510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number:

K252932

B Applicant:

Autonomous Medical Devices Incorporated

C Proprietary and Established Names:

Fast PCR Mini Respiratory Panel

D Regulatory Information:

Product Code(s)	Classification	Regulation Section	Panel
QOF	Class II	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	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To demonstrate that the Fast PCR Mini Respiratory Panel (MRP) is substantially equivalent to the Xpert Xpress CoV-2/Flu/RSV *plus* (K242071) on the GeneXpert Xpress System and to obtain clearance for the Fast PCR MRP.

B Measurand:

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

- Influenza A RNA
- Influenza B RNA
- Respiratory Syncytial Virus (RSV) RNA

C Type of Test:

Qualitative reverse transcriptase polymerase chain reaction (RT-PCR)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

For In Vitro Diagnostic Use Only

D Special Instrument Requirements:

For use with the Fast PCR Instrument

IV Device/System Characteristics:

A 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 SARS-CoV-2, influenza A, influenza B, and RSV from nucleic acids in anterior nasal swab (ANS) specimens in approximately 10 minutes.

To perform the test, an anterior nasal swab is collected and added to the AMDI Sample Buffer tube. A provided fixed volume pipette is used to add 400 µL of the eluted sample to the Fast PCR MRP Test Disc sample port. Each specimen is processed individually. An operator logs into the Fast PCR App and scans the Patient ID on the AMDI sample buffer tube containing the collected ANS specimen and the unique barcode on the Fast PCR Mini Respiratory Panel Test Disc. A disposable pipette provided with the Test Disc kit is used to remove a fixed volume of the AMDI sample buffer from the sample buffer tube. The pipette is inserted into the sample port of the Test Disc and the sample buffer is dispensed into the Test Disc. The Test Disc contains all necessary reagents for the detection of SARS-CoV-2, influenza A, influenza B and RSV RNA and the internal control (RNase P). The pipette is removed and the closure for the Test Disc is pressed into place. The disc loading tray on the Operating Module (part of the Fast PCR instrument) is opened, and the Test Disc is inserted into the Operating Module.

The Fast PCR instrument automatically performs the test process, and the Operator has no further hands-on tasks.

B Principle of Operation:

The Fast PCR MRP is performed using the Fast PCR instrument, which automates all test processes from sample processing, through RT-PCR and detection steps, to result interpretation and result reporting.

The Fast PCR MRP uses a sample preparation technology called Hyperbaric Heating (HBH) that is applied to ANS specimens. This process simultaneously lyses the viruses present in the sample, neutralizes PCR inhibitors, and protects single-stranded 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 the fluidics in the Test Disc are then driven by centrifugal forces produced when rotating the Test Disc inside the Operating Module within the Fast PCR instrument.

The assay RT-PCR primers and probes target the ORF1ab non-structural region, ORF8, and the nucleocapsid genes of SARS-CoV-2 and target the matrix genes of influenza A, influenza B, and RSV. The RNase P internal control is included to control for adequate processing of the target

viruses through all steps of the assay process and to monitor the presence of inhibitors in the RT-PCR processes.

The Fast PCR instrument automatically analyzes and interprets the results, reporting results directly in the Fast PCR App.

C Instrument Description Information:

1. Instrument Name:

   Fast PCR instrument

2. Specimen Identification:

   Specimen identification is either entered manually or scanned via a barcode scanner.

3. Specimen Sampling and Handling:

   Anterior nasal swabs in AMDI Sample Buffer.

4. Calibration:

   Not applicable.

5. Quality Control:

   Internal Controls

   The assay uses RNase P as an internal control (IC) to ensure adequate sample collection and processing. The internal control monitors the overall performance of the RT-PCR reaction for potential sample mediated inhibition or failure of the reagents. If the internal control result fails, all four target analytes (Influenza A, Influenza B, RSV and SARS-CoV-2) will have an invalid result. If the internal control result passes, the four target analytes will have either a positive or a negative result.

   External Controls

   The recommended Fast PCR MRP External Controls (Positive and Negative) are packaged and sold separately from the assay kit. The positive control is a lyophilized bead containing inactivated whole viruses (influenza A, influenza B, Respiratory Syncytial Virus, and SARS-CoV-2) and armored RNase P RNA. The negative control is a lyophilized bead containing armored RNase P RNA. External Controls (EC) may be performed to conform with internal Quality Control (QC) procedures, or with local, state, or federal regulations. The Fast PCR MRP External Controls were evaluated in the analytical and clinical studies.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Xpert Xpress CoV-2/Flu/RSV *plus*

B Predicate 510(k) Number(s):

K242071

C Comparison with Predicate(s):

Device & Predicate Device(s):	K252932	K242071
Device Trade Name	Fast PCR Mini Respiratory Panel	Xpert Xpress CoV-2/Flu/RSV *plus*
General Device Characteristic Similarities	K252932	K242071
Technology/Detection	Same	Multiplexed Real-time Reverse Transcription Polymerase Chain Reaction (RT-PCR)
Intended Use/Indications For 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,	The Xpert Xpress CoV-2/Flu/RSV *plus* test, performed on the GeneXpert Xpress System, is an automated multiplexed real-time 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.

