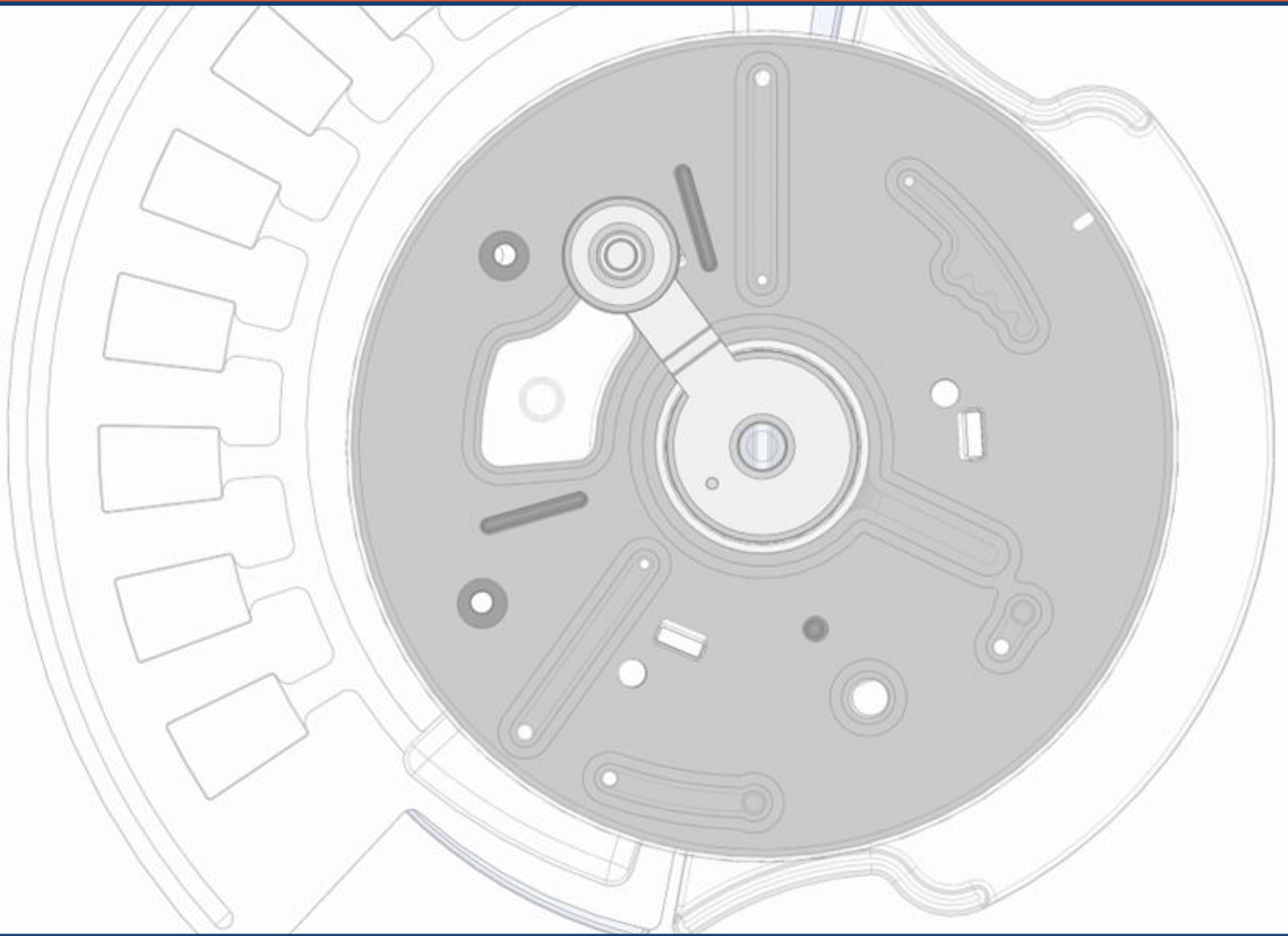


Fast PCR Mini Respiratory Panel Instructions for Use



For in vitro Diagnostic Use – EN
For Prescription Use Only

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.

Summary and Explanation of Test

The Fast PCR Mini Respiratory Panel, designed for use solely with the Fast PCR Instrument, is a polymerase chain reaction (PCR) sample-to-answer diagnostic test for the simultaneous, qualitative detection and identification of 4 different respiratory viruses in nasal swab specimens collected in AMDI Sample Buffer from individuals with signs and symptoms of respiratory tract infections.

Summary of Detected Organisms

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)

- Enveloped, positive-sense RNA beta coronavirus first detected in 2019^{1,4}.
- Transmitted primarily by respiratory droplets/aerosols; incubation is typically a few days².
- Illness ranges from asymptomatic to severe pneumonia; risk is higher in older adults, the immunocompromised, and those with cardiopulmonary disease¹.
- Multiple variants continue to circulate; symptoms overlap with other respiratory viruses¹.
- Viral RNA is most often detected in upper-respiratory specimens. A positive result does not rule out co-infection; a negative result does not exclude infection if sampling or timing is suboptimal³.

Influenza A and B

- Enveloped, negative-sense RNA viruses (Orthomyxoviridae) with frequent antigenic drift; type A can also undergo shift via reassortment^{5,6}.
- Type A is subtyped by hemagglutinin (H) and neuraminidase (N); H1N1pdm09 and H3N2 are the main human strains (H3N2 often causes more severe disease in older adults)^{7,9}.
- Type B is not subtyped; it circulates as Victoria and Yamagata lineages⁵.
- Abrupt onset of fever, myalgia, and cough; complications include pneumonia, especially in young children, pregnant individuals, older adults, and those with chronic conditions^{8,9}.
- Seasonality is typically late fall through spring in temperate regions⁸.
- Highest viral loads are usually in the first few days of illness; co-infections with other respiratory pathogens can occur⁸.



Summary of Detected Organisms (cont.)

Respiratory syncytial virus (RSV)

- Enveloped, negative-sense RNA virus (Pneumoviridae, genus Orthopneumovirus); two major subtypes, A and B, with year-to-year variation in dominance^{10,11,13}.
- Leading cause of bronchiolitis and pneumonia in infants and young children; severe disease also occurs in adults ≥ 60 years and in those with cardiopulmonary disease or immunocompromise^{10,11,12}.
- Reinfections are common throughout life; seasonality typically peaks in winter in temperate climates and varies in tropical regions^{10,11,12}.
- Prolonged shedding may occur in infants and immunocompromised patients. Detection of RSV does not preclude other respiratory infections¹⁴.

References

SARS-CoV-2 (COVID-19)

1. Centers for Disease Control and Prevention. "About COVID-19." CDC, <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19.html>. Accessed 10 Sept. 2025.
2. Centers for Disease Control and Prevention. "Scientific Brief: SARS-CoV-2 Transmission." CDC, <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html>. Accessed 10 Sept. 2025.
3. Centers for Disease Control and Prevention. "Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing." CDC, <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>. Accessed 10 Sept. 2025.
4. International Committee on Taxonomy of Viruses (ICTV). "Genus: *Betacoronavirus*." *ICTV Online Report*, <https://ictv.global/report/chapter/coronaviridae/coronaviridae/betacoronavirus>. Accessed 10 Sept. 2025.

Influenza A & B

5. Centers for Disease Control and Prevention. "Types of Influenza Viruses." CDC, <https://www.cdc.gov/flu/about/viruses/types.htm>. Accessed 10 Sept. 2025.
6. Centers for Disease Control and Prevention. "How Flu Viruses Can Change: 'Drift' and 'Shift.'" CDC, <https://www.cdc.gov/flu/about/viruses/change.htm>. Accessed 10 Sept. 2025.
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8. Centers for Disease Control and Prevention. *Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book)*, Chapter 12: Influenza. CDC, <https://www.cdc.gov/vaccines/pubs/pinkbook/flu.html>. Accessed 10 Sept. 2025.
9. Centers for Disease Control and Prevention. "Flu and People 65 Years and Older." CDC, <https://www.cdc.gov/flu/highrisk/65over.htm>. Accessed 10 Sept. 2025.

Respiratory Syncytial Virus (RSV)

10. Centers for Disease Control and Prevention. "About RSV." CDC, <https://www.cdc.gov/rsv/about/index.html>. Accessed 10 Sept. 2025.
11. Centers for Disease Control and Prevention. "Clinical Overview of RSV." CDC, <https://www.cdc.gov/rsv/hcp/clinical-overview/index.html>. Accessed 10 Sept. 2025.
12. World Health Organization. "Respiratory Syncytial Virus (RSV)." WHO, <https://www.who.int/news-room/fact-sheets/detail/respiratory-syncytial-virus-rsv>. Accessed 10 Sept. 2025.
13. International Committee on Taxonomy of Viruses (ICTV). "Family: *Pneumoviridae* (Genus *Orthopneumovirus*)." *ICTV Online Report*, <https://ictv.global/report/chapter/pneumoviridae/pneumoviridae/orthopneumovirus>. Accessed 10 Sept. 2025.
14. Lehnert, Nicola, et al. "Long-Term Shedding of Respiratory Syncytial Virus, Human Metapneumovirus, and Parainfluenza Virus in Patients with Hematological Disorders." *PLOS ONE*, vol. 11, no. 2, 2016, e0147437. <https://doi.org/10.1371/journal.pone.0147437>. Accessed 10 Sept. 2025.

