CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW250018

II. Parent Document Number

K252932

III. CLIA Waiver Type

Dual 510(k) and CLIA Waiver by Application (Dual Submission)

IV. Applicant

Autonomous Medical Devices Incorporated

V. Proprietary and Established Names

Fast PCR Mini Respiratory Panel

VI. Measurand (analyte)

- Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA
- Influenza A RNA
- Influenza B RNA
- Respiratory Syncytial Virus (RSV) RNA

VII. Sample Type(s)

Anterior nasal swabs

VIII. Type of Test

Qualitative reverse transcriptase polymerase chain reaction (RT-PCR)

IX. Test System Description

A Overview

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 from individuals with signs and symptoms of respiratory tract infection. The Fast PCR System is comprised of a single-use Fast PCR MRP and the Fast PCR Instrument. To perform the test, an ANS specimen is collected in AMDI Sample Buffer. A disposable pipette provided with the Fast PCR MRP is used to remove a fixed volume of the AMDI sample buffer and insert the sample into the Fast PCR MRP Test Disc sample port. 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). Once the Test Disc sample port is closed and the Test Disc is loaded onto the Fast PCR Instrument, all subsequent test steps, including sample processing, target amplification by real-time RT-PCR, detection, result interpretation and result reporting are performed automatically by the Fast PCR Instrument.

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

B Test System Components

Each Fast PCR Mini Respiratory Panel includes sufficient materials and reagents to process twenty ANS specimens and consists of the following:

- Twenty (20) individually pouched Fast PCR MRP Test Discs per kit
- Twenty-one (21) sterile anterior nasal swabs individually packaged in peel pouches per kit
- Twenty-one (21) tubes of AMDI Sample Buffer (1.5 mL each)
- Twenty-two (22) fixed volume (400 µL) transfer pipettes
- One Quick Reference Guide for the Fast PCR MRP

The Fast PCR Instrument is provided separately and is not included within the Fast PCR MRP kit. The Fast PCR Instrument is packaged with a Base Station with an integrated barcode scanner, an Operating Module, an Operating Module Connecting Cord, a Power Cable, a System Tablet (iOS) with the Fast PCR App installed, the Fast PCR Instrument User Manual, and the Fast PCR Instrument Quick Reference Guide. Up to four (4) Operating Modules may be stacked.

X. Specific Contents for CLIA Waiver

A Demonstrating “Simple”:

The Fast PCR MRP performed on the Fast PCR Instrument was designed to be simple and easy to use. **Table 1** summarizes features that are built into the device design to make it simple to use with minimal risk of erroneous results.

Table 1. Demonstration of Simplicity for the Fast PCR Mini Respiratory Panel performed on the Fast PCR Instrument

'Simple' Criteria	Device Characteristics
Is a fully automated instrument or a unitized or self-contained test.	The device has a fully automated system and only requires sample collection and insertion into the Test Disc. The Test Disc, which contains all the reagents required for sample processing and analysis, is then loaded into the instrument, where all test steps are completed by the instrument without further user intervention.
Uses direct unprocessed specimens, such as capillary blood (fingerstick), venous whole blood, nasal swabs, throat swabs, or urine.	The test uses anterior nasal swab specimens that are placed in a supplied sample tube containing a pre-measured amount of collection buffer. No additional sample processing is required.
Needs only basic, non- technique-dependent specimen manipulation, including any for decontamination.	• The sample tube is flicked to mix the contents and an aliquot is transferred onto the Fast PCR MRP Test Disc device using the provided fixed volume pipette. • The device is packaged with a fixed volume pipette which ensures that an appropriate sample volume is loaded onto the Fast PCR MRP Test Disc device. Sample volume measurement is not needed for the operator. • Once the sample is loaded and sample port closed on the Fast PCR MRP Test Disc, the Fast PCR MRP Test Disc is loaded onto the Fast PCR Instrument. After insertion, all test steps are completed by the instrument without further user intervention.
Needs only basic, non- technique-dependent reagent manipulation, such as "mix reagent A and reagent B."	The device consists of a single use, ready-to-use Test Disc that contains all the reagents required for sample processing and analysis. No reagent handling or manipulation is required.
Needs no operator intervention during the analysis steps.	The device has a fully automated analysis workflow and results output and does not require any operator intervention during the analysis step.
Needs no technical or specialized training with respect to troubleshooting or interpretation of multiple or complex error codes.	Technical or specialized training is not required for operating the device. If an error code is shown, simple on-screen instructions are provided to the user. In addition, Fast PCR Instrument User Manual provides information regarding error handling and contact information for technical support.
Needs no electronic or mechanical maintenance beyond simple tasks, e.g., changing a battery or power cord.	The Fast PCR Instrument is maintenance-free and has no serviceable parts.
Produces results that require no operator calibration, interpretation, or calculation.	The test requires no calibration. Interpretation of results is automated. Results are displayed via the Fast PCR App on the System Tablet and no additional interpretation or calculations are required.

'Simple' Criteria	Device Characteristics
Produces results that are easy to determine, such as 'positive' or 'negative,' a direct readout of numerical values, the clear presence or absence of a line, or obvious color gradations.	Interpretation of results is automated. Qualitative test results ("Positive", "Negative", "Invalid", or "Error") are automatically displayed on the integrated view screen of the Fast PCR Instrument and no additional interpretation or calculations are required.
Includes quick reference instructions (QRI, Operator's Instrument Manual (if applicable), etc.) that are written at no higher than a 7th grade reading level.	A Quick Reference Guide (QRG) for the Fast PCR MRP and a Quick Reference Guide (QRG) for the Fast PCR Instrument are provided to the user. The documents are written in simple language at a 7th grade reading level and include clear diagrams to guide the user.

B Demonstrating "Insignificant Risk of an Erroneous Result"- Failure Alerts and Fail-Safe Mechanisms

1. Risk Analysis:

   A comprehensive risk analysis of the Fast PCR MRP and the Fast PCR Instrument (together, the Fast PCR System) was performed in accordance with ISO 14971 to identify potential hazards, hazardous situations and the associated harms. The detailed device hazard analysis was included in the submission and used to assess the risk of failure (false positive, false negative or delayed test results) that may occur during use or misuse of the device. Severity and probability of occurrence for each potential hazardous situation were evaluated to generate an overall assessment of the risk of the Fast PCR System. The risks considered included operator errors (human factors); sample handling and storage; device handling and storage; and environmental factors.

   Based on the hazard analysis, potential sources of errors that could adversely affect system performance were identified and mitigated first through system design and then through additional cautions in the labeling. The identified risks which could result in erroneous test results were evaluated in flex studies that stressed the functional limits of the test system (see below).

2. Fail-Safe and Failure Alert Mechanisms:

   The Fast PCR Mini Respiratory Panel performed on the Fast PCR Instrument was designed to include various features and fail-safe mechanisms built into the system to prevent erroneous results, summarized in **Table 2**.

