June 12, 2026

Autonomous Medical Devices Incorporated
Aiying Sun
EVP, Quality, Regulatory & Clinical Affairs
3511 West Sunflower Avenue
Santa Ana, California 92704

Re: K252932
Trade/Device Name: Fast PCR Mini Respiratory Panel
Regulation Number: 21 CFR 866.3981
Regulation Name: Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test
Regulatory Class: Class II
Product Code: QOF
Dated: March 6, 2026
Received: March 11, 2026

Dear Aiying Sun:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Noel J. Gerald -S

Noel J. Gerald, Ph.D.
Deputy Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252932

Device Name
Fast PCR Mini Respiratory Panel

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary – Basic Information

As required by 21 CFR Part 807.92, Content and Format of a 510(k) Summary

Submitted by:	Autonomous Medical Devices Incorporated (AMDI) 3511 West Sunflower Avenue Santa Ana, CA 92704
Contact:	Aiying Sun EVP, Quality, Regulatory & Clinical Affairs Email: Aiying.Sun@amdilabs.com Phone: (951) 271-6319
Date of Preparation:	June 4, 2026
Device Names:	
Trade Name:	Fast PCR Mini Respiratory Panel
Common Name:	Fast PCR Mini Respiratory Panel
Type of Test:	Qualitative Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) and Detection Test
Regulation:	21 CFR 866.3981, Device to Detect and Identify Nucleic Acid Targets in Respiratory Specimens from Microbial Agents that Cause the SARS-CoV-2 Respiratory Infection and Other Microbial Agents When in a Multi-Target Test
Product Code:	QOF, Multi-Target Respiratory Specimen Nucleic Acid Test Including SARS-CoV-2 and Other Microbial Agents
Predicate Device:	Xpert Xpress CoV-2/Flu/RSV *plus,* performed on the GeneXpert Xpress System (K242071)

2. Device Description

The Fast PCR Mini Respiratory Panel (MRP) is a multiplexed RT-PCR test for use with the Fast PCR instrument for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids in anterior nasal swab specimens. The following organism types and subtypes are identified and differentiated using the Fast PCR MRP:

- Influenza A virus
- Influenza B virus
- Respiratory Syncytial Virus (RSV)
- SARS-CoV-2

The AMDI Fast PCR Instrument is an automated in vitro diagnostic (IVD) device for use with compatible AMDI Fast PCR test discs, such as the Fast PCR MRP Test Disc. The AMDI 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.

The Fast PCR System is based on a novel sample preparation technology called **H**yper**b**aric **H**eating (HBH) and ultrafast polymerase chain reaction (PCR) thermocycling technology built into the Fast PCR instrument. Combined, they can deliver results in approximately 10 minutes.

The HBH technology is a 15-second process applied to an anterior nasal swab sample collected from the patient being tested with the Fast PCR MRP. The hyperbaric heating and reagents in the HBH process simultaneously lyse the viruses in the sample, neutralize PCR inhibitors, and protect single strand RNA in part by eliminating RNase activity in the sample. The HBH process is performed in the Fast PCR MRP consumable Test Disc that derives all its liquids from the AMDI Sample Buffer, and therefore requires no on-board storage of liquids. All fluidic movement is centrifugally driven, so the consumable requires no pumps or complex instrument-consumable interfaces.

The Fast PCR System uses the Fast PCR Instrument to perform thermocycling, the Fast PCR MRP Test Disc capable of performing HBH and all other PCR chemistry to detect SARS-CoV-2, Influenza A, Influenza B and RSV.

3. Device 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.

4. Substantial Equivalence

The Fast PCR Mini Respiratory Panel is predicated on Cepheid's Xpert Xpress CoV-2/Flu/RSV *plus* on the GeneXpert Xpress System (K242071). Table 1 provides a side-by-side comparison of the Intended Use and technological characteristics of the subject device and the Predicate Device.

Based on the comparison, the Fast PCR Mini Respiratory Panel has the same intended use and similar technological characteristics as the Predicate Device. As such, the Fast PCR Mini Respiratory Panel is substantially equivalent to the Xpert Xpress CoV-2/Flu/RSV *plus* (K242071).