	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
Test Format	Same	Single Use
Automation	Same	Automated Nucleic Acid Extraction, Detection and Results Interpretation
Assay Result	Same	Qualitative
Test Interpretation	Same	Automated test interpretation and reporting

General Device Characteristic Differences	K252932	K242071
Specimen Types	Anterior nasal swab	• Nasopharyngeal swab (NPS) • Anterior nasal swab (ANS)
Transport Media	AMDI Sample Buffer	• Universal Transport Medium (UTM) /Viral Transport Medium (VTM) • eNAT
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

VI Standards/Guidance Documents Referenced:

- 21 CFR Part 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"
- 21 CFR 862.2570, “Instrumentation for Clinical Multiplex Test Systems”
- FDA Guidance: "Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses" (July 15, 2011)
- FDA Guidance: "Respiratory Viral Panel Multiplex Nucleic Acid Assay – Class II Special Controls Guidance for Industry and FDA Staff" (October 9, 2009)
- FDA Guidance: "Instrumentation for Clinical Multiplex Test Systems - Class II Special Controls Guidance for Industry and FDA Staff" (March 10, 2005)
- FDA Guidance: "Recommendations for CLIA Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" (February 2020)
- FDA Guidance: "Recommendations for Dual 510(k) and CLIA Waiver by Application Studies" (February 2020)
- FDA Guidance: "Content of Premarket Submissions for Device Software Functions” (June 2023)
- FDA Guidance: "Cybersecurity in Medical Devices – Quality System Considerations and Content of Premarket Submission" (February 2026)
- FDA Guidance: “Electromagnetic Compatibility (EMC) of Medical Devices” (June 2022)

- CLSI EP12 3rd Edition, 7-315
- CLSI EP17-A2, 7-233
- CLSI EP25 2nd Edition, 7-318
- CLSI EP07 3rd Edition, 7-275
- IEC 61010-1Edition 3.1 2017-01 CONSOLIDATED VERSION, 19-34
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, 19-36
- IEC 60825-1 Edition 2.0 2007-03, 12-273
- IEC 61326-1 Edition 3.0 2020-10, 19-42
- IEC 61326-2-6 Edition 3.0 2020-10, 19-43
- ISTA 3A 2018, 5-126
- CISPR11 ed.5.0 (2024), Class A
- FCC 47 CFR Part 18 – Industrial, Scientific, and Medical Equipment
- FCC Part 15B/ICES-003 – Radio Frequency Devices
- ISO 14971

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

A precision and reproducibility study was conducted to assess the total variability of the Fast PCR Mini Respiratory Panel (MRP) across untrained operators, study sites, testing days, device lots, and instruments. Test panels, consisting of three different concentrations of samples, were prepared by AMDI and were aliquoted, blinded and labeled for distribution to the testing sites.

Variability was assessed using a test panel at three study sites with two untrained operators per site. Testing was carried out over at least five non-consecutive testing days at each site with three Fast PCR instruments per site. Three lots of the Fast PCR MRP kit, three lots of Fast PCR MRP Positive External Controls, three lots of Fast PCR MRP Negative External Controls, and three replicates per test condition were used.

The four target analytes (influenza A, influenza B, RSV, and SARS-CoV-2) were diluted to 2x Limit of Detection (LoD) (weak positive) and 5x LoD (moderate positive) in pooled negative anterior nasal swab matrix. The negative sample consisted of pooled negative anterior nasal swab matrix without analyte. Strains and concentrations are shown in **Table 1**.

Table 2 presents the qualitative summary for influenza A, influenza B, RSV, and SARS-CoV-2 during panel member testing. The reproducibility of the Fast PCR System for each sample of the test panel stratified by operator is summarized in **Table 3** and the Ct Value analysis is summarized in **Table 4**. The results of the study demonstrate acceptable assay precision and reproducibility.

Table 1. Strains used in the Precision and Reproducibility Study

Target	Strain	Weak Positive (2x LoD)	Moderate Positive (5x LoD)
Negative	Negative Anterior Nasal Swab in AMDI sample Buffer	N/A	N/A
Influenza A	Influenza A/Darwin/9/2021 (H3N2)	500 copies/mL	1250 copies/mL
Influenza B	Influenza B/Colorado/06/2017 (Victoria lineage)	1000 copies/mL	2500 copies/mL
RSV	RSV A 2006 Isolate	500 copies/mL	1250 copies/mL
SARS-CoV-2	USA/WA1/2020	1000 copies/mL	2500 copies/mL

Table 2. Fast PCR MRP Reproducibility Across Study Sites

Sample	Analyte	Site	Invalid	Negative	Positive	#Pass	N Valid	%Pass	95% CI
Negative	Influenza A	A	0	87	2	87	89	97.8%	92.2%-99.4%
	Influenza A	B	2	95	0	95	95	100.0%	96.1%-100.0%
	Influenza A	C	5	94	0	94	94	100.0%	96.1%-100.0%
	Influenza B	A	0	89	0	89	89	100.0%	95.9%-100.0%
	Influenza B	B	2	95	0	95	95	100.0%	96.1%-100.0%
	Influenza B	C	5	94	0	94	94	100.0%	96.1%-100.0%
	RSV	A	0	89	0	89	89	100.0%	95.9%-100.0%
	RSV	B	2	95	0	95	95	100.0%	96.1%-100.0%
	RSV	C	5	94	0	94	94	100.0%	96.1%-100.0%
	SC2	A	0	88	1	89	89	98.9%	93.9%-99.8%
	SC2	B	2	95	0	95	95	100.0%	96.1%-100.0%
	SC2	C	5	94	0	94	94	100.0%	96.1%-100.0%
Negative Overall	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%

