

Fast PCR Mini Respiratory Panel Quick Reference Guide

Laboratories with a Certificate of Waiver may use this test.

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

This test is only for anterior nasal swab specimens.

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.

- A Certificate of Waiver is required to perform this test in a CLIA Waived setting. Failure to follow the instructions or any modifications to the test will result in the test no longer meeting the requirements for waived classification.
- 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.
- Test Discs should be stored at room temperature (15-30°C). Use of improperly stored discs may result in inaccurate results.
- Deviation from instructions may lead to inaccurate results. For additional information, please find the full IFU at www.AMDIFastPCR.com. The full IFU is also included in each Fast PCR Mini Respiratory Panel Kit.
- 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



Test Disc



Sample Buffer
and Nasal
Swab



450uL Transfer
Pipette

Required But Not
Provided with a Fast
PCR Mini Respiratory
Kit



Fast PCR
Instrument

Intended Use

The Fast PCR Mini Respiratory Panel is an automated, multiplexed real-time reverse transcriptase polymerase chain reaction (RT-PCR) test intended for the simultaneous qualitative detection and differentiation of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, influenza B and respiratory syncytial virus (RSV) nucleic acids in anterior nasal swab specimens obtained from individuals with signs and symptoms of respiratory tract infections. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, influenza B and RSV can be similar. This test is intended to aid in the differential diagnosis of SARS-CoV-2, influenza A, influenza B and RSV infections in humans and is not intended to detect influenza C virus infection.

Nucleic acids from the viral organisms identified by this test are generally detectable in anterior nasal swab specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory tract infection are indicative of the presence of the identified virus and aid 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.

Positive results do not rule out co-infection with other organisms. The organism(s) detected by the Fast PCR Mini Respiratory Panel may not be the definitive cause of disease. Negative results do not preclude SARS-CoV-2, influenza A, influenza B or RSV infections.

Specimen Collection and Storage

Accurate test results depend on proper specimen collection, storage, and transport. Inadequate collection or handling may result in inaccurate results. For best performance, anterior nasal swabs collected in AMDI Sample Buffer should be tested as soon as possible after collection.

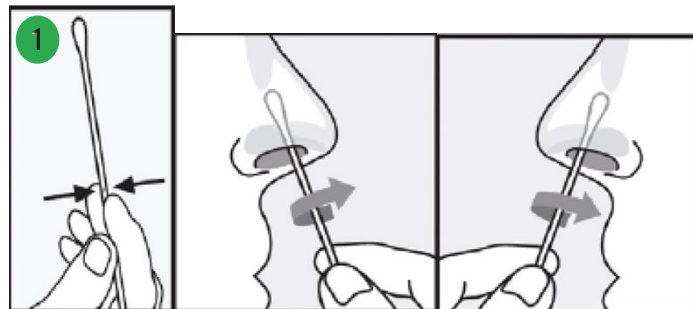
If immediate testing is not possible, and to maintain best performance, anterior nasal swab specimens collected in AMDI Sample Buffer can be stored at room temperature (15 - 30°C) for up to four hours or refrigerated (2–8°C) for up to 72 hours.

