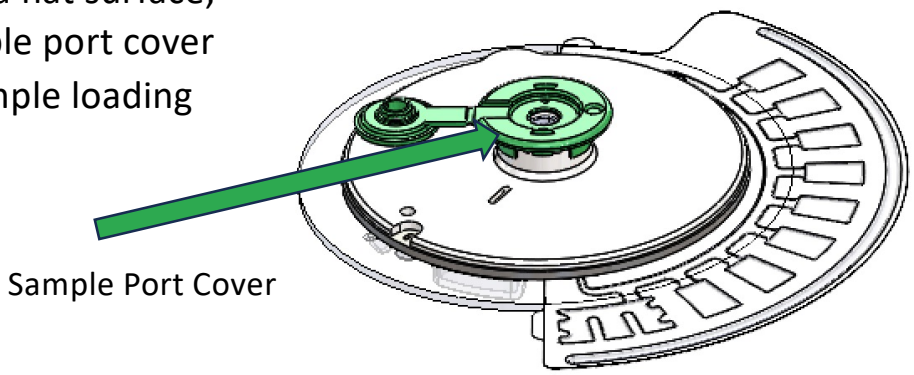
Error Messaging:

a. Error messages will display on the screen if the Operator ID or Patient ID are not valid.

b. Error messages will display on the screen if the Test Disc ID
   - is not valid
   - has expired
   - has been recalled or placed on hold
   - has been previously run

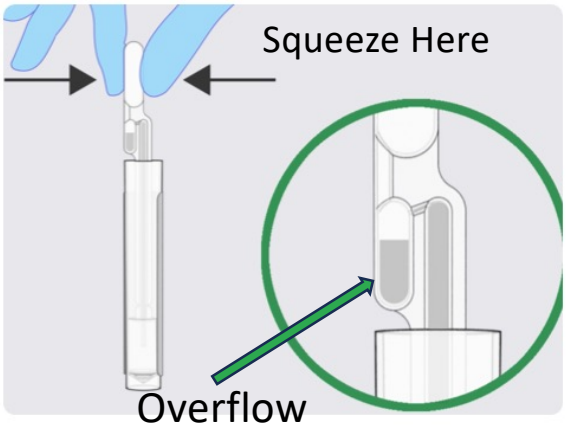
Step 4: Load Sample into Test Disc

1. With Test Disc placed on a flat surface, in its holder, ensure sample port cover is open to expose the sample loading port.

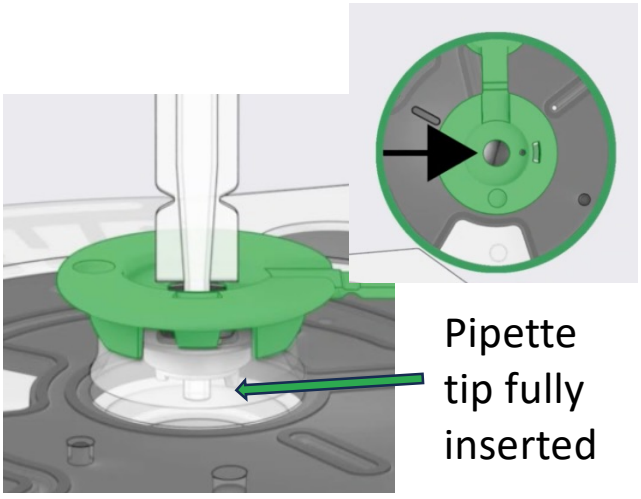


2. Transfer the sample from the AMDI Sample Buffer tube using the fixed volume (400uL) pipette.

- Firmly squeeze the top bulb of the transfer pipette.
- While squeezing, place the transfer pipette tip into the sample
- With the pipette tip in the sample, release the pressure on the bulb to fill the transfer pipette. You should see some fluid in the overflow portion of the transfer pipette confirming you have adequate sample.