Sample	Analyte	Site	Invalid	Negative	Positive	#Pass	N Valid	%Pass	95% CI
	SC2		7	277	1	277	278	99.6%	98.0%-99.9%
2x LoD	Influenza A	A	8	1	89	89	90	98.9%	94.0%-99.8%
	Influenza A	B	2	1	89	89	90	98.9%	94.0%-99.8%
	Influenza A	C	11	1	92	92	93	98.9%	94.2%-99.8%
	Influenza B	A	8	0	90	90	90	100.0%	95.9%-100.0%
	Influenza B	B	2	0	90	90	90	100.0%	95.9%-100.0%
	Influenza B	C	11	1	92	92	93	98.9%	94.2%-99.8%
	RSV	A	8	1	89	89	90	98.9%	94.0%-99.8%
	RSV	B	2	1	89	89	90	98.9%	94.0%-99.8%
	RSV	C	11	3	90	90	93	96.8%	90.9%-99.8%
	SC2	A	8	1	89	89	90	98.9%	94.0%-99.8%
	SC2	B	2	1	89	89	90	98.9%	94.0%-99.8%
	SC2	C	11	1	92	92	93	98.9%	94.2%-99.8%
2x LoD Overall	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%
	SC2		21	3	270	270	273	98.9%	96.8%-99.6%
5x LoD	Influenza A	A	4	0	91	91	91	100.0%	95.9%-100.0%
	Influenza A	B	0	0	91	91	91	100.0%	95.9%-100.0%
	Influenza A	C	6	0	90	90	90	100.0%	95.9%-100.0%
	Influenza B	A	4	0	91	91	91	100.0%	95.9%-100.0%
	Influenza B	B	0	0	91	91	91	100.0%	95.9%-100.0%
	Influenza B	C	6	0	90	90	90	100.0%	95.9%-100.0%
	RSV	A	4	0	91	91	91	100.0%	95.9%-100.0%

Sample	Analyte	Site	Invalid	Negative	Positive	#Pass	N Valid	%Pass	95% CI
	RSV	B	0	1	90	90	91	98.9%	94.0%-99.8%
	RSV	C	6	0	90	90	90	100.0%	95.9%-100.0%
	SC2	A	4	0	91	91	91	100.0%	95.9%-100.0%
	SC2	B	0	0	91	91	91	100.0%	95.9%-100.0%
	SC2	C	6	0	90	90	90	100.0%	95.9%-100.0%
5x LoD Overall	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%
	SC2		10	0	272	272	272	100.0%	98.6%-100.0%

Table 3. Fast PCR Reproducibility Across Operators

Site:		Site A					
Operator:		Operator 1			Operator 2		
Sample	Analyte	Pass	Valid	%Pass	Pass	Valid	%Pass
Negative	Influenza A	44	45	97.8%	43	44	97.7%
	Influenza B	45	45	100.0%	44	44	100.0%
	RSV	45	45	100.0%	44	44	100.0%
	SC2	44	45	97.8%	44	44	100.0%
2x LoD	Influenza A	44	45	97.8%	45	45	100.0%
	Influenza B	45	45	100.0%	45	45	100.0%
	RSV	44	45	97.8%	45	45	100.0%
	SC2	44	45	97.8%	45	45	100.0%
5x LoD	Influenza A	46	46	100.0%	45	45	100.0%
	Influenza B	46	46	100.0%	45	45	100.0%
	RSV	46	46	100.0%	45	45	100.0%
	SC2	46	46	100.0%	45	45	100.0%
Site:		**Site B**					
Operator:		**Operator 1**			**Operator 2**		
Sample	**Analyte**	**Pass**	**Valid**	**%Pass**	**Pass**	**Valid**	**%Pass**
Negative	Influenza A	47	47	100.0%	48	48	100.0%
	Influenza B	47	47	100.0%	48	48	100.0%
	RSV	47	47	100.0%	48	48	100.0%
	SC2	47	47	100.0%	48	48	100.0%
2x LoD	Influenza A	44	45	97.8%	45	45	100.0%
	Influenza B	45	45	100.0%	45	45	100.0%
	RSV	44	45	97.8%	45	45	100.0%
	SC2	44	45	97.8%	45	45	100.0%
5x LoD	Influenza A	45	45	100.0%	46	46	100.0%
	Influenza B	45	45	100.0%	46	46	100.0%

	RSV	45	45	100.0%	45	46	97.8%
	SC2	45	45	100.0%	46	46	100.0%
Site:		**Site C**					
Operator:		**Operator 1**			**Operator 2**		
Sample	**Analyte**	**Pass**	**Valid**	**%Pass**	**Pass**	**Valid**	**%Pass**
Negative	Influenza A	49	49	100.0%	45	45	100.0%
	Influenza B	49	49	100.0%	45	45	100.0%
	RSV	49	49	100.0%	45	45	100.0%
	SC2	49	49	100.0%	45	45	100.0%
2x LoD	Influenza A	45	45	100.0%	47	48	97.9%
	Influenza B	45	45	100.0%	47	48	97.9%
	RSV	43	45	95.6%	47	48	97.9%
	SC2	45	45	100.0%	47	48	97.9%
5x LoD	Influenza A	45	45	100.0%	45	45	100.0%
	Influenza B	45	45	100.0%	45	45	100.0%
	RSV	45	45	100.0%	45	45	100.0%
	SC2	45	45	100.0%	45	45	100.0%

Overall			
Sample	**Analyte**	**%Pass**	**95% CI**
Negative	Influenza A	99.8%	97.4 – 99.8
	Influenza B	100.0%	98.6 – 100.0
	RSV	100.0%	98.6 – 100.0
	SC2	99.9%	98.0 – 99.9
2x LoD	Influenza A	99.6%	96.8 – 99.6
	Influenza B	99.9%	98.0 – 99.9
	RSV	99.2%	95.8 – 99.2
	SC2	99.6%	96.8 – 99.6
5x LoD	Influenza A	100.0%	98.6 – 100.0
	Influenza B	100.0%	98.6 – 100.0
	RSV	99.9%	97.9 – 99.9
	SC2	100.0%	98.6 – 100.0