Test Procedure

Step 1: Collect Anterior Nasal Swab (ANS) Sample

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

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



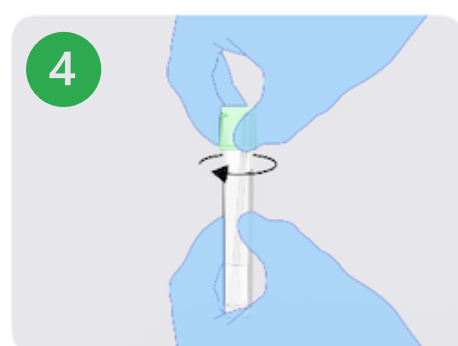
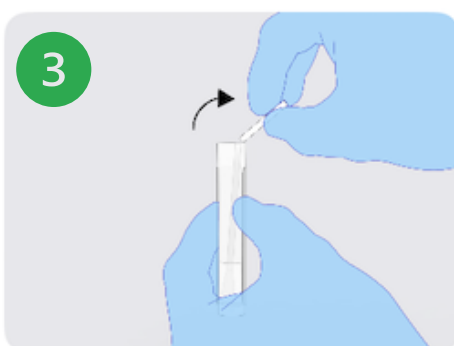
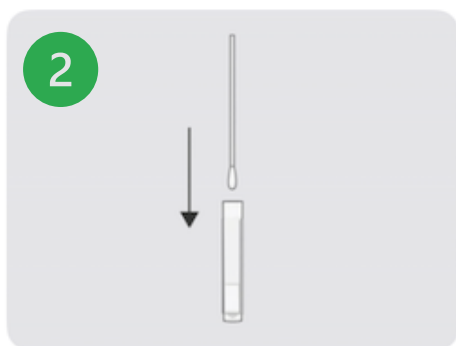
Note: Do not let the swab touch any surface before placing it into the collection tube.

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

Note: AMDI Sample Buffer is the only validated media for sample elution.

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

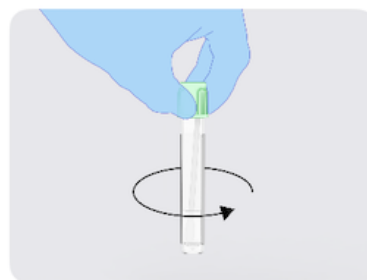
4. Close: Tightly re-cap the collection tube properly without the shaft interfering with the thread on the rim to prevent the AMDI Sample Buffer from leaking.



Test Procedure (cont.)

Step 2: Prepare the Sample

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



Step 3: Log into Instrument 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.

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

5. Remove Test Disc from pouch.
6. Scan (or enter manually) Test Disc ID barcode to associate it with Patient ID.

NOTE: Test Disc should be used within 30 minutes of removal from pouch. Delayed use of disc after removal from pouch may result in invalid or inaccurate results.

NOTE: Test Disc should be stored at room temperature (15-30°C). Use of improperly stored discs may result in inaccurate results.

NOTE: Test Discs should not be used if dropped or show signs of breakage. It could contaminate the Operating Module and surrounding area.

NOTE: Error messages will display on the screen if the Test Disc ID:

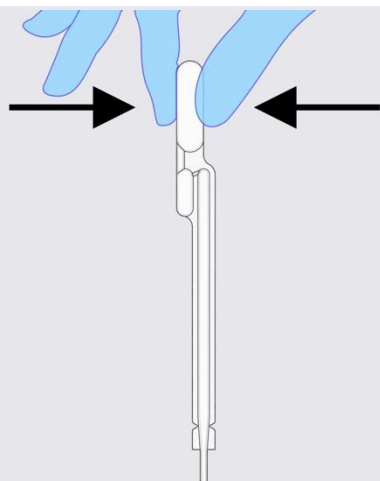
- is not valid
- has expired
- has been recalled or placed on hold
- has been previously run



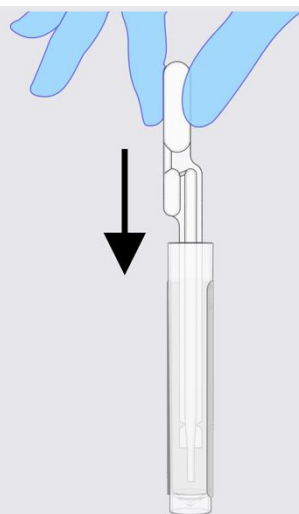
Test Procedure (cont.)

Step 4: Load Sample into Test Disc

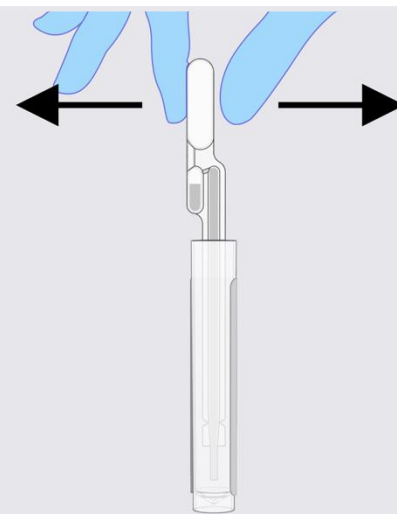
1. Place the Test Disc in its holder on a flat surface. Ensure sample port is open.