Principle of the Procedure

The Fast PCR Mini Respiratory Panel is a closed system disposable test disc that stores all necessary reagents for sample preparation, reverse transcription, polymerase chain reaction (PCR), and detection. It enables amplification and detection of nucleic acids from 4 respiratory pathogens within a single anterior nasal (AN) sample.

After a sample is collected, the user transfers the sample (in AMDI sample buffer) into the sample port, closes the sample port lid and places the test disc into the Fast PCR Instrument to start the run. The entire process takes approximately 10 minutes.

During a run, the Fast PCR Instrument:

- Performs automated sample preparation to lyse pathogens, protect single-stranded RNA, remove PCR inhibitors and inactivate RNAses.
- Executes multiplex PCR by reverse transcription, followed by a multiplexed PCR reaction.
- Applies cycle threshold (Ct) analysis to monitor amplification curves and interprets the data to generate a qualitative result for each analyte.

Warnings

- A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA. Failure to follow the instructions or any modifications to the test will result in the test no longer meeting the requirements for waived classification.
- For in vitro diagnostic use.
- For prescription use only.
- Federal law restricts this device to sale by or on the order of a licensed physician.
- Treat all specimens as potentially infectious. Follow universal precautions when handling samples and the Test Disc. The use of gloves is recommended when handling patient samples.
- 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 and nasal swabs are for single use only. Do not use with multiple specimens.
- Viral culture should not be attempted in cases of positive results for SARS-CoV-2 and/or any similar microbial agents unless a facility with an appropriate level of laboratory biosafety (e.g., BSL 3 and BSL 3+, etc.) is available.



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 (CLSI) 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. Change gloves often and between each test.

Disposable gloves and safety glasses are recommended when running this test. Wash hands thoroughly after handling any patient sample.

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

General PCR Precautions

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

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

Limitations of Use

- The Fast PCR Instrument is intended to be used in combination with Fast PCR Test Discs.
- The Fast PCR Mini Respiratory Panel is a qualitative test and does not provide a quantitative value for viruses detected within the sample.
- The Fast PCR Mini Respiratory Panel has not been validated for testing specimens other than anterior nasal swabs (ANS) in AMDI Sample Buffer. Testing of other specimen types or use of other media has not been validated and may result in erroneous or invalid results.
- The Fast PCR Mini Respiratory Panel has been evaluated for use with human specimen material only.
- The effect of treatment with antibiotics or antiretrovirals on test performance has not been evaluated.
- Fast PCR Test Discs should be stored at room temperature (15-30 °C). Use of improperly stored discs may result in inaccurate results.
- Do not use any consumables not provided by AMDI.
- Do not remove Base Station or Operating Module covers during a test.
- Use only the supplied cables when connecting the Base Station and Operating Modules.
- Keep system tablet within 3 meters of Base Station for optimal performance
- Check with your IT policies to ensure that the System Tablet is up-to-date.
- The System Tablet should only be used for the Fast PCR App. Do not use the device for other purposes.
- Do not attempt to re-use a Fast PCR Test disc associated with an error or invalid result.
- Only authorized AMDI personnel should perform service or repairs on the Fast PCR Instrument.
- Do not move Base Station or Operating Modules while the System is running.
- Do not use near active high frequency surgical equipment, the shielded room of an MRI system or other locations where electromagnetic disturbances are high.
- 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.
- Accurate results are dependent on proper sample collection, processing, handling, and storage. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
- Careful compliance with these instructions is necessary to avoid inaccurate results.

Limitations of Use (Cont.)

- This test is not intended to differentiate influenza A subtypes, influenza B lineages, RSV subtypes, or SARS-CoV-2 variants. If differentiation of specific influenza, RSV, or SARS-CoV-2 subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2, influenza A, influenza B, and RSV and their prevalence, which change over time.
- Mutations within the target region of influenza A, influenza B, SARS-CoV-2, and RSV could affect primer and/or probe binding, resulting in failure to detect the presence of virus, or the virus being detected less predictably.
- Performance characteristics for influenza A were established during the 202X-202X influenza season, when influenza A/H1N1pdm09 and H3N2 were predominant. When other influenza A viruses are emerging, performance characteristics may differ.
- Due to the low prevalence of circulating RSV during the prospective clinical study, performance characteristics for RSV were established using a combination of prospective and retrospective clinical specimens.
- Positive and negative predictive values are dependent upon prevalence. False negative results are more likely during peak activity when disease prevalence is high and false positive results are more likely during periods of low activity.
- A false negative result may occur if an inadequate (below the detection limit) number of organisms are present in the sample.
- A live intranasal influenza vaccine may result in positive results for influenza A and influenza B. Performance of this test has not been evaluated for patients who recently received an intranasally administered influenza vaccine.
- The Fast PCR Mini Respiratory Panel has not been specifically evaluated for specimens collected from immunocompromised individuals.
- Performance of the Fast PCR Mini Respiratory Panel has not been evaluated in pooled specimens or the screening of specimens from asymptomatic individuals who do not have signs and symptoms of respiratory infection.
- Negative results do not preclude SARS-CoV-2, influenza A, influenza B, or RSV infection.
- Patient management decisions should not be made solely on the Fast PCR Mini Respiratory Panel results, but rather with the consideration of clinical observations, patient history, recent exposures, epidemiological information and other diagnostic information, including laboratory data.
- This test cannot rule out diseases caused by other viral or bacterial pathogens.
- The effect of interfering substances has been evaluated for only those listed within the labeling. Interference by substances other than those described may lead to invalid or erroneous results.

Symbols

Symbol	Description
	Caution: Pay Attention
	Manufacturer
	Date of Manufacture
	Expiration Date (YYYY-MM-DD)
	Keep Away from Water
	Serial Number
	Lot Number
	Temperature Limits (High and Low)
	Do Not Use if Package is Damaged
	Do Not Reuse
	Catalog Number
	Prescription Use Only
	In Vitro Diagnostic Medical Device
	Consult Instructions for Use
	Laser Beam
	Separate Collection for Waste and Electronic Equipment is Required

Materials Provided

The Fast PCR Mini Respiratory Panel Test Disc contains materials consisting of primers, buffers, dNTPS, and enzymes.

Each kit contains sufficient reagents and materials for 20 tests.

- Individually packaged Fast PCR Mini Respiratory Panel Test Discs (20).
- AMDI Sample Buffer Tubes and Nasal Swabs (21).
- Fixed volume (400 ~~400~~ 450ul) transfer pipettes (22).
- Fast PCR Mini Respiratory Panel Instructions for Use (IFU) (1)
- Fast PCR Mini Respiratory Panel Quick Reference Guide (QRG) (1)



Test Disc



Sample Buffer and Nasal Swab



450uL Transfer Pipette

Materials Required But Not Provided

1. Fast PCR Instrument

- Fast PCR Base Station
- Fast PCR Operating Module
- Fast PCR System Tablet with Fast PCR App

2. Quality Control Kit

- 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

3. 10% bleach solution or similar disinfectant.



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.