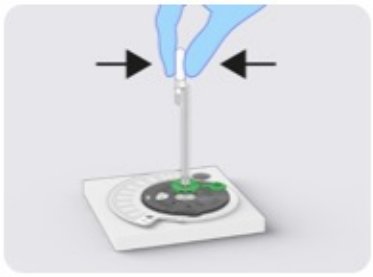


3. Transfer the liquid sample into the Test Disc by inserting the pipette tip into center of Test Disc port (center region surrounded by green sample port and cover) until tip seats at the bottom.



Note: Pipette tip should be inside the sample port opening and not resting on the outside.

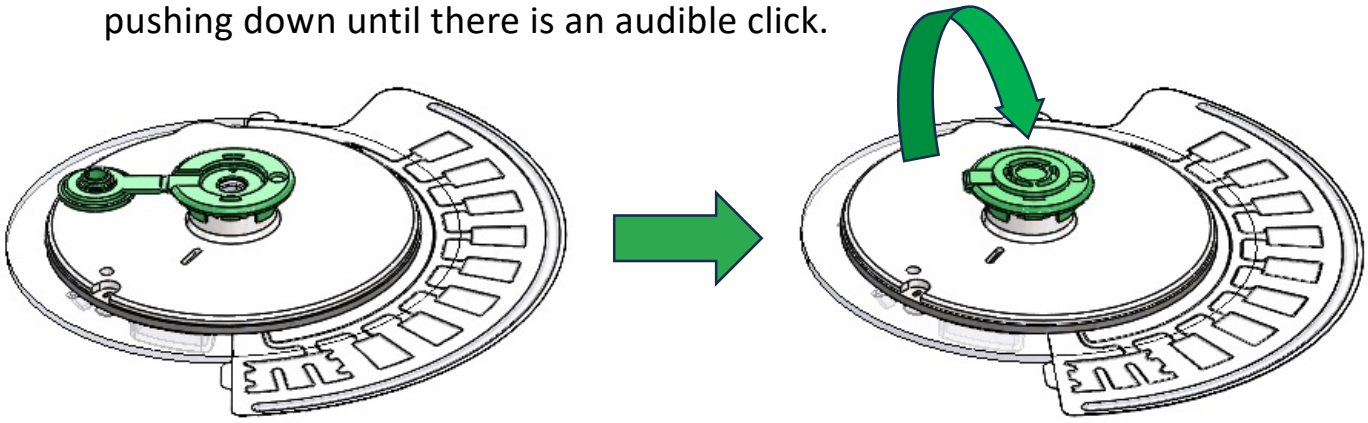
4. Firmly squeeze the top of the bulb of the transfer pipette to empty the liquid into the sample port and remove the pipette while still depressing top bulb and ensuring Test Disc does not lift off tray.



Note: Avoid getting any sample liquid on the outside of the sample port as it may lead to contamination of the instrument.

Step 4: Load Sample into Test Disc (cont.)

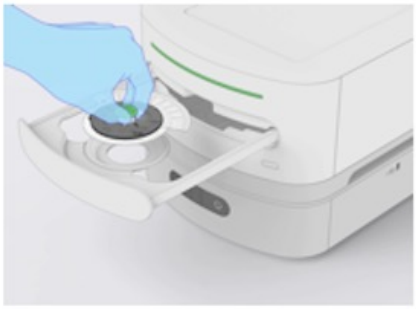
5. Close the sample port by closing the cover over the sample port and firmly pushing down until there is an audible click.



Note: Test Disc should be run in the AMDI Fast PCR instrument immediately after loading sample into disc.

