CLIA Waiver by Application Approval Determination
Decision Summary

I. Document Number

CW250008

II. Parent Document Number

K251978

III. CLIA Waiver Type

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

IV. Applicant

Diasorin Molecular LLC

V. Proprietary and Established Names

LIAISON NES FLU A/B, RSV & COVID-19

VI. Measurand (analyte)

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

VII. Sample Type(s)

Anterior nasal swabs

VIII. Type of Test

Qualitative RT-PCR

IX. Test System Description

A Overview

The LIAISON NES Instrument (NES1001) is capable of analysis of a single cartridge containing a single specimen. A set of parameters specific to the assay is included in the instrument software to name target molecules, assign dyes to probes, specify cycling conditions, and to analyze data from runs. Fluorescence intensity is monitored at each PCR cycle by detection modules within the instrument. The instrument software controls the thermocycling and, upon completion of the run, automatically interprets and displays results for the specimen.

The LIAISON NES Instrument comprises the following:

- Touchscreen User Interface
- Status LED Indicator
- Audio Speaker
- Barcode Scanner

The LIAISON NES software is a graphical user interface (GUI) application that is the end-user interface to the LIAISON NES Instrument. The software is installed in an embedded computer and is responsible for providing the environment in which a user runs assays and obtains results.

The barcode scanner, which is capable of reading 1D and 2D barcodes, is intended to scan the user's ID badge and patient test order forms. The scanner can be manually activated through the touch screen or automatically activated in response to movement in front of the system.

B Test System Components

The LIAISON NES disposables consist of three primary components packaged individually for single-use: a cartridge specific to the assay type, a NES Sample Vial, and a NES Swab. Each set of these disposables is packaged individually within a single-test kit divider, with ten of these single-test kits combined into one assay carton.

The cartridge is assay-specific and individually sealed within a foil pouch. It includes a small, slightly open port for inserting prepared patient or QC samples and a foil-covered cuvette utilized by the instrument. The cartridge is labeled clearly with the assay type, lot number, and expiration date, and provides a space for user identification. Reagents and other assay materials are pre-loaded into chambers beneath the cartridge.

The NES Sample Vial is a tube containing an aqueous solution used for transferring the patient sample (or QC sample) from the swab into the cartridge. It is sealed with a removable foil, covered by a blue vial cap and a clear nozzle cap. The vial and caps are packaged together in translucent plastic. To dispense the contents, the clear nozzle cap must be twisted off. The vial features labeling indicating lot number and expiration date.

The NES Swab consists of a Copan 'FLOQSwab' housed within a sealed tube container. Users can remove and replace the swab in the tube after sample collection. The swab has a breakpoint 60 mm above the tip, aligning with the vial's rim for proper handling. The tube exterior includes a label displaying the swab expiration date and an area for patient identification.

Quality Control (QC) materials are packaged separately in a dedicated QC swab kit carton. This

carton includes both positive and negative control swabs, distinctively packaged—positive controls in red and negative controls in green.

A Quick Reference Guide (QRG) titled 'Preparing for a Quality Control Test' is included within each QC swab carton.

X. Specific Contents for CLIA Waiver

A Demonstrating “Simple”:

- The system consists of an instrument and a test cartridge. The cartridge is supplied pre-loaded with the reaction reagents. The user prepares the specimen and loads the cartridge into the instrument. After the user starts the assay via the touchscreen graphical user interface (GUI), no additional user interaction is required to generate a test result. An additional feature automatically starts the run after 30 seconds once the user has loaded the cartridge into the instrument.
- The assay uses an unprocessed dry nasal swab that is placed into a pre-measured rinse buffer in the sample vial.
- The specimen rinse buffer is pre-measured and provided in the sample vial. All other reagents are pre-loaded in the assay cartridge at the time of manufacturing.
- The assay requires only basic specimen manipulation after collection with a dry nasal swab, specifically rotation of the swab within the sample vial while squeezing the swab head to release the sample. After rotating the swab within the sample vial, the swab shaft is snapped off at a pre-defined mark on the swab shaft. The sample vial is re-capped and the cap at the end of the sample vial is removed. The sample vial is inserted into the sample port of the cartridge and the complete contents are squeezed into the cartridge. The user closes the cartridge lid and inserts the loaded cartridge into the instrument.
- No operator action is required to generate a result after the run is started.
- Technical or specialized training is not required for troubleshooting or interpretation of error codes. When an error is detected, it is assigned a predefined error code and error message, with suggested mitigation displayed on the graphical user interface (GUI).
- There are no maintenance tasks other than routine cleaning. The instrument performs self-checks at initialization and between runs. External quality controls are also available for the user to check proper functioning of the instrument.
- The instrument incorporates algorithms for processing data that eliminate the need for operator calibration, interpretation, or calculation. The instrument displays results on the graphical user interface (GUI) after completion of the test.
- The system produces a “Positive”, “Negative” or “Invalid” result readout for each target in the assay that is displayed on the graphical user interface (GUI). Quality control result readouts are “Pass” and “Fail”.
- The supplied Quick Reference Guides and User Manual are written using language appropriate for untrained operators.
- The cartridge is designed to allow insertion into the instrument in only one direction/orientation.
- The cartridge has a visual indicator that is automatically detected by a sensor in any instrument, preventing cartridge re-use in the same instrument or in another

instrument.

- The cartridge lid is easily opened and allows easy loading of specimen using the sample vial.
- The cartridge lid provides tactile feedback when the user snaps it shut. Once snapped shut, the cartridge lid is designed to prevent re-opening and prevent additional sample loading.
- The instrument has a has a color touchscreen display design for ease of use and facilitates easy-to-read messages.
- The test result is automatically displayed upon completion of a run and the test result report can be printed or saved as a .pdf file. The report is designed to be easy to understand and provides a Test Results summary which includes the operator ID, test date and time, Patient ID, assay name and test type, sample type, cartridge lot, expiry and serial number, instrument serial number, and the software and assay version. On the GUI display and in the test report, test results are reported for each target (Flu A, Flu B, RSV, or COVID-19) as "Negative" if the target was not detected, or "Positive" if the target was detected. For patient specimens, a result of "Invalid" is displayed if there is an instrument or software error, incomplete or aborted run, or Internal Control failure. The test report for the external quality control materials contains the same information except the Swab Type is identified (Positive or Negative QC) instead of a Patient ID. In the case of external quality controls, a "Pass" or "Fail" result is displayed.

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

1. Risk Analysis:

   Risk analysis was performed according to ISO 14971 *Medical Devices – Application of risk management to medical devices* and Diasorin's internal risk management process. 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. All risks of harm to the patient or operator were mitigated to an acceptable level and were supported by flex studies and/or operator instructions.

2. Fail-Safe and Failure Alert Mechanisms:

   The LIAISON NES system is designed with numerous fail-safe and failure alert mechanisms to prevent operator and instrument errors as described in **Table 1**.

Table 1. LIAISON NES Fail-Safes and Failure Alert Mechanisms

User Engagement with Assay-Instrument System	Desired/Expected Outcome	Fail-safe and Failure Alert Mechanism(s)
Ambient temperature outside of the instrument specifications (below and above the range limits).	Expected results obtained, or system provides an alert of failure (with cause).	The instrument has a sensor to prevent a test being started if the temperature inside the instrument is outside of the operating range.
Test was stopped before results were obtained.	Error message rendered with cause identified.	The instrument is capable of automatically aborting a test when a critical error is detected.

User turned off the instrument before the test was completed and tried to resume the test once the instrument was back on.	Error message rendered with cause identified.	In the event of power loss during a test, the instrument does not allow the user to restart the test upon powering on.
Cartridge reaction cuvette foil is broken.	Error message rendered with cause identified.	The system is capable of pressurizing the cuvette. The instrument checks that the cuvette is sealed after filling.
Wrong cartridge is used.	Error message rendered with cause identified.	The cartridge packaging includes a label which displays key information about the cartridge. The instrument allows the user to review a run summary before a test is started. The cartridge packaging label is color-coded to represent the test type.
Incorrect assay definition.	Error message rendered with cause identified.	The cartridge barcode contains the cartridge unique ID, lot, expiration date and test type. The system registers the cartridge assay type via the cartridge barcode upon insertion. The instrument automatically selects the protocol to be run from the assay and specimen input type. The instrument informs the user if an appropriate protocol is not available.
Try to utilize damaged or incomplete barcode	Error message rendered with cause identified.	If the instrument cannot read the cartridge barcode, it informs the user and prevents the run from being performed.
Try to start a test using a cartridge that has already been used.	Provide an error message and/or prevent cartridge loading.	The cartridge has a visual indicator to show that it has not already been used. The system has features to prevent a test being run on the same cartridge more than once.
Move the instrument while the assay is running by tilting the instrument during the test.	Expected results obtained, or system provides an alert of failure (with cause).	Visual indication shown to the user to not move the instrument while running.
Incorrect orientation of cartridge insertion into instrument.	Prevent user from inserting the cartridge in the incorrect orientation.	The cartridge is designed to allow insertion into the instrument in only one direction/orientation.
The altitude of the instrument is above specifications (above the range limits).	Expected results obtained, or system provides an alert of failure (with cause).	The instrument has a sensor to prevent a test being started if the atmospheric pressure inside the instrument is outside of the operating range.
The door is forced opened during a run, exposing internal machinery to the user	Internal machinery is halted. Error message rendered with cause identified.	The instrument has a sensor to detect the open/closed state of the door. If the door is detected as ‘open’ during an assay run, it halts the operation of motors and heaters, aborting the test.
Try to start a test using a cartridge that has expired.	Provide an error message and/or prevent the test from starting.	The cartridge has the expiration date embedded into the instrument-readable QR code. The system has a feature to check the expiration date of the cartridge and prevent a test being started with an expired cartridge.
Wrong QC sample is used.	Error message rendered with cause identified.	The positive and negative QC packaging includes a label which displays key information about the controls, and an instrument-readable QR code. The system has a feature to check the QC sample type and prevent a test being started with an incorrect QC sample.
Try to start a QC test using a QC sample that has expired.	Provide an error message and/or prevent the test from starting.	The QC sample has the expiration date embedded into the instrument-readable QR code. The system has a feature to check the expiration date of the QC sample and prevent a test being started with an expired sample.