Table 2. Fail-Safe and Failure Alert Mechanisms

Device	Design Feature	Description
Fast PCR Mini	**Endogenous Internal Control (RNase P)**	The internal control built into each Fast PCR MRP Test Disc controls for all test processes from sample collection to result. This ensures a given test run is

Device	Design Feature	Description
Respiratory Panel		controlled for sample quality, inhibition and sample loading without end user interaction.
	External Controls	The Fast PCR MRP Positive External Control and the Fast PCR MRP Negative External Control are recommended for use when receiving new device shipments or lots of Fast PCR MRP Test Discs, training new operators, when problems with testing are suspected or identified, to conform with internal quality control procedures, and in accordance with local, state and federal regulations.
	Fixed-Volume Transfer Pipette	The device is packaged with a fixed volume pipette which ensures that an appropriate sample volume is loaded onto the device.
	Packaging	Each Fast PCR MRP Test Disc is individually packaged in a protective sealed pouch, ensuring the cartridge is only removed from the protective environment immediately prior to use.
	Barcoding	Each Fast PCR MRP Test Disc includes a unique barcode that prevents re-use and the usage of the disc in the event that the disc lot is recalled or expired.
	No External Fluidic Interfaces	The Test Disc is sealed without the need for fluid exchange with the Fast PCR Instrument or environment, this prevents leaks during and after performing a test run, preventing user exposure to reagents.
	Reagents	All necessary reagents are pre-loaded into the Test Disc removing any need for the user to add additional reagents during the test run.
	Direct Swab Loading	The swab specimen collected in AMDI Sample Buffer is loaded directly into the Test Disc's sample port, minimizing additional sample preparation steps and reducing the risk of user errors.
Fast PCR Instrument	**Operator Lockout**	• The Fast PCR Instrument will only start a test if the tray is fully closed and the internal lift is fully raised. • The test is only run if a disc is inserted that was not previously used (checked via active cloud connection) and the disc is not expired or recalled.
	Instrument Self-Test	The Fast PCR Instrument executes a power-on-self-test immediately after power on to confirm required system functionality. The user is notified if performance is not met and instructed to contact customer support.
	Electronic Sensors	The Fast PCR Instrument continuously checks critical internal system parameters and will notify the user if

Device	Design Feature	Description
		assay critical performance is not reached and instructs the user to contact customer support.

3. Flex Studies:

Flex Studies were performed to evaluate the robustness of the Fast PCR Mini Respiratory Panel on the Fast PCR Instrument when challenged outside the operational limits of the system and with variations in workflow and operating environment that may reasonably be expected to occur with untrained operators in the intended use CLIA Waived setting. Test conditions were designed based on a risk analysis of the complete test system and included conditions intended to verify the effectiveness of in-built controls, lock-out features and failure alerts.

Contrived samples consisting of pooled negative human anterior nasal swab (ANS) matrix collected in AMDI Sample Buffer (unless otherwise noted) without assay targets (i.e., negative samples) or with assay targets at 2x Limit of Detection (LoD) (i.e., positive "quadspike ANS" samples, see **Table 3**) were used for flex study testing. Five (5) replicates of positive and negative samples were tested for each flex condition in each category of potential error unless otherwise described. Fast PCR MRP Positive and Negative External Controls were also tested in replicates of five (5) for the flex conditions assessing performance of external controls. Testing was conducted according to the Instructions for Use (IFU) for the assay and the Fast PCR Mini Respiratory Panel External Control Kit IFU.

Table 3. Strains Used for Quadspike Contrived Samples in Flex Studies

Target	Strain	Concentration (2x LoD)
Influenza A	Influenza A/Darwin/9/2021 (H3N2)	500 copies/mL
Influenza B	Influenza B/Colorado/06/2017 (Victoria Lineage)	1000 copies/mL
RSV	RSV A 2006 Isolate	500 copies/mL
SARS-CoV-2	USA/WA1/2020	1000 copies/mL

Types of potential sources of error include: operator error or human factors, specimen integrity and handling, reagent integrity, hardware, software, and electronic integrity, stability of reagents and controls, environmental factors, and foreseeable misuses. A listing of the specific potential sources of error evaluated in flex studies is presented in **Table 4.** In most cases, the expected positive or negative results were observed under each of the test conditions, or the in-built fail-safe mechanisms or failure alerts were shown to function as intended to prevent reporting of erroneous results. However, four conditions across three flex studies were identified that were associated with false-negative or false-positive results for some or all analytes (see Flex Study results below for additional details).

Overall, the Flex Studies demonstrated that the Fast PCR MRP using the Fast PCR Instrument is robust to foreseeable user-dependent variations in the assay workflow and that

in-built assay controls and fail-safe and/or failure alert mechanisms are effective in preventing the generation of erroneous results due to operator error and/or use of the Fast PCR MRP outside the specified operating environmental conditions.

Table 4. Potential Sources of Error Evaluated in the Flex Studies for Assay and External Controls

Study	Topic
A	Incorrect swab elution: incorrect media for sample elution
B	Incorrect Handling of Reagents: Dropped Fast PCR MRP Test Disc
C	Incorrect Handling of Reagents: Touching the Cuvettes 1-5
D	Incorrect Handling of Reagents: Disc Inverted before Loading
E	Use of Incorrect Reagents: External Control Bead Reconstituted in Alternate Collection Media
F	Incorrect order of reagent application: No sample added to AMDI Sample Buffer (SB)
G	Use of incorrect amount of reagent: Incorrect volume loaded into Disc
H	Use of Incorrect Amount of Reagent: Incorrect volume used for EC reconstitution
I	Use of Incorrect Amount of Reagent: Use of Incorrect Transfer Pipette
J	Incorrect timing of procedures: Delay after removing disc from Pouch
K	Incorrect timing of procedures: Delay after loading sample into disc
L	Use of improperly stored reagents: Discs in pouches not stored at room temperature
M	Use of improperly stored reagents: External Control Kit not stored at room temperature
N	Use of improperly mixed reagents: Sample not mixed before loading
O	Temperature and Humidity: Operational Range for the Fast PCR Instrument
P	Vibration
Q	Altitude
R	ISTA 3A Shipping Study for Fast PCR Instrument
S	ISTA 3A Shipping Study for Fast PCR MRP Kit
T	ISTA 3A Shipping Study for Fast PCR MRP External Controls Kit
U	Temperature and Humidity Storage
V	Interruption to Operation
W	Tilting and Sliding Flex Conditions
X	Test Disc Placement Flex Conditions
Y	Test Interruption and System Reset

Flex Study A. Incorrect swab elution: incorrect media for sample elution

- **Flex Condition 1:** ANS matrix was collected in UTM
- **Flex Condition 2:** ANS matrix was collected in saline
- **Flex Collection 3:** ANS matrix was collected in M4RT

Test samples: Five quadspike ANS and negative ANS were collected in UTM, saline or M4RT and tested. Results are shown in **Table 5**.

All replicates were invalid for both quadspike ANS and Negative ANS for UTM and saline (Flex Conditions 1 and 2). For Flex Condition 3 (M4RT), all replicates had a positive result for the quadspike ANS sample and a negative result for the Negative ANS sample. There were no erroneous results generated, demonstrating that the risk of erroneous results due to incorrected media for sample elution is minimal. These instrument errors are mitigated by clear labeling which instructs the user to only use reagents provided with the test kit.

Table 5. Flex Study A Results - Incorrect Media for Sample Elution

Flex Condition #	Media	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
1	UTM	Quadspike ANS	All replicates invalid				
		Negative	All replicates invalid				
2	Saline	Quadspike ANS	All replicates invalid				
		Negative	All replicates invalid				
3	M4RT	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

Flex Study B. Incorrect handling of reagents: dropped Fast PCR MRP Test Disc

- **Flex Condition 4**: Disc dropped approximately four (4) feet while still in pouch
- **Flex Condition 5**: Disc dropped approximately four (4) feet after removal from pouch but before loading sample
- **Flex Condition 6**: Disc dropped approximately four (4) feet after loading sample

Results are presented in **Table 6**. All samples generated expected results demonstrating that the risks of erroneous results due to dropping the Fast PCR MRP Test Discs are minimal. As a precaution, the labeling instructs the user not to use Test Discs that have been dropped or show signs of breakage.

