December 23, 2025

Diasorin Molecular LLC
Sarah Baumann
Principal Regulatory Affairs Specialist
11331 Valley View Street
Cypress, California 90630

Re: K251978
Trade/Device Name: LIAISON NES FLU A/B, RSV & COVID-19
Regulation Number: 21 CFR 866.3981
Regulation Name: Device To Detect And Identify Nucleic Acid Targets In Respiratory Specimens From Microbial Agents That Cause The SARS-Cov-2 Respiratory Infection And Other Microbial Agents When In A Multi-Target Test
Regulatory Class: Class II
Product Code: QOF
Dated: June 27, 2025
Received: June 27, 2025

Dear Sarah Baumann:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH BRIGGS -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K251978

Device Name

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

Indications for Use *(Describe)*

The LIAISON NES FLU A/B, RSV & COVID-19 assay is a real-time RT-PCR assay intended for use on the LIAISON NES instrument for the simultaneous in vitro qualitative detection and differentiation of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A (Flu A) virus, influenza B (Flu B) virus, and respiratory syncytial virus (RSV) in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, influenza B, and RSV can be similar.

The LIAISON NES FLU A/B, RSV & COVID-19 assay is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, influenza B, and RSV infections when used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, influenza B, and RSV viral RNA are generally detectable in anterior nasal swab specimens during the acute phase of infection. This test is not intended to detect influenza C virus infections.

Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent(s) detected by the LIAISON NES FLU A/B, RSV & COVID-19 assay may not be the definite cause of the disease. Negative results do not preclude SARS-CoV-2, influenza A, influenza B or RSV infection and should not be used as the sole basis for patient management decisions.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CRF 807.92.

A. 510(k) Number:

K251978

B. Purpose of Submission:

Traditional 510(k), New Device
CLIA Waived

C. Measurand:

Target RNA sequences for Influenza A virus, Influenza B virus, Respiratory Syncytial Virus, and SARS-CoV-2

D. Type of Test:

Qualitative Real Time Reverse Transcription-Polymerase Chain Reaction (RT-PCR)

E. Applicant:

Sarah Baumann
Diasorin Molecular LLC
11331 Valley View Street
Cypress, CA 90630

F. Proprietary and Established Names:
LIAISON® NES FLU A/B, RSV & COVID-19

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
QOF	II	21 CFR 866.3981 – Multi Target Respiratory Specimen Nucleic Acid Test Including SARS-CoV-2 and Other Microbial Agents	Microbiology

510(k) Summary

H. Intended Use:

1. Intended Use(s):

The LIAISON® NES FLU A/B, RSV & COVID-19 assay is a real-time RT-PCR assay intended for use on the LIAISON® NES instrument for the simultaneous in vitro qualitative detection and differentiation of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A (Flu A) virus, influenza B (Flu B) virus, and respiratory syncytial virus (RSV) in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, influenza B, and RSV can be similar.

The LIAISON® NES FLU A/B, RSV & COVID-19 assay is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, influenza B, and RSV infections when used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, influenza B, and RSV viral RNA are generally detectable in anterior nasal swab specimens during the acute phase of infection. This test is not intended to detect influenza C virus infections.

Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent(s) detected by the LIAISON® NES FLU A/B, RSV & COVID-19 assay may not be the definite cause of the disease. Negative results do not preclude SARS-CoV-2, influenza A, influenza B or RSV infection and should not be used as the sole basis for patient management decisions.

2. Indication(s) for use:

Same as intended use.

510(k) Summary

3. Special conditions for use statement(s):

   For prescription use only.

4. Special instrument requirements:

   For use with LIAISON® NES Instrument.

I. Device Description:

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 is comprised of 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. The LIAISON® NES software is responsible for providing the environment in which a user runs assays and obtains results.

The LIAISON® NES instrument is intended to accept a cartridge, containing either a quality control (QC) or patient sample, to process and detect for the target nucleic acid.

The LIAISON® NES FLU A/B, RSV & COVID-19 assay used on the LIAISON® NES instrument is a real-time RT-PCR system that enables the direct amplification, detection, and differentiation of influenza A viral RNA, influenza B viral RNA, RSV RNA, and SARS-CoV-2 RNA directly from nasal swabs. Nasal swabs can be professionally collected by a healthcare provider or self-collected under the healthcare provider's supervision.