Table 1: Substantial Equivalence Comparison

Attribute	Subject Device	Predicate Device
	Fast PCR Mini Respiratory Panel	**Xpert Xpress CoV-2/Flu/RSV *plus***
Regulation	Same	21 CFR 866.3981 Devices to detect and identify nucleic acid targets in respiratory samples from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-analyte test
Product Code	Same	QOF
Device Class	Same	II
Technology /Detection	Same	Real-time Reverse Transcription Polymerase Chain Reaction (RT-PCR)
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	The Xpert Xpress CoV-2/Flu/RSV *plus* test, performed on the GeneXpert Xpress System, is an automated multiplexed realtime reverse transcriptase polymerase chain reaction (RT-PCR) test intended for use in the simultaneous *in vitro* qualitative detection and differentiation of severe acute respiratory syndrome coronavirus (SARS-CoV-2), influenza A, influenza B, and/or respiratory syncytial virus (RSV) viral RNA in nasopharyngeal swab and anterior nasal swab specimens collected from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, influenza B, and RSV can be similar.

Attribute	Subject Device	Predicate Device
	Fast PCR Mini Respiratory Panel	**Xpert Xpress CoV-2/Flu/RSV *plus***
	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.	The Xpert Xpress CoV-2/Flu/RSV *plus* is intended for use in the differential detection of SARS-CoV-2, influenza A, influenza B and/or RSV RNA and aids in the diagnosis of COVID-19, influenza and/or RSV infections if used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, influenza B, and RSV viral RNA are generally detectable in nasopharyngeal swab and anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent(s) detected by the Xpert Xpress CoV-2/Flu/RSV *plus* test may not be the definite cause of disease. Negative results do not preclude SARSCoV-2, influenza A, influenza B and/or RSV infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.
Assay Targets	Same	SARS-CoV-2, Influenza A, Influenza B, RSV viral RNA
Specimen Types	Anterior nasal swab	• Nasopharyngeal swab (NPS) • Anterior nasal swab (NS)
Transport Media	AMDI Sample Buffer	• Universal Transport Medium (UTM) /Viral Transport Medium (VTM) • eNAT

Attribute	Subject Device	Predicate Device
	Fast PCR Mini Respiratory Panel	**Xpert Xpress CoV-2/Flu/RSV *plus***
Test Format	Same	Single Use
Automation	Same	Automated Nucleic Acid Extraction, Detection and Results Interpretation
Assay Result	Same	Qualitative
Internal Control	RNase P	Sample Processing Control (SPC) Probe Check Control (PCC)
External Controls	• Fast PCR MRP Positive External Control • Fast PCR MRP Negative External Control	• External Positive Control: NATtrol Flu/RSV/SARS-CoV-2; Cat # NATFRC-6C-IVD • External Negative Control: Coxsackievirus A9; Cat # NATCV9-6C-IVD
Instrument	Fast PCR Instrument	Cepheid GeneXpert Xpress System
Time to Result	10 min for sample preparation and RT-PCR	36 min or less for sample preparation and RT-PCR
Test Interpretation	Same	Automated test interpretation and reporting
User Complexity	Same	CLIA-waived

The following performance data (analytical and clinical) were provided in support of the substantial equivalence determination.

5. Summary of Performance Data

5.1. Analytical Performance

5.1.1. Limit of Detection (Analytical Sensitivity)

The Limit of Detection (LoD) of the Fast PCR Mini Respiratory Panel test was established by testing viral strains (SARS-CoV-2, Influenza A H1N1, Influenza A H3N2, Influenza B Victoria linage, Influenza B Yamagata lineage, RSV A and RSV B) spiked in pooled negative anterior nasal swab (ANS) matrix. Preliminary LoD for each strain was established as the lowest concentration having 100% positivity from testing five (5) levels of a 3-fold serial dilution, in triplicate. LoD was confirmed for each strain by testing twenty (20) replicates at the preliminary LoD as well as twenty (20) replicates for at least one (1) level above, and twenty (20) replicates for at least one (1) level below, the preliminary LoD. The confirmatory LoD is defined as the lowest concentration for each strain at which ≥95% (19/20) of replicates yield a positive result. The LoD values established for the viral strains tested are summarized in Table 2.