Table 6. Flex Study B Results - Dropped Fast PCR MRP Test

Flex Condition #	Drop Conditions	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
4	Drop disc in pouch	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
5	Drop disc after	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)

Flex Condition #	Drop Conditions	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
	removing from pouch	Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
6	Drop disc after loading sample	Quadspike ANS [a]	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)	75% (3/4)
		Negative [b]	0% (0/2)	0% (0/2)	0% (0/2)	0% (0/2)	100% (2/2)

[a] One disc gave an invalid result. One disc was scanned but not run due to broken weld after drop. Test was cancelled.
[b] Three discs were scanned but not run due to broken welds after drop. Tests were cancelled.

Flex Study C. Incorrect Handling of Reagents: Touching the Cuvettes 1-5

- **Flex Condition 7**: Cuvettes 1-5 touched with dry gloves before loading the sample.
- **Flex Condition 8**: Cuvettes 1-5 touched with wet gloves (hand sanitizer) before loading the sample.
- **Flex Condition 9**: Cuvettes 1-5 touched with wet gloves (tap water) before loading the sample.
- **Flex Condition 10**: Cuvettes 1-5 touched with a bare hand.

Results are presented in **Table 7**. All samples generated expected results demonstrating that the risks of erroneous results due to touching the cuvettes are minimal. As a precaution, the labeling instructs the user to use appropriate PPE such as gloves when conducting the test.

Table 7. Flex Study C Results - Touching the Cuvettes 1-5

Flex Condition #	Cuvette Handling	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
7	Dry gloves	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
8	Wet gloves (hand sanitizer)	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)
9	Wet gloves (water)	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)

Flex Condition #	Cuvette Handling	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
10	Bare hands	Quadspike ANS [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

[a] One invalid result

Flex Study D. Incorrect Handling of Reagents: Disc Inverted before Loading

- **Flex Condition 11**: Loaded disc is inverted then flipped right side up, prior to loading into device.

Results are presented in **Table 8**. All samples generated expected results demonstrating that the risks of erroneous results due to inverted disc are minimal.

Table 8. Flex Study D Results - Disc Inverted before Loading

Flex Condition #	Test Disc Handling	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
11	Disc inverted before loading into device right side up	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)

Flex Study E. Use of Incorrect Reagents: External Control Bead Reconstituted in Alternate Collection Media

- **Flex Condition 12**: EC beads reconstituted in UTM
- **Flex Condition 13**: EC beads reconstituted in saline
- **Flex Condition 14**: EC beads reconstituted in M4RT

Results are presented in **Table 9**. All replicates were invalid for both quadspike ANS and Negative ANS for UTM and saline (Flex Conditions 12 and 13). For Flex Condition 14 (M4RT), all replicates had a positive result for the quadspike ANS sample and a negative result for the Negative ANS sample. There were no erroneous results generated, demonstrating that the risk of erroneous results due to external control bead reconstituted in alternate collection media is minimal. These errors are mitigated by clear labeling which instructs the user to only use reagents provided with the test kit.

Table 9. Flex Study E Results - External Control Bead Reconstituted in Alternate Collection Media

Flex Condition #	Media	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
12	UTM	Positive EC	All replicates invalid				
		Negative EC	All replicates invalid				
13	Saline	Positive EC	All replicates invalid				
		Negative EC	All replicates invalid				
14	M4RT	Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)

Flex Study F. Incorrect order of reagent application: No sample added to AMDI Sample Buffer (SB)

- **Flex Condition 15**: Load SB instead of EC or swab sample.

Results are presented in **Table 10**. All replicates were invalid for both quadspike ANS and Negative ANS for UTM and saline (Flex Condition 15). There were no erroneous results generated, demonstrating that the risk of erroneous results due to external control bead reconstituted in alternate collection media is minimal. These errors are mitigated by clear labeling which instructs the user to carefully comply with provided instructions and that deviations from instructions may lead to invalid or inaccurate results.

Table 10. Flex Study F Results - No Sample Added to AMDI Sample Buffer (SB)

Flex Condition #	Flex Condition	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
15	Load SB instead of EC or swab sample	Positive EC Negative EC	All replicates invalid				

Flex Study G. Use of incorrect amount of reagent: Incorrect volume loaded into Disc

- **Flex Condition 16**: 0 (No sample loaded into disc)
- **Flex Condition 17**: 250 µL Loaded into Disc
- **Flex Condition 18**: 300 µL Loaded into Disc
- **Flex Condition 19**: 325 µL Loaded into Disc
- **Flex Condition 20**: 350 µL Loaded into Disc
- **Flex Condition 21**: 375 µL Loaded into Disc

- **Flex Condition 22**: 400 µL Loaded into Disc
- **Flex Condition 23**: 450 µL Loaded into Disc
- **Flex Condition 24**: 500 µL Loaded into Disc
- **Flex Condition 25**: 600 µL Loaded into Disc
- **Flex Condition 26**: 800 µL Loaded into Disc
- **Flex Condition 27**: 1000 µL Loaded into Disc

Results are presented in **Table 11**. The assay was shown to be robust to incorrect volume loaded into the Test Disc for volumes of 350 µL, 375 µL, 400 µL, and 500 µL (achieved 100% expected results for positive external controls and all assay and internal control targets in the quadspike ANS). For volumes of 325 µL and below or 600 µL and above, either invalids were observed or did not achieve 100% expected results for positive external controls and all assay and internal control targets in the quadspike ANS. At 450 µL, two false positive results were observed in negative ANS controls. At a volume of 1000 µL for quadspike ANS samples, three out of five replicates were invalid and a false negative result was observed for influenza A, influenza B, SARS-CoV-2, and RSV. To reduce the likelihood of invalid results, the Fast PCR MRP Instructions for Use (IFU) and the Quick Reference Guide (QRG) include a warning that deviation from instructions may lead to inaccurate results. The IFU also includes a limitation that compliance with instructions is necessary to avoid inaccurate results. Both the IFU and QRG also include a specific warning in the step-by-step instructions that loading an incorrect sample volume may lead to invalid or inaccurate results.

Table 11. Flex Study G Results - Incorrect Volume Loaded into Disc

Flex Condition #	Volume Loaded (µL)	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
16	0	Quadspike ANS	All replicates invalid				
		Negative ANS	All replicates invalid				
		Positive EC	All replicates invalid				
17	250	Quadspike ANS	All replicates invalid				
		Negative ANS	All replicates invalid				
		Positive EC	All replicates invalid				
		Negative EC	All replicates invalid				
18	300	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)

Flex Condition #	Volume Loaded (µL)	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC [a]	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)	60% (3/5)
		Negative EC [b]	0% (0/1)	0% (0/1)	0% (0/1)	0% (0/1)	20% (1/5)
19	325	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC [c]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative EC [a]	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	60% (3/5)
20	350	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
21	375	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
22	400	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
23	450	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS [d]	**20% (1/5)**	0% (0/5)	**20% (1/5)**	0% (0/5)	100% (5/5)

Flex Condition #	Volume Loaded (µL)	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
24	500	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
25	600	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC [a]	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)	60% (3/5)
		Negative EC [c]	0% (0/4)	0% (0/4)	0% (0/4)	0% (0/4)	80% (4/5)
26	800	Quadspike ANS [a]	100% (3/3)	100% (3/3	100% (3/3	100% (3/3	60% (3/5)
		Negative ANS [a]	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	60% (3/5)
27	1000	Quadspike ANS [e]	**50% (1/2)**	**50% (1/2)**	**50% (1/2)**	**50% (1/2)**	**40% (2/5)**
		Negative ANS [a]	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	60% (3/5)

[a] Two invalid results.
[b] Four invalid results.
[c] One invalid result.
[d] Erroneous result: false positive for influenza A and RSV (High Ct values)
[e] Erroneous result: false negative for all four analytes; three invalid results.