Table 4. Precision and Reproducibility of the Fast PCR MRP, Ct Value Analysis

Panel	**Target**	**N**	**Mean Ct**	**Within Run (Repeatability)**		**Between Days**		**Between Instruments**		**Between Lots**		**Between Operators**		**Between Sites**		**Overall (Reproducibility)**	
				SD	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Low Positive (2x LoD)	Influenza A	269	38.68	0.99	2.57	0.38	0.97	0.35	0.91	0.25	0.66	0.17	0.45	0.13	0.35	1.17	3.02
	Influenza B	270	38.71	0.67	1.73	0.26	0.68	0.22	0.56	0.13	0.34	0.11	0.28	0.10	0.27	0.78	2.01
	RSV	268	39.28	1.07	2.73	0.21	0.54	0.20	0.50	0.18	0.46	0.15	0.37	0.28	0.70	1.17	2.97
	SARS-COV-2	265	37.52	0.63	1.67	0.13	0.35	0.35	0.93	0.09	0.24	0.12	0.33	0.27	0.71	0.79	2.11
Moderate Positive (5x LoD)	Influenza A	271	37.13	0.68	1.82	0.17	0.45	0.45	1.22	0.27	0.72	0.17	0.46	0.22	0.60	0.92	2.47
	Influenza B	272	37.24	0.50	1.36	0.11	0.29	0.16	0.42	0.10	0.27	0.02	0.05	0.09	0.23	0.56	1.49
	RSV	271	37.82	0.95	2.51	0.23	0.61	0.24	0.64	0.04	0.11	0.12	0.33	0.13	0.34	1.02	2.71
	SARS-COV-2	269	36.11	0.61	1.69	0.14	0.40	0.21	0.59	0.09	0.26	0.10	0.28	0.21	0.57	0.71	1.96

SD = standard deviation; CV(%) = percent coefficient of variation.; N = total number of samples

2. Linearity:

Not applicable. This is a qualitative assay.

3. Analytical Specificity/Interference:

a. *Analytical Reactivity (Inclusivity):*

Wet-Testing: The inclusivity of the Fast PCR MRP was established through wet testing by evaluating a total of forty-two (42) strains, including 22 influenza A strains, six (6) influenza B strains, six (6) RSV strains, and eight (8) SARS-CoV-2 strains. The Fast PCR MRP was able to detect 100% of the strains tested for all analytes. Inactivated strains were used for SARS-CoV-2 and cultured virus were used for RSV and influenza strains. Each virus was spiked into pooled negative nasal matrix at analyte concentrations of 3x LoD and tested in triplicate. All strains of influenza A (**Table 5**), influenza B (**Table 6**), RSV (**Table 7**), and SARS-CoV-2 (**Table 8**) tested positive in all three replicates. Additionally, a total of twelve aliquots of anterior negative swab matrix were tested, and all were negative for each of the four target analytes.

Table 5. Influenza A Analytical Reactivity Wet-Testing Results

Subtype	Strain	Concentration	% Positive
H1N1 pdm09	A/California/07/2009	250 copies/mL	100% (3/3)
	A/NY/01/09	27 TCID50/mL	100% (3/3)
	A/NY/02/09	27 TCID50/mL	100% (3/3)
	A/NY/03/09	27 TCID50/mL	100% (3/3)
	A/Sydney/05/2021	250 copies/mL	100% (3/3) [a]
	A/Wisconsin/588/2019	250 copies/mL	100% (3/3)
	A/Wisconsin/67/2022	2.17E4 copies/mL	100% (3/3)
H1N1	A/Brisbane/59/2007	250 copies/mL	100% (3/3)
	A/Michigan/45/15	27 TCID50/mL	100% (3/3)
	A/New Caledonia/20/99	27 TCID50/mL	100% (3/3)
	A/Taiwan/42/06	27 TCID50/mL	100% (3/3)
	A/Victoria/2570/2019	250 copies/mL	100% (3/3)
H3N2	A/Brisbane/10/07	2.4 TCID50/mL	100% (3/3)
	A/Cambodia/E0826360/2020	750 copies/mL	100% (3/3) [b]
	A/Hong Kong/2671/2019	750 copies/mL	100% (3/3)
	A/Hong Kong/4801/2014	750 copies/mL	100% (3/3)
	A/Massachusetts/18/2022	750 copies/mL	100% (3/3)
	A/Perth/16/2009	750 copies/mL	100% (3/3)
	A/Singapore/INFIMH-16-0019/2016	750 copies/mL	100% (3/3)
	A/Tasmania/503/2020	750 copies/mL	100% (3/3)
	A/Texas/50/12	2.4 TCID50/mL	100% (3/3)
	A/Thailand/08/2022	750 copies/mL	100% (3/3)

[a] RSV false positive result

[b] Influenza B false positive result

Table 6. Influenza B Analytical Reactivity Wet-Testing Results

Sub-lineage	Strain	Concentration	% Positive
Victoria	B/Austria/1359417/2021	1500 copies/mL	100% (3/3)
	B/Brisbane/60/2008	1500 copies/mL	100% (3/3) [a]
	B/Maryland/15/2016	1500 copies/mL	100% (3/3)
	B/Washington/02/2019	1500 copies/mL	100% (3/3)
Yamagata	B/Brisbane/09/2014	750 copies/mL	100% (3/3)
	B/Massachusetts/02/2012	750 copies/mL	100% (3/3)

[a] Influenza A false positive result

Table 7. RSV Analytical Reactivity Wet-Testing Results

Subtype	Strain	Concentration	% Positive
RSV A	2013 Isolate	0.78 TCID50/mL	100% (3/3)
	4/2015 Isolate #1	0.78 TCID50/mL	100% (3/3)
	A2	750 copies/mL	100% (3/3) [a]
RSV B	3/2015 Isolate #1	3.27 TCID50/mL	100% (3/3)
	9320	2250 copies/mL	100% (3/3)
	CH93(18)-18	3.27 TCID50/mL	100% (3/3)