- 2.A. Squeeze the top bulb of the transfer pipette.



- 2.B. Keep it squeezed as you put the tip fully into the sample.



3. Let go of the bulb while the tip is still in the sample. This pulls the sample into the pipette.

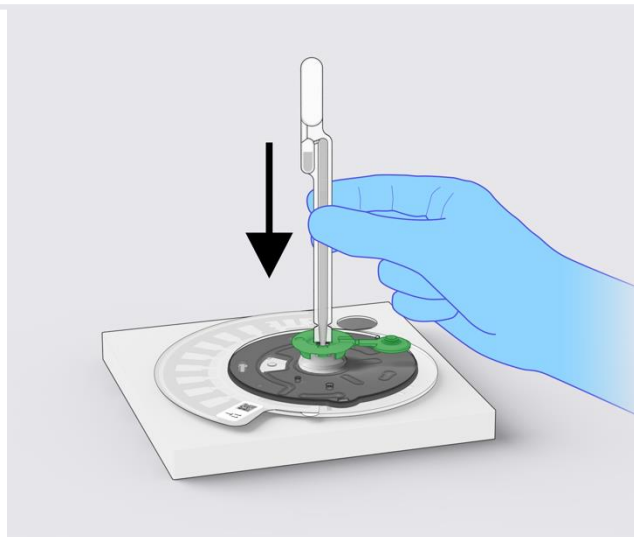


Caution: Air bubbles in the tip of the 450uL transfer pipette may lead to an invalid result. 450uL is required for adequate sample volume. Loading an incorrect sample volume may lead to invalid or inaccurate results.

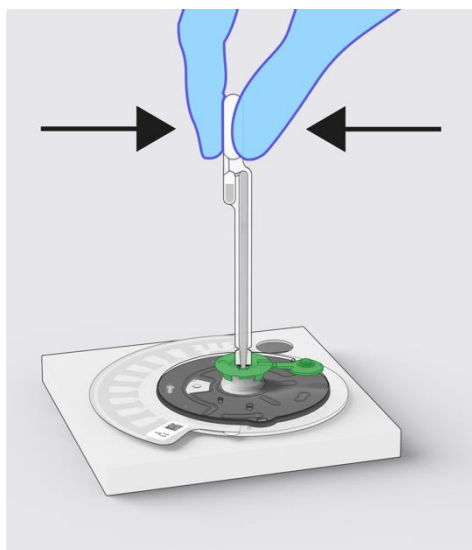
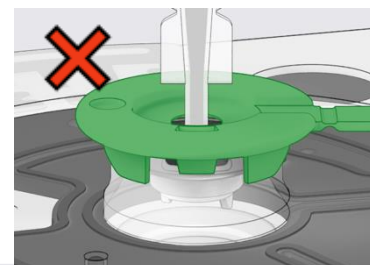
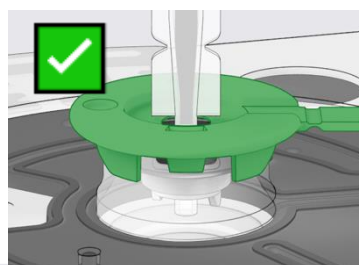
Test Procedure (cont.)

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

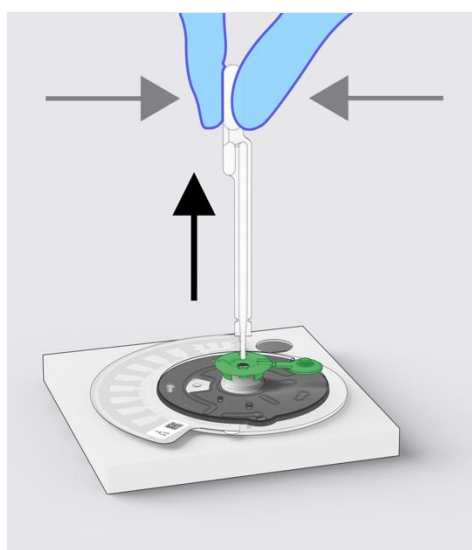
4. Keep the disc flat in the tray. Grasp the transfer pipette by the stem, insert the tip into the center opening until it reaches the bottom, then push it fully through the bottom until the side wings rest on the edge of the port.