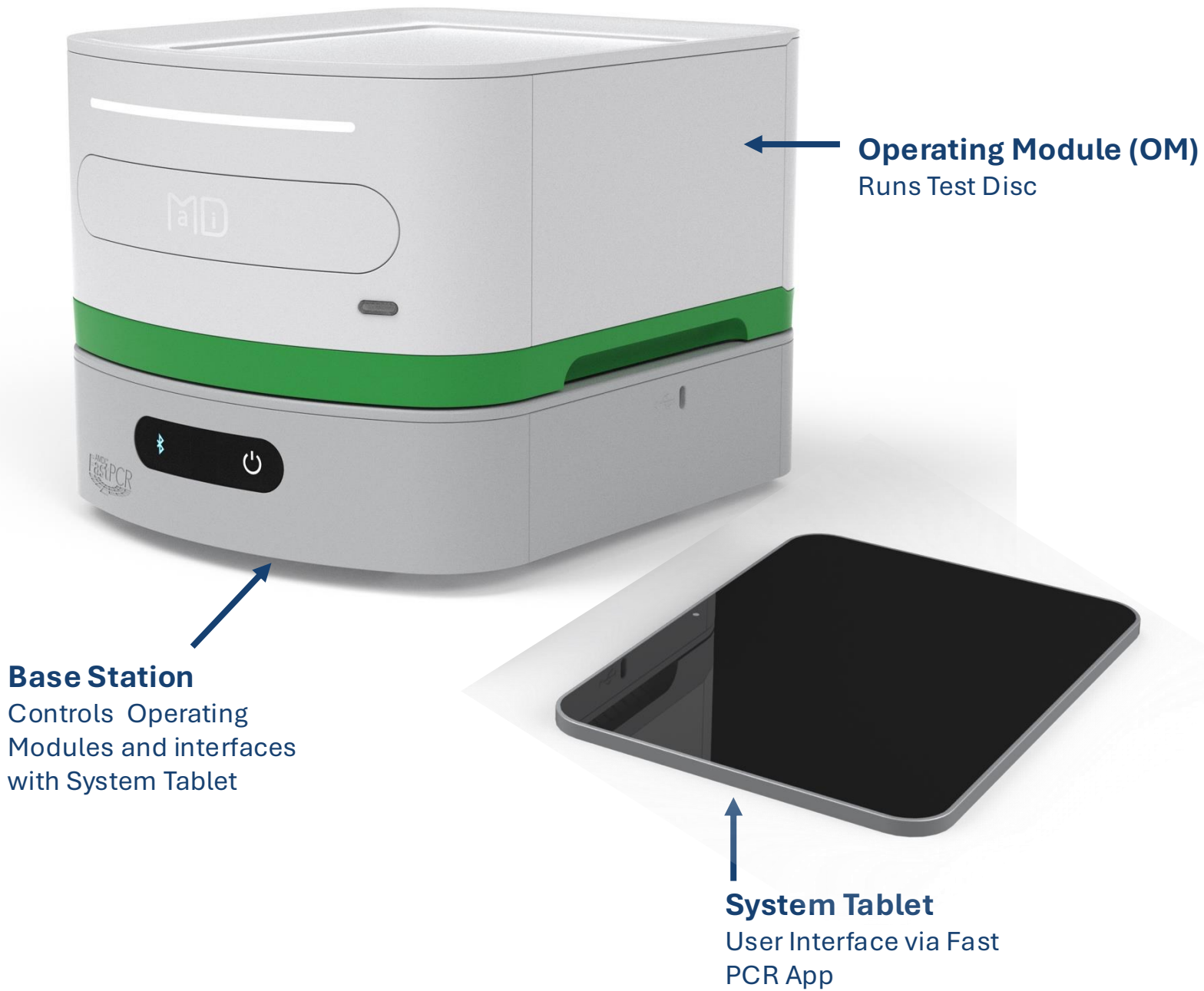
Alternatively, anterior nasal swab specimens collected in AMDI Sample Buffer can be frozen ($\leq -15^{\circ}\text{C}$ or $\leq -70^{\circ}\text{C}$) and undergo up to one freeze/thaw cycles.

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.

Fast PCR Instrument Overview

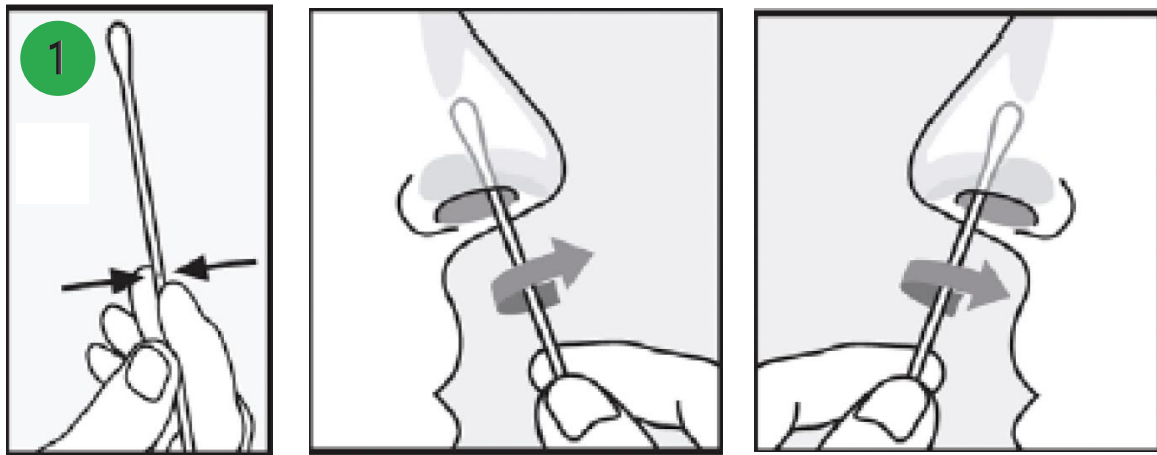
The Fast PCR Instrument consists of a System Tablet, a Base Station and up to 4 Operating Modules. Each System Tablet connects via Bluetooth to a single base station.



Step 1: Collect Anterior Nasal (ANS) Swab Sample

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



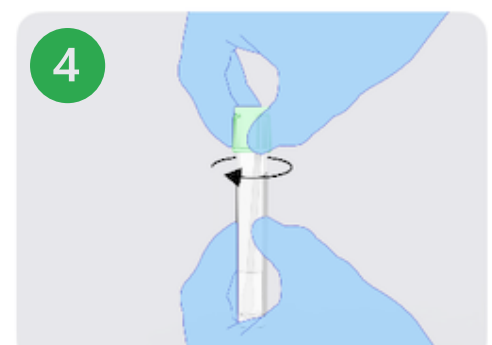
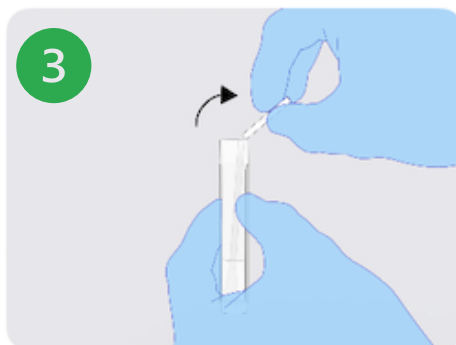
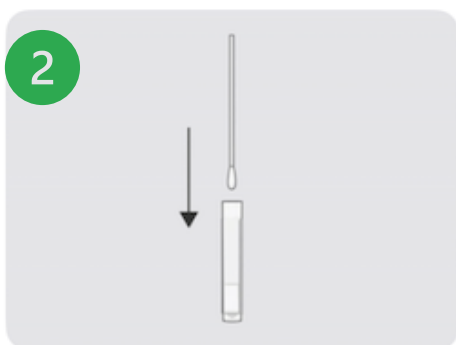
NOTE: Do not let the swab touch any surface before placing it into the collection tube.

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.

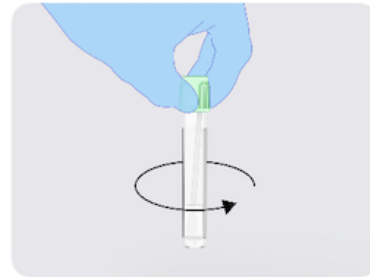
3. Break: Carefully bend the swab against the tube rim to break the swab shaft to fit into tube.

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.



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.

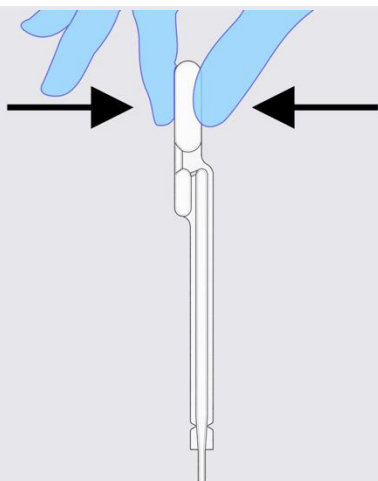
NOTE: Test Discs should not be used if dropped or show signs of breakage. It could contaminate the Operating Module and surrounding area.

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

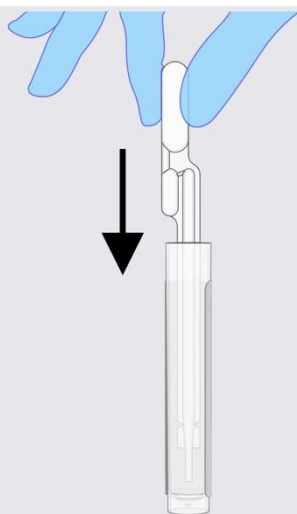
- is not valid
- has expired
- has been recalled or placed on hold
- has been previously run

Step 4: Load Sample into Test Disc

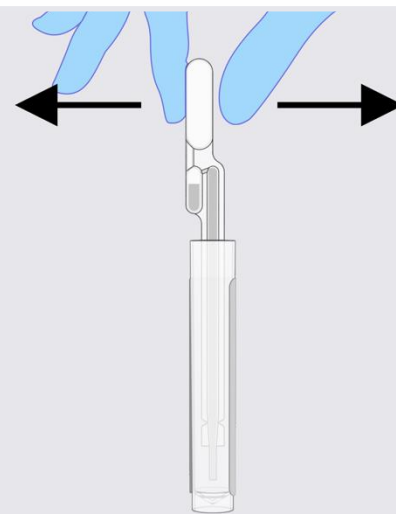
1. Place the Test Disc in its holder on a flat surface. Ensure sample port is open.