[a] Influenza A false positive result

Table 8. SARS-CoV-2 Analytical Reactivity Wet-Testing Results

Strain	Concentration	% Positive
Japan/TY7-503/2021	0.72 TCID50/mL	100% (3/3)
USA/CA-Stanford-139_S23/2023	1500 copies/mL	100% (3/3)
USA/MDHP20874/2021	1500 copies/mL	100% (3/3)
USA/MD-HP47946/2023	0.72 TCID50/mL	100% (3/3)
USA/MD-HP49152/2023	0.72 TCID50/mL	100% (3/3)
USA/NY-Wadsworth-21006055-01/2021	0.72 TCID50/mL	100% (3/3)
USA/NY-Wadsworth-23068107-01/2023	0.72 TCID50/mL	100% (3/3)
USA/PHC658/2021	0.72 TCID50/mL	100% (3/3)

In Silico Analysis: The inclusivity of the Fast PCR Mini Respiratory Panel was evaluated using *in silico* analysis of the forward primers, reverse primers, and probes for SARS-CoV-2 against sequences from GISAID (sequences from November 2021 onward) and the NCBI Virus database (sequences from June 2024 onward). The analysis of the three SARS-CoV-2 targets (N2, ORF1ab and ORF8) was conducted with over 1.3 million SARS-CoV-2 genomic RNA sequences. Results of the *in-silico* analysis predict that the Fast PCR Mini Respiratory Panel will detect greater than 99.99% of SARS-CoV-2 variants.

b. *Cross-reactivity / Microbial Interference:*

Cross-reactivity (exclusivity) and microbial interference of the Fast PCR Mini Respiratory Panel was evaluated against a panel of 40 non-targeted microorganisms to determine the assay's ability to detect influenza A, influenza B, RSV, or SARS-CoV-2 in the presence of related pathogens, high prevalence disease agents, and normal or pathogenic microorganisms reasonably likely to be present in a clinical ANS sample.

For cross-reactivity studies, each non-targeted microorganism was spiked independently into negative anterior nasal swab matrix without the presence of on-panel targets and tested in triplicate. Exclusivity was determined if 0/3 replicates returned a detected result for each of the four (4) viral targets. None of the evaluated organisms demonstrated cross-reactivity with the Fast PCR MRP at the tested concentrations listed in **Table 9**.

For microbial interference studies, each non-targeted microorganism was spiked into negative anterior nasal swab matrix in the presence of on-panel targets at 3x LoD and tested in triplicate. Absence of microbial interference was determined if 3/3 replicates returned a detected result for each of the four (4) target analytes. With the exception of *Streptococcus pneumoniae*, none of the evaluated microorganisms demonstrated interference with the Fast PCR MRP at the tested concentrations listed in **Table 9**, with each returning 3/3 replicates detected for each of the four viral targets. *Streptococcus pneumoniae* at 1E6 CFU/mL was found to interfere with detection of one of three replicates of influenza B, RSV and SARS-CoV-2. Three additional replicates of *S. pneumoniae* were tested at 1E6 CFU/mL, for a total of six replicates. Three replicates of *S. pneumoniae* were also tested at concentrations of 5E5 CFU/mL and 2.5E5 CFU/mL. No interference (100% positivity) was observed upon retesting of *S. pneumoniae* at 1E6 CFU/mL or with *S. pneumoniae* at 5E5 or 2.5E5 CFU/mL. The overall positivity rate was 83.3% (5/6) for influenza B, RSV, and SARS-CoV-2 and 100% (6/6) for influenza A with *S. pneumoniae* at 1E6 CFU/mL.

Across both cross-reactivity and microbial interference studies, 23 negative external control samples and 23 positive control samples were run alongside contrived test samples. External controls yielded expected results.

Table 9. Non-targeted Microorganisms Evaluated in the Cross-reactivity and Microbial Interference Wet-Testing Studies

Organism	Concentration
Adenovirus Type 1	1E5 TCID50/mL
Adenovirus Type 7	1E5 TCID50/mL
Cytomegalovirus	4.7E3 TCID50/mL
Enterovirus D68	1.67E4 TCID50/mL
Epstein-Barr virus	1E5 copies/mL
Human coronavirus 229E	1.39E4 TCID50/mL
Human coronavirus NL63	1.18E4 TCID50/mL
Human coronavirus OC43	1E5 TCID50/mL
Human Metapneumovirus (hMPV)	6.27E3 TCID50/mL
Influenza A/Victoria/4897/2022	1E5 copies/mL

Organism	Concentration
Influenza B/Colorado06/2017	1E5 copies/mL
Measles virus	1.68E4 TCID50/mL
MERS-CoV	1E5 genome equivalents/mL
Mumps virus	1E5 TCID50/mL
Parainfluenza virus 1	1E5 TCID50/mL
Parainfluenza virus 2	1E5 TCID50/mL
Parainfluenza virus 3	1E5 TCID50/mL
Parainfluenza virus 4	1E5 TCID50/mL
Rhinovirus 1A	1.39E4 TCID50/mL
RSV A	1E5 copies/mL
RSV B	1E5 copies/mL
SARS-CoV-2 USA/WA1/2020	1E5 copies/mL
Bordetella parapertussis	1E6 CFU/mL
Bordetella pertussis	1E6 CFU/mL
Corynebacterium diphtheriae	1E6 CFU/mL
Escherichia coli	1E6 CFU/mL
Fusobacterium necrophorum	1E6 CFU/mL
Haemophilus influenzae	1E6 CFU/mL
Lactobacillus plantarum	1E6 CFU/mL
Legionella pneumophila	1E6 CFU/mL
Moraxella catarrhalis	1E6 CFU/mL
Mycobacterium tuberculosis	1E6 CFU/mL
Mycoplasma genitalium	1E6 CFU/mL
Mycoplasma pneumoniae	1E6 CFU/mL
Neisseria meningitidis	1E6 CFU/mL
Neisseria elongata	1E6 CFU/mL
Pseudomonas aeruginosa	1E6 CFU/mL
Staphylococcus aureus (coagulase negative)	1E6 CFU/mL
Staphylococcus aureus (Protein A producer)	1E6 CFU/mL
Staphylococcus epidermidis	1E6 CFU/mL
Streptococcus pneumoniae [a]	1E6 CFU/mL
Streptococcus pyogenes	1E6 CFU/mL
Streptococcus salivarius	1E6 CFU/mL
Aspergillus fumigatus	1E6 CFU/mL
Candida albicans	1E6 CFU/mL
**Pneumocystis jirovecii*-S. *cerevisiae recombinant*	1E6 CFU/mL