Table 2: Fast PCR Mini Respiratory Panel Limit of Detection in Clinical ANS / AMDI Sample Buffer Matrix

Virus	Subtype	Strain	LoD (copies / mL)
Influenza A	H1N1 post-2009	Victoria/4897/2022	83.3
	H3N2	Darwin/9/2021	250
Influenza B	Victoria lineage	Colorado/06/2017	500
	Yamagata lineage	Phuket/3073/2013	250
RSV	A	RSV A 2006 isolate	250
	B	Washington	500
SARS-CoV-2	N/A	USA/WA1/2020	500

5.1.2. Analytical Reactivity (Inclusivity)

5.1.2.1. *In Silico* Analyses for SARS-CoV-2

The inclusivity of Fast PCR Mini Respiratory Panel SARS-CoV-2 test was evaluated using *in silico* analysis of the assay oligonucleotides in relation to SARS-CoV-2 sequences available in the GISAID gene database from November 23, 2021 through June 11, 2024, and NCBI Virus database for sequences from June 12, 2024 through July 28, 2025. Genomic sequences that contained ambiguous nucleotides or those that did not cover the full length of all three (3) oligonucleotides of a given assay were removed from analysis. In total, number of complete sequences constituted 1,317,624 sequences for the N2 target, 1,307,131 sequences for the ORF1ab target, and 1,304,923 sequences for the ORF8 target. Based on the built-in redundancy of Fast PCR Mini Respiratory Panel SARS-CoV-2 assay (i.e., 3 independent targets, only 1 of 3 must be detected to assign a positive result), all variants in circulation as of the time of this analysis are predicted to be detected by the Fast PCR Mini Respiratory Panel.

5.1.2.2. *In Silico* Analyses for Influenza A, Influenza B and RSV

The inclusivity of Fast PCR Mini Respiratory Panel assays for Influenza A, Influenza B and RSV was evaluated using *in silico* analysis of the assay oligonucleotides in relation to all available sequences through August 08, 2025 in the NCBI Virus (for Influenza A and Influenza B) and NCBI (for RSV) databases restricted to a human host. Genomic sequences that contained ambiguous nucleotides or those that did not cover the full length of all three (3) oligonucleotides of a given assay were removed from analysis. The total number of sequences analyzed for each analyte is 92,480 for Influenza A, 19,435 for Influenza B, 11,679 for RSV, and 1,198,411 for SARS-CoV-2. Allowing no mismatches at the 3' end of the oligonucleotides and up to two (2) mismatches for the oligonucleotides, the *in silico* predicted inclusivity for Influenza A is 99.98%, for Influenza B is 99.92% and for RSV is 98.78% in Fast PCR Mini Respiratory Panel.

5.1.2.3. SARS-CoV-2, Influenza A, Influenza B and RSV Inclusivity Wet Testing

In addition to the *in silico* analysis, the inclusivity of the Fast PCR Mini Respiratory Panel was evaluated by wet testing against multiple strains of SARS-CoV-2, Influenza A H1N1 (pdm09), Influenza A H3N2, Influenza B Victoria and Yamagata lineages, RSV A and RSV B at concentrations of 3x LoD of the virus strain in negative anterior nasal swab matrix. A total of forty-two (42) respiratory viral strains comprised of eight (8) SARS-CoV-2 strains, twenty-two (22) Influenza A strains, six (6) Influenza B strains and six (6) RSV strains were evaluated for analytical reactivity (inclusivity) with the Fast PCR Mini Respiratory Panel. Three (3) replicates were tested for each strain. All SARS- CoV-2, Influenza A, Influenza B and RSV strains tested positive in all 3 replicates. Results are shown in Table 3.

Table 3: Analytical Reactivity (Inclusivity) of the Fast PCR Mini Respiratory Panel

Virus	Strain	Concentration	% Positive
Influenza A	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	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 TCID50/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 TCID50/mL	100.0% (3/3)
	A/Thailand/08/2022 (H3N2)	750 copies/mL	100.0% (3/3)

Virus	Strain	Concentration	% Positive
Influenza B	B/Austria/1359417/2021 (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)
RSV	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	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)

5.1.3. Analytical Specificity (Cross-Reactivity & Exclusivity)

The analytical specificity of Fast PCR Mini Respiratory Panel was evaluated by wet testing a panel of 40 microorganisms potentially encountered in upper respiratory specimens. Each microorganism tested was diluted into negative anterior nasal swab matrix and tested in triplicate. No cross reactivity was observed with any of the microorganisms at the concentrations tested. The concentration of each organism tested and Fast PCR Mini Respiratory Panel results are shown in Table 4.