The LIAISON® NES FLU A/B, RSV & COVID-19 assay consists of the LIAISON® NES instrument, the LIAISON® NES FLU A/B, RSV & COVID-19 Cartridge containing all the

510(k) Summary

required PCR reagents, the NES Sample Vial containing sample release buffer, and the NES Swab for sample collection.

In the LIAISON® NES FLU A/B, RSV & COVID-19 assay, fluorescent probes are used with corresponding forward and reverse primers to amplify influenza A, influenza B, RSV, and SARS-CoV-2, and internal control (IC) RNA. Conserved regions of influenza A viral RNA, influenza B viral RNA, RSV RNA, and SARS-CoV-2 RNA are targeted to identify the viruses in the specimen, while the internal control (IC) RNA is used to detect any PCR failures and/or inhibition.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Biofire® SPOTFIRE® Respiratory (R) Panel Mini

2. Predicate 510(k) number(s):

   K230719

3. Comparison with predicate:

   The following table compares the similarities and differences between the LIAISON® NES FLU A/B, RSV & COVID-19 assay and the BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE R Panel Mini) (K230719).

Device & Predicate Device:	**Predicate Device: K230719**	**Candidate Device**
Device Trade Name	BIOFIRE® SPOTFIRE Respiratory (R) Panel Mini (SPOTFIRE R Panel Mini)	LIAISON® NES FLU A/B, RSV & COVID-19
General Device Characteristic Similarities		
Intended Use/Indications for Use	The BIOFIRE® SPOTFIRE® Respiratory (R) Panel Mini (SPOTFIRE R Panel Mini) is a multiplexed polymerase chain reaction (PCR) test intended for use with the BIOFIRE®	The LIAISON® NES FLU A/B, RSV & COVID-19 assay is a real-time RT-PCR assay intended for use on the LIAISON® NES instrument for the simultaneous in vitro qualitative detection and

510(k) Summary

	SPOTFIRE® System for the simultaneous, qualitative detection and identification of multiple respiratory viral nucleic acids in nasopharyngeal swab (NPS) specimens obtained from individuals with signs and symptoms of respiratory tract infection, including COVID-19. The following organism types and subtypes are identified and differentiated using the SPOTFIRE R Panel Mini: • Coronavirus SARS-CoV-2 • Human rhinovirus • Influenza A virus • Influenza B virus • Respiratory syncytial virus Nucleic acids from the viral organisms identified by this test are generally detectable in NPS specimens during the acute phase of infection. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and/or symptoms of respiratory infection are indicative of the presence of the identified microorganism and aids in diagnosis if used in conjunction with other clinical and epidemiological information, and laboratory findings. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.	differentiation of nucleic acid from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A (Flu A) virus, influenza B (Flu B) virus, and respiratory syncytial virus (RSV) in anterior nasal swab specimens from individuals with signs and symptoms of respiratory tract infection. Clinical signs and symptoms of respiratory tract infection due to SARS-CoV-2, influenza A, influenza B, and RSV can be similar. The LIAISON® NES FLU A/B, RSV & COVID-19 assay is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, influenza B, and RSV infections when used in conjunction with other clinical and epidemiological information, and laboratory findings. SARS-CoV-2, influenza A, influenza B, and RSV viral RNA are generally detectable in anterior nasal swab specimens during the acute phase of infection. This test is not intended to detect influenza C virus infections. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test. The agent(s) detected by the LIAISON® NES FLU A/B, RSV & COVID-19 assay may not be the definite cause of the disease. Negative results do not

510(k) Summary

	Negative results in the setting of a respiratory illness may be due to infection with pathogens that are not detected by this test, or lower respiratory tract infection that may not be detected by an NPS specimen. Positive results do not rule out coinfection with other organisms. The agent(s) detected by the SPOTFIRE R Panel Mini may not be the definite cause of disease. Additional laboratory testing (e.g., bacterial and viral culture, immunofluorescence, and radiography) may be necessary when evaluating a patient with possible respiratory tract infection.	preclude SARS-CoV-2, influenza A, influenza B or RSV infection and should not be used as the sole basis for patient management decisions.
Measurand	Nucleic acid from Organisms detected	Same
Patient Population	Individuals with signs and symptoms of respiratory tract infection, including COVID-19.	Individuals with signs and symptoms of respiratory tract infection
Organisms detected	• Coronavirus SARS-CoV-2 • Human rhinovirus • Influenza A virus • Influenza B virus • Respiratory syncytial virus	Same, except no assay for Human rhinovirus
Automated System (Sample to Answer)	Automated test interpretation and reporting. User cannot access raw data.	Same
Reporting Features	System software analyzes processed image data and provides test results for each panel target	Same