** This organism is a recombinant and not a valid source of Pneumocystis jirovecii. In silico analysis further supports lack of cross-reactivity against this organism.*

† Cross-reactivity testing for one negative sample yielded a false positive result.

[a] Microbial interference testing for *Streptococcus pneumoniae* yielded a false negative result for influenza B, RSV, and SARS-CoV-2.

c. *Competitive Interference:*

Competitive interference of the Fast PCR Mini Respiratory Panel caused by co-infections of on-panel targets were evaluated by testing a quadspike sample of influenza A (A/Darwin/9/2021), influenza B (B/Colorado/06/2017), RSV (A 2006 Isolate), and SARS-CoV-2 (USA/WA1/2020). Each quadspike sample included one on-panel target spiked at a high concentration of 1E5 copies/mL while the remaining three on-panel targets were each spiked at 3x LoD. Each combination was tested in triplicate. No competitive interference was observed for the potential co-infections evaluated at the concentrations tested.

Table 10. Results for Competitive Interference Study

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/2006 Isolate (1E5 copies/mL)	3/3
Influenza B		3/3
RSV		3/3
SARS-CoV-2		3/3
Influenza A	RSV B/Washington (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

d. *Interfering Substances:*

The performance of the Fast PCR MRP was evaluated in the presence of endogenous and exogenous substances that may be commonly found in ANS specimens. Potentially interfering endogenous and exogenous substances (**Table 11**) were tested at or above clinically relevant levels in pooled negative nasal matrix in the presence and absence of test target analytes. Positive samples were prepared by co-spiking the test target analytes, influenza A (A/Darwin/9/2021), influenza B (B/Colorado/06/2017), RSV (A 2006 Isolate), and SARS-CoV-2 (USA/WA1/2020) each at 3x LoD in pooled negative nasal matrix containing an individual exogenous or endogenous substance. Negative samples consisted of

pooled negative nasal matrix containing an individual exogenous or endogenous substance. Each sample was tested in triplicate.

For each substance tested, interference was not observed with the following exceptions: whole blood was found to cause interference with the detection of influenza A at 4% (v/v) but not at 3% (v/v) and nasal spray containing oxymetazoline was found to cause interference with the detection of SARS-CoV-2 at a concentration of 15% (v/v), but not at 12% (v/v). The FluMist nasal vaccine was not tested as cross-reactivity with the influenza test targets is expected.

Qualitative results for test samples containing potentially interfering substances are shown in **Table 11**.

Table 11. Results for Potentially Interfering Substances

Potential Interferent	Active Ingredient	Concentration	Percent Positivity				
			Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
Negative Sample	N/A	N/A	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	0.0% (0/9)	100.0% (9/9)
Baseline (3x LoD)	N/A	N/A	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% (9/9)	100.0% s(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)	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)	100.0% (3/3)
Homeopathic Nasal Wash (Alkalol)	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)	100.0% (3/3)
Human Whole Blood (EDTA collection tube)	N/A	4% (v/v)	**33.3% (1/3)** [a]	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)	100.0% (3/3)
		2% (v/v)	100.0% (3/3)	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)	100.0% (3/3)
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)	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)	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)	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)	100.0% (3/3)

Potential Interferent	Active Ingredient	Concentration	Percent Positivity				
			Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
Nasal Spray	Oxymetazoline	15% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	**66.7% (2/3)** [b]	100.0% (3/3)
		12% (v/v)	100.0% (3/3)	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)	100.0% (3/3)
		6% (v/v)	100.0% (3/3)	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)	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)	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)	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)	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)	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)	100.0% (3/3)
Zicam	Galphimia glauca, Luffa opperculata, Sabadilla	5% (v/v)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)	100.0% (3/3)

[a] Two false negative results for influenza A
[b] One false negative result for SARS-CoV-2

4. Assay Reportable Range:

   Not applicable, this is a qualitative assay.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

a. *Controls – External Control Evaluation:*

   See Section **IV.C.5. Quality Control**.

b. *Specimen Stability:*
   The stability of the viral targets influenza A (A/Darwin/9/2021), influenza B (B/Colorado/06/2017), RSV (A 2006 Isolate), and SARS-CoV-2 (USA/WA1/2020) at 3x LoD in anterior nasal swab matrix collected in AMDI Sample Buffer and stored at either 2-8°C or 30°C was established for the Fast PCR Mini Respiratory Panel.

   Results from these studies support the following:
   - Anterior nasal swab specimens collected in AMDI Sample Buffer may be stored for up to 72 hours at 2-8°C or for up to four (4) hours at 15-30°C.

c. *Fresh vs. Frozen - Specimen Stability:*

The stability of the viral targets influenza A (A/Darwin/9/2021), influenza B (B/Colorado/06/2017), RSV (A 2006 Isolate), and SARS-CoV-2 (USA/WA1/2020) at either 2x or 5x LoD in anterior nasal swab matrix collected in AMDI Sample Buffer and stored frozen (≤ -15°C or ≤ -70°C) was established following one and two freeze/thaw cycles and tested using the Fast PCR Mini Respiratory Panel.