NOTE: The side wings must rest fully on the edge of the port to be inserted correctly.



- 5.A. Once correctly inserted, squeeze the bulb firmly to push all the liquid into the disc.



- 5.B. Remove the pipette while still squeezing the bulb.



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

Test Procedure (cont.)

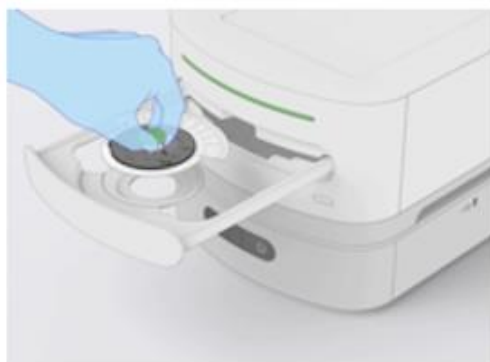
Step 4: Load Sample into Test Disc (cont.)

6. 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 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).



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.

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.



Step 6: Run Test

1. Close the loading tray to start the test. The instrument runs the test automatically.
2. The screen shows the time remaining. Do not open the tray during the run.
3. When the test is finished, the result appears on the screen. The result can also print and send to the EHR/LIS if connected.
4. Press DONE on the screen or the button next to the module. The tray will open.
5. Remove the Test Disc. Dispose of it in biohazard waste.
6. Press the button to close the tray.
7. Dispose of all used materials, including the Test Disc, samples, transfer pipettes and AMDI Sample Buffer tubes, as biohazard 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.

Caution: Do not tamper or attempt to open the test disc after it has been used to prevent exposure to amplicon from the PCR reaction.

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

Note: Refer to the Fast PCR Instrument QRG and/or IFU for cleaning and safety instructions.



Patient Results

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

1:49 PM Wed Aug 27

HomeRun a Test

Test Information

Operator Information

ROSEFIELD, Ken
ID: 01234567

Patient Information

ID: 1000
SMITH, Alex
Feb 12, 1994
Male

Disc ID

98765432

Date and Time

August 27, 2025
1:35 PM

External Control Status

Positive: Pass
Tested On: October 16, 2024
Negative: Pass
Tested On: December 18, 2024

Site and Location

Main Office
Doctor Room 1

Module Serial Number

FP12024100051

Test Result

Positive

Mini Respiratory Panel

Flu A: Positive

Flu B: Negative

RSV: Negative

SC2: Negative

Note

Print Result

Done

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.

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 Fast PCR Mini Respiratory Panel External Control kit. If more information is needed, contact Customer Service.

External Quality Control (QC) testing may be performed to conform with internal laboratory Quality Control (QC) procedures, or with local, state, or federal guidance. The use of external controls may be appropriate when:

- Training a new Operator
- Receiving a new shipment or lot of Fast PCR Test Discs
- Receiving a new Fast PCR Base Station
- Problems with testing are suspected or identified

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.

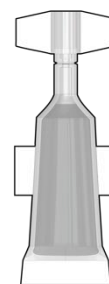
Fast PCR Mini Respiratory Panel External Control Kit Materials



Positive Control
Vial – Green Cap



Negative Control
Vial – White Cap



AMDI QC
Sample Buffer

Documents: Fast PCR Mini Respiratory Panel External Control Kit IFU

Quality Control Testing Instructions

Gather materials needed for testing

Fast PCR Mini Respiratory Panel Kit:

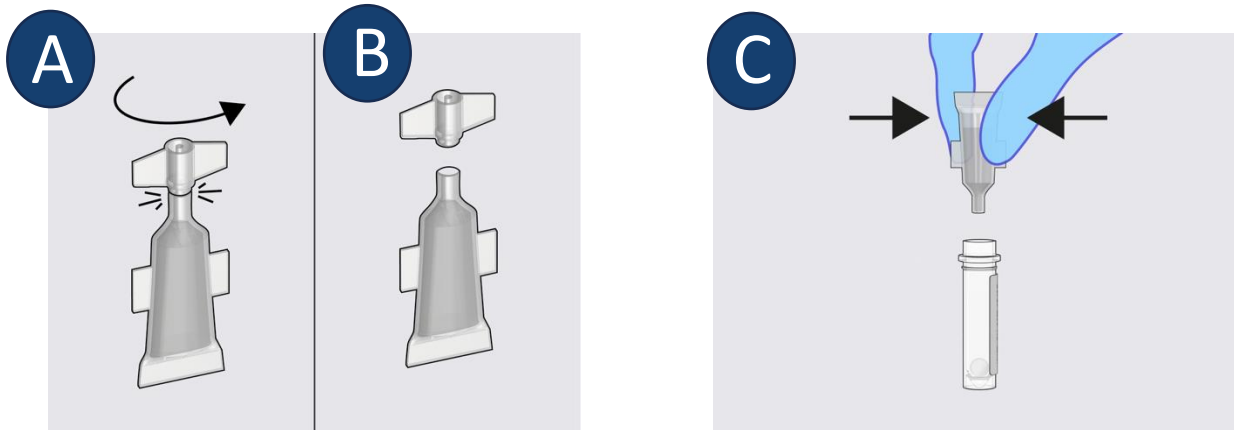
(1) Fast PCR Test Disc, (1) 450uL transfer pipette

Fast PCR Mini Respiratory Panel External Control Kit:

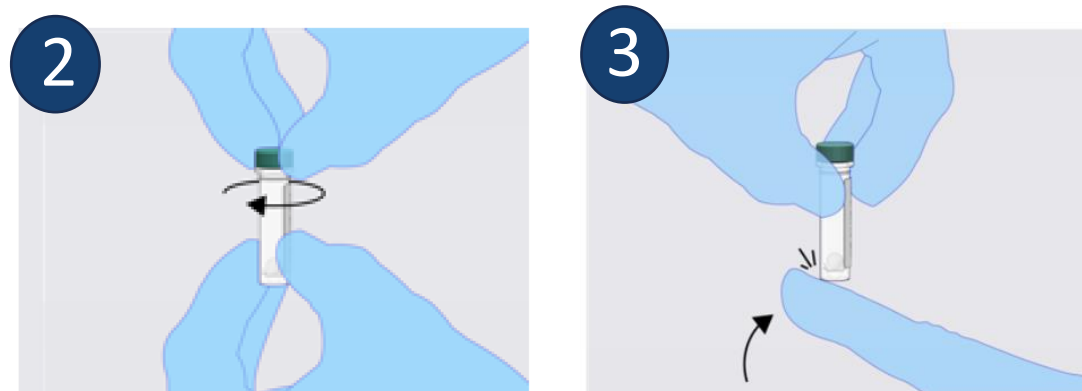
(1) QC vial, (1) AMDI QC Sample Buffer ampoule

Step 1: Hydrate External Control Bead

1. Empty the QC Buffer ampoule into the QC vial.
 - A. Firmly grasp the QC Buffer ampoule and twist off the top.
 - B. Remove the cap to the QC Vial.
 - C. Invert the opened QC Buffer ampoule and firmly squeeze the contents in to the QC vial.
 - D. Dispose of QC Sample Buffer ampoule.



2. Replace the cap on the QC vial.
3. Mix the QC sample before testing by flicking sealed QC vial a minimum of 5 times.



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

Quality Control Testing Instructions (cont.)

Step 2: Select QC and Initiate Test

Note: User logs into the system with Operator 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 (or enter manually) Operator ID barcode to ensure each test run is associated to the specific Operator running the test.
4. Scan/Input QC Barcode.
5. Remove Test Disc from pouch.
6. Scan (or enter manually) Test Disc ID barcode.

NOTE: Test Disc should be stored at room temperature (15-30°C). Use of improperly stored discs may result in inaccurate results.

