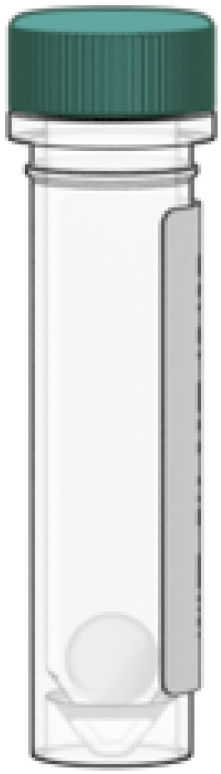
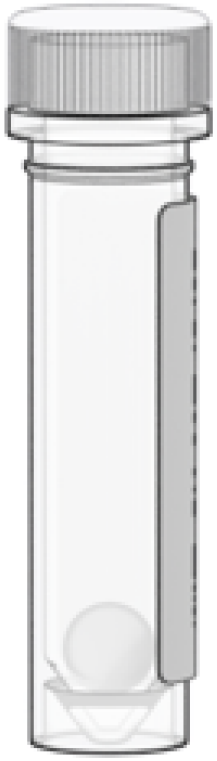
# Fast PCR Mini Respiratory Panel External Control Kit Instructions for Use





For in vitro Diagnostic Use – EN
For Prescription Use Only

LABL-000060 Rev. B; July 2026

Autonomous Medical Devices Incorporated

# Intended Use

The Fast PCR Mini Respiratory Panel External Controls are external positive and negative quality control material intended to monitor the performance of the Fast PCR Mini Respiratory Panel that detects and differentiates respiratory targets including SARS-CoV-2, Respiratory Syncytial Virus, Influenza A, and Influenza B in CLIA waived settings. The controls are processed like a patient specimen after rehydration and are used to verify assay, operator and device performance. This material has no assigned quantitative value and is not intended for screening, monitoring or diagnosis of disease.  For in vitro diagnostic use only.

# Summary and Explanation of Test

Routine use of external controls helps monitor test variability, lot-to-lot performance, operator technique and random/systemic error. The Fast PCR Mini Respiratory Panel External Controls are provided as single-use, lyophilized beads that are rehydrated at the time of use and then introduced into the test workflow similar to a clinical specimen.

# Composition

The Fast PCR Mini Respiratory Panel External Controls are individually packaged (with desiccant), lyophilized positive and negative control beads. They are to be rehydrated immediately before use. Chemical (beta-propiolactone) treatments were used for inactivation of the viral targets. The positive control beads contain Respiratory Syncytial Virus A2, SARS-CoV-2 Washington-1/2020, Influenza A H1N1 California/07/09, and Influenza B Phuket/3073/2013 strains. The organisms are prepared in a buffered solution suitable for lyophilization.

## Warnings

- For in vitro diagnostic use.
- For professional use only.
- For prescription use only.
- These are external controls with no assigned quantitative value. Do not use for patient diagnosis, screening or monitoring.
- Handle according to Biosafety Level 1 practices and institutional policies. Even though materials are inactivated, no inactivation method can guarantee zero risk of infections. Use appropriate PPE and standard precautions.
- Each bead/vial is intended for a single rehydration and control run. Do not reuse.
- Do not open pouch/vial until ready to use. Discard any control that shows damage (e.g., evidence of excessive exposure to heat or moisture), has been stored improperly or is past its expiration date.
- Use only as directed. Rehydrate with the specified volume of provided buffer and follow test instructions for control processing. Improper rehydration may impact results.
- Use with the Fast PCR system only. Performance has not been established on other systems.
- SDS available at www.AMDIFastPCR.com or by contacting customer service at +1-657-660-6800, customerservice@amdilabs.com or contact your local distributor.

## Precautions

### General PCR Precautions

Wear appropriate PPE when loading Test Discs and refrain from touching one's face while preparing specimens and performing the test procedure.

Laboratory area decontamination procedures should be performed daily and PPE should be changed after cleaning.

## Laboratory Precautions

Handle all samples and waste materials as if they could contain infectious materials.

Observe common laboratory safety guidelines:

- Clinical and Laboratory Standards Institute (CSLI) protection of Laboratory Workers from Occupational Acquired Infections, Approved Guideline M29m and other appropriate safety guidelines
- Biosafety in Microbiological and Biomedical Laboratories (Centers for Disease Control and Prevention and National Institutes of Health) or other appropriate biosafety procedures

Wear personal protective equipment (PPE) and disposable powder-free gloves while handling samples and/or controls. Change gloves often and between each test.