Results from these studies support the following:

- Anterior nasal swab specimens collected in AMDI Sample Buffer may undergo one (1) freeze/thaw cycle.

d. *Kit Shelf-life Stability:*

Real-time kit stability data for the Fast PCR MRP supports the recommended shelf-life stability claim of ambient room temperature storage (15-30°C / 59-86°F) for up to six (6) months.

e. *AMDI Fast PCR MRP External Control Kit Shelf-life Stability:*
Real-time kit stability data for the AMDI Fast PCR MRP External Control Kit supports the recommended shelf-life stability claim of ambient room temperature storage (15-30°C / 59-86°F) for up to nine (9) months.

6. Detection Limit:

a. *Individual Analyte Detection Limits:*
Limit of detection (LoD) studies for the Fast PCR MRP were conducted to determine the lowest detectable concentration of influenza A, influenza B, RSV, and SARS-CoV-2 at which ≥ 95% of all replicates test positive. Viral strains tested are shown in **Table 12**. Testing used pooled negative nasal matrix. The preliminary LoD was established as the minimum concentration yielding 3/3 detected results in a limited dilution series for each target viral strain. The confirmatory LoD was determined by testing at the preliminary LoD plus at least one higher and one lower dilution with 20 replicates. Confirmed LoD values are shown in **Table 12**.

Table 12. Confirmed LoD for Target Analytes

Virus	Strain	LoD (copies/mL)
Influenza A H1N1	A/Victoria/4897/2022	83.3
Influenza A H3N2	A/Darwin/9/2021	250
Influenza B (Victoria)	B/Colorado/06/2017	500
Influenza B (Yamagata)	B/Phuket/3073/2013	250
RSV A	2006 isolate	250

RSV B	Washington	500
SARS CoV-2	USA/WA1/2020	500

As part of the influenza A/Victoria/4897/2022 confirmatory LoD testing, one replicate at 41.7 copies/mL resulted in false positive for SARS-CoV-2. As part of the influenza B/Colorado/06/2017 confirmatory LoD testing, two replicates at 500 copies/mL and one replicate at 150 copies/mL resulted in false positive for influenza A.

b. *Co-spiked Analyte Detection Limit:*
A Co-Spiked LoD study for the Fast PCR MRP was conducted to determine the lowest detectable concentration of influenza A (A/Darwin/9/2021), influenza B (B/Colorado/06/2017), RSV (A 2006 Isolate), and SARS-CoV-2 (USA/WA1/2020) in a co-spiked sample at which ≥ 95% of all replicates test positive. Testing used pooled negative nasal matrix. The preliminary LoD concentrations used were the LoD concentrations determined for individual analytes above. The confirmatory LoD was determined by testing at the preliminary LoD with 20 replicates. This study confirmed that the LoD concentrations for influenza A (A/Darwin/9/2021), influenza B (B/Colorado/06/2017), RSV (A 2006 Isolate), and SARS-CoV-2 (USA/WA1/2020) are the same whether spiked individually or co-spiked in the same contrived sample.

7. Assay Cut-Off:

The Fast PCR MRP Analysis Algorithm is responsible for converting PCR test data from the Fast PCR Instrument into test results. The cut-off for determining if an amplification curve should be classified as "Amplified" or "Not Amplified" utilizes a set of Amplification Curve Analysis Parameters (including the Ct value). The influenza A, influenza B, RSV, SARS-CoV-2, and RNase P assays each have their own Amplification Curve Analysis Parameters that were validated. For influenza A, influenza B, and RSV, if Ct ≥50, the status is "Not Amplified", else it is "Amplified". For SARS-CoV-2, if Ct ≥42.2, the status is "Not Amplified", else it is "Amplified". For RNase P, if Ct ≥40.8, the status is "Not Amplified", else it is "Amplified".

8. Accuracy (Instrument):

Not Applicable.

9. Carry-Over:

A study was conducted to assess potential carryover or cross-contamination in the single-use, self-contained Fast PCR Mini Respiratory Panel Test Disc by testing high positive and no template samples in an alternating fashion 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 high positive quadspike sample consisted of influenza A (influenza A/Darwin/9/2021 at 2.0E7 copies/mL), influenza B (influenza B/Colorado/06/2017 at 2.9E8 copies/mL), RSV (RSV A 2006 isolate at 4.8E7 copies/mL), and SARS-CoV-2 (USA/WA1/2020 at 2.9E7 copies/mL) in negative anterior nasal swab matrix. The study consisted of five (5) total runs on three (3) Fast PCR Instruments, with each run consisting of eight (8) replicates of alternating high positive quadspike and negative samples run on the same Fast PCR Instrument. A total of 40 high

positive quadspike samples and 40 negative samples were tested. All 40 high positive quadspike samples correctly reported as positive for all four targets. All negative samples correctly reported as negative for all four targets. No cross-contamination was observed.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   Not Applicable.

2. Matrix Comparison:

   The Fast PCR Mini Respiratory Panel is to be used with the AMDI Sample Buffer only. No additional collection devices have been evaluated for use with the device.

C Clinical Studies:

1. Prospective Study:

   The clinical performance of the Fast PCR Mini Respiratory Panel assay was evaluated using clinical specimens prospectively collected between December 2024 and May 2025 from nine (9) geographically diverse clinical sites located within the United States with 27 untrained test operators. The clinical study utilized prospective specimens collected from pediatric and adult patients exhibiting clinical signs and symptoms of respiratory tract infection. All collection and assay testing were performed at CLIA-waived facilities, representative of the intended use environment, by untrained operators according to the test QRG. The results of all four viral targets were compared to results from an FDA-cleared, CLIA waived RT-PCR assay (comparative reference method).