3. Flex Studies:

Flex studies were carried out to evaluate the performance of the LIAISON NES Instrument, LIAISON NES FLU A/B, RSV & COVID-19 nucleic acid test, and the LIAISON NES FLU A/B, RSV & COVID-19 Control Swab kit. Variations in workflow and operating environment that may reasonably be expected to occur with untrained operators in the intended use CLIA-waived setting were evaluated. Test conditions were designed based on risk analyses that considered the complete test system.

Contrived samples consisting of pooled negative human nasal matrix without viral targets (negative input) or with viral targets at 2x LoD (positive multitarget input) were tested. Testing was conducted according to the Instructions for Use (IFU) for the assay and the Control Swab Kit.

Comparative controls were carried out under conditions consistent with use of the device according to its labeling. Following execution of comparative controls, flex study conditions were evaluated. A negative result was considered in agreement when all targets resulted "Negative" with a valid Internal control result while a positive result was considered in agreement when all targets resulted "Positive".

At the beginning of each testing day, negative and positive controls were tested on each test instrument. All controls performed as expected.

All flex conditions were evaluated using the organisms at the concentrations shown in **Table 2**.

Table 2. Organisms and Testing Concentrations for Flex Studies

	Organism	Concentration
Multitarget Positive Input	Influenza A Darwin/9/21	~2x LoD
	Influenza B Phuket/3073/2013	~2x LoD
	RSV B Isolate 12/2014	~2x LoD
	SARS-CoV-2 USA/WA 1/2020	~2x LoD
Negative Input	Pooled Negative Human Nasal Matrix	N/A

In the majority of cases, the expected positive or negative results were generated for each test condition. However, the following five conditions were associated with false negative results for some targets or the inability to perform the testing:

- Dropping of the LIAISON NES Cartridge (pre- and post-fill) (Study #2)
- Insertion of USB into the front or rear USB port during operation (Study #3)
- Running the instrument at temperature above 35°C (Study #4)
- Inadequate sample mixing/sample processing (Study #6)
- Incorrect sample volume dispensed into the cartridge (Study #9)

Flex Study #1: Instrument Installation

This study was conducted to evaluate the impact of operating the LIAISON NES instrument when the device has been installed outside of the standard setup conditions outlined in the User Manual and Quick Start Guide. The study assessed operation when the instrument is installed on a non-level surface, in an area with restricted airflow, in a drafty area, next to

other NES instruments, next to a centrifuge, and next to a window receiving direct sunlight. The study assessed device performance across the six test cases presented in **Table 3**.

Table 3. Instrument Installation Flex Study Test Cases

Test Case	Description
1A	Non-level surface. Instrument set up on wedge for positive 7.5-degree roll
1B	Non-level surface. Instrument set up on wedge for negative 7.5-degree roll
1C	Non-level surface. Instrument set up on wedge for positive 7.5-degree pitch
1D	Non-level surface. Instrument set up on wedge for negative 7.5-degree pitch
2	Restricted airflow. Instrument set up in simulated cubby environment allowing 3 inches of space to left and right, 1.5 inches of space in rear, and 6 inches of space above.
3	Drafty conditions. Instrument set up with box fans in front and rear blowing air directly towards instrument.
4	Multi-instrument operation. Instrument performing assay between instruments also performing assay.
5	Centrifuge. Instrument performing assay next to an operating centrifuge
6	Sunlight. Instrument performing assay while receiving direct sunlight through a window.

Comparative control testing was performed on three instruments that were installed following the instructions outlined in the User Manual and Quick Start Guide. Following negative and positive QC tests, five negative and five positive 2x LoD multitarget sample inputs were tested on each instrument.

Following the completion of comparative control testing, instruments were installed outside of the installation parameters indicated in the User Manual and Quick Start Guide according to the various test cases outlined in **Table 3**. Five negative and five positive 2x LoD multitarget sample inputs were tested on each instrument. **Table 4** contains the summary of results for the Instrument Installation Flex Study.

Table 4. Summary of Results – Instrument Installation Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control [a]	0	20/20	20/20
1A – Positive 7.5-Degree Roll	0	15/15	15/15
1B – Negative 7.5-Degree Roll	0	15/15	15/15
1C – Positive 7.5-Degree Pitch	0	15/15	15/15
1D – Negative 7.5-Degree Pitch	0	15/15	15/15
2 – Restricted Airflow	0	15/15	15/15
3 – Drafty Conditions	0	15/15	15/15
4 – Proximal Concurrent Operation	0	15/15	15/15
5 – Proximal Centrifuge Operation	0	15/15	15/15
6 – Sunlight Exposure	0	15/15	15/15

[a] Instrument NES00263 was used in place of NES00254 starting in Test Case 1B and continuing through Test Case 5. Since testing was performed with NES00263, an additional Comparative Control test was performed on this instrument.

All test runs generated expected results (100%). The LIAISON NES instrument is robust to the indicated installation environments that were outside of the instructions specified in the User Manual and Instrument Quick Reference Guide. In cases where the instrument is installed on an angled surface, in a location with restricted or extreme airflow, directly next to other instruments or centrifuges, or in a location receiving direct sunlight, the instrument is expected

to produce results consistent with an instrument installed as described by the User Manual and Quick Start Guide.

Flex Study #2: Cartridge Handling

This study was conducted to evaluate the impact of mishandling a cartridge during operation of the instrument. The study assessed LIAISON NES FLU A/B, RSV & COVID-19 assay results for situations in which a cartridge was dropped prior to or after sample addition, handled by the cuvette and when the cap was not properly closed prior to loading the cartridge onto an instrument. The study assessed device performance across the three test cases outlined in **Table 5**.

Table 5. LIAISON NES Cartridge Handling Flex Study Test Cases

Test Case	Description
1A	Cartridge Drop. Prior to sample loading, the cartridge is dropped 6 inches.
1B	Cartridge Drop. Prior to sample loading, the cartridge is dropped 42 inches.
1C	Cartridge Drop. After sample loading, the cartridge is dropped 6 inches.
1D	Cartridge Drop. After sample loading, the cartridge is dropped 42 inches.
2	Cuvette Handling. Prior to sample loading, the cartridge is handled by the cuvette with an ungloved hand.
3	Sample Port Open. After sample loading, the cartridge cap is not fully closed before running the test.

Comparative control testing was performed on three lots of LIAISON NES FLU A/B, RSV & COVID-19 cartridges handled in accordance with device labeling. Following passing negative and positive QC tests, five negative and five positive 2x LoD multitarget sample inputs were tested.

Following completion of comparative control testing, three lots of cartridges were handled according to the various test cases outlined in **Table 5**. Five negative and five positive 2x LoD multitarget sample inputs were tested with each cartridge lot. **Table 6** contains the summary of results for the cartridge handling flex study.

Table 6. Summary of Results – Cartridge Handling Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control - Instrument	0	15/15	15/15
Comparative Control - Cartridge	0	15/15	15/15
1A – Drop, 6 Inches, Pre-Fill	0	15/15	19/20[a]
1B – Drop, 42 Inches, Pre-Fill	0	10/20[b]	4/15[b]
1C – Drop, 6 Inches, Post-Fill	0	15/15	15/15
1D – Drop, 42 Inches, Post-Fill	2	5/15[b,c]	0/15[b]
2 – Cuvette Handling	0	15/15	15/15
3 – Sample Port Open	0	15/15	15/15

[a] One Flu A false negative was obtained. A repeat of this test condition produced 5/5 in agreement.
[b] Results not in agreement due to dislodged pipettes rendering cartridges unusable.
[c] Two instances of invalid results due to insufficient sample volume after dropping cartridge.

The false negative for Flu A in Test Case 1A was determined likely to be due to the challenging sample input rather than the condition as the expected detection in the repeat testing was observed. A 6-inch drop before adding sample to the cartridge is unlikely to have an impact on the detection of only one target.

The 42-inch drop height used in this testing is representative of a drop from the LIAISON NES cartridge door to the floor for an instrument installed on a standard 36-inch-tall table. In approximately 71% of cases (46/65), the cartridge was rendered useless from the drop. When a cartridge is still usable, there is a high likelihood that the remaining sample volume is insufficient for the completion of an assay.

Handling cartridges by the cuvette did not impact results. Notably, there were no signs of cross-contamination or inhibition introduced when using cartridges without fully closing the cap.

The LIAISON NES cartridge is robust to handling by the cuvette or failing to properly close the cap. Significant cartridge drops typically result in the inability to use the cartridge to perform an assay. Dropped cartridges, as indicated in the User Manual, should not be used even if the pipette is not dislodged, as the drop can result in insufficient sample volume for the completion of an assay.