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



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



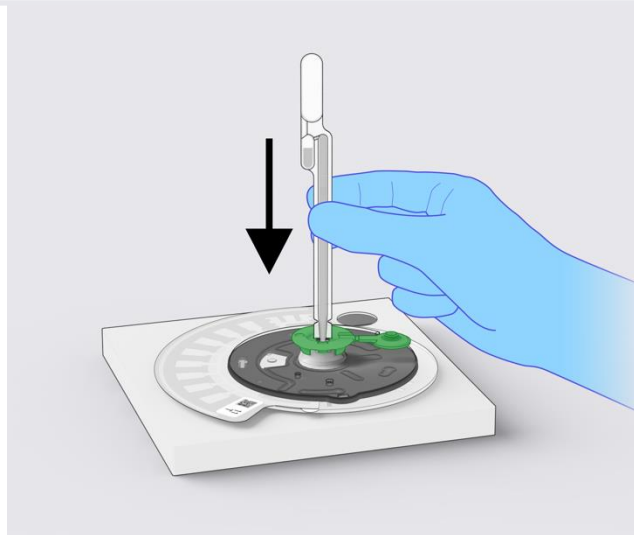
3. Let go of the bulb while the tip is still in the sample. This pulls the sample into the pipette.



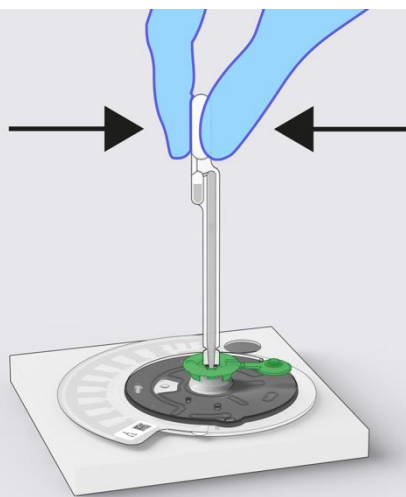
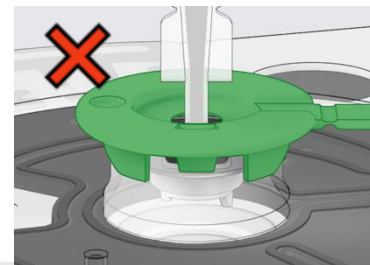
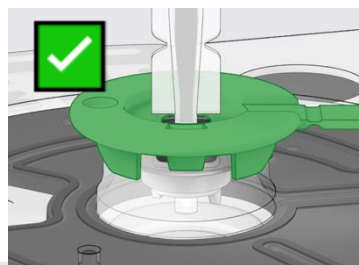
Caution: Air bubbles in the tip of the 450uL transfer pipette may lead to an invalid result. 450uL is required for adequate sample volume. Loading an incorrect sample volume may lead to invalid or inaccurate results.

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

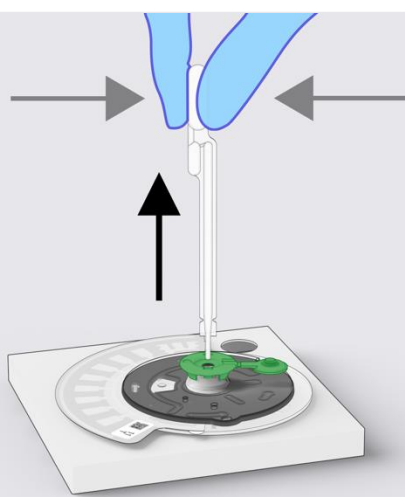
4. Keep the disc flat in the tray. Grasp the transfer pipette by the stem, insert the tip into the center opening until it reaches the bottom, then push it fully through the bottom until the side wings rest on the edge of the port.



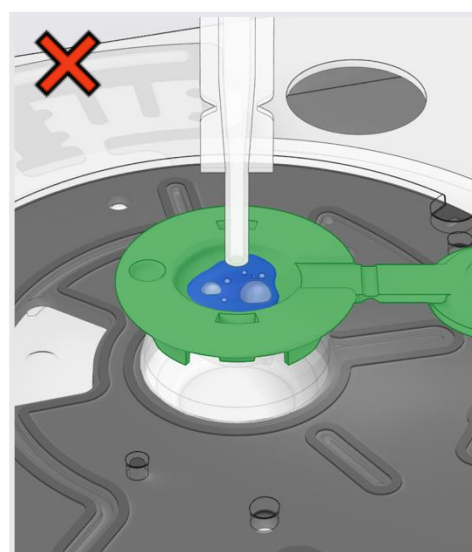
NOTE: The side wings must rest fully on the edge of the port to be inserted correctly.



- 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.

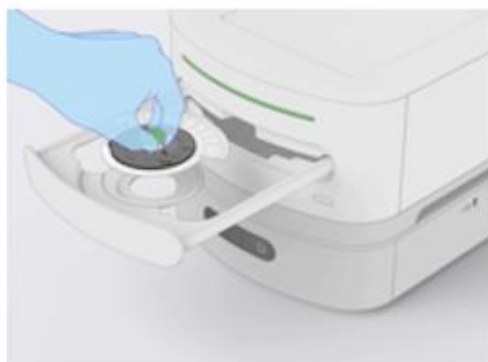
Step 4: Load Sample into Test Disc (cont.)

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

Refer to the Fast PCR Mini Respiratory External Control Kit Instructions for Use for a complete AMDI Fast PCR Control procedures.

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.

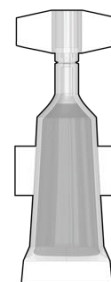
Fast PCR Mini Respiratory Panel External Control Kit Materials



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:

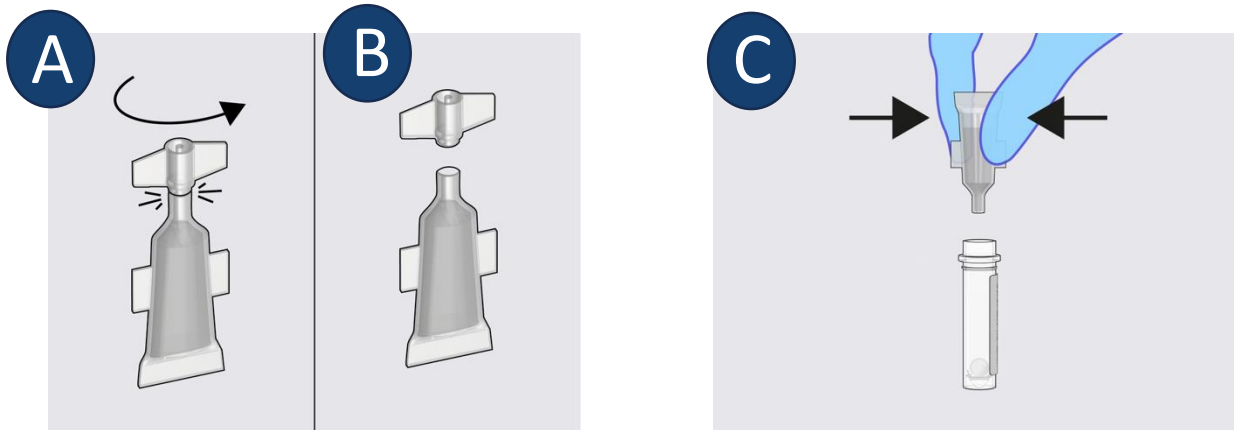
(1) Fast PCR Test Disc, (1) 450uL transfer pipette

Fast PCR Mini Respiratory Panel External Control Kit:

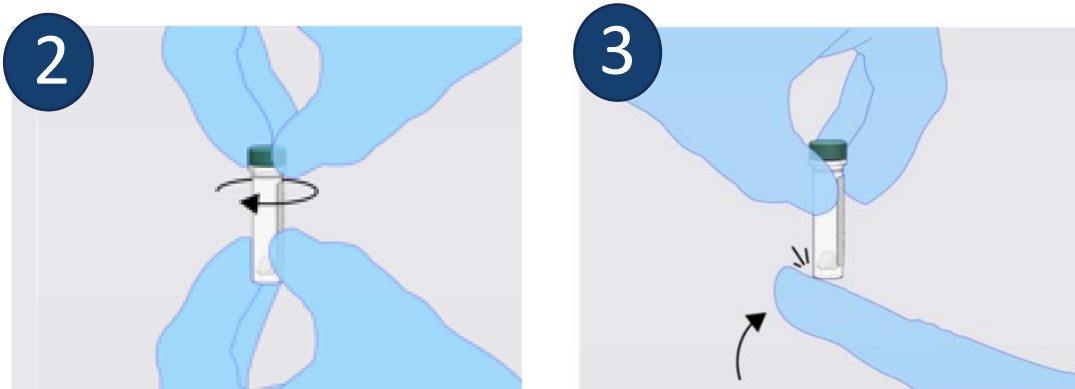
(1) QC vial, (1) AMDI QC Sample Buffer ampoule

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.

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.