**NOTE: Do not attempt to lift or carry an Operating Module while running or connected to a Base Station.**

## Operating and Storage Conditions for Kits

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

# Symbols

| Symbol | Description |
|---|---|
| ⚠ | Caution: Pay Attention |
| | Manufacturer |
| | Date of Manufacture |
| | Expiration Date (YYYY-MM-DD) |
| | Keep Away from Water |
| SN | Serial Number |
| LOT | Lot Number |
| 30°C 15°C | Temperature Limits (High and Low) |
| | Do Not Use if Package is Damaged |
| 2 | Do Not Reuse |
| REF | Catalog Number |
| Rx | Prescription Use Only |
| IVD | In Vitro Diagnostic Medical Device |
| | Consult Instructions for Use |

# Quality Control Testing

Fast PCR Mini Respiratory Panel External 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 Controls 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 appropriate when:

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

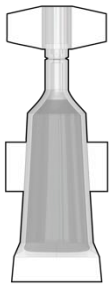
Ensure Quality Control Material is stored appropriately and according to Manufacturer's Instructions.

**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

# Quality Control Testing Instructions

**Gather materials needed for testing**

Fast PCR Mini Respiratory Panel Kit:

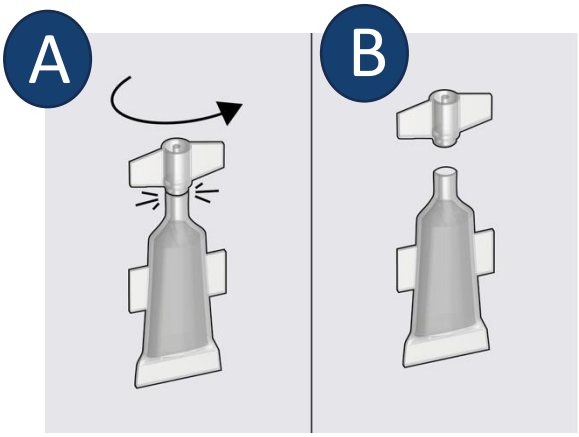
(1) Fast PCR Mini Respiratory Panel Test Disc, (1) 450uL transfer pipette

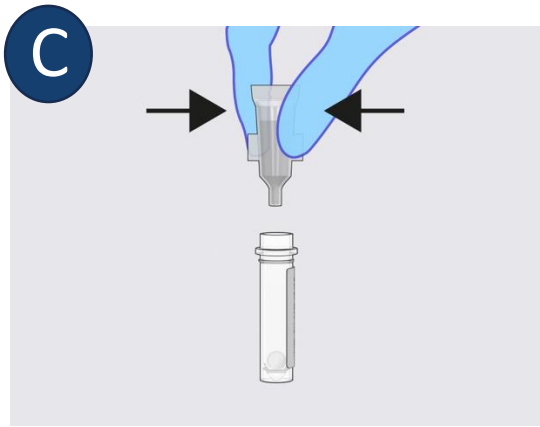
Fast PCR Mini Respiratory Panel External Control Kit:

(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.**

## Step 2: Select QC and Initiate Test

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 (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.**

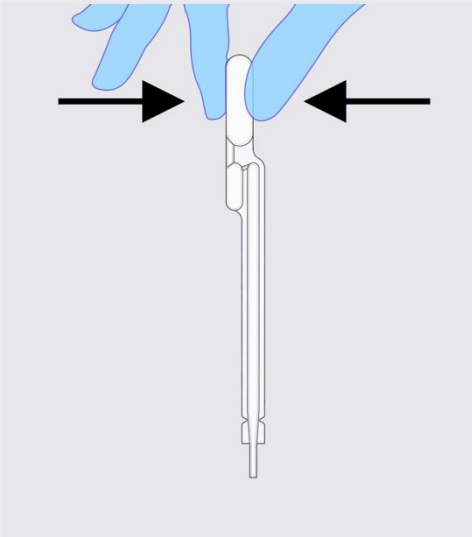
**NOTE: Error messages will display on the screen if the Test Disc ID:**

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

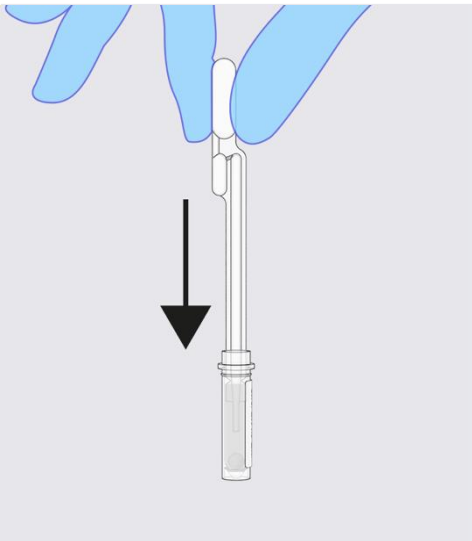
# Quality Control Testing Instructions (cont.)