510(k) Summary

Assay Software Functions	Defines panel-specific parameters, instrument protocols and report requirements.	Same
Time to Result	~15 minutes	~18 minutes
General Device Characteristic Differences		
Sample Type	Nasopharyngeal Swab (NPS)	Direct Anterior Nasal Swab (NS)
Instrumentation	BIOFIRE SPOTFIRE System	LIAISON® NES Instrument
Technological Principle	Highly multiplexed PCR with DNA melting analysis	Highly multiplexed real-time RT-PCR with fluorescence detection and analysis

K. Standards/Guidance Documents Referenced:

- FDA Guidance – *Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay*.
- AAMI. Principles for medical device security – Risk Management. AAMI document TIR57:2016. Association for the Advancement of Medical Instrumentation; 2016.
- AAMI. Principles for medical device security – Postmarket risk management for device manufacturers. AAMI document TIR97:2019. Association for the Advancement of Medical Instrumentation; 2019.
- CLSI. Information Technology Security of *In Vitro* Diagnostic Instruments and Software Systems; Approved Standard – Second Edition. CLSI document AUTO11-A2. Wayne, PA: Clinical Laboratory Standards Institute; 2014.
- CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical Laboratory Standards Institute; 2019.
- CLSI. Interference Testing in Clinical Chemistry. 3rd Ed. CLSI Document EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
- CLSI. Evaluation of Qualitative, Binary Output Examination Performance; Approved Guideline – Third Edition. CLSI document EP12. Wayne, PA: Clinical Laboratory Standards Institute; 2023.
- CLSI. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. CLSI document EP17-A2. Wayne, PA: Clinical Laboratory Standards Institute; 2012.
- CLSI. Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline – Second Edition. CLSI document EP24-A2. Wayne, PA: Clinical Laboratory Standards Institute; 2011.

510(k) Summary

- CLSI. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI document EP25-A. Wayne, PA: Clinical Laboratory Standards Institute; 2009.
- CLSI. Collection Transport Preparation and Storage of Specimens for Molecular Methods. 2nd Edition. CLSI Document MM13. Wayne, PA: Clinical Laboratory Standards Institute; 2020.
- CLSI. Verification and Validation of Multiplex Nucleic Acid Assays. 2nd Edition. CLSI Document MM17. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
- ISTA. Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less. ISTA Document 3A. International Safe Transit Association. 2018.
- IEC 62366-1 Edition 1.1 2020-06 Consolidated Version; Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 61010-1 Edition 3.1 2017-01 Consolidated Version; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements
- IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version; Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 61326-1 Edition 3.0 2020-10; Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
- IEC 61326-2 Edition 3.0 2020-10; Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- IEC 62304 Edition 1.1 2015-06 Consolidated Version; Medical device software – Software life cycle processes
- IEC TR 60878 Ed. 4.0 2022-11; Graphical symbols for electrical equipment in medical practice [Including: Corrigendum 1 (2023)]
- IEC TR 80001-2-2:2012. Application of risk management for IT Networks incorporating medical devices – Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls
- IEC TR 80001-2-8 Edition 1.0 206-05; Application of risk management for IT – networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2
- ISO 14971:2019 Medical Devices – Application of risk management to medical devices
- ISO 15223-1: 2021-07 – Medical Devices- Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- UL ANSI 2900-1 First Edition 2017; Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements
- UL ANSI 2900-2-1 First Edition 2017; Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

510(k) Summary

L. Test Principle:

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 is comprised of 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. The LIAISON® NES software is responsible for providing the environment in which a user runs assays and obtains results.

The LIAISON® NES instrument is intended to accept a cartridge, containing either a quality control (QC) or patient sample, to process and detect for the target nucleic acid.

The LIAISON® NES FLU A/B, RSV & COVID-19 assay used on the LIAISON® NES instrument is a real-time RT-PCR system that enables the direct amplification, detection, and differentiation of influenza A viral RNA, influenza B viral RNA, RSV RNA, and SARS-CoV-2 RNA directly from nasal swabs. Nasal swabs can be professionally collected by a healthcare provider or self-collected under the healthcare provider's supervision.