Table 4: Microorganisms tested for Cross Reactivity, their concentrations and Fast PCR Mini Respiratory Panel results

Organism	Test Concentration	Number of positive Calls			
		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)
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)

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

Organism	Test Concentration	Number of positive Calls			
		Influenza A	Influenza B	RSV	SARS-CoV-2
Streptococcus pneumoniae	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Streptococcus pyogenes	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Streptococcus salivarius	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Aspergillus fumigatus	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)
Candida albicans	1E6 CFU/mL	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)	0.0% (0/3)

5.1.4. Microbial Interference

Microbial interference of Fast PCR Mini Respiratory Panel caused by the presence of bacterial or viral strains that might be encountered in human upper respiratory tract specimens was evaluated by testing the same cross-reactivity organisms at the same testing concentration of each organism. Refer to Table *4* for details. Quadspike samples were prepared using screened negative anterior nasal swab matrix with viruses (Influenza A/Darwin/9/2021, Influenza B/Colorado/06/2017, RSV A 2006 isolate and SARS-CoV-2 isolate USA/WA1/2020) spiked at 3X LoD determined for each strain. Contrived samples with potentially interfering microorganism were prepared by spiking viruses (at 1e5 copies/mL or 1e5 $TCID_{50}$/mL) or bacteria/fungi (at 1e6 CFU/mL) and tested in triplicate using Fast PCR Mini Respiratory Panel.

Streptococcus pneumoniae interfered with Influenza B, RSV and SARS-CoV-2 targets when present at a concentration of 1e6 CFU/mL. No microbial interference was observed when *S. pneumoniae* was present at a concentration of 5e5 CFU/mL. For all other potentially interfering microorganisms, each target (Influenza A, Influenza B, RSV and SARS-CoV-2) was correctly identified as positive by the Fast PCR Mini Respiratory Panel.

5.1.5. Competitive Interference

Competitive interference of the Fast PCR Mini Respiratory Panel caused by co-infections were evaluated by testing a quadspike sample of Influenza A, Influenza B, RSV and SARS-CoV-2 contrived at 3X LoD determined for each strain in the presence of a different on-panel strain at a higher concentration. The 3X LoD concentration used was 750 copies/mL for Influenza A/Darwin/9/2021, 1500 copies/mL for Influenza B/Colorado/06/2017, 750 copies/mL for RSV A 2006 isolate and 1500 copies/mL for SARS-CoV-2 isolate USA/WA1/2020. The competitive strains were evaluated at 1e5 copies/mL.

The quadspike sample spiked with high concentration of competitive strain was tested in triplicate. The results of the competitive interference study are presented in Table 5. for high concentration of Influenza A, Influenza B, RSV A, RSV B and SARS-CoV-2. No competitive inhibition was observed for the potential co-infections evaluated.

Table 5:Summary of Competitive Interference Study at High Concentration of Potentially Interferent Virus

Test Virus at 3X LoD	Interferent Virus (concentration)	Positive Calls
Influenza A	Influenza A/Victoria/4897/2022 (1e5 copies/mL)	3/3
Influenza B		3/3
RSV		3/3
SARS-CoV-2		3/3
Influenza A	Influenza B/Colorado/06/2017 (1e5 copies/mL)	3/3
Influenza B		3/3
RSV		3/3
SARS-CoV-2		3/3
Influenza A	RSV A (1e5 copies/mL)	3/3
Influenza B		3/3
RSV		3/3
SARS-CoV-2		3/3
Influenza A	RSV B (1e5 copies/mL)	3/3
Influenza B		3/3
RSV		3/3
SARS-CoV-2		3/3
Influenza A	SARS-CoV-2 USA/WA1/2020 (1e5 copies/mL)	3/3
Influenza B		3/3
RSV		3/3
SARS-CoV-2		3/3

5.1.6. Potentially Interfering Substances

Substances that are normally found in or may be introduced into clinical anterior nasal swab matrix that could potentially interfere with accurate detection of Influenza A, Influenza B, RSV and SARS-CoV-2 were evaluated with direct testing on the Fast PCR Mini Respiratory Panel.