## Step 3: Load Quality Control Sample into Test Disc

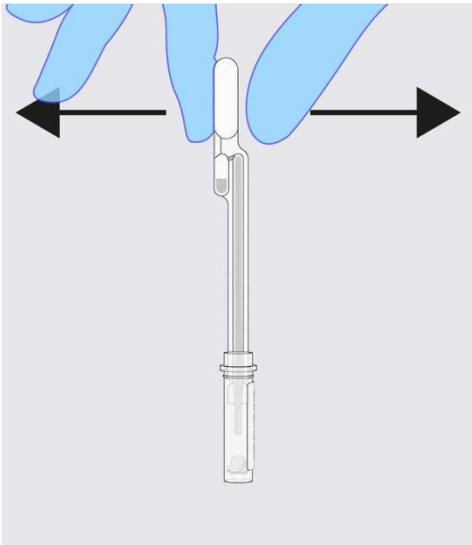
1. Place the Test Disc in its holder on a flat surface. Ensure sample port is open.



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.

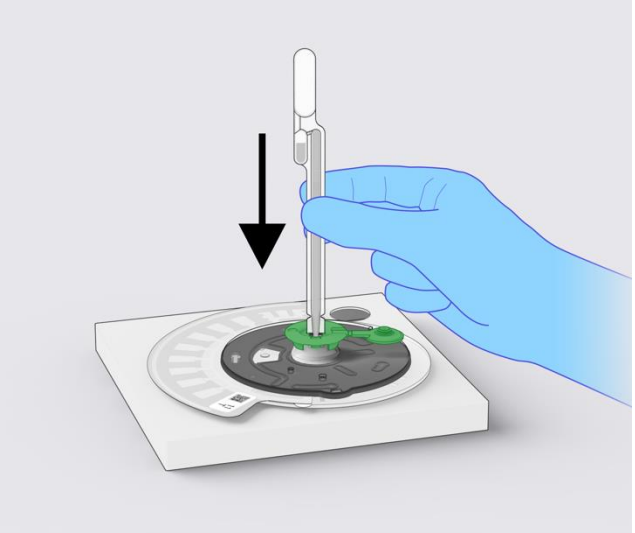


3. Let go of the bulb while the tip is still in the sample. This pulls the Quality Control into the pipette.

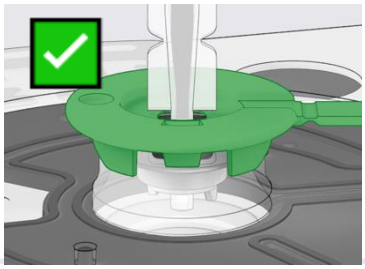
**NOTE: Ensure there are no air bubbles in transfer pipette.**

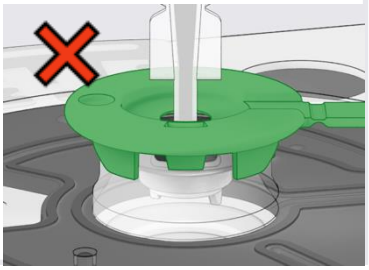
## Step 3: Load Quality Control Sample into Test Disc (cont.)

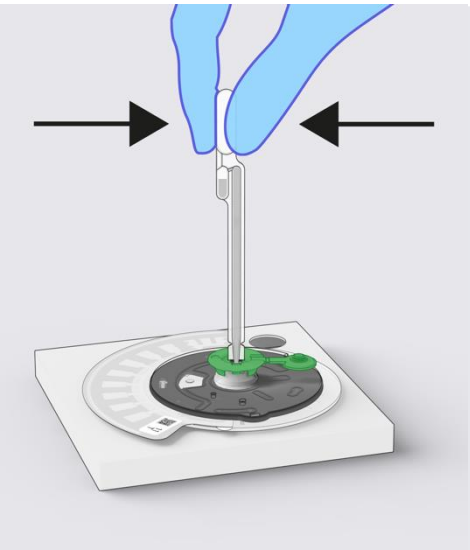
4. Keep the disc flat in the tray. Grasp the transfer pipette by the stem, insert the tip into the center opening unit it reaches the bottom, then push it fully through the bottom until the side wings rest on the edge of the port.