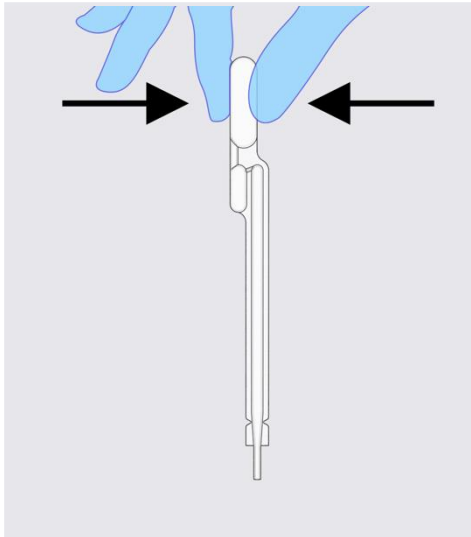
NOTE: Error messages will display on the screen if the Test Disc ID:

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

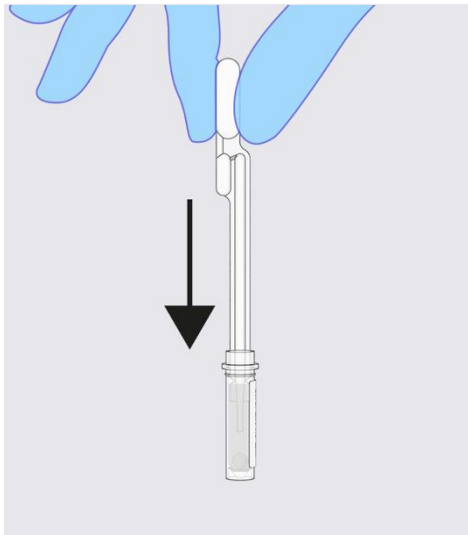
Quality Control Testing Instructions (cont.)

Step 3: Load Quality Control Sample into Test Disc

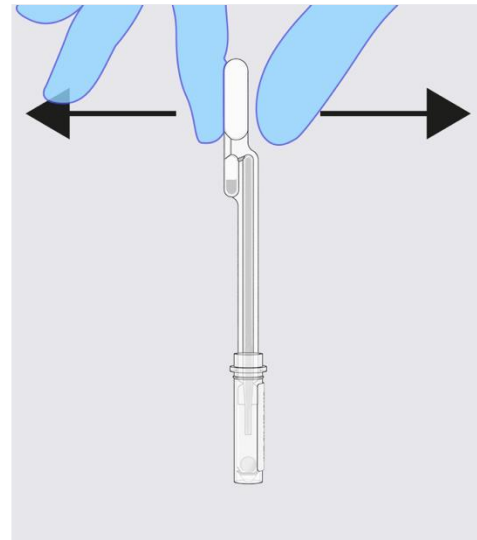
1. Place the Test Disc in its holder on a flat surface. Ensure sample port is open.



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.



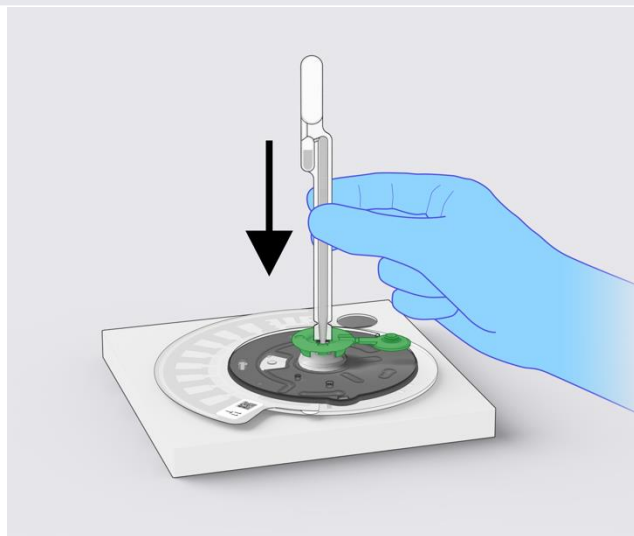
3. Let go of the bulb while the tip is still in the sample. This pulls the Quality Control into the pipette.

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

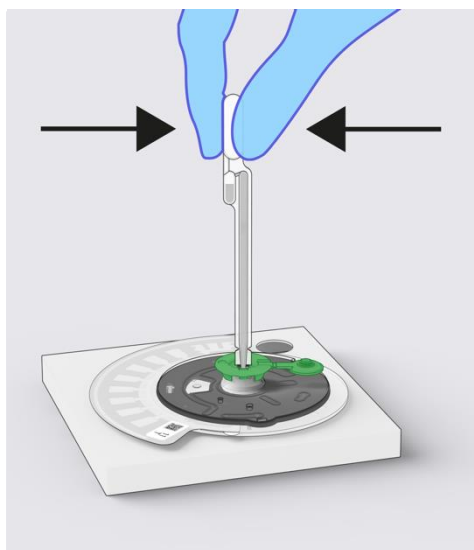
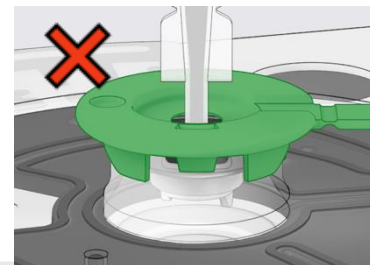
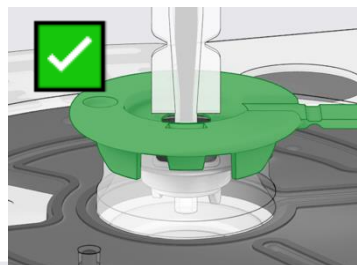
Quality Control Testing Instructions (cont.)

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

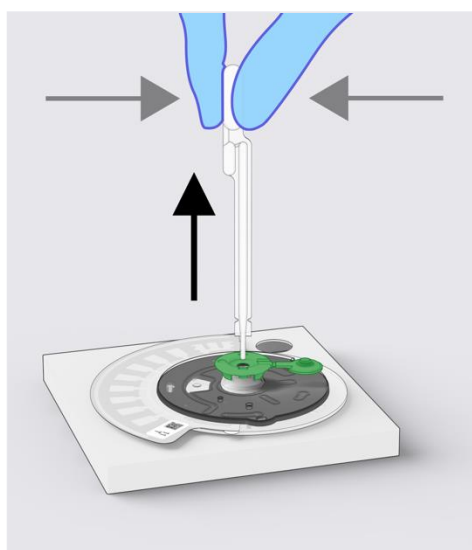
4. Keep the disc flat in the tray. Grasp the transfer pipette by the stem, insert the tip into the center opening unit it reaches the bottom, then push it fully through the bottom until the side wings rest on the edge of the port.



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.

Quality Control Testing Instructions (cont.)

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.

Test Result

Positive
QC Pass

Mini Respiratory Panel

Note

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.

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.

Expected Values

In a multicenter clinical study for the Fast PCR Mini Respiratory Panel, 1788 prospective Clinical Samples were analyzed. The number and percentage of positive results across the 4 analytes are listed below by age group and sex.

Positive Results and Prevalence by Age Group, Prospective Samples

Target		≤5 yr	6-18 yr	19-40 yr	41-60 yr	≥61 yr	Total
Influenza A	# Pos	9	45	127	67	33	281
	% Prev	9.6%	14.5%	19.1%	13.5%	14.8%	15.7%
Influenza B	# Pos	3	34	28	17	0	82
	% Prev	3.2%	10.9%	4.2%	3.4%	0.0%	4.6%
RSV	# Pos	2	9	8	13	10	42
	% Prev	2.1%	2.9%	1.2%	2.6%	4.5%	2.3%
SARS-CoV-2	# Pos	3	9	28	40	16	96
	% Prev	3.2%	2.9%	4.2%	8.1%	7.2%	5.4%

Positive Results and Prevalence by Sex, Prospective Samples

Target		Male	Female	Unknown	Total
Influenza A	# Pos	102	178	1	281
	% Prev	14.9%	16.1%	100%	15.7%
Influenza B	# Pos	34	48	0	82
	% Prev	5.0%	4.3%	0.0%	4.6%
RSV	# Pos	17	25	0	42
	% Prev	2.5%	2.3%	0.0%	2.3%
SARS-CoV-2	# Pos	37	59	0	96
	% Prev	5.4%	5.3%	0.0%	5.4%

Clinical Performance

A prospective, multicenter study established the clinical performance of the Fast PCR Mini Respiratory Panel. Collections from the 9 geographically diverse CLIA Waived study sites in the US occurred from un-trained operators between December 2024 and May 2025. Due to low prevalence of RSV positivity at the time of the prospective collection, archived samples with the same inclusion and exclusion criteria were utilized to supplement the overall study. All testing was performed according to the manufacturer's instructions with no hands-on training. Training was limited to written material (i.e. quick reference guides) that were intended to be provided with the Fast PCR System (consisting of the Fast PCR Mini Respiratory Panel used on the Fast PCR Instrument).