Potentially interfering substances in the nasal passage may include, but are not limited to, blood, nasal secretions or mucus, and nasal and throat medications used to relieve congestion, nasal dryness, irritation, or asthma and allergy symptoms, as well as antibiotics and antivirals. Positive and negative samples were prepared in anterior nasal swab matrix screened to be negative for the four targets tested in the Fast PCR Mini Respiratory Panel. Positive quadspike samples were prepared using the screened

negative anterior nasal swab matrix with viruses (Influenza A/Darwin/9/2021, Influenza B/Colorado/06/2017, RSV A 2006 isolate and SARS-CoV-2 isolate USA/WA1/2020) spiked at 3X LoD determined for each strain. Baseline negative and quadspike samples (N=9) were tested as zero interferent controls. Quadspike samples spiked with interferents were tested with the Fast PCR Mini Respiratory Panel in triplicate to evaluate potential interference. The substances, with their active ingredients and test concentrations, that were evaluated are listed in Table 6.

The results from the study (Table 6) show that for most cases, all replicates showed 100% positivity for all viral targets, and no interference was observed. In the presence of whole blood at 4%, interference was observed for Influenza A. No interference was observed for any viral target in the presence of 1% - 3% of whole blood. In the presence of Oxymetazoline nasal spray, interference was observed for SARS-CoV-2. No interference was observed for any viral target in the presence of 3% - 12% of oxymetazoline nasal spray. All negative samples returned expected negative results.

Table 6: Number of correct calls and percent positivity for Fast PCR Mini Respiratory Panel in the presence of potentially interfering substances

Substance	Active Ingredient	Interferent Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
Negative Sample	N/A	N/A	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)
Quadspike Sample Baseline (3x LoD)	N/A	N/A	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)
Chloraseptic	Menthol, Benzocaine	1.5 mg product/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Nasal Spray	Fluticasone Propionate	5% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Homeopathic Nasal Wash	Eucalyptol, menthol, thymol, camphor, benzoin; oils of wintergreen, spearmint, pine and cinnamon	10% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Human Whole Blood (EDTA collection tube)	N/A	4% (v/v)	33.3% (1/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
		3% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
		2% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
		1% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)

Substance	Active Ingredient	Interferent Concentration	Influenza A	Influenza B	RSV	SARS-CoV-2
Mucin from bovine submaxillary glands	Purified mucin protein	0.5% (w/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Mupirocin	Mupirocin	10 mg product/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Nasal Drops	Phenylephrine	15% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Nasal Spray	Cromolyn	15% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Nasal Spray	Oxymetazoline	15% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	66.7% (2/3)
		12% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
		9% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
		6% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
		3% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Naso GEL (NeilMed)	Sodium hyaluronate, Aloe vera	5% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Sore Throat Phenol Spray	Phenol	15% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Tamiflu	Oseltamivir Phosphate	5 mg/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Tobramycin	Tobramycin	4 µg/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Zanamivir	Zanamivir	282 ng/mL	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)
Zicam	Galphimia glauca 4x, Luffa opperculata 4x, Sabadilla 4x	5% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)

5.1.7. Carryover Contamination

A study was conducted to assess whether the single-use, self-contained Fast PCR Mini Respiratory test disc prevents specimen and amplicon carryover by testing negative sample immediately after testing a very high positive sample on the same Fast PCR Instrument. The negative sample used in this study was negative anterior nasal swab matrix screened to be negative for the four viral targets in the Fast PCR Mini Respiratory Panel. The positive sample consisted of a quadspike sample consisting of high Influenza A (Influenza A/Darwin/9/2021 at 2.0e7 copies/mL), high Influenza B (Influenza B/Colorado/06/2017 at 2.9e8 copies/mL), high RSV (RSV A 2006 isolate at 4.8e7 copies/mL) and high SARS-CoV-2 (USA/WA1/2020 at 2.9e7 copies/mL) in negative anterior nasal swab matrix. The study consisted of total of five (5) runs on three (3) Fast PCR Instruments, with each run consisting of eight (8) replicates of alternating quadspike and negative samples run on the same Fast PCR Instrument. A total of 40 quadspike samples and 40 negative samples were tested. All 40 quadspike samples correctly reported as positive for all four targets. All negative samples correctly reported as negative for all four targets. No specimen or amplicon carry-over contamination was observed in this study.