NOTE: Test Disc should be used within 30 minutes of removal from pouch. Delayed use of disc after removal from pouch may result in invalid or inaccurate results.

NOTE: Test Discs should not be used if dropped or show signs of breakage. It could contaminate the Operating Module and surrounding area.

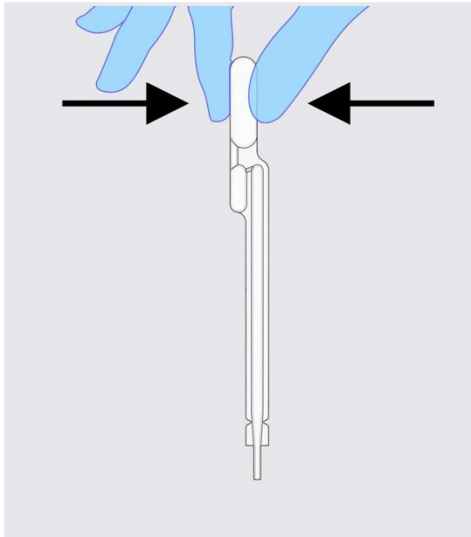
NOTE: Error messages will display on the screen if the Test Disc ID:

- is not valid
- has expired
- has been recalled or placed on hold
- has been previously run

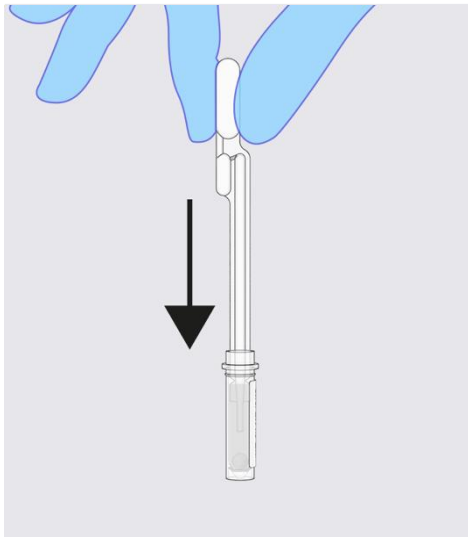
Quality Control Testing Instructions (cont.)

Step 3: Load Quality Control Sample into Test Disc

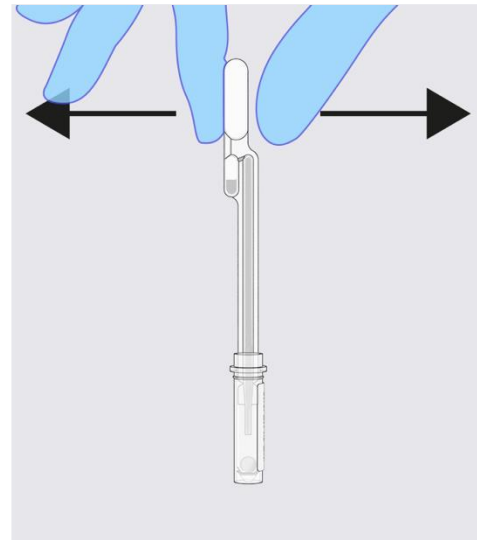
1. Place the Test Disc in its holder on a flat surface. Ensure sample port is open.



2.A. Squeeze the top bulb of the transfer pipette.



2.B. Keep it squeezed as you put the tip fully into the Quality Control Vial.