The LIAISON® NES FLU A/B, RSV & COVID-19 assay consists of the LIAISON® NES instrument, the LIAISON® NES FLU A/B, RSV & COVID-19 Cartridge containing all the required PCR reagents, the NES Sample Vial containing sample release buffer, and the NES Swab for sample collection.

In the LIAISON® NES FLU A/B, RSV & COVID-19 assay, fluorescent probes are used with corresponding forward and reverse primers to amplify influenza A, influenza B, RSV, and SARS- CoV-2, and internal control (IC) RNA. Conserved regions of influenza A viral RNA, influenza B viral RNA, RSV RNA, and SARS-CoV-2 RNA are targeted to identify the viruses in the specimen, while the internal control (IC) RNA is used to detect any PCR failures and/or inhibition.

M. Clinical Performance Characteristics:

510(k) Summary

CLINICAL AGREEMENT

The clinical performance of the LIAISON® NES FLU A/B, RSV & COVID-19 Assay was evaluated using clinical specimens prospectively collected between October 2024 and March 2025 from seven geographically diverse clinical sites within the United States. The clinical study utilized prospective specimens collected from pediatric and adult patients exhibiting clinical signs and symptoms of respiratory tract infection. Nasal swabs were professionally collected by a Healthcare Provider or self-collected under the Healthcare Provider's supervision. All collection and LIAISON® NES FLU A/B, RSV & COVID-19 Assay testing were performed at CLIA-Waived facilities, representative of the intended use, point-of-care environment.

A total of 1692 unique prospectively collected specimens that met the pre-determined inclusion criteria were enrolled in the study. Clinical sample testing using the LIAISON® NES FLU A/B, RSV & COVID-19 Assay was performed using the LIAISON® NES device by untrained operators at all seven collection sites.

Of the 1692 specimens enrolled in the prospective arm of the study, 101 (6.0%) specimens were disqualified and removed from further analysis. After a single test of each specimen, 1571 specimens generated valid LIAISON® NES results for a final success rate of 98.7% (1571/1591).

Demographic data for the prospective study population are presented in Table 1.

Table 1: Demographic Data for the Prospective Study Population (N=1591)

	Site 01	Site 02	Site 03	Site 04	Site 05	Site 06	Site 13	Total
Sex								
Male	191 (53.1%)	129 (42.7%)	104 (53.3%)	31 (40.3%)	99 (46.3%)	107 (51.4%)	100 (42.6%)	761 (47.8%)
Female	169 (46.9%)	173 (57.3%)	91 (46.7%)	46 (59.7%)	115 (53.7%)	101 (48.6%)	135 (57.4%)	830 (52.2%)
Total	360 (100.0%)	302 (100.0%)	195 (100.0%)	77 (100.0%)	214 (100.0%)	208 (100.0%)	235 (100.0%)	1591 (100.0%)
Age (years)								
0-1	47 (13.1%)	33 (10.9%)	42 (21.5%)	0 (0.0%)	9 (4.2%)	10 (4.8%)	5 (2.1%)	146 (9.2%)
>1-5	87 (24.2%)	47 (15.6%)	60 (30.8%)	0 (0.0%)	5 (2.3%)	32 (15.4%)	23 (9.8%)	254 (16.0%)
>5-21	208 (57.8%)	169 (56.0%)	90 (46.2%)	0 (0.0%)	22 (10.3%)	138 (66.3%)	59 (25.1%)	686 (43.1%)
>21-65	18 (5.0%)	52 (17.2%)	3 (1.5%)	68 (88.3%)	142 (66.4%)	28 (13.5%)	132 (56.2%)	443 (27.8%)
>65	0 (0.0%)	1 (0.3%)	0 (0.0%)	9 (11.7%)	36 (16.8%)	0 (0.0%)	16 (6.8%)	62 (3.9%)
Total	360 (100.0%)	302 (100.0%)	195 (100.0%)	77 (100.0%)	214 (100.0%)	208 (100.0%)	235 (100.0%)	1591 (100.0%)