A total of 1947 unique anterior nasal specimens that met the pre-determined inclusion criteria were enrolled from consented individuals of all ages presenting with signs of symptoms of a viral respiratory infection for the prospective clinical study. A total of 159 were excluded and not tested. The most common reasons for exclusion were protocol deviations (126 or 6.5%) and no Fast PCR result obtained (33 or 1.7%). The final dataset included 1788 prospectively enrolled samples as well as 118 archived samples from the same flu season, for a total of 1906 samples.

Sex Demographics

Sex	All Subjects n (%)	Prospective n (%)	Archived n (%)
All	1906	1788 (93.8%)	118 (6.2%)
Female	1169 (61.3%)	1104 (61.7%)	65 (55.1%)
Male	736 (38.6%)	683 (38.2%)	53 (44.9%)
Unknown	1 (0.1%)	1 (0.1%)	0 (0.0%)

Age Demographics

Age Group	All Subjects n (%)	Prospective n (%)	Archived n (%)
All	1906	1788	118
≤5 yr	98 (5.1%)	94 (5.3%)	4 (3.4%)
6-18 yr	344 (18.0%)	311 (17.4%)	33 (28.0%)
19-40 yr	687 (36.0%)	664 (37.1%)	23 (19.5%)
41-60 yr	519 (27.2%)	496 (27.7%)	23 (19.5%)
≥61 yr	258 (13.5%)	223 (12.5%)	35 (29.7%)



Race Demographics

Race	All Subjects n (%)	Prospective n (%)	Archived n (%)
All	1906	1788	118
Am Indian or Alaskan Nat	4 (0.2%)	4 (0.2%)	0 (0.0%)
Asian	86 (4.5%)	81 (4.5%)	5 (4.2%)
Black or African Am	284 (14.9%)	283 (15.8%)	1 (0.8%)
Not Reported	31 (1.6%)	29 (1.6%)	2 (1.7%)
Other or Mixed Race	70 (3.7%)	70 (3.9%)	0 (0.0%)
Unknown	21 (1.1%)	20 (1.1%)	1 (0.8%)
White	1410 (74.0%)	1301 (72.8%)	109 (92.4%)

Ethnicity Demographics

Ethnicity	All Subjects n (%)	Prospective n (%)	Archived n (%)
All	1906	1788	118
Hispanic	343 (18.0%)	339 (19.0%)	4 (3.4%)
Not Hispanic	1498 (78.6%)	1384 (77.4%)	114 (96.6%)
Not Reported	58 (3.0%)	58 (3.2%)	0 (0.0%)
Unknown	7 (0.4%)	7 (0.4%)	0 (0.0%)

The Fast PCR System was assessed across four analytes by comparing its results with those from an FDA-cleared (510(k)) multiplex respiratory panel, using both prospective and archived specimens. Both Positive and Negative Agreement are summarized using:

- Positive Percent Agreement (PPA) : $100 \times (TP/(TP+FN))$. A true positive (TP) means both the Fast PCR System and the comparator reported the analyte was positive; a false negative (FN) means the Fast PCR System reported the analyte as negative, and the comparator reported the analyte as positive.
- Negative Percent Agreement (NPA): $100 \times (TN/(TN+FP))$. A true negative (TN) means both the Fast PCR System and the comparator reported the analyte was negative; a false positive (FP) means the Fast PCR System reported the analyte as positive, and the comparator reported the analyte as negative.



Clinical Performance: Prospective and Archived Samples

Analyte	Sample Category	Total n	True Positive n	False Positive n	False Negative n	True Negative n	PPA (%)	95% CI	NPA (%)	95% CI
Influenza A	All	1906	236	47	6	1617	97.5	94.7 – 98.9	97.2	96.3 – 97.9
	Prospective	1788	236	45	6	1501	97.5	94.7 – 98.9	97.1	96.1 – 97.8
	Archived	118	0	2	0	116	-	-	98.3	94.0 – 99.5
Influenza B	All	1906	77	5	0	1824	100.0	95.2 – 100.0	99.7	99.4 – 99.9
	Prospective	1788	77	5	0	1706	100.0	95.2 – 100.0	99.7	99.3 – 99.9
	Archived	118	0	0	0	118	-	-	100.0	96.8 – 100.0
RSV	All	1906	66	9	5	1826	93.0	84.6 – 97.0	99.5	99.1 – 99.7
	Prospective	1788	33	9	3	1743	91.7	78.2 – 97.1	99.5	99.0 – 99.7
	Archived	118	33	0	2	83	94.3	81.4 – 98.4	100.0	95.6 – 100.0
SARS-CoV-2	All	1906	85	11	2	1808	97.7	92.0 – 99.4	99.4	98.9 – 99.7
	Prospective	1788	85	11	2	1690	97.7	92.0 – 99.4	99.4	98.8 – 99.6
	Archived	118	0	0	0	118	-	-	100.0	96.8 – 100.0

A total of 1169 specimens were collected at the clinical sites, then immediately frozen for later testing at the site. The remaining 619 were collected and tested fresh (no freezing). Performance was equivalent between fresh and frozen specimens, so results from 1169 valid frozen and 619 valid fresh specimens were pooled for prospective analysis.

Across both methods, 15 specimens showed co-infections. Five specimens were reported as co-infections by both the Fast PCR System and the comparator. The remaining 10 specimens were reported as co-infections by the Fast PCR System only: in 9 of these, the comparator reported a single pathogen that matched one of the Fast PCR System targets; in 1 specimen, the comparator was negative.

Co-Infections in Clinical Agreement Study

Co-Infection Detected	Specimen	Comparator Positive Results	Fast PCR Positive Result
Co-Infections on both Fast PCR System and Comparator System	1	RSV, SARS-CoV-2	RSV, SARS-CoV-2
	2	Influenza A, RSV	Influenza A, RSV
	3	Influenza A, SARS-CoV-2	Influenza A, SARS-CoV-2
	4	Influenza A, SARS-CoV-2	Influenza A, SARS-CoV-2
	5	Influenza B, RSV	Influenza B, RSV
Co-Infections on the Fast PCR System, one (1) analyte detected by Comparator	6	Influenza A	Influenza A, Influenza B
	7	SARS-CoV-2	Influenza A, SARS-CoV-2
	8	Influenza A	Influenza A, SARS-CoV-2
	9	SARS-CoV-2	Influenza A, SARS-CoV-2
	10 (archived sample)	RSV	Influenza A, RSV
	11	SARS-CoV-2	RSV, SARS-CoV-2
	12	SARS-CoV-2	Influenza A, SARS-CoV-2
	13	Influenza B	Influenza B, SARS-CoV-2
	14	RSV	RSV, SARS-CoV-2
Co-Infection on the Fast PCR System Only	15	NEG	Influenza A, RSV

Limit of Detection (LoD)

The limit of detection (LoD) for the Fast PCR Mini Respiratory Panel analytes was estimated by testing dilutions of contrived samples containing known concentrations of organism in anterior nasal swab matrix collected in AMDI Sample Buffer. The LoD concentrations were confirmed by testing 20 replicates at the estimated LoD as well as 20 replicates at one (1) level above and 20 replicates at one (1) level below the estimated LoD. The confirmed LoD was defined as the lowest level with at least 95% (19/20) positivity.

Limit of Detection (LoD)

Analyte	Isolate	Source	LoD Concentration
Influenza A	Victoria/4897/2022 (H1N1)	Microbiologics	83.3 copies/mL
	Darwin/9/2021 (H3N2)	Microbiologics	250 copies/mL
Influenza B	Colorado/06/2017 (Victoria lineage)	Microbiologics	500 copies/mL
	Phuket/3073/2013 (Yamagata lineage)	Microbiologics	250 copies/mL
Respiratory Syncytial Virus	RSV A 2006 isolate	Zeptomatrix	250 copies/mL
	RSV B Washington	Microbiologics	500 copies/mL
SARS-CoV-2	USA/WA1/2020	Microbiologics	500 copies/mL

Analytical Reactivity (inclusivity)

The analytical reactivity (inclusivity) of the Fast PCR Mini Respiratory Panel was assessed by both *in silico* analysis and *in vitro* analysis.

In Silico Analysis

SARS-CoV-2: *In silico* analysis performed on available full-length SARS-CoV-2 sequences from GISAID and/or NCBI (>1.19M sequences) between November 23, 2021 and July 28, 2025 indicates >99.99% detection with the SARS-CoV-2 assay.

Analytical Reactivity (inclusivity)

In vitro testing included 42 different strains that were diluted in pooled negative anterior nasal swab matrix at ~3x LoD. All organisms at the concentrations shown below were successfully detected. Additionally, a total of 12 aliquots of anterior negative nasal swab matrix were tested and all were negative for each of the 4 analytes.