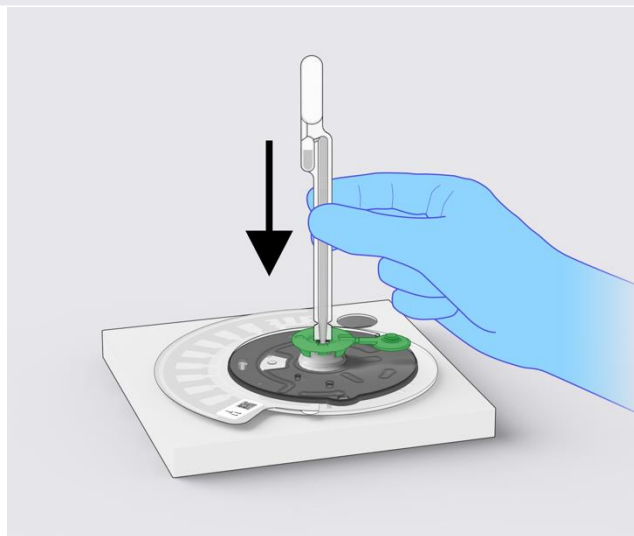


3. Let go of the bulb while the tip is still in the sample. This pulls the Quality Control into the pipette.

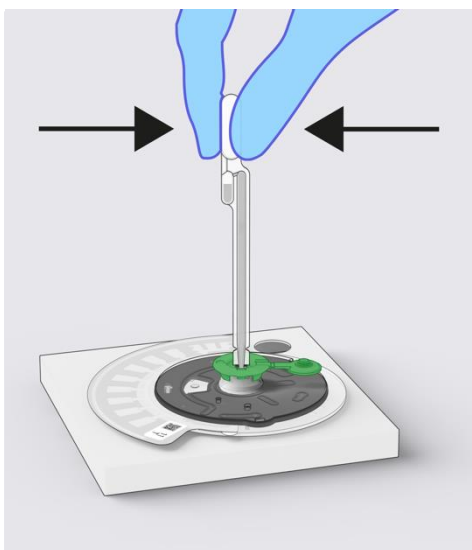
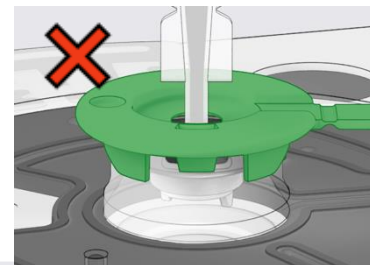
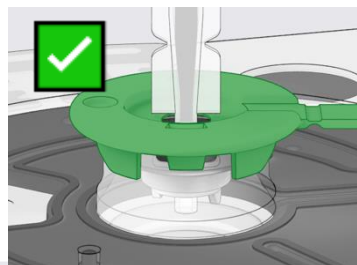
NOTE: Ensure there are no air bubbles in transfer pipette.

Step 3: Load Quality Control Sample into Test Disc (cont.)

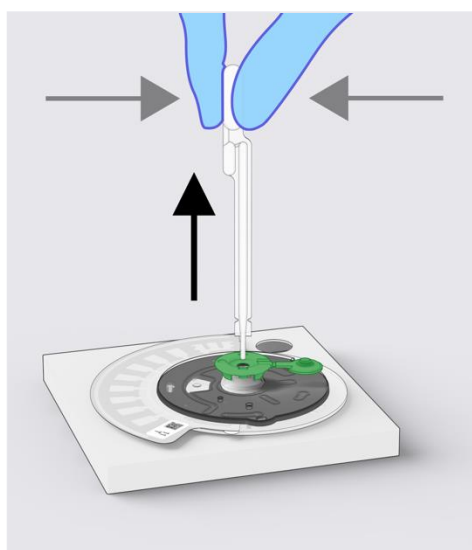
4. Keep the disc flat in the tray. Grasp the transfer pipette by the stem, insert the tip into the center opening unit it reaches the bottom, then push it fully through the bottom until the side wings rest on the edge of the port.



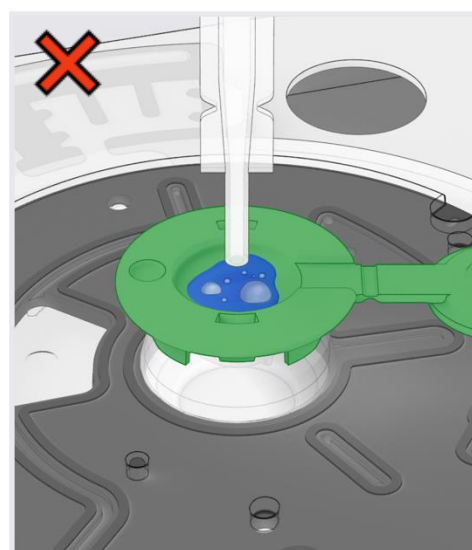
NOTE: The side wings must rest fully on the edge of the port to be inserted correctly.