Flex Study H. Use of Incorrect Amount of Reagent: Incorrect volume of Sample Buffer (SB) used for EC reconstitution

- **Flex Condition 28**: Reconstitute EC bead with 300 µL of SB
- **Flex Condition 29**: Reconstitute EC bead with 400 µL of SB
- **Flex Condition 30**: Reconstitute EC bead with 500 µL of SB
- **Flex Condition 31**: Reconstitute EC bead with 600 µL of SB
- **Flex Condition 32**: Reconstitute EC bead with 800 µL of SB
- **Flex Condition 33**: Reconstitute EC bead with 1000 µL of SB

Results are presented in **Table 12**. All replicates were invalid for both quadspike ANS and Negative ANS for UTM and saline (Flex Conditions 28 and 29). There were no erroneous results generated, demonstrating that the risk of erroneous results due to external control bead reconstituted in incorrect volume of sample buffer is minimal. These errors are mitigated by clear labeling which instructs the user to carefully comply with provided instructions and that deviations from instructions may lead to invalid or inaccurate results.

Table 12. Flex Study H Results - Incorrect Volume Used for EC Reconstitution

Flex Condition #	Reconstitution volume (µL)	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
28	300	Positive EC	All replicates invalid				
		Negative EC	All replicates invalid				
29	400	Positive EC [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
30	500	Positive EC [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
31	600	Positive EC [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
32	800	Positive EC [b]	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)	60% (3/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
33	1000	Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

[a] One invalid result
[b] Two invalid results

Flex Study I. Use of Incorrect Amount of Reagent: Use of Incorrect Transfer Pipette

- **Flex Condition 34**: Use 600 µL QC transfer pipette to load disc

Results are presented in **Table 13**. All samples generated expected results demonstrating that the risks of erroneous results due to use of incorrect transfer pipette are minimal. As a

precaution, the labeling instructs the user to select the correct fixed-volume pipette for the given task.

Table 13. Flex Study I Results - Use of Incorrect Transfer Pipette (600 µL)

Flex Condition #	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
34	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
	Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
	Positive EC [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/5)
	Negative EC [a]	0% (0/4)	0% (0/4)	0% (0/4)	0% (0/4)	100% (4/5)

[a] One invalid result

Flex Study J. Incorrect timing of procedures: Delay after removing disc from Pouch

- **Flex Condition 35**: Open ten (10) minutes before loading.
- **Flex Condition 36**: Open thirty (30) minutes before loading.
- **Flex Condition 37**: Open one (1) hour before loading.
- **Flex Condition 38**: Open four (4) hours before loading.
- **Flex Condition 39**: Open eight (8) hours before loading.

Results are presented in **Table 14**. The assay was shown to be robust to a 10-minute delay after removing the Test Disc from its pouch (achieved 100% expected results for positive external controls and all assay and internal control targets in the quadspike ANS). After a 30-minute delay, an invalid result was observed for one of five replicates for each the negative ANS, positive external control, and negative external control groups. After a 1-hour delay, a false positive result was observed for the SARS-CoV-2 target in a negative ANS replicate and a negative external control replicate. After an 8-hour delay, a false positive result was observed for influenza A in a negative ANS replicate. To reduce the likelihood that operators will delay using the test following disc unpackaging, the Fast PCR MRP IFU and QRG include a warning (and a limitation in the IFU) to use the Test Disc within 30 minutes of removal from pouch because delayed use of Test Disc may lead to invalid or inaccurate results.

Table 14. Flex Study J Results - Delay After Removing Disc from Pouch

Flex Condition #	Length of Delay	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
35	10 minutes	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)

Flex Condition #	Length of Delay	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
36	30 minutes	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS [a]	0% (0/4)	0% (0/4)	0% (0/4)	0% (0/4)	80% (4/5)
		Positive EC [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative EC [a]	0% (0/4)	0% (0/4)	0% (0/4)	0% (0/4)	100% (4/5)
37	1 hour	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS [b]	0% (0/5)	0% (0/5)	0% (0/5)	**20% (1/5)**	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC [b]	0% (0/5)	0% (0/5)	0% (0/5)	**20% (1/5)**	100% (5/5)
38	4 hours	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
39	8 hours	Quadspike ANS [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative ANS [b]	**20% (1/5)**	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

[a] One invalid result
[b] False positive

Flex Study K. Incorrect timing of procedures: Delay after loading sample into disc

- **Flex Condition 40**: Load sample ten (10) minutes before starting test
- **Flex Condition 41**: Load sample thirty (30) minutes before starting test
- **Flex Condition 42**: Load sample one (1) hour before starting test

Results are presented in **Table 15**. All samples generated expected results demonstrating that the risks of erroneous results due to delay after loading sample into disc are minimal. As a precaution, the labeling instructs the user to use the Test Disc within 30 minutes of removing from pouch and that delayed use of disc after pouch removal may lead to invalid or inaccurate results.

Table 15. Flex Study K Results - Delay after Loading Sample

Flex Condition #	Length of Delay	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
40	10 minutes	Quadspike ANS [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
41	30 minutes	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
42	1 hour	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
		Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

[a] One invalid result

Flex Study L. Use of improperly stored reagents: Discs in pouches not stored at room temperature

- **Flex Condition 43**: Discs stored at 2-8 °C for twenty-seven (27) to thirty (30) hours. Note: for two (2) repeat runs, discs were stored at 2-8 °C for twenty-four (24) hours.
- **Flex Condition 44**: Discs stored at <-15 °C for twenty-six (26) hours.
- **Flex Condition 45**: Discs stored at 40 °C for twenty-four (24) hours.

Results are presented in **Table 16**. The assay was shown to be robust to Test Disc storage at 2-8ºC stored for a duration between 24-30 hours. When stored at <-15 °C for 26 hours, one invalid was observed for quadspike ANS samples. When stored at 40 °C for 24 hours for the quadspike ANS samples, one out of five replicates was invalid and a false negative result was observed for influenza A. To reduce the likelihood of invalid results, the Fast PCR IFU and QRG include a warning (and a limitation in the IFU) to store Test Discs at room temperature (15-30°C) and that use of improperly stored Test Discs may result in inaccurate results.

Table 16. Flex Study L Results - Discs in Pouches Not Stored at Room Temperature

Flex Condition #	Storage Temperature (ºC)	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
43	2-8 ºC	Quadspike ANS	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
44	<-15 ºC	Quadspike ANS [a]	100% (4/4)	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)[a]
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
45	40 ºC	Quadspike ANS [a, b]	**75% (3/4)**	100% (4/4)	100% (4/4)	100% (4/4)	80% (4/5)
		Negative ANS	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

[a] One invalid result
[b] One false negative for influenza A

Flex Study M. Use of improperly stored reagents: External Control Kit not stored at room temperature

- **Flex Condition 46**: EC Kit stored at 2-8 °C for sixty-three (63) hours. Note: for one (1) repeat run, the EC Kit was stored for twenty-four (24) hours.
- **Flex Condition 47**: EC Kit stored at <-15 °C for C for sixty-three (63) hours.
- **Flex Condition 48**: EC Kit stored at 40 °C for twenty-six (26) hours. Note: for repeat runs, the EC kit was stored for twenty-four (24) hours.