Step 5: Load Test Disc into Instrument

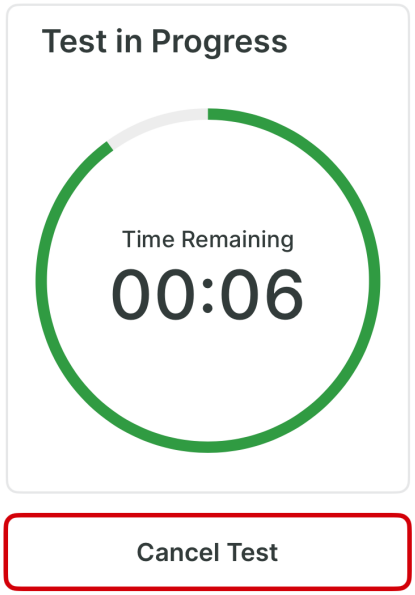
1. With the Test Disc still in the holder, scan the Test Disc ID barcode to open the Fast PCR Loading Tray.
2. Place the Test Disc in the Open Loading Tray by grasping by the sample port and lifting straight up. Place the Test Disc in the same orientation as it was in the disc holder (sample port facing up).
3. Push the button adjacent to the tray, on the front of the instrument, to close the tray. The instrument will ensure the Test Disc is correctly seated inside the instrument prior to running the test.

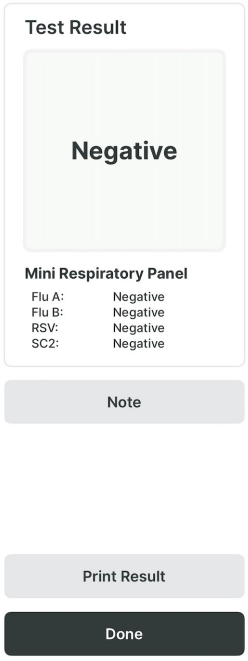


Note: Test Disc should only be picked up by the green sample port, once it has been closed. Do not use any disc if it has been dropped.

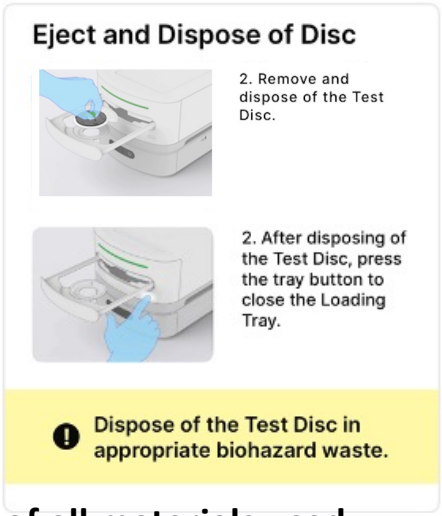
Step 6: Run Test

1. The Fast PCR instrument will auto-run the test when the tray closes and will display the time to test completion on the screen. **Do Not** open loading Tray while the Test Disc is running.
2. Once the system has completed running a Test Disc, the Test Result will display on the screen, can be printed out and will automatically be transmitted to the EHR/LIS if it has been set up.
3. By pressing done on the bottom of the results screen or pushing the button adjacent to the Operating Module that ran the Test Disc, the loading tray can be opened, and the Test Disc removed for disposal in appropriate Biohazardous Waste. Press the button again to close the tray.