Flex Study #3: Instrument Operation

This study was conducted to evaluate the impact of interacting with the instrument while a test is in progress. The study assessed assay functionality of the instrument when it is moved during a test, "connected to" via I/O ports during a test and powered on for an extended time without power cycling. Each of these test cases were assessed individually to determine the impact on device operation. The study assessed device performance across the three test cases outlined in **Table 7**.

Table 7. Instrument Operation Flex Study Test Cases

Test Case	Description
1	Moving instrument during assay.
2A	I/O port connection during assay. USB flash drive to front USB port.
2B	I/O port connection during assay. USB flash drive to rear USB port.
2C	I/O port connection during assay. Printer to front USB port.
2D	I/O port connection during assay. Printer to rear USB port.
2E	I/O port connection during assay. Ethernet cable to ethernet port.
3	Extended Instrument Uptime.

Comparative control testing was performed on three instruments operated in accordance with device labeling. Following passing negative and positive QC tests, five negative and five positive 2x LoD multitarget sample inputs were tested on each instrument.

Following completion of comparative control testing, runs were performed on three instruments according to the various test cases outlined in **Table 7**. Five negative and five positive 2x LoD multitarget sample inputs were tested with each cartridge lot. The summary of results for the LIAISON NES Instrument Operation Flex Study and presented in **Table 8**.

Table 8. Summary of Results – LIAISON NES Instrument Operation Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control [a]	0	20/20	20/20
1 – Movement During Operation	0	15/15	19/20[b]
2A – USB Drive to Front Port	0	13/15[c]	15/15
2B – USB Drive to Rear Port	0	11/15[c]	13/15[c]
2C – Printer to Front Port	0	15/15	19/20[b]

2D – Printer to Rear Port	0	15/15	15/15
2E – Ethernet Cable to Rear Port	0	15/15	15/15
3 – Extended Uptime	0	15/15	15/15

[a] Instrument NES00263 was used in place of NES00254 starting in Test Case 3. Since testing was performed with NES00263, an additional comparative control test was performed on this instrument.

[b] One Flu A false negative in first five replicates. Repeat testing produced 5/5 in agreement.

[c] Instances of instrument reboot are considered not in agreement.

The expected detection in repeat testing for positive inputs for Test Case 1 and 2C indicates that the false negatives for Flu A are likely due to the challenging sample input rather than the condition. Movement of the instrument during operation or connecting and disconnecting to a peripheral device are both unlikely to impact detection of only one target.

The instrument produced expected results after extended idle time and with movement during assay testing. Unexpected reboots associated with USB drive connection during operation occurred at a frequency of approximately 1.5% based on the eight instances from sixty runs with USB drive connection every two minutes.

The LIAISON NES instrument is robust to movement during operation and allowing the instrument to idle over an extended period of time. There is a risk of delayed results arising from the instrument rebooting if USB drives are connected during an assay run; however, the user manual includes a warning against connecting or disconnecting peripheral equipment during operation. Furthermore, while a test is in progress there is no ability to export data or print, disincentivizing peripheral connection during operation.

Flex Study #4: Barometric Pressure, Temperature and Humidity Extremes

This study was conducted to evaluate the impact of extreme temperature, humidity and barometric pressure conditions on the functionality and accuracy of the LIAISON NES FLU A/B, RSV & COVID-19 assay as well as the LIAISON NES instruments, simulating the execution of the test at extreme environmental conditions (temperature, relative humidity or high altitude). The study assessed device performance across three test cases outlined in **Table 9**.

Table 9. Barometric Pressure, Temperature and Humidity Extremes Flex Study Test Cases

Test Case	Description
1	Execution with climatic chamber settings of 8000 ft at 22°C
2	Execution with climatic chamber settings of 15°C with 80% RH
3	Execution with climatic chamber settings of 32°C with 80% RH

Following completion of the comparative control testing, the instruments were subjected to the environmental conditions outlined in the test cases identified in **Table 9**. Five negative and five positive 2x LoD multitarget sample inputs were tested on each instrument.

To execute Test Case 1, the climate chamber, in which the tests were carried out, was set at 22°C and 8000 ft (approximately 2438 meters and ~752.6 mbar) to simulate high altitude. Upon setting the climate chamber at 8000ft, a warning notification on screen of "Invalid pressure" was observed and it resulted in the inability to test samples as described in the protocol. Upon the gradual increase of pressure within the chamber, the operational

capabilities of the instruments were restored at a simulated altitude of 6594 feet (approximately 2010 meters and ~795.0 mbar), thereby enabling the successful testing of samples. **Table 10** contains the summary of results for the barometric pressure, temperature and humidity extremes flex study.

Table 10. Summary of Results – Barometric Pressure, Temperature and Humidity Extremes Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1 – Climatic Chamber settings of 8000 ft at 22°C	0	*	*
2 – Climatic Chamber settings of 15°C with 80% RH	0	5/5	5/5
3 – Climatic Chamber settings of 32°C with 80% RH	0	5/5	5/5

*Warning message was obtained at 8000 ft (~2438 m) and testing was not possible. 5/5 Negative Agreement and 5/5 Positive Agreement was obtained at 6594 ft (~2010 m), the condition under which the instruments restored their full operational functionality.

For Test Case 1 (extreme barometric pressure), it was not possible to perform the test under the conditions indicated by the protocol (chamber settings at 8000 ft (~2438 m) at 22°C). The most extreme condition at which the instrument screen did not show a warning message was tested instead (chamber settings at 6594 ft (~2010 m) at 22°C). The LIAISON NES Instrument is not robust to extreme barometric pressure. Under this condition, the system is unable to function and displays a warning message. The LIAISON NES User Manual indicates an operating altitude up to 2000 m. The results of Test Cases 2 and 3 demonstrate that operation of the system under conditions of extreme humidity does not impact the accuracy of results.

Testing of the LIAISON NES instrument was then carried out under an expanded range of temperatures as shown in **Table 11**.

Table 11. LIAISON NES Temperature Extremes

Test Case	Description
1A	Execution with climate chamber setting of 5°C
1B	Execution with climate chamber setting of 10°C
1C	Execution with climate chamber setting of 15°C
1D	Execution with climate chamber setting of 30°C
1E	Execution with climate chamber setting of 35°C
1F	Execution with climate chamber setting of 40°C

Following completion of the comparative control testing, the instruments were subjected to the environmental conditions outlined in the test cases identified in **Table 11**. Five negative and five positive 2x LoD multitarget sample inputs were tested on each instrument. The test results are shown in **Table 12**.

Table 12. Summary of Results – Temperature Extremes

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5

1A – Climate Chamber setting of 5°C	0	5/5	5/5
1B – Climate Chamber setting of 10°C	0	5/5	5/5
1C – Climate Chamber setting of 15°C	0	5/5	5/5
1D – Climate Chamber setting of 30°C	0	5/5	5/5
1E – Climate Chamber setting of 35°C	0	5/5	5/5
1F – Climate Chamber setting of 40°C	0	5/5	1/3[a]

[a] Two (2) replicates resulted in a false negative for the Flu A target and two (2) runs were aborted due to photodiode [0] dark value out of range; aborted runs did not generate a result.

The LIAISON NES Instrument and NES FLU A/B, RSV & COVID-19 Cartridge provided expected results at temperatures ranging from 5°C to 35°C. For Test Cases 1A-1E, all positive inputs were correctly detected as "Positive" for each target. All negative inputs were "Negative" for each target with a valid internal control result. Based on the results of this testing, there is an insignificant risk of erroneous result reporting when performing the test at operating temperatures ranging from 5°C to 35°C.

However, false negative and delayed results were obtained when performing the test at 40°C using the 2x LoD multitarget sample (Test Case 1F). Two runs resulted in the loss of detection of the influenza A target, leading to a False Negative result. Two runs were aborted due to photodiode [0] dark value out of range; no results were generated for these runs. Based on these test results, there is a risk of false negative or delayed results when testing is performed at temperatures above 35°C.

Detection of negative samples was not adversely impacted at all temperatures evaluated in this study. For all Test Cases evaluated, all negative sample inputs were reported as "Negative" for all targets with a valid Internal Control result. There is an insignificant risk of erroneous result reporting for negative samples when testing across the wide range of temperatures, including the extremes (5°C - 40°C).

Flex Study #5: LIAISON NES FLU A/B, RSV & COVID-19 Cartridge Sunlight Exposure

This study was conducted to evaluate the impact of sunlight exposure on the LIAISON NES FLU A/B, RSV & COVID-19 Cartridge. The LIAISON NES FLU A/B, RSV & COVID-19 Cartridge was removed from the protective desiccated foil pouch and exposed to sunlight for various durations before testing. The study assessed device performance across the test cases outlined in **Table 13**.

Table 13. Cartridge Sunlight Exposure Flex Study Test Cases

Test Case	Description
1A	30 minutes of exposure of cartridge to direct sunlight through a window
1B	2 hours of exposure of cartridge to direct sunlight through a window
1C	4 hours of exposure of cartridge to direct sunlight through a window

Comparative control testing was performed using five negative and five positive 2x LoD multitarget sample inputs that were tested immediately after cartridge removal from the pouch, without exposing the cartridge to sunlight. Following completion of the Comparative Control testing, LIAISON NES FLU A/B, RSV & COVID-19 cartridges were removed from their protective desiccated foil pouches and exposed to sunlight for various durations according to the test cases outlined in **Table 13**. Five negative and five positive 2x LoD

multitarget sample inputs were tested using the sunlight-exposed cartridges. The summary of results of the Sunlight Exposure Flex Study is shown in **Table 14**.