5.1.8. Near-LoD /Reproducibility Study

The reproducibility of the Fast PCR Mini Respiratory Panel was established at 3 external CLIA Waived sites using three (3) concentrations of samples (negative, weakly positive 2X LoD, and moderately positive 5X LoD). The negative samples consisted of pooled anterior nasal swab matrix screened negative for on-panel targets. The positive samples were prepared in pooled negative anterior nasal swab matrix spiked with the four (4) target analytes consisting of inactivated SARS-CoV-2 USA/WA1/2020 strain, live viruses Influenza A/Darwin/9/2021 (H3N2), Influenza B/Colorado/06/2017 (Victoria Lineage), and RSV A 2006 Isolate. At each of the three (3) testing sites, testing was conducted over five (5) non-consecutive days, by two (2) different untrained operators testing three (3) different lots of Fast PCR MRP Kit on three (3) different Fast PCR instruments, and three (3) replicates per test condition, for a total of 2 operators x 3 lots x 3 instruments x 3 replicates x 5 days = 90 test results / sample concentration /site.

The overall reproducibility of the Fast PCR Mini Respiratory Panel for each sample concentration stratified by operator and site is summarized in Table 7. In addition, the overall agreement is included in the last column.

In addition, three (3) lots of Fast PCR MRP Positive External Control kits and three (3) lots of Fast PCR Negative External Control Kit were provided to each study site. External Controls were run at the beginning of each of the five (5) non-consecutive testing days, on each of the three (3) Fast PCR Instrument at each study site. The results are summarized in Table 8.

Table 7: Fast PCR System Reproducibility Across Operators and Sites for Each Sample Level

Site:		Site 1						Site 2						Site 3						Overall Agreement	
Operator:		Operator 1			Operator 2			Operator 1			Operator 2			Operator 1			Operator 2				
Sample	Analyte	Pass	Valid	%Pass	Pass	Valid	%Pass	Pass	Valid	%Pass	Pass	Valid	%Pass	Pass	Valid	% Pass	Pass	Valid	% Pass	%Pass	95% CI
Negative	Influenza A	44	45	97.8%	43	44	97.7%	47	47	100.0%	48	48	100.0%	49	49	100.0%	45	45	100.0%	99.8%	97.4 – 99.8
	Influenza B	45	45	100.0%	44	44	100.0%	47	47	100.0%	48	48	100.0%	49	49	100.0%	45	45	100.0%	100.0%	98.6 – 100.0
	RSV	45	45	100.0%	44	44	100.0%	47	47	100.0%	48	48	100.0%	49	49	100.0%	45	45	100.0%	100.0%	98.6 – 100.0
	SARS-CoV-2	44	45	97.8%	44	44	100.0%	47	47	100.0%	48	48	100.0%	49	49	100.0%	45	45	100.0%	99.9%	98.0 – 99.9
2X LoD	Influenza A	44	45	97.8%	45	45	100.0%	44	45	97.8%	45	45	100.0%	45	45	100.0%	47	48	97.9%	99.6%	96.8 – 99.6
	Influenza B	45	45	100.0%	45	45	100.0%	45	45	100.0%	45	45	100.0%	45	45	100.0%	47	48	97.9%	99.9%	98.0 – 99.9
	RSV	44	45	97.8%	45	45	100.0%	44	45	97.8%	45	45	100.0%	43	45	95.6%	47	48	97.9%	99.2%	95.8 – 99.2
	SARS-CoV-2	44	45	97.8%	45	45	100.0%	44	45	97.8%	45	45	100.0%	45	45	100.0%	47	48	97.9%	99.6%	96.8 – 99.6
5X LoD	Influenza A	46	46	100.0%	45	45	100.0%	45	45	100.0%	46	46	100.0%	45	45	100.0%	45	45	100.0%	100.0%	98.6 – 100.0
	Influenza B	46	46	100.0%	45	45	100.0%	45	45	100.0%	46	46	100.0%	45	45	100.0%	45	45	100.0%	100.0%	98.6 – 100.0
	RSV	46	46	100.0%	45	45	100.0%	45	45	100.0%	45	46	97.8%	45	45	100.0%	45	45	100.0%	99.9%	97.9 – 99.9
	SARS-CoV-2	46	46	100.0%	45	45	100.0%	45	45	100.0%	46	46	100.0%	45	45	100.0%	45	45	100.0%	100.0%	98.6 – 100.0