Results are presented in **Table 17**. All samples generated expected results demonstrating that the risks of erroneous results due to external control kit not stored at room temperature are

minimal. As a precaution, the labeling instructs the user to carefully comply with provided instructions and that deviations from instructions may lead to invalid or inaccurate results.

Table 17. Flex Study M Results - EC Kit Not Stored at Room Temperature

Flex Condition #	Storage Temperature (ºC)	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
46	2-8 ºC	Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
47	<-15 ºC	Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)
48	40 ºC	Positive EC [a]	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	83.3% (5/6)
		Negative EC	0% (0/5)	0% (0/5)	0% (0/5)	0% (0/5)	100% (5/5)

[a] One invalid result

Flex Study N. Use of improperly mixed reagents: Sample not mixed before loading

- **Flex Condition 49**: External Controls not mixed after reconstitution

Results are presented in **Table 18**. All samples generated expected results demonstrating that the risks of erroneous results due to sample not mixed before loading are minimal. As a precaution, the labeling instructs the user to swirl/flick the sealed tube a minimum of five (5) times.

Table 18. Flex Study N Results - Sample Not Mixed Before Loading

Flex Condition #	Sample	Influenza A	Influenza B	RSV	SARS-CoV-2	RNase P
49	Positive EC	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)	100% (5/5)
	Negative EC [a]	0% (0/4)	0% (0/4)	0% (0/4)	0% (0/4)	80% (4/5)

[a] One invalid result

Flex Study O. Temperature and Humidity Operational Range for the Fast PCR Instrument

- **Flex Condition 50**: Low temperature: 15°C / Low humidity: 15% RH
- **Flex Condition 51**: Low temperature: 15°C / High humidity: 80% RH
- **Flex Condition 52**: High temperature: 30°C / Low humidity: 15% RH

- **Flex Condition 53**: High temperature: 30°C / High humidity: 80% RH

Results are presented in **Table 19**. The results demonstrate that the Fast PCR system operates properly within the temperature range of 15 °C – 30 °C and humidity range of 15 – 30 %. As a precaution, the labeling instructs the user to conduct the test within the operating temperature limits of the device.

Table 19. Flex Study O Results - Temperature and Humidity Operational Range for the Fast PCR Instrument

Flex Condition #	Temperature (ºC)	Relative Humidity	Sample	Results
50	15ºC	15% RH	Positive EC	3/3 Pass
			Negative EC	3/3 Pass
51	15ºC	80% RH	Positive EC	3/3 Pass
			Negative EC	3/3 Pass
52	30ºC	15% RH	Positive EC	3/3 Pass
			Negative EC	3/3 Pass
53	30ºC	80% RH	Positive EC	3/3 Pass
			Negative EC	3/3 Pass

Flex Study P. Vibration

- **Flex Condition 54**: Low Frequency - Frequency range: 30-75Hz
- **Flex Condition 55**: High Frequency - Frequency range:120-160Hz

Results are presented in **Table 20.** The results demonstrate that the Fast PCR instrument is robust to exposure to a nearby source of indirect vibration in the range of 30 – 75Hz and 120 – 160Hz.

Table 20. Flex Study P Results - Vibration

Flex Condition #	Vibration Frequency (Hz)	Sample	Results
54	30-75 Hz	Positive EC	3/3 Pass
		Negative EC	3/3 Pass
55	120-160 Hz	Positive EC	3/3 Pass
		Negative EC	3/3 Pass

Flex Study Q. Altitude

- **Flex Condition 56**: High Altitude: 8000ft

Results are presented in **Table 21**. The results demonstrate that The Fast PCR system can function properly under conditions that simulate an elevation of 8000 ft. As a precaution, the labeling instructs the user of the appropriate altitude range for the instrument.

Table 21. Flex Study Q Results - Altitude

Flex Condition #	Altitude	Sample	Results
56	8000 ft	Positive EC	3/3 Pass
		Negative EC	3/3 Pass

ISTA 3A Shipping Studies –

ISTA 3A is a specialized pre-shipment certification standard for individual packaged products designed to simulate parcel delivery environments (ground or air). It evaluates packaging durability against hazards like drops, vibrations and compression. Testing scenarios are as indicated.

Flex Study R. ISTA 3A Shipping Study for Fast PCR Instrument

- **Flex Condition 57**: Use the Instrument that has been through ISTA 3A shipping sequences. After the ISTA 3A shipping sequences, the performance of the Instrument was verified using the ECs and Test Discs that have not gone through the shipping ISTA 3A sequences.

Flex Study S. ISTA 3A Shipping Study for Fast PCR MRP Kit

- **Flex Condition 58**: Use Fast PCR MRP Kit that has been through ISTA 3A shipping sequences. After the ISTA 3A shipping sequences, the performance of the Fast PCR MRP Kit was verified using the ECs and a Fast PCR Instrument that have not gone through the shipping ISTA 3A sequences.

Flex Study T. ISTA 3A Shipping Study for Fast PCR MRP External Controls Kit

- **Flex Condition 59**: Use Fast PCR MRP External Controls Kit that has been through ISTA 3A shipping sequences. After the ISTA 3A shipping sequences, the performance of the Fast PCR MRP EC Kit was verified using the Test Discs and a Fast PCR Instrument that have not gone through the shipping ISTA 3A sequences.

Results are presented in **Table 22**. The results demonstrate that the Fast PCR Instrument, Fast PCR MRP Kit and Fast PCR MRP External Controls Kit, can function properly after ISTA 3A shipping sequences.

Table 22. Flex Studies R, S & T Results - Shipping Simulation

Flex Condition #	Test	Sample	Results
57	ISTA 3A Shipping Study for Fast PCR Instrument	Positive EC	3/3 Pass
		Negative EC	3/3 Pass
58	ISTA 3A Shipping Study for Fast PCR MRP Kit	Positive EC	3/3 Pass
		Negative EC	3/3 Pass
59	Shipping Study for Fast PCR MRP External Controls Kit	Positive EC	3/3 Pass
		Negative EC	3/3 Pass

Flex Study U. Temperature and Humidity Storage

The equipment being tested was stored in a reach-in chamber that was held at the indicated temperature and humidity for 72 hours. The devices under investigation were then held at ambient temperature for one hour prior to the testing of positive and negative ECs as samples.