Table 14. Summary of Results – Cartridge Sunlight Exposure Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A – 30 minutes of sunlight exposure	0	5/5	5/5
1B – 2 hours of sunlight exposure	0	5/5	5/5
1C – 4 hours of sunlight exposure	0	5/5	5/5

The LIAISON NES FLU A/B, RSV & COVID-19 Cartridge is robust to direct sunlight exposure. The results demonstrate that there is an insignificant risk of erroneous results when the test operator does not follow device instructions and exposes the cartridge to direct sunlight for an extended period of time before use.

Flex Study #6: Inadequate Sample Mixing

This study was conducted to evaluate the effect of inadequate sample mixing on LIAISON NES FLU A/B, RSV & COVID-19 function. Samples were prepared by modifying the number of times the swab was rotated in the NES Sample Vial while squeezing the swab head and by dipping the swab into the NES Sample Vial instead of squeezing the swab head and rotating the swab in the NES Sample Vial. The Reference (control) is 10x swab rotations while squeezing the swab head in the NES Sample Vial. The study assessed performance across the test cases outlined in **Table 15**.

Table 15. Inadequate Mixing Flex Study Test Cases

Test Case	Description
1A	Squeezing and 3x swab swirling into NES Sample Vial
1B	0x swab swirling or swirling into NES Sample Vial
1C	3x swab dip into NES Sample Vial without squeezing or swirling
1D	10x swab dip into NES Sample Vial without squeezing or swirling

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs by inserting the swab to the bottom of the NES Sample Vial and squeezing the swab head while rotating the swab ten times. Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were prepared according to the various test cases outlined in **Table 15** and tested with LIAISON NES FLU A/B, RSV & COVID-19. **Table 16** contains the summary of results for the inadequate sample mixing flex study.

Table 16. Summary of Results – Inadequate Sample Mixing Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A – Squeezing and 3x swirling in NES Sample Vial	0	5/5	5/5
1B – 0x squeezing or swirling in NES Sample Vial	0	5/5	3/5[a]

1C – 3x swab dip in NES Sample Vial without squeezing or swirling	0	5/5	6/10[b]
1D – 10x swab dip in NES Sample Vial without squeezing or swirling	0	5/5	3/5[c]

[a] One replicate resulted in a false negative for Flu A and SARS-CoV-2 targets. One replicate resulted in a false negative for Flu A target.
[b] One replicate resulted in a false negative for SARS-CoV-2. Repeat testing resulted in one false negative for SARS- CoV-2, one false negative for Flu A and SARS-CoV-2 targets, and one false negative for Flu B and SARS-CoV-2 targets.
[c] Two replicates resulted in a false negative for the SARS-CoV-2 target.

Squeezing the swab head while rotating the swab within the NES sample vial appears to be a necessary step to ensure adequate transfer of the sample into the Sample Vial. When the swab head was squeezed and rotated 3x, 100% agreement was achieved for positive samples. Dipping alone without squeezing was not sufficient to transfer the sample into the fluid. As shown in test cases 1B, 1C, and 1D, dipping alone achieved 60% agreement for positive samples, indicating a risk for erroneous results when squeezing is not performed. Therefore, there is a risk of false negatives if the device instructions for use are not followed regarding the requirement to squeeze the swab while rotating.

The device Quick Reference Guide (QRG) has bolded the "10 times" requirement as well as the word "squeezing" to process the specimen before dispensing into the cartridge for testing. These instructions are also represented pictorially in the QRG, with red arrows emphasizing rotation of the swab 10x while squeezing the sample vial. Section B of the IFU (*Test Procedure*) contains the same written instructions for preparation of the specimen prior to dispensing the specimen into the cartridge for testing.

Flex Study #7: Incorrect Sample Storage

This study was conducted to evaluate the effect of incorrect storage of samples at 2-8°C on LIAISON NES FLU A/B, RSV & COVID-19. Samples were stored at 2-8°C for various durations prior to testing to assess the impact on performance. The study included the test cases outlined in **Table 17**.

Table 17. Incorrect Sample Flex Study Test Cases

Test Case	Description
1A	Store samples at 2-8°C for 4 hours
1B	Store samples at 2-8°C for 24 hours

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and immediately testing fresh. Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were processed according to the test cases outlined in **Table 17** and tested with LIAISON NES FLU A/B, RSV & COVID-19. **Table 18** contains the summary of results for the incorrect sample storage flex study.

Table 18. Summary of Results – Incorrect Sample Storage Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A-Storage at 2-8°C for 4 hours	0	5/5	5/5
1B-Storage at 2-8°C for 24 hours	0	5/5	5/5

The results demonstrate that storage of samples at 2-8°C for up to 24 hours does not impact performance of LIAISON NES FLU A/B, RSV & COVID-19 and that there is an insignificant risk of erroneous results when the operator does not follow device instructions and stores the collected sample at 2-8°C for an extended period of time prior to testing.

Flex Study #8: Incorrect Kit Storage

This study was conducted to evaluate the effect of incorrect storage conditions for the LIAISON NES FLU A/B, RSV & COVID-19 kit. Kit components, i.e., the LIAISON NES FLU A/B, RSV & COVID-19 Cartridge, NES Nasal Swab and NES Sample Vial were stored under conditions of stress before testing to assess device performance. The study included the test cases outlined in **Table 19**.

Table 19. Incorrect Kit Storage Flex Study Test Cases

Test Case	Storage Condition	Storage Duration (Days)
1A	-20°C	3
1B	-20°C	5
2A	2-8°C	3
2B	2-8°C	5
3A	50°C / 50% RH	3
3B	50°C / 50% RH	5

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and testing using LIAISON NES FLU A/B, RSV & COVID-19 kit components stored in accordance with device labeling (at 15-30°C). Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were tested with kit components stored according to the various test cases outlined in **Table 19**. **Table 20** contains the summary of results for the incorrect kit storage flex study.

Table 20. Summary of Results – Incorrect Kit Storage Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	20/20	20/20
1A – Storage at -20°C for 3 days	0	5/5	5/5
1B – Storage at -20°C for 5 days	0	5/5	5/5
2A – Storage at 2-8°C for 3 days	0	5/5	5/5
2B – Storage at 2-8°C for 5 days	0	5/5	5/5
3A – Storage at 50°C/50% RH for 3 days	0	5/5	5/5

3B – Storage at 50°C/50% RH for 5 days	0	5/5	9/10[a]

[a] One replicate resulted in a false negative for SARS-CoV-2. Repeat testing produced 5/5 in agreement.

Storage of the kit components at -20°C or 2-8°C (up to 5 days) does not compromise assay performance. All components demonstrate stability under these storage conditions. The kit also maintains functional integrity following short-term exposure (up to 3 days) to elevated temperature and relative humidity (50°C / 50% RH). However, extended exposure (5 days) to these extreme environmental conditions has been associated with a minor risk of false negative results. This result is attributable to the combined effects of high temperature and high relative humidity, which may impact reagent stability over prolonged durations.

Flex Study #9: Incorrect Sample Volume

This study was conducted to evaluate the effect of using an incorrect sample volume within the cartridge. Volumes of sample less than the nominal volume contained within the NES Sample Vial (approximately 700µL) were tested to evaluate the effects of incorrect sample volume on testing with LIAISON NES FLU A/B, RSV & COVID-19. The study included the test cases outlined in **Table 21**.

Table 21. Incorrect Sample Volume Flex Study Test Cases

Test Case	Description
1A	Add 250µl of prepared sample to cartridge
1B	Add 150µl of prepared sample to cartridge
1C	Add 100µl of prepared sample to cartridge

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs with the entire sample volume (~700µL) dispensed into the cartridge for testing. Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were tested with volumes of prepared sample according to the various test cases outlined in **Table 21**. **Table 22** contains the summary of results for the incorrect sample volume flex study.

Table 22. Summary of Results – Incorrect Sample Volume Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A – 250µL of sample added	0	5/5	5/5
1B – 150µL of sample added	2	5/5	8/10[a]
1C – 100µL of sample added	2	5/5	3/5[b]

[a] One replicate resulted in a false negative for Flu A, RSV, and SARS-CoV-2 targets. Repeat testing resulted in one false negative for Flu A, Flu B, RSV, and SARS-CoV-2 targets with an invalid Internal Control (IC) result.

[b] One replicate resulted in a false negative for Flu A, Flu B and SARS-CoV-2 targets and one replicate resulted in a false negative for Flu A, Flu B, RSV, and SARS-CoV-2 targets with an invalid IC result.

When an adequate sample volume is not used (less than 250µl), there is a risk of erroneous results (false negatives or invalids). As a result, the candidate device Quick Reference Guide (QRG) and Instructions for Use (IFU) both contain a warning that failure to transfer all the liquid into the cartridge can cause invalid results.

Flex Study #10: Incorrect Workflow

This study was conducted to evaluate the effect of performing an incorrect workflow (incorrect sequence of steps during sample processing) on the performance of the LIAISON NES FLU A/B, RSV & COVID-19. The first flex condition consisted of the correct sample swab processing in the NES Sample Vial except for incorrect disposal of the swab prior to dispensing the sample into the cartridge. The second condition consisted of the incorrect addition of the contents of the NES Sample Vial into the cartridge first, then swirling the swab ten times in the cartridge, followed by disposal of the swab. The study included the test cases outlined in **Table 23**.