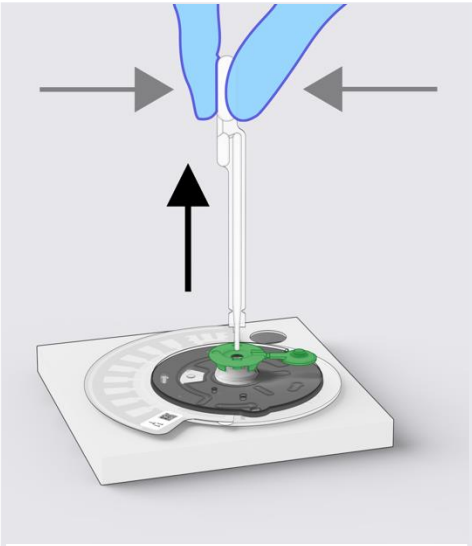
**NOTE:** ***The side wings must rest fully on the edge of the port to be inserted correctly.***



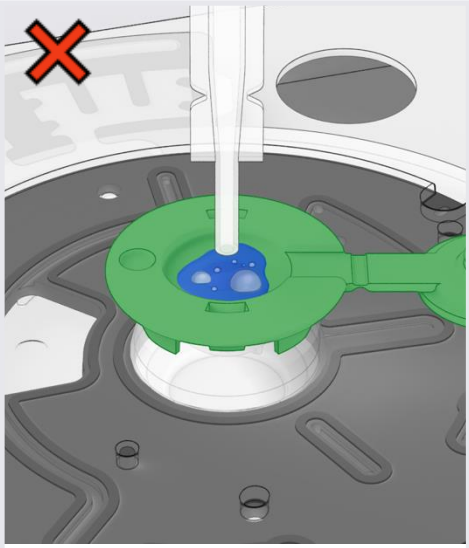




5.A. Once correctly inserted, squeeze the bulb firmly to push all the liquid into the disc.



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.)

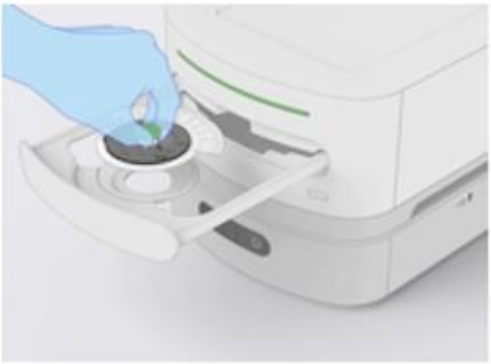
6. Close the sample port by closing the cover over the sample port and firmly pushing down until there is an audible click.

**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.**

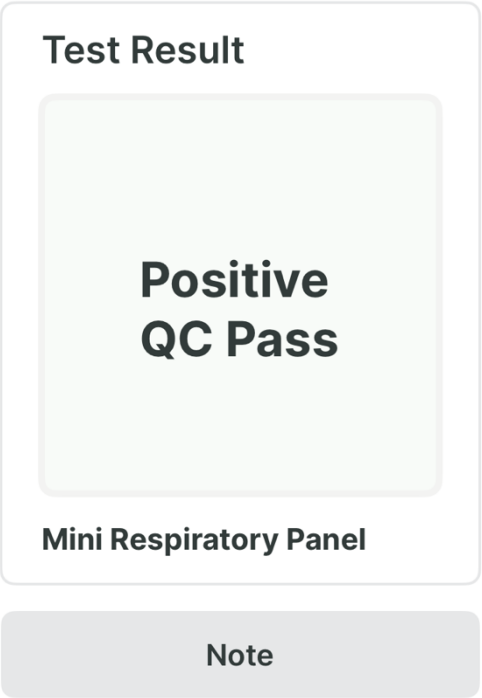
**Caution: Do not tamper or attempt to open the test disc after it has been used to prevent exposure to amplicon from the PCR reaction.**

**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.<br><br>If failure persists, contact Customer Service for further instruction. |

# Decontamination Procedures

Cleaning of the exterior surfaces of the Fast PCR Instrument and the immediate work area should be performed as necessary, including at least daily when in use.

1. Put on clean PPE, such as a lab coat and gloves.
2. Unplug the power cord from the wall outlet and the instrument.
3. Carefully wipe down both the outside and beneath the lid where the Test Disc sits with either a) 10% v/v household bleach diluted with water, or b) 70% v/v alcohol (ethanol or isopropanol) diluted with water.

**NOTE: Do not spray cleaning solution directly on the instrument.**

## General Information

This document is used solely for the purpose of the Fast PCR Mini Respiratory Panel External Control Kit with the Fast PCR Instrument. If the Instrument is used in a manner not specified by Autonomous Medical Devices Incorporated, then protection provided by the equipment may be impaired.

## 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 |

## Customer Support

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 Incorporated Customer Service at +1-657-660-6800, customerservice@amdilabs.com or contact your local distributor.

## Intellectual Property

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