Table 8: Reproducibility of the Fast PCR MRP Positive and Negative External Controls

	Fast PCR MRP Negative Control								Fast PCR MRP Positive Control							
Fast PCR MRP Kit Lot	Lot 1		Lot 2		Lot 3				Lot 1		Lot 2		Lot 3			
	Pass	Fail	Pass	Fail	Pass	Fail	Total	%Pass & 95% CI	Pass	Fail	Pass	Fail	Pass	Fail	Total	%Pass & 95% CI
Site 1	8	0	8	0	8	0	24	100% (86%-100%) 24/24	8	0	7	0	9	0	24	100% (86%-100%) 24/24
Site 2	5	0	5	0	6	0	16	100% (81%-100%) 16/16	6	0	5	0	6	0	17	100% (82%-100%) 17/17
Site 3	6	0	6	0	6	0	18	100% (82%-100%) 18/18	6	0	6	0	6	0	18	100% (82%-100%) 18/18
Total	19	0	19	0	20	0	58	100% (94%-100%) 58/58	20	0	18	0	21	0	59	100% (94%-100%) 59/59
%Pass & 95% CI	100% (83%-100%) 19/19		100% (83%-100%) 19/19		100% (84%-100%) 20/20				100% (84%-100%) 20/20		100% (82%-100%) 18/18		100% (85%-100%) 21/21			

5.2. Flex Studies

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.

5.3. Clinical Performance

From December 2024 to May 2025, a total of nine (9) CLIA waived clinical testing sites in the United States participated in the clinical study for the Fast PCR Mini Respiratory Panel. In this clinical study, paired anterior nasal swab (ANS) clinical specimens from 1906 evaluable subjects were tested at the nine (9) clinical sites. The investigational specimen collected for the Fast PCR Mini Respiratory Panel was tested by untrained operators at the clinical sites using only a Quick Reference Guide (QRG). The comparator ANS specimen was frozen at -80°C at the clinical site after collection and tested at the comparator testing site using a comparator device that is FDA 510(k) cleared.

Additionally, the clinical study was used to assess the ease of use and risk of erroneous test results when untrained operators in a CLIA-waived environment performed testing with the Fast PCR Mini Respiratory Panel.

For a complete demographic description of sex, age, race, and ethnicity within the 1906 evaluable subjects, see Table 9, Table 10, Table 11, and Table 12, respectively.

Table 9: Sex Demographics in the Evaluable Subjects

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%)

Table 10: Age Demographics in the Evaluable Subjects

Age Group	All n (%)	Prospective n (%)	Archived n (%)
All	1,906	1,788	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%)

Table 11: Race Demographics in the Evaluable Subjects

Race	All	Prospective	Archived
	n (%)	n (%)	n (%)
All	1,906	1,788	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%)

Table 12: Ethnicity Demographics in the Evaluable Subjects

Ethnicity	Archived	Prospective	All
	n (%)	n (%)	n (%)
All	118	1,788	1,906
Hispanic	4 (3.4%)	339 (19.0%)	343 (18.0%)
Not Hispanic	114 (96.6%)	1,384 (77.4%)	1,498 (78.6%)
Not Reported	0 (0.0%)	58 (3.2%)	58 (3.0%)
Unknown	0 (0.0%)	7 (0.4%)	7 (0.4%)

5.3.1. Prospective Clinical Evaluation

A total of 1947 subjects were prospectively consented and enrolled in the study in an all-comers fashion at the clinical study sites. A total of 159 were excluded and not tested, leaving 1788 subjects prospectively enrolled. The most common reasons for exclusion were protocol deviations (126 or 6.5%) and no Fast PCR result obtained (33 or 1.7%). A pair of ANS specimens were collected from each subject. The specimens were immediately placed in a -80℃ freezer, unless candidate testing could be performed fresh. For candidate testing of frozen prospective samples, the operators were instructed to 1) take the frozen sample tube(s) out of the -80°C freezer and thaw at room temperature, 2) test on the Fast PCR Mini Respiratory Panel as usual according to the QRG. The comparator samples were sent out for comparator testing.