- 5.A. Once correctly inserted, squeeze the bulb firmly to push all the liquid into the disc.



- 5.B. Remove the pipette while still squeezing the bulb.



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

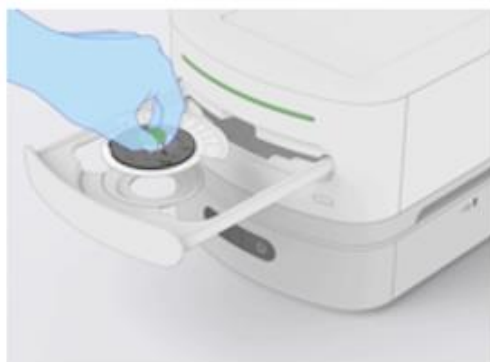
Step 3: Load Quality Control Sample into Test Disc (cont.)

6. 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 4: 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 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).



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.

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.



Step 5: Run Test

1. Close the loading tray to start the test. The instrument runs the test automatically.
2. The screen shows the time remaining. Do not open the tray during the run.
3. When the test is finished, the result appears on the screen. The result can also print and send to the EHR/LIS if connected
4. Press DONE on the screen or the button next to the module. The tray will open.
5. Remove the Test Disc. Dispose of it in biohazard waste.
6. Press the button to close the tray.
7. Dispose of all used materials, including the Test Disc, samples, transfer pipettes and AMDI Sample Buffer tubes, as biohazard 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.

Caution: Do not tamper or attempt to open the test disc after it has been used to prevent exposure to amplicon from the PCR reaction.

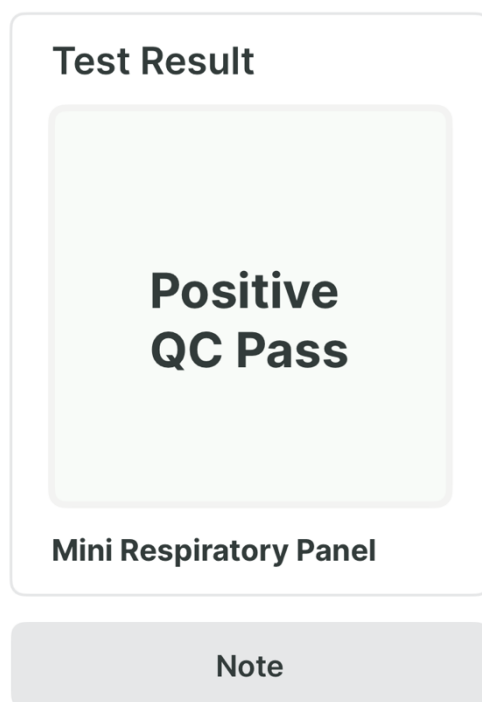
Note: It is recommended to change gloves after disposing of all materials used in running the test to minimize possibility of contamination.

Note: Refer to the Fast PCR Instrument QRG and/or IFU for cleaning and safety instructions.



Quality Control Result

If the Quality Control Test 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.

Operating and Storage Conditions for Kits

The Fast PCR Mini Respiratory Panel Kits and Fast PCR Mini Respiratory External Control Kits should be at room temperature (15–30°C) for both operating conditions and storage.

Available Online

Fast PCR Instrument User Manual	www.AMDIFastPCR.com
Fast PCR Instrument Quick Reference Guide (QRG)	www.AMDIFastPCR.com
Fast PCR Mini Respiratory Panel Instructions for Use (IFU)	www.AMDIFastPCR.com
Fast PCR Mini Respiratory Panel Quick Reference Guide (QRG)	www.AMDIFastPCR.com
Fast PCR Cloud Station Operating Manual	www.AMDICloudStation.com
Safety Data Sheet (SDS)	www.AMDIFastPCR.com

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 Customer Support at: +1-657-660-6800 or customerservice@amdilabs.com or contact your local distributor.



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Autonomous Medical
Devices Incorporated