Influenza A Analytical Reactivity Results

Strain	Concentration	% Positive
A/California/07/2009 (H1N1)pdm09	250 copies/mL	100.0% (3/3)
A/NY/01/09 (H1N1)pdm09	27 TCID ₅₀ /mL	100.0% (3/3)
A/NY/02/09 (H1N1)pdm09	27 TCID ₅₀ /mL	100.0% (3/3)
A/NY/03/09 (H1N1)pdm09	27 TCID ₅₀ /mL	100.0% (3/3)
A/Sydney/05/2021 (H1N1)pdm09	250 copies/mL	100.0% (3/3)
A/Wisconsin/588/2019 (H1N1) pdm09	250 copies/mL	100.0% (3/3)
A/Wisconsin/67/2022 (H1N1)pdm09	27 TCID ₅₀ /mL (2.17E4 copies/mL)	100.0% (3/3)
A/Brisbane/59/2007 (H1N1)	250 copies/mL	100.0% (3/3)
A/Michigan/45/15 (H1N1)	27 TCID ₅₀ /mL	100.0% (3/3)
A/New Caledonia/20/99 (H1N1)	27 TCID ₅₀ /mL	100.0% (3/3)
A/Taiwan/42/06 (H1N1)	27 TCID ₅₀ /mL	100.0% (3/3)
A/Victoria/2570/2019 (H1N1)	250 copies/mL	100.0% (3/3)
A/Brisbane/10/07 (H3N2)	2.4 TCID ₅₀ /mL	100.0% (3/3)
A/Cambodia/E0826360/2020 (H3N2)	750 copies/mL	100.0% (3/3)
A/Hong Kong/2671/2019 (H3N2)	750 copies/mL	100.0% (3/3)
A/Hong Kong/4801/2014 (H3N2)	750 copies/mL	100.0% (3/3)
A/Massachusetts/18/2022 (H3N2)	750 copies/mL	100.0% (3/3)
A/Perth/16/2009 (H3N2)	750 copies/mL	100.0% (3/3)
A/Singapore/INFIMH-16-0019/2016 (H3N2)	750 copies/mL	100.0% (3/3)
A/Tasmania/503/2020 (H3N2)	750 copies/mL	100.0% (3/3)
A/Texas/50/12 (H3N2)	2.4 TCID ₅₀ /mL	100.0% (3/3)
A/Thailand/08/2022 (H3N2)	750 copies/mL	100.0% (3/3)

Influenza B Analytical Reactivity Results

Strain	Concentration	% Positive
B/Austria/13594/17/2021 (Victoria)	1500 copies/mL	100.0% (3/3)
B/Brisbane/60/2008 (Victoria)	1500 copies/mL	100.0% (3/3)
B/Maryland/15/2016 (Victoria)	1500 copies/mL	100.0% (3/3)
B/Washington/02/2019 (Victoria)	1500 copies/mL	100.0% (3/3)
B/Brisbane/09/2014 (Yamagata)	750 copies/mL	100.0% (3/3)
B/Massachusetts/02/2012 (Yamagata)	750 copies/mL	100.0% (3/3)

Respiratory Syncytial Virus Analytical Reactivity Results

Strain	Concentration	% Positive
RSV A 2013 Isolate	0.78 TCID ₅₀ /mL	100.0% (3/3)
RSV A 4/2015 Isolate #1	0.78 TCID ₅₀ /mL	100.0% (3/3)
RSV A2	750 copies/mL	100.0% (3/3)
RSV B 3/2015 Isolate #1	3.27 TCID ₅₀ /mL	100.0% (3/3)
RSV B 9320	2250 copies/mL	100.0% (3/3)
RSV B CH93(18)-18	3.27 TCID ₅₀ /mL	100.0% (3/3)

SARS-CoV-2 Analytical Reactivity Results

Strain	Concentration	% Positive
Japan/TY7-503/2021	0.72 TCID ₅₀ /mL	100.0% (3/3)
USA/CA-Stanford-139_S23/2023	1500 copies/mL	100.0% (3/3)
USA/MDHP20874/2021	1500 copies/mL	100.0% (3/3)
USA/MD-HP47946/2023	0.72 TCID ₅₀ /mL	100.0% (3/3)
USA/MD-HP49152/2023	0.72 TCID ₅₀ /mL	100.0% (3/3)
USA/NY-Wadsworth-21006055-01/2021	0.72 TCID ₅₀ /mL	100.0% (3/3)
USA/NY-Wadsworth-23068107-01/2023	0.72 TCID ₅₀ /mL	100.0% (3/3)
USA/PHC658/2021	0.72 TCID ₅₀ /mL	100.0% (3/3)

Analytical Specificity (Cross-Reactivity & Exclusivity)

Cross reactivity and microbial interference were tested using contrived samples of high titer organisms with or without SARS-CoV-2, Influenza A, Influenza B, and RSV at 3x LoD in pooled anterior nasal swab matrix. No cross-reactivity or microbial interference was observed for the concentrations of organisms tested in these studies.

Cross-reactivity Results for Viruses

Organism	Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
Adenovirus Type 1	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Adenovirus Type 7	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Cytomegalovirus	4.7E3 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Enterovirus D68	1.67E4 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Epstein-Barr virus	1E5 copies/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Human coronavirus 229E	1.39E4 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Human coronavirus NL63	1.18E4 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Human coronavirus OC43	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Human Metapneumovirus (hMPV)	6.27E3 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Influenza A/Victoria/4897/2022	1E5 copies/mL	100.0% (3/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Influenza B/Colorado 06/2017	1E5 copies/mL	0.0% (0/3)	100.0% (3/3)	0.0% (0/3)	0.0% (0/3)
Measles virus	1.68E4 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
MERS-CoV	1E5 genome equivalents/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Mumps virus	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Parainfluenza virus 1	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Parainfluenza virus 2	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Parainfluenza virus 3	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Parainfluenza virus 4	1E5 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Rhinovirus 1A	1.39E4 TCID ₅₀ /mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
RSV A	1E5 copies/mL	0.0% (0/3)	0.0% (0/3)	100.0% (3/3)	0.0% (0/3)
RSV B	1E5 copies/mL	0.0% (0/3)	0.0% (0/3)	100.0% (3/3)	0.0% (0/3)
SARS-CoV-2 USA/WA1/2020	1E5 copies/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	100.0% (3/3)

Cross-reactivity Results for Bacteria

Organism	Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
<i>Bordetella parapertussis</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Bordetella pertussis</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Corynebacterium diphtheriae</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Escherichia coli</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Fusobacterium necrophorum</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Haemophilus influenzae</i>	1E6 CFU/mL	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)	0.0% (0/13)
<i>Lactobacillus plantarum</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Legionella pneumophila</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Moraxella catarrhalis</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Mycobacterium tuberculosis</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Mycoplasma genitalium</i>	1E6 CCU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Mycoplasma pneumoniae</i>	1E6 CCU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Neisseria meningitidis</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Neisseria elongata</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Pseudomonas aeruginosa</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Staphylococcus aureus</i> (coagulase negative)	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Staphylococcus aureus</i> (Protein A producer)	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Staphylococcus epidermidis</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Streptococcus pneumoniae</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Streptococcus pyogenes</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Streptococcus salivarius</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)

Cross-reactivity Results for Fungi

Organism	Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
<i>Aspergillus fumigatus</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Candida albicans</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
<i>Pneumocystis jirovecii</i> - <i>S. cerevisiae</i> <i>recombinant</i>	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)

Microbial Interference Results for Viruses

Organism	Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
Adenovirus Type 1	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Adenovirus Type 7	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Cytomegalovirus	4.7E3 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Enterovirus D68	1.67E4 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Epstein-Barr virus	1E5 copies/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Human coronavirus 229E	1.39E4 TCID ₅₀ /mL	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)	100.0% (4/4)
Human coronavirus NL63	1.18E4 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Human coronavirus OC43	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Human Metapneumovirus (hMPV)	6.27E3 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Influenza A/Victoria/4897/2022	1E5 copies/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Influenza B/Colorado 06/2017	1E5 copies/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Measles virus	1.68E4 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
MERS-CoV	1E5 genome equivalents/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Mumps virus	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Parainfluenza virus 1	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Parainfluenza virus 2	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Parainfluenza virus 3	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Parainfluenza virus 4	1E5 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Rhinovirus 1A	1.39E4 TCID ₅₀ /mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
RSV A	1E5 copies/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
RSV B	1E5 copies/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
SARS-CoV-2 USA/WA1/2020	1E5 copies/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)

Microbial Interference Results for Bacteria

Organism	Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
<i>Bordetella pertussis</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Corynebacterium diphtheriae</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Escherichia coli</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Fusobacterium necrophorum</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Haemophilus influenzae</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Lactobacillus plantarum</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Legionella pneumophila</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Moraxella catarrhalis</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Mycobacterium tuberculosis</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Mycoplasma genitalium</i>	1E6 CCU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Mycoplasma pneumoniae</i>	1E6 CCU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Neisseria meningitidis</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Neisseria elongata</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Pseudomonas aeruginosa</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Staphylococcus aureus</i> (coagulase negative)	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Staphylococcus aureus</i> (Protein A producer)	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Staphylococcus epidermidis</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Streptococcus pneumoniae</i>	1E6 CFU/mL	100.0% (6/6)	83.3% (5/6)	83.3% (5/6)	83.3% (5/6)
	5E5 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
	2.5E5 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Streptococcus pyogenes</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Streptococcus salivarius</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)

Microbial Interference Results for Fungi

Organism	Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
<i>Aspergillus fumigatus</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Candida albicans</i>	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
<i>Pneumocystis jirovecii</i> - <i>S. cerevisiae</i> recombinant	1E6 CFU/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)



Interfering Substances

The Fast PCR Mini Respiratory Panel was evaluated with several different substances that may be encountered in anterior nasal swab specimens to determine potential interference with results. Each substance was tested with SARS-CoV-2, Influenza A, Influenza B, and RSV at 3x LoD in pooled anterior nasal swab matrix and tested in triplicate. Negative and positive control samples tested produced expected results.