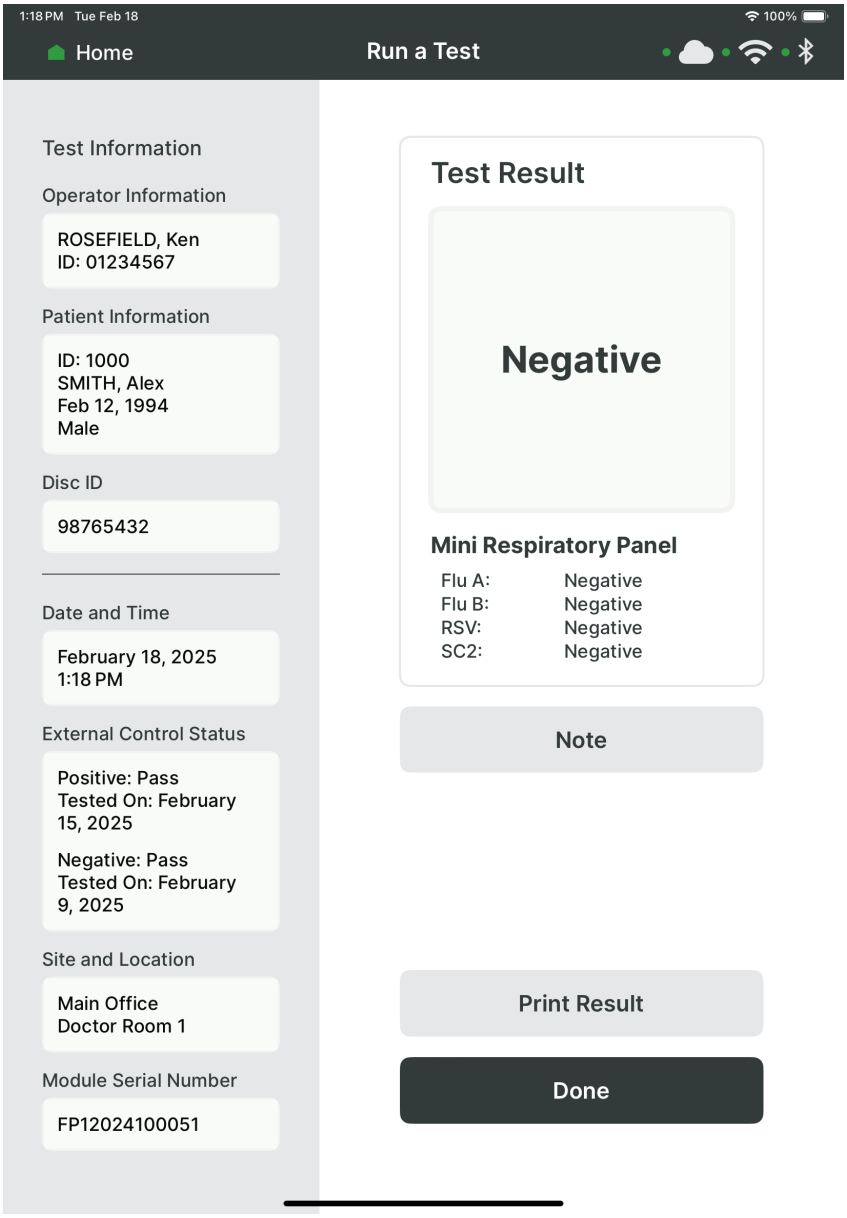
4. Ensure you dispose of all materials used in running the test including used Test Disc, samples, and used Sample Buffer tubes as biological hazard waste according to federal, state and local regulations.



Note: It is recommended to change gloves after disposing of all materials used in running the test to minimize possibility of contamination.

Patient Results

Test Results will be reported as Positive or Negative for each Target tested.



Results	Explanation	Action
Positive	Internal Control: Pass AND Test is positive for organisms listed	Report the Result(s).
Negative	Internal Control: Pass AND Test is negative for organisms listed	Report the Result(s).
Invalid	Internal Control: Fail	Retest the sample once and report the results of the retest.

Intended Use

The Fast PCR Mini Respiratory Panel is a multiplexed polymerase chain reaction (PCR) test intended for use with the Fast PCR instrument for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids in nasal swab specimens obtained from individuals with signs and symptoms of respiratory tract infections, including COVID-19.The following organism types and subtypes are identified and differentiated using the Fast PCR Test Disc:

1. Coronavirus SARS-CoV-2
2. Influenza A virus
3. Influenza B virus
4. Respiratory Syncytial Virus

- Nucleic acids from the viral organisms identified by this test are generally detectable in nasal specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism and aids in the diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment or other patient management decisions.
- Negative results in the setting of respiratory illness may be due to infection with pathogens that are not detected with this test, or lower respiratory tract infection that may not be detected by a nasal swab specimen. Positive results do not rule out co-infection with other organisms. The agent(s) detected by the Fast PCR system may not be the definitive cause of disease.
- Additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.
- Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests. The Fast PCR test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.
- The Fast PCR Test is intended for use by untrained operators. The test may be used in point of care settings.

Questions

If you have any questions regarding the use of this product or if you want to report a test problem, please contact Autonomous Medical Devices Technical Support at: +1-657-660-6818 or customerservice@amdilabs.com or contact your local distributor.

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