Table 23. Incorrect Workflow Flex Study Test Cases

Test Case	Description
1A	Swab correctly processed in the sample vial but disposed before dispensing the sample contents into the cartridge
1B	Sample vial content added to the cartridge first, followed by swab swirled 10x in the cartridge and disposed

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and testing in accordance with LIAISON NES FLU A/B, RSV & COVID-19 Instructions for use. Specifically, the swab was inserted into the NES Sample Vial (NES1502) and processed. The swab shaft was broken at a visible breakpoint on the swab shaft, leaving the remaining portion containing the swab head in the sample vial. Then, the processed sample was dispensed from the sample vial into the cartridge, after which time the cartridge was loaded into the instrument and tested.

Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were tested with incorrect specimen preparation workflows according to the test cases outlined in **Table 23**. **Table 24** contains the summary of results for the incorrect workflow flex study.

Table 24. Summary of Results – Incorrect Workflow Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A – Swab disposed before dispensing sample	0	5/5	5/5
1B – Sample buffer added to cartridge first with swab swirled 10x in cartridge and disposed	0	5/5	5/5

Neither of the incorrect sample processing workflows demonstrated any impact on the assay results. Specifically, neither the method of discarding the swab from the sample vial prior to dispensing the liquid into the cartridge, nor the method of first dispensing the liquid into the cartridge, then inserting the swab to be tested, swirling ten times, and subsequently discarding the swab, affected the performance of LIAISON NES FLU A/B, RSV & COVID-19. The results demonstrate that there is an insignificant risk of erroneous results when the test

operator does not follow device instructions and performs an incorrect sequence of steps to prepare and test the sample.

Flex Study #11: Hold Time Post-Sample Processing (Sample Vial)

This study was conducted to evaluate the effect of storing processed samples in the NES Sample Vial prior to testing using LIAISON NES FLU A/B, RSV & COVID-19. Samples were prepared, processed in the NES Sample Vial, and then stored inside the sample vial before testing for different time points at room temperature. The study included the test cases outlined in **Table 25**.

Table 25. Hold Time Post-Sample Processing (Sample Vial) Flex Study Test Cases

Test Case	Description
1A	Sample stored for 120 minutes inside the sample vial at room temperature
1B	Sample stored for 150 minutes inside the sample vial at room temperature

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and testing in accordance with LIAISON NES FLU A/B, RSV & COVID-19 Instructions for use. Following sample processing in the NES Sample Vial, the sample was dispensed immediately into the LIAISON NES FLU A/B, RSV & COVID-19 cartridge and tested. Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were tested after storing the prepared samples in the sample vial according to the test cases outlined in **Table 25**. **Table 26** presents the summary of results for the hold time post-sample processing (sample vial) flex study.

Table 26. Summary of Results – Hold Time Post Sample Processing (Sample Vial) Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A – Sample stored for 120 minutes in NES Sample Vial at room temperature	0	5/5	5/5
1B – Sample stored for 150 minutes in NES Sample Vial at room temperature	0	5/5	5/5

The results demonstrate that retaining the processed sample within the NES Sample Vial for up to 150 minutes at room temperature does not affect the performance of LIAISON NES FLU A/B, RSV & COVID-19. The results further demonstrate that there is an insignificant risk of erroneous results when the test operator does not follow device instructions and stores the processed sample in the NES Sample Vial for an extended period of time before testing.

Flex Study #12: Hold Time Post-Sample Processing (Cartridge)

This study was conducted to evaluate the effect of storing processed samples in the LIAISON NES FLU A/B, RSV & COVID-19 cartridge at room temperature prior to testing. Samples were prepared, processed, and delivered from the NES Sample Vial into the cartridge, and then stored inside the cartridge before testing for different time points at room temperature. The study included the test cases outlined in **Table 27**.

Table 27. Hold Time Post-Sample Processing (Cartridge) Flex Study Test Cases

Test Case	Description
1A	Sample stored for 120 minutes inside the cartridge at room temperature
1B	Sample stored for 150 minutes inside the cartridge at room temperature

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and testing in accordance with instructions for use. Following sample processing in the NES Sample Vial, the sample was dispensed into the LIAISON NES FLU A/B, RSV & COVID-19 cartridge and tested immediately. Following completion of the Comparative Controls, five negative and five positive 2x LoD multitarget sample inputs were tested after storing the prepared samples in the cartridge according to the test cases outlined in **Table 27**. **Table 28** presents the summary of results for the hold time post-sample processing (cartridge) flex study.

Table 28. Summary of Results – Hold Time Post Sample Processing (Cartridge) Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	5/5	5/5
1A – Sample stored for 120 minutes in NES Cartridge at room temperature	0	5/5	5/5
1B – Sample stored for 150 minutes in NES Cartridge at room temperature	0	5/5	5/5

The results demonstrate that retaining the processed sample within the NES cartridge for up to 150 minutes does not affect the performance of LIAISON NES FLU A/B, RSV & COVID-19. The results further demonstrate that there is an insignificant risk of erroneous results when the test operator does not follow device instructions and stores the processed sample in the NES cartridge for an extended period of time before testing.

Flex Study #13: Delay in Sample Testing

The purpose of this study was to evaluate the effect of a delay in sample testing on LIAISON NES FLU A/B, RSV & COVID-19. Contrived swabs were stored in NES Nasal Swab in different environmental conditions for different time points before testing. The study included the test cases outlined in **Table 29**.

Table 29. Delay in Sample Testing Flex Study Test Cases

Test Case	Description
1A	Storage for 2 hours at 15°C and 30% RH
1B	Storage for 2 hours at 15°C and 80% RH

2A	Storage for 2 hours at 32°C and 30% RH
2B	Storage for 2 hours at 32°C and 80% RH
3A	Storage for 4 hours at 15°C and 30% RH
3B	Storage for 4 hours at 15°C and 80% RH
4A	Storage for 4 hours at 32°C and 30% RH
4B	Storage for 4 hours at 32°C and 80% RH

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and testing in accordance with LIAISON NES FLU A/B, RSV & COVID-19 Instructions for use immediately after preparation. Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were tested after storing the prepared samples in the NES swab tube according to the test cases outlined in **Table 29**. **Table 30** shows the summary of results for the delay in sample testing flex study.

Table 30. Summary of Results – Delay in Sample Testing Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	20/20	20/20
1A – Storage for 2 hours at 15°C and 30% RH	0	5/5	5/5
1B – Storage for 2 hours at 15°C and 80% RH	0	5/5	5/5
2A – Storage for 2 hours at 32°C and 30% RH	0	5/5	5/5
2B – Storage for 2 hours at 32°C and 80% RH	0	5/5	5/5
3A – Storage for 4 hours at 15°C and 30% RH	0	5/5	5/5
3B – Storage for 4 hours at 15°C and 80% RH	0	5/5	5/5
4A – Storage for 4 hours at 32°C and 30% RH	0	5/5	5/5
4B – Storage for 4 hours at 32°C and 80% RH	0	5/5	5/5

The results demonstrate that a delay in testing samples stored in the swab tube for up to four hours including under critical environmental conditions (32°C and 80% RH) does not affect the performance of LIAISON NES FLU A/B, RSV & COVID-19. The results further demonstrate that there is an insignificant risk of erroneous results when the test operator does not follow device instructions and stores the collected sample in the swab tube for an extended period under extreme environmental conditions before testing.

Flex Study #14: Incorrect Reagent Storage (Cartridge Open Pouch)

The purpose of this study was to evaluate the effect of incorrect reagent storage (cartridge open pouch) on LIAISON NES FLU A/B, RSV & COVID-19. The cartridge was stored in different environmental conditions after opening the cartridge pouch for different time points before testing. The study included the test cases outlined in **Table 31**.

Table 31. Incorrect Reagent Storage (Cartridge Open Pouch) Flex Study Test Cases

Test Case	Description

1A	Storage for 2 hours at 15°C and 30% RH
1B	Storage for 4 hours at 15°C and 30% RH
1C	Storage for 24 hours at 15°C and 30% RH
2A	Storage for 2 hours at 15°C and 80% RH
2B	Storage for 4 hours at 15°C and 80% RH
2C	Storage for 24 hours at 15°C and 80% RH
3A	Storage for 2 hours at 32°C and 30% RH
3B	Storage for 4 hours at 32°C and 30% RH
3C	Storage for 24 hours at 32°C and 30% RH
4A	Storage for 2 hours at 32°C and 80% RH
4B	Storage for 4 hours at 32°C and 80% RH
4C	Storage for 24 hours at 32°C and 80% RH

Comparative control testing was performed by preparing five negative and five positive 2x LoD multitarget sample inputs and testing immediately after the removal of the cartridge from the protective foil pouch. Following completion of the comparative controls, five negative and five positive 2x LoD multitarget sample inputs were tested after removing the NES cartridges from the protective foil pouches and storing according to the test cases outlined in **Table 31**. **Table 32** contains the summary of results for the incorrect reagent storage.