For each substance tested, interference was not observed with the following exceptions: whole blood was found to interfere with detection of Influenza A at 4% (v/v) but not at 3% (v/v) and nasal spray containing oxymetazoline was found to interfere with detection of SARS-CoV-2 at a concentration of 15% (v/v), but not at 12% (v/v).

Interfering Substance	Concentration	Result
Homeopathic Nasal Wash (Alkalol)	10% (v/v)	No Interference
Human Whole Blood (EDTA collection tube)	4% (v/v)	Interference with Influenza A assay
	3% (v/v)	No Interference
Mucin from bovine submaxillary glands	0.5% (w/v)	No Interference
Mupirocin	10 mg/mL	No Interference
Nasal Drops (Phenylephrine)	15% (v/v)	No Interference
Nasal Spray (Cromolyn)	15% (v/v)	No Interference
Nasal Spray (Oxymetazoline)	15% (v/v)	Interference with SARS-CoV-2 assay
	12% (v/v)	No Interference
Naso GEL (NeilMed)	5% (v/v)	No Interference
Sore Throat Phenol Spray	15% (v/v)	No Interference
Tamiflu (Oseltamivir Phosphate)	5 mg/mL	No Interference
Tobramycin	4 µg/mL	No Interference
Zanamivir	282 ng/mL	No Interference
Zicam	5% (v/v)	No Interference

Reproducibility Data

A multi-site reproducibility study was conducted to show that the Fast PCR Mini Respiratory Panel consistently delivers accurate results for weak-positive, moderate-positive, and negative specimens when run by untrained users. Contrived samples spiked with each of the four target analytes were evaluated at three clinical sites. At each site, two untrained operators used three different Fast PCR instruments. Three manufacturing lots of the Fast PCR Mini Respiratory Panel Test Disc kits were tested, along with three lots of both positive and negative controls. Testing was performed over at least five non-consecutive days to capture day-to-day variation. On each test day, both operators at each site performed Quality Control (QC) checks on all three instruments. For each operator at each site, 18 true negatives, 18 low positives, and 18 moderate positives were run in triplicate. This study demonstrates acceptable assay reproducibility.

Test Panel Member	Target	Strain	Test Sample Concentration
True Negative Sample	N/A	Negative Anterior Nasal Swab in AMDI Sample Buffer.	N/A
Weak Positive Sample (2X LoD)	Influenza A	Influenza A/Darwin/9/2021 (H3N2)	500 copies/mL
	Influenza B	Influenza B/Colorado/06/2017 (Victoria Lineage)	1000 copies/mL
	RSV	RSV A 2006 Isolate	500 copies/mL
	SARS-CoV-2	USA/WA1/2020	1000 copies/mL
Moderately Positive Sample (5X LoD)	Influenza A	Influenza A/Darwin/9/2021 (H3N2)	1250 copies/mL
	Influenza B	Influenza B/Colorado/06/2017 (Victoria Lineage)	2500 copies/mL
	RSV	RSV A 2006 Isolate	1250 copies/mL
	SARS-CoV-2	USA/WA1/2020	2500 copies/mL

Reproducibility Data

Overall Reproducibility

Panel	Target	Invalid	Negative	Positive	#Pass	N Valid	% Pass	95% LCL	95% UCL
Negative	Influenza A	7	276	2	276	278	99.3%	97.4%	99.8%
	Influenza B	7	278	0	278	278	100.0%	98.6%	100.0%
	RSV	7	278	0	278	278	100.0%	98.6%	100.0%
	SARS-CoV-2	7	277	1	277	278	99.6%	98.0%	99.9%
2X LoD	Influenza A	21	3	270	270	273	98.9%	96.8%	99.6%
	Influenza B	21	1	272	272	273	99.6%	98.0%	99.9%
	RSV	21	5	268	268	273	98.2%	95.8%	99.2%
	SARS-CoV-2	21	3	270	270	273	98.9%	96.8%	99.6%
5X LoD	Influenza A	10	0	272	272	272	100.0%	98.6%	100.0%
	Influenza B	10	0	272	272	272	100.0%	98.6%	100.0%
	RSV	10	1	271	271	272	99.6%	97.9%	99.9%
	SARS-CoV-2	10	0	272	272	272	100.0%	98.6%	100.0%

Reproducibility Data

Site to Site Reproducibility

Panel	Target	Site	Invalid	Negative	Positive	#Pass	N Valid	% Pass	95% LCL	95% UCL
Negative	Influenza A	AER	0	87	2	87	89	97.8%	92.2%	99.4%
	Influenza A	ALP	2	95	0	95	95	100.0%	96.1%	100.0%
	Influenza A	ERA	5	94	0	94	94	100.0%	96.1%	100.0%
	Influenza B	AER	0	89	0	89	89	100.0%	95.9%	100.0%
	Influenza B	ALP	2	95	0	95	95	100.0%	96.1%	100.0%
	Influenza B	ERA	5	94	0	94	94	100.0%	96.1%	100.0%
	RSV	AER	0	89	0	89	89	100.0%	95.9%	100.0%
	RSV	ALP	2	95	0	95	95	100.0%	96.1%	100.0%
	RSV	ERA	5	94	0	94	94	100.0%	96.1%	100.0%
	SARS-CoV-2	AER	0	88	1	88	89	98.9%	93.9%	99.8%
	SARS-CoV-2	ALP	2	95	0	95	95	100.0%	96.1%	100.0%
	SARS-CoV-2	ERA	5	94	0	94	94	100.0%	96.1%	100.0%
2X LoD	Influenza A	AER	8	1	89	89	90	98.9%	94.0%	99.8%
	Influenza A	ALP	2	1	89	89	90	98.9%	94.0%	99.8%
	Influenza A	ERA	11	1	92	92	93	98.9%	94.2%	99.8%
	Influenza B	AER	8	0	90	90	90	100.0%	95.9%	100.0%
	Influenza B	ALP	2	0	90	90	90	100.0%	95.9%	100.0%
	Influenza B	ERA	11	1	92	92	93	98.9%	94.2%	99.8%
	RSV	AER	8	1	89	89	90	98.9%	94.0%	99.8%
	RSV	ALP	2	1	89	89	90	98.9%	94.0%	99.8%
	RSV	ERA	11	3	90	90	93	96.8%	90.9%	98.9%
	SARS-CoV-2	AER	8	1	89	89	90	98.9%	94.0%	99.8%
	SARS-CoV-2	ALP	2	1	89	89	90	98.9%	94.0%	99.8%
	SARS-CoV-2	ERA	11	1	92	92	93	98.9%	94.2%	99.8%
5X LoD	Influenza A	AER	4	0	91	91	91	100.0%	95.9%	100.0%
	Influenza A	ALP	0	0	91	91	91	100.0%	95.9%	100.0%
	Influenza A	ERA	6	0	90	90	90	100.0%	95.9%	100.0%
	Influenza B	AER	4	0	91	91	91	100.0%	95.9%	100.0%
	Influenza B	ALP	0	0	91	91	91	100.0%	95.9%	100.0%
	Influenza B	ERA	6	0	90	90	90	100.0%	95.9%	100.0%
	RSV	AER	4	0	91	91	91	100.0%	95.9%	100.0%
	RSV	ALP	0	1	90	90	91	98.9%	94.0%	99.8%
	RSV	ERA	6	0	90	90	90	100.0%	95.9%	100.0%
	SARS-CoV-2	AER	4	0	91	91	91	100.0%	95.9%	100.0%
	SARS-CoV-2	ALP	0	0	91	91	91	100.0%	95.9%	100.0%
	SARS-CoV-2	ERA	6	0	90	90	90	100.0%	95.9%	100.0%

Flex studies were performed to evaluate the robustness of the Fast PCR Mini Respiratory Panel. Variations in workflow and operating environment that may reasonably be expected to occur with untrained operators in the intended use CLIA waived setting were evaluated. Results of the flex studies conducted demonstrate robust performance of the Fast PCR Mini Respiratory Panel under conditions of stress.

General Information

This document is used solely for the purpose of the Fast PCR System. If the System 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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