- **Flex Condition 60**: High Temperature and High Humidity Storage for Fast PCR Instrument
    - Stored for 72 hours at
        - High temp: 40℃
        - High humidity: 90%
    - Held at ambient for 1 hour prior to testing
        - Ambient temp: 23°C
        - Ambient humidity: 50%

- **Flex Condition 61**: Low Temperature and Low Humidity Storage for Fast PCR Instrument
    - Stored for 72 hours at
        - Low temp: -20°C
        - Low humidity: off
    - Held at ambient for 1 hour prior to testing
        - Ambient temp: 23°C
        - Ambient humidity: 50%

- **Flex Condition 62**: High Temperature and High Humidity Storage for Fast PCR MRP Test Disc
    - Stored for 72 hours at
        - High temp: 40℃
        - High humidity: 90%
    - Held at ambient for 1 hour prior to testing
        - Ambient temp: 23°C

        - Ambient humidity: 50%

- **Flex Condition 63**: Low Temperature and Low Humidity Storage for Fast PCR MRP Test Disc
    - Stored for 72 hours at
        - Low temp: -20°C
        - Low humidity: off
    - Held at ambient for 1 hour prior to testing
        - Ambient temp: 23°C
        - Ambient humidity: 50%

- **Flex Condition 64**: High Temperature and High Humidity Storage for Fast PCR MRP External Controls
    - Stored for 72 hours at
        - High temp: 40℃
        - High humidity: 90%
    - Held at ambient for 1 hour prior to testing
        - Ambient temp: 23°C
        - Ambient humidity: 50%

- **Flex Condition 65**: Low Temperature and Low Humidity Storage for Fast PCR MRP External Controls
    - Stored for 72 hours at
        - Low temp: -20°C
        - Low humidity: off
    - Held at ambient for 1 hour prior to testing
        - Ambient temp: 23°C
        - Ambient humidity: 50%

Results are presented in **Table 23**. The test results demonstrate that the Fast PCR Instrument, Fast PCR MRP Test Discs, and Fast PCR MRP External Controls can function properly after storage at temperatures of -20°C and 40°C/90% RH with an hour of acclimation to ambient temperatures after storage.

Table 23. Flex Study U Results - Temperature and Humidity Storage

Flex Condition #	Test Item	Temperature (ºC)	Relative Humidity	Sample	Results
60	Instrument	40ºC	90% RH	Positive EC	3/3 Pass
				Negative EC	3/3 Pass
61		-20ºC	Off	Positive EC	3/3 Pass
				Negative EC	3/3 Pass
62	MRP Test Disc	40ºC	90% RH	Positive EC	3/3 Pass
				Negative EC	3/3 Pass
63		-20ºC	Off	Positive EC	3/3 Pass

Flex Condition #	Test Item	Temperature (ºC)	Relative Humidity	Sample	Results
				Negative EC	3/3 Pass
64	MRP External Controls	40ºC	90% RH	Positive EC	3/3 Pass
				Negative EC	3/3 Pass
65		-20ºC	Off	Positive EC	3/3 Pass
				Negative EC	3/3 Pass

Flex Study V. Interruption to Operation - Ability to add or remove modules.

- **Flex Condition 66**: Add Module during run: While a Fast PCR Instrument consisting of one Fast PCR Base Station and one Fast PCR Operating Modules was running a test, a second Fast PCR Operating Module was added to the stack and a second test was started on the new Module.
- **Flex Condition 67**: Remove Module during run: While a Fast PCR Instrument consisting of one Fast PCR Base Station and two Fast PCR Operating Modules was running a test, the Fast PCR Operating Module that was not running a test was removed from the stack.

Results are presented in **Table 24.** The test results demonstrate that the Fast PCR Instrument is able to operate without disruption when a Fast PCR Module is added during a run and when a Fast PCR Module is removed during a run. As a precaution, the labeling instructs the user not to move the Base Station or Operating Modules while the system is running.

Table 24. Flex Study V Results - Adding or Removing Module During Run

Flex Condition #	Add / Remove Module	Results
66	Add	2/2 Positive ECs Passed
67	Remove	1/1 Positive EC Passed

Flex Study W. Tilting and Sliding Flex Conditions
Operation of Fast PCR Instrument

- **Flex Condition 68**: Tilting Instrument - 20° angle, or the angle at which the Test Disc in the Test Disc Holder starts to slide without added force, whichever is smaller.
- **Flex Condition 69**: Sliding Instrument - Sliding the system while running discs - Slide 12” in <20s

Operation of Fast PCR Instrument

- **Flex Condition 70**: Tilting Instrument - 20° angle, or the angle at which the Test Disc in the Test Disc Holder starts to slide without added force, whichever is smaller - AMDI used a 15° angle.
- **Flex Condition 71**: Sliding the system while running discs - Slide 12” in <20s

Results are presented in **Table 25.** The test results demonstrate that the Fast PCR Instrument is able to operate without disruption when operated at an angle or while sliding 12 inches in less than twenty seconds. As a precaution, the labeling instructs the user to use the instrument on a flat surface.

Table 25. Flex Study W Results - Instrument Tilting and Sliding Flex Conditions

Flex Condition #	Flex Condition	Result
68	20º Tilt	3/3 Positive ECs Passed
		3/3 Negative ECs Passed
69	12” slide in <20 sec	3/3 Positive ECs Passed
		3/3 Negative ECs Passed
70	15º Tilt	3/3 Positive ECs Passed
		3/3 Negative ECs Passed
71	12” slide in <20 sec	3/3 Positive ECs Passed
		3/3 Negative ECs Passed

Flex Study X. Test Disc Placement Flex Conditions

- **Flex Condition 72**: Disc misplaced in the most sideways supported by the Disc core
- **Flex Condition 73**: Disc misplaced in the most sideways supported by the insert
- **Flex Condition 74**: Disc misplaced in the most inward position away from the user
- **Flex Condition 75**: Disc misplaced in the most outward position toward the user
- **Flex Condition 76**: Disc position in the intended position. Cuvette 4 oriented away from the user (12 o’clock position).
- **Flex Condition 77**: Disc position in the intended position. Cuvette 4 oriented to the right of user (3 o’clock position).
- **Flex Condition 78**: Disc position in the intended position. Cuvette 4 oriented to the right of user (6 o’clock position).
- **Flex Condition 79**: Disc position in the intended position. Cuvette 4 oriented to the left of user (9 o’clock position).
- **Flex Condition 80**: Disc in the intended position. Cuvette 4 oriented in the mid sections of the 4 quadrants

Test Instructions:
I. Run Discs using Fast PCR Instrument. During Disc loading, place Test Disc in tray as specified in the flex condition. If Disc is impinged during tray closure leading to tray stall, then do not run Test Disc and inspect for leaks and damage. If Test Disc is successfully loaded, run test until completion then inspect Test Disc for leaks and damage.
- Three Discs with sample buffer were used for flex conditions 72-75.

II. Run Discs using Fast PCR Instrument. During Disc loading, place Test Disc in tray as specified in flex condition
- Three Negative EC samples were used for flex conditions 76-79.

III. Run 1 Disc in each of the specified orientation using Fast PCR Instrument. During Disc loading, place Test Disc in tray as specified in flex condition
- Four Negative EC samples were used for flex condition 80.

Results are presented in **Table 26**. The test results demonstrate that the Fast PCR Instrument is able to operate when with various disc placement during loading. As a precaution, the labeling instructs the user to carefully comply with provided instructions and that deviations from instructions may lead to invalid or inaccurate results.

Table 26. Flex Study X Results – Test Disc Placement Flex Conditions

Flex Condition #	Flex Condition	Test Instructions	Result
72	Disc misplaced in the most sideway supported by the Disc core.	I	N/A, Disc stalled, 3/3
73	Disc misplaced in the most sideway supported by the insert.	I	N/A, Disc stalled, 3/3
74	Disc misplaced in the most inward position away from the user.	I	Passed 2/2 [a]
75	Disc misplaced in the most outward position toward the user.	I	N/A, Disc stalled, 3/3
76	Disc position in the intended position. Cuvette 4 oriented away from the user (12 o'clock position).	II	Passed 3/3
77	Disc position in the intended position. Cuvette 4 oriented to the right of user (3 o'clock position).	II	Passed 3/3
78	Disc position in the intended position. Cuvette 4 oriented to the right of user (6 o'clock position).	II	Passed 3/3
79	Disc position in the intended position. Cuvette 4 oriented to the left of user (9 o'clock position).	II	Passed 3/3
80	Disc in the intended position. Cuvette 4 oriented in the mid sections of the 4 quadrants.	III	Passed 4/4

[a] Bluetooth connection lost. Test cancelled.