5.3.2. Evaluation of Preselected Archived Specimens

Due to low prevalence of RSV positivity at the time the prospective samples were collected (December 2024 to May 2025), an additional 132 preselected archived samples (35 RSV Positive, 83 RSV Negative by Comparator Method) were enrolled in the study. Of these, 14 were excluded leaving 118 subjects in the archived cohort. These archived samples were previously collected under an IRB approved collection protocol. Briefly, paired ANS swabs were collected from each enrolled subject, with one swab placed in the AMDI Sample Buffer, the other swab placed in transport media for comparator testing. Both samples were immediately frozen at -80°C and remained at -80℃ until thawed and tested at the clinical sites or at the comparator testing site.

5.3.3. Summary of Fast PCR System's Clinical Performance

Of the 1906 samples included in the data analysis, 93.8% (1788/1906) samples were prospective samples and 6.2% (118/1906) were archived samples. Of the 1788 prospective samples, 34.6% (619/1788) samples were tested fresh, while 65.4% (1169/1788) were tested after frozen samples were thawed at room temperature, with the Fast PCR MRP on the Fast PCR Instrument.

A summary of the Fast PCR MRP clinical study performance is provided in Table 13: Fast PCR MRP Clinical Performance – Prospective Samples and Table 14: Fast PCR MRP Clinical Performance – Prospective and Archived Samples.

Table 13: Fast PCR MRP Clinical Performance – Prospective Samples

Analyte	Sample Category	All Samples n	True Positive n	False Positive n	False Negative n	True Negative n	PPA		NPA	
							%	95% CI	%	95% CI
Influenza A	Prospective Fresh	619	25	7	1	586	96.2	81.1 – 99.3	98.8	97.6 – 99.4
	Prospective Frozen	1169	211	38	5	915	97.7	94.7 – 99.0	96.0	94.6 – 97.1
	Overall	1788	236	45	6	1501	97.5	94.7 – 98.9	97.1	96.1 – 97.8
Influenza B	Prospective Fresh	619	52	2	0	565	100.0	93.1 – 100.0	99.6	98.7 – 99.9
	Prospective Frozen	1169	25	3	0	1,141	100.0	86.7 – 100.0	99.7	99.2 – 99.9
	Overall	1788	77	5	0	1706	100.0	95.2 – 100.0	99.7	99.3 – 99.9
RSV	Prospective Fresh	619	9	4	0	606	100.0	70.1 – 100.0	99.3	98.3 – 99.7
	Prospective Frozen	1169	24	5	3	1,137	88.9	71.9 – 96.1	99.6	99.0 – 99.8
	Overall	1788	33	9	3	1743	91.7	78.2 – 97.1	99.5	99.0 – 99.7
SARS-CoV-2	Prospective Fresh	619	18	4	0	597	100.0	82.4 – 100.0	99.3	98.3 – 99.7
	Prospective Frozen	1169	67	7	2	1093	97.1	90.0 – 99.2	99.4	98.7 – 99.7
	Overall	1788	85	11	2	1690	97.7	92.0 – 99.4	99.4	98.8 – 99.6

Table 14: Fast PCR MRP Clinical Performance – Prospective and Archived Samples

Analyte	Sample Category	All Samples n	True Positive n	False Positive n	False Negative n	True Negative n	PPA		NPA	
							%	95% CI	%	95% CI
Influenza A	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
	All	1906	236	47	6	1617	97.5	94.7 – 98.9	97.2	96.3 – 97.9
Influenza B	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
	All	1906	77	5	0	1824	100.0	95.2 – 100.0	99.7	99.4 – 99.9
RSV	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
	All	1906	66	9	5	1826	93.0	84.6 – 97.0	99.5	99.1 – 99.7
SARS-CoV-2	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
	All	1906	85	11	2	1808	97.7	92.0 – 99.4	99.4	98.9 – 99.7

6. Conclusion

The results of the analytical and clinical performance studies summarized above demonstrate that the Fast PCR Mini Respiratory Panel is substantially equivalent to the predicate device.