Table 32. Summary of Results – Incorrect Reagent Storage (Cartridge Open Pouch)

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	20/20	20/20
1A – Storage for 2 hours at 15°C and 30% RH	0	5/5	5/5
1B – Storage for 4 hours at 15°C and 30% RH	0	5/5	5/5
1C – Storage for 24 hours at 15°C and 30% RH	0	5/5	5/5
2A – Storage for 2 hours at 15°C and 80% RH	0	5/5	5/5
2B – Storage for 4 hours at 15°C and 80% RH	0	5/5	5/5
2C – Storage for 24 hours at 15°C and 80% RH	0	5/5	5/5
3A – Storage for 2 hours at 32°C and 30% RH	0	5/5	5/5
3B – Storage for 4 hours at 32°C and 30% RH	0	5/5	5/5
3C – Storage for 24 hours at 32°C and 30% RH	0	5/5	5/5
4A – Storage for 2 hours at 32°C and 80% RH	0	5/5	5/5
4B – Storage for 4 hours at 32°C and 80% RH	0	5/5	5/5
4C – Storage for 24 hours at 32°C and 80% RH	0	5/5	5/5

Storage of LIAISON NES FLU A/B, RSV & COVID-19 Cartridge in critical environmental conditions for up to 24 hours does not have an impact on the performance of the candidate device. The results further demonstrate that there is an insignificant risk of erroneous results when the test operator does not follow device instructions and stores the unpouched cartridge for an extended period under extreme environmental conditions before testing

Flex Study #15: Control Swab Kit – Incorrect Kit Storage

This study was conducted to evaluate the effect of incorrect storage conditions on the Control Swab Kit. The samples consisted of both Positive and Negative Control Swabs. Both

controls were stored under conditions of stress before testing. The study included the test cases outlined in **Table 33**.

Table 33. Control Swab Kit – Incorrect Kit Storage Flex Study Test Cases

Test Case	Storage Condition	Storage Duration (Days)
1A	-20°C	3
1B	-20°C	5
2A	2-8°C	3
2B	2-8°C	5
3A	50°C / 50%RH	3
3B	50°C / 50%RH	5

Comparative control testing was performed by testing positive and negative control swabs that were stored in accordance with device labeling (15-30°C). Following comparative control testing, five positive controls and five negative controls stored according to the test cases outlined in **Table 33** were tested. **Table 34** contains the summary of results for the control swab kit incorrect kit storage flex study.

Table 34. Summary of Results – Control Swab Kit Incorrect Kit Storage Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	0	20/20	20/20
1A – Storage at -20°C for 3 days	0	5/5	5/5
1B – Storage at -20°C for 5 days	0	5/5	5/5
2A – Storage at 2-8°C for 3 days	0	5/5	5/5
2B – Storage at 2-8°C for 5 days	0	5/5	5/5
3A – Storage at 50°C/50% RH for 3 days	0	5/5	5/5
3B – Storage at 50°C/50% RH for 5 days	0	5/5	5/5

The LIAISON NES FLU A/B, RSV & COVID-19 Control Swab Kit is robust to incorrect storage of -20°C or 2-8°C or 50°C at 50% RH for up to five days.

Flex Study #16: Control Swab Kit Incorrect Control Swab Storage (Open Pouch)

The purpose of this study was to evaluate the effect of incorrect storage conditions (swab open pouch) on the Control Swab Kit. Components belonging to the Control Swab Kit (LIAISON NES FLU A/B, RSV & COVID-19 Positive Control Swab and LIAISON NES FLU A/B, RSV & COVID-19 Negative Control Swab) were stored in different environmental conditions after opening the swab pouch for different periods of time before testing. The study included the test cases outlined in **Table 35**.

Table 35. Control Swab Kit Incorrect Control Swab Storage (Open Pouch) Flex Study Test Cases

Test Case	Description
1A	Storage for 2 hours at 15°C and 30% RH
1B	Storage for 4 hours at 15°C and 30% RH
1C	Storage for 24 hours at 15°C and 30% RH
2A	Storage for 2 hours at 15°C and 80% RH
2B	Storage for 4 hours at 15°C and 80% RH
2C	Storage for 24 hours at 15°C and 80% RH
3A	Storage for 2 hours at 32°C and 30% RH
3B	Storage for 4 hours at 32°C and 30% RH
3C	Storage for 24 hours at 32°C and 30% RH
4A	Storage for 2 hours at 32°C and 80% RH
4B	Storage for 4 hours at 32°C and 80% RH
4C	Storage for 24 hours at 32°C and 80% RH

Comparative control testing was performed by testing positive and negative control swabs immediately after removing from the pouch. Following comparative control testing, five positive controls and five negative controls stored according to the test cases outlined in **Table 35**. **Table 36** presents the summary of results for the control swab kit incorrect control swab storage (open pouch) flex study.

Table 36. Summary of Results – Control Swab Kit Incorrect Control Swab Storage (Open Pouch) Flex Study

Test Case	Invalid Results	Negative Agreement	Positive Agreement
Comparative Control	1[a]	20/20	20/20
1A – Storage for 2 hours at 15°C and 30% RH	0	5/5	5/5
1B – Storage for 4 hours at 15°C and 30% RH	0	5/5	5/5
1C – Storage for 24 hours at 15°C and 30% RH	0	5/5	5/5
2A – Storage for 2 hours at 15°C and 80% RH	0	5/5	5/5
2B – Storage for 4 hours at 15°C and 80% RH	0	5/5	5/5
2C – Storage for 24 hours at 15°C and 80% RH	0	5/5	5/5
3A – Storage for 2 hours at 32°C and 30% RH	0	5/5	5/5
3B – Storage for 4 hours at 32°C and 30% RH	0	5/5	5/5
3C – Storage for 24 hours at 32°C and 30% RH	0	5/5	5/5
4A – Storage for 2 hours at 32°C and 80% RH	0	5/5	5/5
4B – Storage for 4 hours at 32°C and 80% RH	0	5/5	5/5
4C – Storage for 24 hours at 32°C and 80% RH	0	5/5	5/5

[a] Invalid result obtained (IC detection failure). Replicate was repeated in accordance with device labeling.

Storage of the LIAISON NES FLU A/B, RSV & COVID-19 Positive Control Swab and Negative Control Swab in critical environmental conditions for up to 24 hours after opening the pouch does not impact device performance.

Overall, the Flex Studies and supporting data from the Prospective Clinical Study by untrained operators (refer to section C of this document) demonstrated that the LIAISON NES FLU A/B, RSV & COVID-19 assay performed on the LIAISON NES 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 outside of the specified operating environmental conditions.

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

1. Comparison Study

a. Study Design

i. Study Sites and Duration

The performance of the LIAISON NES FLU A/B, RSV & COVID-19 assay in the hands of untrained users was evaluated in a Prospective Clinical Study that was performed at seven sites, all of which were in the U.S. All seven sites followed the same protocol and procedures, were subject to the same monitoring process, and were considered representative of CLIA-Waived intended use sites. The sites included two pediatric outpatient and urgent care clinics, two emergency departments, one pediatric outpatient clinic, one family medicine, pediatric outpatient and urgent care clinic, and one outpatient clinic. Specimen enrollment began in October, 2024 and concluded in March, 2025. Specimens were collected under informed consent. Comparator Method testing was conducted at two external sites and one internal site.

ii. Operators

A total of 30 operators participated in the Prospective Clinical Study, with between 2 and 9 operators per site. The participating operators were selected from among site staff currently employed at each site and represented a diverse range of educational backgrounds and work experience who were considered representative of untrained, naïve operators in the intended use setting. No hands-on training was given to the LIAISON NES FLU A/B, RSV & COVID-19 test operators, who were only provided with the LIAISON NES Instrument User Manual and Quick Reference Guides for running a quality control test and running a patient sample.

Of the 30 operators who participated in the Prospective Clinical Study, 27 (90%) processed at least 3 nasal swab samples that were positive for one or more of the targeted respiratory analytes, as determined by the applicable comparator method (**Table 37**).

Table 37. Summary of samples tested in the Prospective Clinical Study, stratified by site and operator

Clinical Site #	Operator #	Samples Tested	# of Positives	% Positive	# of Invalids	% Invalid
1	2[1]	358	122	34.1%	3	0.8%
	Unknown[2]	2	0	0.0%	2	100%
	Subtotal	**360**	**122**	**33.9%**	**5**	**1.4%**
2	1	244	80	32.8%	1	0.4%
	2	58	22	37.9%	0	0.0%
	Subtotal	**302**	**102**	**33.8%**	**1**	**0.3%**
3	1	21	9	42.9 %	2	9.5%
	2	30	15	50.0 %	0	0.0%
	3	16	10	62.5 %	1	6.3%
	4	73	38	52.1 %	0	0.0%

	5	24	17	70.8 %	0	0.0%
	6	29	15	51.7 %	1	3.4%
	Unknown[3]	2	0	0.0%	2	100%
	Subtotal	**195**	**104**	**53.3%**	**6**	**3.1%**
4	1	69	18	26.1%	2	2.9%
	2	1	0	0.0%	0	0.0%
	3	7	3	42.9%	0	0.0%
	Subtotal	**77**	**21**	**27.3%**	**2**	**2.6%**
5	1	40	13	32.5%	0	0.0%
	2	29	11	37.9%	1	3.4%
	3	7	1	14.3%	0	0.0%
	4	31	17	54.8%	0	0.0%
	5	23	14	60.9%	0	0.0%
	6	36	15	41.7%	0	0.0%
	7	30	15	50.0%	0	0.0%
	8	17	8	47.1%	0	0.0%
	9	1	0	0.0%	0	0.0%
	Subtotal	**214**	**94**	**43.9%**	**1**	**0.5%**
6	1	165	68	41.2%	2	1.2%
	2	43	22	51.2%	1	2.3%
	Subtotal	**208**	**90**	**43.3%**	**3**	**1.4%**
13	1	38	18	47.4%	0	0.0%
	2	6	3	50.0%	0	0.0%
	3	59	31	52.5%	0	0.0%
	4	26	7	26.9%	0	0.0%
	5	106	31	29.2%	2	1.9%
	Subtotal	**235**	**90**	**38.3%**	**2**	**0.9%**
Total		**1591**	**623**	**39.2%**	**20**	**1.3%**

[1]Two (2) operators at Site 1 used a single instrument login/user ID and therefore the testing could not be stratified by operator.
[2]Two (2) invalid runs at Site 1 were not assigned to an operator as no source data is available for these runs.
[3]Two (2) invalid runs at Site 3 were not assigned to an operator as no source data is available for these runs.

iii. Instructions for Use

Operators who participated in evaluating the clinical performance of the LIAISON NES FLU A/B, RSV & COVID-19 assay received no training on how to install and setup the instrument or perform the assay. They were instructed to refer solely to the LIAISON NES Instrument Quick Start Guide, Instrument User Manual, Quick Reference Guides for running a Quality Control test and running a Patient Sample, or the LIAISON NES FLU A/B, RSV & COVID-19 Instructions for Use. Telephone technical support was provided as intended for the commercial device.

iv. Subjects (Patients)

The Prospective Clinical Study included specimens that were collected under informed consent. Study participants aged 14 years and above were eligible to self-collect the specimen under Healthcare Provider supervision. Specimens included 53% collected by a Healthcare Provider and 47% self-collected under Healthcare Provider supervision.