Flex Study Y. Test Interruption and System Reset

- **Flex Condition 81**: Turn off power button in the back while running a Test Disc.
- **Flex Condition 82**: Hold the power button in the front for 5s while running a Test Disc.
- **Flex Condition 83**: Hold on the power button in the front for 12s while running a Test Disc.

Results are presented in **Table 27**. The test results demonstrate that the Fast PCR Instrument does not produce erroneous results after system recovery from test interruption and system reset.

Table 27. Flex Study Y Results - Test Interruption and System Reset

Flex Condition #	Flex Condition	Test Instructions	Result
81	Turn off power button in the back while running a Test Disc.	While a test is currently running, turn off the power button on the back of the Fast PCR Instrument. Record what happens to the current run and what recovery actions are taken by the Fast PCR Instrument. **Confirm that another Test Disc is able to be run successfully after the recovery.**	2/2 Positive EC
82	Hold the power button in the front for 5s while running a Test Disc.	While a test is currently running, hold on the power button on the front of the Fast PCR Instrument for 5 seconds. Record what happens to the current run and what recovery actions are taken by the Fast PCR Instrument. **Confirm that another Test Disc is able to be run successfully after the recovery.**	2/2 Positive EC
83	Hold on the power button in the front for 12s while running a Test Disc.	While a test is currently running, hold on the power button on the front of the Fast PCR Instrument for 12 seconds. Record what happens to the current run and what recovery actions are taken by the Fast PCR Instrument. **Confirm that another Test Disc is able to be run successfully after the recovery.**	2/2 Positive EC

C Demonstrating "Insignificant Risk of an Erroneous Result" - Accuracy

1. Comparison Study:

a. Study Design:

i. Study Sites and Duration:
The performance of the Fast PCR Mini Respiratory Panel (MRP) performed on the Fast PCR Instrument in the hands of untrained users was evaluated in a multi-site prospective clinical study from December 2024 to May 2025, during the 2024-2025 respiratory season within the United States. The prospective clinical study was performed at nine geographically diverse sites considered representative of CLIA-waived intended use sites CLIA-Waived (CW) settings, including adult clinics, pediatric clinics, urgent care clinics, and clinics attached to hospitals.

ii. Operators:
A total of 27 untrained operators, representative of CLIA-waived users, participated in the clinical study with between two and four operators per site. The operators were personnel employed at the selected CLIA-waived testing sites. Information on the operators' current job title, education level and any laboratory or relevant work experience was provided. The operators were representative of operators conducting testing at a CLIA Waived setting and did not receive any training on the use of the Fast PCR MRP or the Fast PCR Instrument. The participating operators conducted the test by following the instructions in the Quick Reference Guides (QRGs) for the Fast PCR MRP and the Fast PCR Instrument.

iii. Subjects (Patients):
A total of 1,947 subjects were initially enrolled for the prospective clinical study. Of these, 126 specimens were excluded from the performance analysis due to protocol deviations and 33 were excluded due to a lack of valid Fast PCR MRP result. Of the remaining 1,788 study participants the mean age was 36 years, with a range between < 1 month to 92 years of age. Specimens for the prospective clinical study were collected under informed consent and according to the following inclusion or exclusion criteria summarized below:

Inclusion Criteria (included if meet all criteria):

- Subjects with one or more signs/symptoms of respiratory infection, including but not limited to fever, cough, sore throat, runny nose, myalgia, headache, chills or fatigue.
- If ≥ age of majority (i.e., 18 years), subject has provided Informed Consent. If <age of majority, parent/legal guardian consent provided, and subject assent provided. The following consent/assent is required per age group:
    - Minors <7 years of age: written consent by the parent/legal guardian.
    - Minors 7 to the age of majority will provide assent (specific for age-appropriate language) followed by parent/legal guardian consent.
    - Age of majority: written consent
- Subject willing to provide two (2) anterior nasal swab (ANS) specimens.

Exclusion Criteria (excluded if meet any one of following criteria):

- Subject or legal guardian is unable or unwilling to provide Informed Consent or assent (if required), or
- Subject is unable or unwilling to provide the required specimens, or
- Subjects who have received an influenza vaccine by an influenza nasal spray/mist vaccine within the previous 30 days, or
- Subject's healthcare provider determined that specimen collection represented an unacceptable healthcare risk, or
- Previously participated in the study

iv. Samples:
Two anterior nasal swab (ANS) specimens were collected sequentially from each eligible subject. One of the ANS specimens was placed into transport media and stored frozen at -80°C for comparator testing at the comparator testing site. The other ANS specimen was

tested using the Fast PCR MRP according to the instructions in the QRG. The order of swab collection was alternated between the comparator swab and the Fast PCR MRP. Collection of each swab occurred 15 minutes apart.

v. Comparative Method:
A multi-analyte FDA-cleared nucleic acid amplification test (NAAT) for SARS-CoV-2, influenza A, influenza B, and RSV targets was used as the comparator method in the prospective clinical study to establish the performance of the Fast PCR MRP with anterior nasal swab specimens.

b. Results:

i. Prospective Study:
A total of 1,947 subjects were initially enrolled for the prospective clinical study. Of these, 126 specimens were excluded from the performance analysis due to protocol deviations and 33 were excluded due to a lack of valid Fast PCR MRP result. This gives a final invalid rate of 1.69% (33/1947) with a 95% CI: 1.12 – 2.27% for the prospective study.

The clinical performance of the Fast PCR MRP with prospectively collected ANS samples, when used by untrained operators in CLIA-waived settings, is presented in **Table 28**.

Table 28. Fast PCR MRP Prospective Clinical Performance

Analyte	N	TP	FP	TN	FN	PPA		NPA	
						%	95% CI	%	95% CI
Influenza A	1788	236	45	1501	6	97.5	94.7 – 98.9	97.1	96.1 – 97.8
Influenza B	1788	77	5	1706	0	100.0	95.2 – 100.0	99.7	99.3 – 99.9
RSV	1788	33	9	1743	3	91.7	78.2 – 97.1	99.5	99.0 – 99.7
SARS-CoV-2	1788	85	11	1690	2	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.

ii. 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. This gives a final invalid rate of 0.76% (1/132) with a 95% CI: -0.72 – 2.24% for the retrospective study. Clinical performance for archived samples is shown in **Table 29.**

Table 29. Fast PCR MRP Retrospective Clinical Performance

Analyte	N	TP	FP	TN	FN	PPA		NPA	
						%	95% CI	%	95% CI
RSV	118	33	2	83	2	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.

2. Device Performance with Analyte Concentrations Near the Cutoff:

The performance of the Fast PCR MRP was evaluated with low positive samples to demonstrate that untrained operators can reproducibly generate accurate results testing specimens containing low concentrations of the target organisms. Testing was performed at three distinct external CLIA-waived sites with two untrained operators per site. A 3-member panel of contrived nasal swabs was evaluated consisting of a true negative (no analyte), low positive (2x LoD of all four targets), and a moderate positive (5x LoD of all four targets). The negative swab samples were contrived in pooled negative anterior nasal swab matrix and the positive swab samples were contrived in pooled negative anterior nasal swab matrix co-spiked with SARS-CoV-2, influenza A, influenza B, and RSV viruses. Testing was carried out over at least five non-consecutive testing days at each site with three 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 participating operators conducted the testing by following the instructions in the QRG. No significant differences between sites, instruments, lots or operators were observed, demonstrating that untrained users could perform the test accurately when testing samples with organism concentrations near the assay LoD.