   Initial enrollment included a total of 1947 unique prospectively collected specimens that met the pre-determined inclusion criteria. Of these, a total of 159 (8.2%) specimens were excluded. 33 (1.7%) specimens were excluded due to an invalid result produced by the Fast PCR MRP and 126 (6.5%) specimens were excluded due to protocol deviations. **Table 13** provides a summary of the demographic information for the remaining 1788 subjects included in the data analysis. Of the 1788 samples included in the data analysis, 34.6% (619/1788) were tested fresh while 65.4% (1169/1788) were tested frozen. Clinical performance of the fast PCR MRP with prospectively collected samples is presented in **Table 14**.

   Table 13. Subject Demographics - Prospective Symptomatic Population

Characteristics	Symptomatic Subjects
Total, N	1788
Age Group (Years), n (%)	
≤ 5 yr	94 (5.3%)

6-18 yr	311 (17.4%)
19-40 yr	664 (37.1%)
41-60 yr	496 (27.7%)
≥ 61 yr	223 (12.5%)
Sex, n (%)	
Male	683 (38.2%)
Female	1104 (61.7%)
Unknown	1 (0.1%)
Ethnicity, n (%)	
Hispanic / Latino	339 (19.0%)
Not Hispanic / Not Latino	1,384 (77.4%)
Note Reported	58 (3.2%)
Unknown	7 (0.4%)
Race, n (%)	
American Indian / Alaskan Native	4 (0.2%)
Asian	81 (4.5%)
Black / African-American	283 (15.8%)
White	1301 (72.8%)
Other or Mixed Race	70 (3.9%)
Uknown	20 (1.1%)
Not Reported	29 (1.6%)

Table 14. Fast PCR MRP Prospective Clinical Performance

Analyte	Sample Category	N	TP	FP	FN	TN	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

Analyte	Sample Category	N	TP	FP	FN	TN	PPA		NPA	
							%	95% CI	%	95% CI
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

PPA = Positive Percent Agreement, NPA = Negative Percent Agreement
TP=true positive; FP=false positive; TN=true negative; FN=false negative
Five specimens tested positive for co-infections by the Fast PCR MRP that were also identified as the same co-infections by the comparator. Eight specimens tested positive for co-infections by the Fast PCR MRP that were identified as single infections by the comparator. One specimen tested positive for co-infection by the Fast PCR MRP that was identified as negative by the comparator.

2. Retrospective/Archived Study:

To supplement the prospective clinical study results for RSV, retrospective frozen clinical ANS specimens collected from individuals with signs and symptoms of influenza infection during the 2024-2025 North American respiratory season were evaluated. Paired ANS swabs were collected from each enrolled subject, with one swab placed in the AMDI Sample Buffer, the other swab placed in a transport media for comparator testing. Both samples were immediately frozen at -80°C and remained at -80°C until thawed and tested at the clinical sites (integrated into the daily testing workflow) or at the comparator testing site. Of the 132 enrolled archived specimens, 14 were excluded (one due to an invalid Fast PCR MRP result and 13 due to protocol deviations) for a total of 118 archived specimens. Clinical performance for archived samples is shown in **Table 15**.

Table 15. Fast PCR MRP Retrospective Clinical Performance

Analyte	N	TP	FP	FN	TN	PPA		NPA	
						%	95% CI	%	95% CI
RSV	118	33	2	2	83	94.3	81.4 – 98.4	100	95.6 – 100.0

PPA = Positive Percent Agreement, NPA = Negative Percent Agreement
TP=true positive; FP=false positive; TN=true negative; FN=false negative
One specimen tested positive for co-infection with RSV and influenza A by the Fast PCR MRP, which was only positive for RSV by the comparator.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

The positivity rate for SARS-CoV-2, influenza A and influenza B, as determined by the Fast PCR MRP, are shown below, stratified by the study site (**Table 16**), by age group (**Table 17**), and by sex (**Table 18**).

Table 16. Expected Results – Positive Results and Prevalence by Site

Clinical Site ID	Site Location (City, State)	SARS-Cov-2			Influenza A			Influenza B			RSV		
		Total No.	No. Pos.	Exp. Value	Total No.	No. Pos.	Exp. Value	Total No.	No. Pos.	Exp. Value	Total No.	No. Pos.	Exp. Value
Overall		**1788**	**96**	**5.4%**	**1788**	281	15.7%	**1788**	**82**	**4.6%**	**1788**	**42**	**2.3%**
1	Laredo, TX	214	5	2.3%	214	11	5.1%	214	2	0.9%	214	2	0.9%
2	Bellevue, WA	89	0	0.0%	89	3	3.4%	89	5	5.6%	89	2	2.2%
3	Birmingham, AL	211	23	10.9%	211	47	22.3%	211	3	1.4%	211	5	2.4%
4	Forney, TX	203	17	8.4%	203	54	26.6%	203	1	0.5%	203	3	1.5%
5	Riverdale, GA	165	5	3.0%	165	10	6.1%	165	0	0.0%	165	4	2.4%
6	Kansas City, KS	164	6	3.7%	164	9	5.5%	164	0	0.0%	164	2	1.2%
7	Redmond, WA	256	6	1.9%	256	33	12.9%	256	16	6.3%	256	3	1.2%
8	Smithfield, RI	413	28	6.8%	413	86	20.8%	413	50	12.1%	413	20	4.8%
9	Chicago, IL	73	6	8.2%	73	28	38.4%	73	5	6.8%	73	1	1.4%

Table 17. Expected Results – Positive Results and Prevalence by Age Group

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

Table 18. Expected Results – Positive Results and Prevalence by Sex

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

F Other Supportive Instrument Performance Characteristics Data:

Not Applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.