Specimens for the Prospective Clinical Study were collected under Informed Consent or, if the subject was <18 years of age, with parental permission and assent according to the following Inclusion Criteria:

1. Specimen is from patients with active signs and symptoms of respiratory tract infection at the time of specimen collection
2. Specimen is from a patient that consents to participate in the study
3. Patient provides matched anterior nasal swab (ANS) specimens. The swabs collected were as follows:

    a. Dry ANS (candidate device testing)
    b. ANS in UTM (Comparator Method testing)
    c. NPS in UTM (Comparator Method testing) (Optional)

The Exclusion Criteria for the study were as follows:

1. Incorrect swab type
2. Incorrect transport media
3. Incorrect specimen handling
4. Specimen is from a patient that does not provide informed consent or withdraws informed consent

v. Samples

The clinical performance of the LIAISON NES FLU A/B, RSV & COVID-19 assay was evaluated using prospectively collected specimens. A Clinical Study with prospectively collected specimens was conducted at seven sites in the U.S., two pediatric outpatient and urgent care clinics, two emergency departments, one pediatric outpatient clinic, one family medicine, pediatric outpatient and urgent care clinic, and one outpatient clinic, that were considered representative of the intended use settings for the LIAISON NES Instrument and LIAISON NES FLU A/B, RSV & COVID-19 assay. The specimens in the study were collected under Informed Consent or with parental permission for minors <18 years of age.

A total of 1692 anterior nasal swab (ANS) specimens were initially enrolled in the Prospective Clinical Study, of which 101 were disqualified and removed from analysis for the reasons listed in **Table 38**.

Table 38. Summary of Data Exclusions from the Prospective Clinical Study

Rationale for Exclusion	Number of Specimens (n=1692)
Specimen did not have a Comparator Method result due to fresh specimen testing time window violations	55
Candidate device testing occurred outside allowed time window	19
Improper sample collection	19
Sample handling error	5
Operator error	1

Patient withdrew consent	1
Comparator Method testing swab could not be collected	1
Total Excluded	**101**
Total Included	**1591**

vi. Comparative Method

A Multi-Analyte Panel FDA-Cleared Comparator Method was used to establish the performance of the LIAISON NES FLU A/B, RSV & COVID-19 assay.

b. Results and Analysis

i. Statistical Analysis of Comparison Study Results

A summary of the results from testing prospectively collected anterior nasal swabs is shown in **Table 39**. Positive Percent Agreement (PPA) ranged from 90.3 – 98.4%, whereas Negative Percent Agreement (NPA) ranged from 97.2 – 99.8%.

Table 39. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) (N=1571)

Pathogen Target	Positive Percent Agreement			Negative Percent Agreement		
	TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Influenza A	384/398[a]	96.5%	94.2%-97.9%	1140/1173[b]	97.2%	96.1%-98.0%
Influenza B	34/35[c]	97.1%	85.5%-99.5%	1531/1536[d]	99.7%	99.2%-99.9%
Respiratory Syncytial Virus	102/113[e]	90.3%	83.4%-94.5%	1455/1458[f]	99.8%	99.4%-99.9%
COVID-19	63/64[g]	98.4%	91.7%-99.7%	1498/1507[h]	99.4%	98.9%-99.7%

[a] Eight (8) of the 14 Influenza A False Negative specimens were negative by Standard of Care.
[b] Twelve (12) of the 33 Influenza A False Positive specimens were positive by bi-directional sequencing (BDS).
[c] The one (1) Influenza B False Negative specimen was negative by BDS.
[d] Two (2) of the five (5) Influenza B False Positive specimens were positive by Standard of Care.
[e] One (1) of the 11 RSV False Negative specimens was negative by BDS, and another two (2) specimens were negative by Standard of Care.
[f] Two (2) of the three (3) RSV False Positive specimens were positive by another FDA-cleared molecular assay.
[g] The one (1) COVID-19 False Negative specimen was negative by Standard of Care.
[h] Five (5) of the nine (9) COVID-19 False Positive specimens were positive by Standard of Care.

ii. Invalid Rate for Clinical Evaluation Samples

After a single test of each specimen, 1571 specimens generated valid LIAISON NES results for a success rate of 98.7% (1571/1591). There were 20 specimens (1.3%) with invalid results. Due to sample type limitations, repeat testing of specimens with invalid results was not possible.

Specimens infected by multiple targets and stratified by age are shown in **Table 40**. Of the 4 specimens in which both influenza A and COVID-19 were detected by the LIAISON NES FLU A/B, RSV & COVID-19 Assay, influenza A was detected in 4/4 specimens by the comparator and COVID-19 was detected in 1/4 samples by the comparator. Of the 6

specimens in which both influenza A and RSV were detected by the assay, influenza A was detected in 5/6 specimens by the comparator and RSV was detected in 5/6 specimens by the comparator.

Table 40. Observed Co-infection Combinations by the LIAISON NES FLU A/B, RSV & COVID-19 Assay Stratified by Age (N=1571)

Age (years)	0-1 Years (N=145)		2-5 Years (N=246)		6-21 Years (N=679)		22-65 Years (N=439)		>65 Year (N=62)		Overall (N=1571)	
Co-infection	**#POS**	**%**	**#POS**	**%**	**#POS**	**%**	**#POS**	**%**	**#POS**	**%**	**#POS**	**%**
Influenza A | COVID-19	0	0.00% (0/145)	0	0.00% (0/246)	3	0.44% (3/679)	1	0.23% (1/439)	0	0.00% (0/62)	4	0.25% (4/1571)
Influenza A | RSV	1	0.68% (1/145)	2	0.79% (2/246)	1	0.15% (1/679)	1	0.23% (1/439)	1	1.61% (1/62)	6	0.38% (6/1571)

2. Device Performance with Analyte Concentrations Near the Cutoff

A reproducibility study was conducted assessing the total variability of the LIAISON NES FLU A/B, RSV & COVID-19 assay across operators, study sites, testing days and instruments.

Samples were prepared by a designated staff member of the Diasorin Molecular R&D study team. Each contrived sample panel member was randomized and labeled with a sample ID that did not contain any information regarding sample content to ensure a minimum level of bias. Eight positive panel members consisted of contrived samples of influenza A, influenza B, RSV, and SARS-CoV-2 individually spiked onto dry nasal swabs at low positive (~2X LoD) and moderately positive (~5X LoD) concentrations. The panel members are shown in **Table 41**. The reproducibility study was performed at three geographically distinct external sites, all under CLIA-waived status. There were two operators at each site and each operator tested two (2) replicates of each panel member each day for eight non-consecutive days.

Table 41. Reproducibility Panel Members

Panel Member		Strain	Concentration
1	Influenza A	Darwin/9/21	2X LoD
2	Influenza A		5X LoD
3	Influenza B	Phuket 3073/2013	2X LoD
4	Influenza B		5X LoD
5	RSV	RSV B 12/2014	2X LoD
6	RSV		5X LoD
7	SARS-CoV-2	USA/WA 1/2020	2X LoD
8	SARS-CoV-2		5X LoD

Table 42 shows the qualitative summary for Influenza A, Influenza B, RSV and SARS-CoV-2 during panel member testing.