Table 30 presents the qualitative summary for influenza A, influenza B, RSV and SARS-CoV-2 during panel member testing.

Table 30. Summary of Results Testing Samples Near Assay LoD

Sample	Analyte	Site	Invalid	Negative	Positive	#Pass	N Valid	%Pass	95% CI
Negative	Influenza A	AER	0	87	2	87	89	97.8%	92.2%-99.4%
	Influenza A	ALP	2	95	0	95	95	100.0%	96.1%-100.0%
	Influenza A	ERA	5	94	0	94	94	100.0%	96.1%-100.0%

Sample	Analyte	Site	Invalid	Negative	Positive	#Pass	N Valid	%Pass	95% CI
	Influenza B	AER	0	89	0	89	89	100.0%	95.9%-100.0%
	Influenza B	ALP	2	95	0	95	95	100.0%	96.1%-100.0%
	Influenza B	ERA	5	94	0	94	94	100.0%	96.1%-100.0%
	RSV	AER	0	89	0	89	89	100.0%	95.9%-100.0%
	RSV	ALP	2	95	0	95	95	100.0%	96.1%-100.0%
	RSV	ERA	5	94	0	94	94	100.0%	96.1%-100.0%
	SARS-CoV-2	AER	0	88	1	89	89	98.9%	93.9%-99.8%
	SARS-CoV-2	ALP	2	95	0	95	95	100.0%	96.1%-100.0%
	SARS-CoV-2	ERA	5	94	0	94	94	100.0%	96.1%-100.0%
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%
	SARS-CoV-2		7	277	1	277	278	99.6%	98.0%-99.9%
2x LoD	Influenza A	AER	8	1	89	89	90	98.9%	94.0%-99.8%
	Influenza A	ALP	2	1	89	89	90	98.9%	94.0%-99.8%
	Influenza A	ERA	11	1	92	92	93	98.9%	94.2%-99.8%
	Influenza B	AER	8	0	90	90	90	100.0%	95.9%-100.0%
	Influenza B	ALP	2	0	90	90	90	100.0%	95.9%-100.0%
	Influenza B	ERA	11	1	92	92	93	98.9%	94.2%-99.8%
	RSV	AER	8	1	89	89	90	98.9%	94.0%-99.8%
	RSV	ALP	2	1	89	89	90	98.9%	94.0%-99.8%
	RSV	ERA	11	3	90	90	93	96.8%	90.9%-99.8%
	SARS-CoV-2	AER	8	1	89	89	90	98.9%	94.0%-99.8%

Sample	Analyte	Site	Invalid	Negative	Positive	#Pass	N Valid	%Pass	95% CI
	SARS-CoV-2	ALP	2	1	89	89	90	98.9%	94.0%-99.8%
	SARS-CoV-2	ERA	11	1	92	92	93	98.9%	94.2%-99.8%
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%
	SARS-CoV-2		21	3	270	270	273	98.9%	96.8%-99.6%
5x LoD	Influenza A	AER	4	0	91	91	91	100.0%	95.9%-100.0%
	Influenza A	ALP	0	0	91	91	91	100.0%	95.9%-100.0%
	Influenza A	ERA	6	0	90	90	90	100.0%	95.9%-100.0%
	Influenza B	AER	4	0	91	91	91	100.0%	95.9%-100.0%
	Influenza B	ALP	0	0	91	91	91	100.0%	95.9%-100.0%
	Influenza B	ERA	6	0	90	90	90	100.0%	95.9%-100.0%
	RSV	AER	4	0	91	91	91	100.0%	95.9%-100.0%
	RSV	ALP	0	1	90	90	91	98.9%	94.0%-99.8%
	RSV	ERA	6	0	90	90	90	100.0%	95.9%-100.0%
	SARS-CoV-2	AER	4	0	91	91	91	100.0%	95.9%-100.0%
	SARS-CoV-2	ALP	0	0	91	91	91	100.0%	95.9%-100.0%
	SARS-CoV-2	ERA	6	0	90	90	90	100.0%	95.9%-100.0%
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%
	SARS-CoV-2		10	0	272	272	272	100.0%	98.6%-100.0%

3. Operator Questionnaire:

Operators at each CLIA-waived site were asked to complete an operator usability questionnaire (post study) to help assess whether participants understood how to install the Fast PCR Instrument and how to use the Fast PCR MRP. These questionnaires consisted of seven and six statements respectively pertaining to the ease of installation of the instrument and Fast PCR App, how easy QRG instructions were to follow for the instrument and test, ability to load a sample, ability to interpret sample and Quality Control results, and the need for assistance. Each statement had five possible answers rated on a scale from strongly agree to strongly disagree and where applicable specific comments could be added in addition to the rated response. All 27 operators provided responses to the questionnaire. Based on the study operator responses, by following the instructions provided in the respective QRGs, the Fast PCR Instrument was easy to set up and the Fast PCR MRP was easy to use.

D Labeling for Waived Devices

The labeling for the Fast PCR Mini Respiratory Panel (MRP) consists of:

1. Instructions for Use/Package Insert (IFU)
2. Quick Reference Guide (QRG)
3. Kit and individual device outer packaging labels

The labeling for the Fast PCR Instrument consists of:

1. User Manual
2. Quick Reference Guide (QRG)
3. Fast PCR Cloud Station Operating Manual
4. Kit and individual device outer packaging labels

The labeling for the Fast PCR MRP External Controls (Positive and Negative) consists of:

1. Instructions for Use/Package Insert (IFU)
2. Kit and individual device outer packaging labels

The following elements are appropriately present:

- The Fast PCR Instrument User Manual and QRG for the Fast PCR Instrument specifies the environmental operating conditions under which testing may be performed.
- The Fast PCR Instrument User Manual and QRG, the Fast PCR MRP IFU and QRG, and the Fast PCR MRP External Controls IFU are clear and easy to understand.
- The Fast PCR Instrument User Manual and QRG, and the Fast PCR MRP IFU and QRG identify the system as CLIA-waived.
- A statement informing the user that the test procedure must be followed as written to maintain the CLIA-waived status is present in the Fast PCR Instrument User Manual and QRG, and the Fast PCR MRP IFU and QRG.
- The Fast PCR MRP IFU and QRG include the statement that a Certificate of Waiver is required to perform the test in a waived setting.
- The Fast PCR MRP IFU and QRG include instructions for performing Quality Control testing.

- Technical support telephone number is prominently displayed in both the Fast PCR MRP IFU and QRG, as well as Fast PCR Instrument User Manual and QRG.
- All appropriate cautions regarding sample handling and processing are present.

- The Fast PCR MRP Instructions for Use:
    - Indicates that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
    - Includes step-by-step instructions for performing the test.
    - Includes safety considerations applicable for untrained users.
    - Specifies the actions to be taken if an invalid test result is obtained.
    - Includes a summary of the studies performed to support CLIA Waiver.
    - Includes appropriate warnings and/or limitations pertaining to clinical interpretation of test results.

XI. Benefit-Risk Considerations

Not applicable.

XII. Conclusion

The submitted information in this CLIA waiver application supports a CLIA waiver approval decision.