Table 42. Qualitative Summary of Results and Mean Ct Values +/- SD (%CV)

	Site 1		Site 2		Site 3		All Sites		
Sample	**Agreement with expected results**	**Mean Ct ± SD (%CV)**	**Agreement with expected results**	**Mean Ct ± SD (%CV)**	**Agreement with expected results**	**Mean Ct ± SD (%CV)**	**Agreement with expected results**	**Mean Ct ± SD (%CV)**	**95% CI**
Influenza A 2X	100% (32/32)	36.6 ± 0.77 (2.1%)	100% (32/32)	36.8 ± 1.28 (3.5%)	100% (32/32)	36.9 ± 1.18 (3.2%)	100% (96/96)	36.8 ± 1.09 (3.0%)	96.2% - 100%
Influenza A 5X	100% (32/32)	34.6 ± 1.09 (3.2%)	100% (32/32)	34.7 ± 1.16 (3.4%)	100% (32/32)	35.7 ± 1.73 (4.8%)	100% (96/96)	35.0 ± 1.43 (4.1%)	96.2% - 100%
Influenza B 2X	100% (32/32)	39.0 ± 1.89 (4.8%)	100% (32/32)	38.2 ± 0.88 (2.3%)	96.9% (31/32[a]	38.2 ± 1.42 (3.7%)	99% (95/96)	38.5 ± 1.48 (3.9%)	94.3% - 99.8%
Influenza B 5X	100% (32/32)	37.1 ± 1.40 (3.8%)	100% (32/32)	36.1 ± 0.78 (2.2%)	100% (32/32)	36.2 ± 1.47 (4.1%)	100% (96/96)	36.4 ± 1.32 (3.6%)	96.2% - 100%
RSV 2X	100% (32/32)	36.7 ± 0.96 (2.6%)	100% (32/32)	37.1 ± 1.05 (2.8%)	100% (32/32)	37.1 ± 1.38 (3.7%)	100% (96/96)	37.0 ± 1.15 (3.1%)	96.2% - 100%
RSV 5X	100% (32/32)	35.2 ± 1.01 (2.9%)	100% (32/32)	35.1 ± 0.85 (2.4%)	100% (32/32)	35.3 ± 1.57 (4.4%)	100% (96/96)	35.2 ± 1.17 (3.3%)	96.2% - 100%
SARS-CoV-2 2X	100% (32/32)	37.5 ± 1.41 (3.8%)	100% (32/32)	36.6 ± 0.93 (2.6%)	100% (32/32)	37.2 ± 1.73 (4.7%)	100% (96/96)	37.1 ± 1.43 (3.9%)	96.2% - 100%
SARS-CoV-2 5X	100% (32/32)	35.2 ± 0.91 (2.6%)	100% (32/32)	35.0 ± 0.67 (1.9%)	100% (32/32)	35.5 ± 1.84 (5.2%)	100% (96/96)	35.2 ± 1.25 (3.5%)	96.2% - 100%

n = number of replicates, Ct = Cycle threshold, SD= Standard Deviation, %CV = Percent Coefficient of Variation,
[a] One NTC tested at site 3 failed to detect the IC and was repeated in accordance with device labeling.

The total Ct variability, as measured by the standard deviation, was less than or equal to 1.72 across all target viruses and concentrations. These results, shown in **Table 43**, indicate that the reproducibility of the Diasorin LIAISON NES FLU A/B, RSV & COVID-19 nucleic acid test is acceptable.

Table 43. Quantitative Summary of Reproducibility

			Reproducibility									
			Between Sites		**Between Operator (Site)**		**Between Day (Operator Site)**		**Between Instruments (Days Operator Site)**		**Total Reproducibility**	
Sample	**N**	**Mean Ct**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**	**SD**	**CV (%)**
Influenza A 2X	96	36.8	0.14	0.4	0.58	1.6	0.80	2.2	1.07	2.9	1.20	3.3
Influenza A 5X	96	35.0	0.61	1.8	0.97	2.8	1.20	3.4	1.03	3.0	1.60	4.6
Influenza B 2X	95	38.5	0.44	1.1	0.86	2.2	1.20	3.1	1.48	3.9	1.50	4.0
Influenza B 5X	96	36.4	0.54	1.5	0.82	2.3	1.06	2.9	1.22	3.3	1.54	4.2
RSV 2X	96	37.0	0.21	0.6	0.66	1.8	0.88	2.4	1.04	2.8	1.33	3.6
RSV 5X	96	35.2	0.09	0.3	0.82	2.3	1.02	2.9	0.81	2.3	1.33	3.8

SARS-CoV-2 2X	96	37.1	0.45	1.2	0.83	2.2	1.08	2.9	1.30	3.5	1.72	4.6
SARS-CoV-2 5X	96	35.2	0.26	0.7	0.91	2.6	1.12	3.2	0.76	2.2	1.52	4.3

N = Number of replicates, Ct = Cycle threshold, SD= Standard Deviation, %CV = Percent Coefficient of Variation

3. Operator Questionnaire

Prior to the start of the clinical study, all participating personnel were asked to complete a questionnaire to evaluate their level of education, current job responsibilities and experience with in vitro diagnostic test methods. The responses to this questionnaire were used to confirm that the participants were representative of typical operators in the intended use environment for near-patient testing.

Following completion of the study, a Post-Study questionnaire was administered to the operators to assess the ease of instrument installation/setup, usefulness of the LIAISON NES Instrument and LIAISON NES FLU A/B, RSV & COVID-19 assay Quick Reference Guides, the ability of operators to follow the instructions for Quality Control testing, ease of running the LIAISON NES FLU A/B, RSV & COVID-19 assay, the ease of interpreting assay results and ease of troubleshooting the LIAISON NES Instrument. All operators that participated in study testing (30) completed the questionnaire. The questionnaire contained 17 questions related to ease of use and 8 questions assessing operators' ability to correctly interpret results as displayed on the instrument.

The ease-of-use portion asked operators to respond to statements such as, "It was easy to run a test using the LIAISON NES FLU A/B, RSV & COVID-19 assay" by indicating their agreement on a scale of 1 – 5 (1 = strongly disagree, 5 = strongly agree) and also included 7 'Yes/No' questions. All ratings were 4.0 or above, with the exception of ease of troubleshooting issues with the NES system using the documentation provided (instrument user manual, QRG, IFU), which scored a 3.3. **Table 44** presents the tabulation from the agreement with statement scores portion of the ease-of-use questionnaire.

Table 44: Operators Ease of Use Questionnaire Statement Agreement Results

Statement	Average Agreement with Statement Score (1 = Strongly Disagree, 5 = Strongly Agree)
The NES instrument was easy to install	4.0
The NES instrument was easy to use overall	4.2
The NES instrument software was easy to use	4.2
The Quick Reference Guide was easy to read and understand	4.3
QC testing was easy to run on the NES system.	4.5
It was easy to troubleshoot issues with the NES system using the documentation provided (manual, QRG, IFU).	3.3
It was easy to prepare a sample for testing on the FLU A/B, RSV & COVID- 19 Assay.	4.5
It was easy to run a test using the FLU A/B, RSV & COVID-19 Assay.	4.5
It was easy to see and interpret the test results.	4.7

Statements were scored as follows: 1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree.

Most users (97%) found that the Quick Reference Guide provided all of the information needed to successfully set up the LIAISON NES Instrument, while 97% indicated that the LIAISON NES FLU A/B, RSV & COVID-19 Quick Reference Guide provided all of the information needed to successfully run a test. A total of 93% of the operators found that the documentation provided (Instrument User Manual, Quick Reference Guides and Instructions for Use) were adequate to perform testing without additional instruction. **Table 45** presents a tabulation of the 'Yes'/'No' responses from the ease-of-use portion of the questionnaire.

The proficiency section of the questionnaire included example screenshots from the LIAISON NES Instrument and asked the operators to select the multiple-choice response that best represented how they would interpret the results. The images included examples of passing and failing Quality Control runs, invalid runs and positive and negative results for each target in the assay. The overall score for the proficiency portion was 100% (240/240), with all operators correctly interpreting each result.

Table 45. Operators Ease of Use Questionnaire 'Yes/No' Question Results

Question	Yes (%)	No (%)
Did you encounter any technical issues with the NES instrument? If yes, please describe.	76%	23%
Did you read the Quick Reference Guide before the first time you used the instrument?	93%	7%
Did you require assistance the first time you used the instrument?	46%	64%
Did the Quick Reference Guide provide all the information you needed to successfully set up your NES instrument?	97%	3%
Did you refer back to the Quick Reference Guide after the first time you used the instrument?	62%	38%
Did you read the Quick Reference Guide before the first time you ran a test?	90%	10%
Did the Quick Reference Guide provide all the information you needed to successfully run a test?	97%	3%
Was the documentation provided (manual, QRG and IFU) adequate to perform testing without additional instruction?	93%	7%

Overall, the operators reported that the LIAISON NES Instrument and LIAISON NES FLU A/B, RSV & COVID-19 assay were easy to use and that the training materials provided (instrument user manual, Quick Reference Guides and Instructions for Use) were adequate to perform the test without additional instruction.

D Labeling for Waived Devices

1. The labeling consists of:

   a. LIAISON NES FLU A/B, RSV & COVID-19 assay Instructions for Use

b. LIAISON NES FLU A/B, RSV & COVID-19 assay Quick Reference Guide

c. LIAISON NES User Manual

2. The following elements are appropriately present:

- The LIAISON NES User Manual specifies the environmental operating conditions under which testing may be performed.
- The LIAISON NES User Manual and LIAISON NES FLU A/B, RSV & COVID-19 assay Instructions for Use are clear and easy to understand.
- The LIAISON NES FLU A/B, RSV & COVID-19 assay Instructions for Use and LIAISON NES FLU A/B, RSV & COVID-19 assay Quick Reference Guide identify the test as CLIA Waived.
- The LIAISON NES FLU A/B, RSV & COVID-19 assay Instructions for Use:
    - Indicate that laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test.
    - Include step-by-step instructions for performing the test.
    - Include safety considerations applicable for untrained users.
    - Specify the actions to be taken if an invalid test result is obtained.
    - Include a summary of the studies performed to support CLIA Waiver.
    - Include appropriate warnings and/or limitations pertaining to clinical interpretation of test results.
    - Include recommendations for Quality Control testing including the source of appropriate control materials and the frequency of testing.
- The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10

XI. Conclusion

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