510(k) Summary

	Site 01	Site 02	Site 03	Site 04	Site 05	Site 06	Site 13	Total
Subject Status								
Emergency Department	0 (0.0%)	0 (0.0%)	184 (94.4%)	41 (53.2%)	214 (100.0%)	0 (0.0%)	0 (0.0%)	439 (27.6%)
Outpatient	360 (100.0%)	302 (100.0%)	6 (3.1%)	35 (45.5%)	0 (0.0%)	208 (100.0%)	235 (100.0%)	1146 (72.0%)
Other	0 (0.0%)	0 (0.0%)	5 (2.6%)	1 (1.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (0.4%)
Total	360 (100.0%)	302 (100.0%)	195 (100.0%)	77 (100.0%)	214 (100.0%)	208 (100.0%)	235 (100.0%)	1591 (100.0%)
Collection Method								
Healthcare Professional	285 (79.2%)	258 (85.4%)	186 (95.4%)	37 (48.1%)	153 (71.5%)	183 (88.0%)	155 (66.0%)	1257 (79.0%)
Self-collected	75 (20.8%)	44 (14.6%)	9 (4.6%)	40 (51.9%)	61 (28.5%)	25 (12.0%)	80 (34.0%)	334 (21.0%)
Total	360 (100.0%)	302 (100.0%)	195 (100.0%)	77 (100.0%)	214 (100.0%)	208 (100.0%)	235 (100.0%)	1591 (100.0%)

Comparator testing was performed at two external and one internal testing facility. LIAISON® NES FLU A/B, RSV & COVID-19 Assay results were compared to an FDA-cleared molecular assay to determine the Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA), along with the associated 95% confidence intervals. The results for prospective specimen analysis are summarized in Table 2.

Table 2: Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of Prospective Data Set

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%
RSV	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.

510(k) Summary

REPRODUCIBILITY

Site-to-site reproducibility of the LIAISON® NES FLU A/B, RSV & COVID-19 assay was evaluated by testing LIAISON® NES FLU A/B, RSV & COVID-19 assay cartridges with a reproducibility panel, blinded to operators, consisting of ten panel members including negative samples (Pooled Negative Human Nasal Matrix spiked onto dry nasal swabs (NTC)), positive control (PC) and eight (8) positive panel members. The eight (8) positive panel members consisted of contrived samples containing one (1) strain of SARS-CoV-2, influenza A, influenza B, or RSV viral particles individually. Each strain was spiked onto dry nasal swabs at two different concentrations [Low Positive (LP) ~ 2X Limit of Detection (LoD), Moderate Positive (MP) ~ 5X LoD].

Each sample panel member was tested by two (2) different operators at each testing site. Each operator tested each panel member in two (2) replicates each day for a total of eight (8) non-consecutive testing days. A total of ninety-six (96) replicates [two (2) replicates X two (2) operators X three (3) sites X eight (8) days] were evaluated for each panel member. A total of seven (7) LIAISON® NES instruments [at least two (2) per site] were used to evaluate the reproducibility study.

Table 3: Reproducibility Panel Member Details

Panel Member		Concentration	Panel Member Replicates per day per site	Total panel member replicates per site (16 days)	Total panel member replicates across study
1	Influenza A Low Positive (LP)	2X LoD	2	32	96
2	Influenza B Low Positive (LP)	2X LoD	2	32	96
3	RSV Low Positive (LP)	2X LoD	2	32	96
4	SARS-CoV-2 Low Positive (LP)	2X LoD	2	32	96
5	Influenza A Moderate Positive (MP)	5X LoD	2	32	96
6	Influenza B Moderate Positive (MP)	5X LoD	2	32	96
7	RSV Moderate Positive (MP)	5X LoD	2	32	96
8	SARS-CoV-2 Moderate Positive (MP)	5X LoD	2	32	96
9	NTC – Pooled Negative Human Nasal Matrix	NA	2	32	96
10	PC - LIAISON® NES FLU A/B, RSV & COVID-19 Positive Control Swab (PC)	5-10X LoD	2	32	96
Total			**20**	**320**	**960**

LP = Low Positive, MP = Moderate Positive, LoD = Limit of Detection, NTC = No Template Control, PC = Positive Control

510(k) Summary

Table 4: LIAISON® NES FLU A/B, RSV & COVID-19 Reproducibility

Sample	Site 1		Site 2		Site 3		All Sites		
	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 LP	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 MP	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 LP	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 MP	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%
Sars-CoV-2 LP	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 MP	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%
RSV LP	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 MP	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%
PC Influenza A	100% (32/32)	28.6 ± 0.43 (1.5%)	100% (32/32)	28.9 ± 0.43 (1.5%)	100% (32/32)	28.0 ± 1.15 (4.1%)	100% (96/96)	28.5 ± 0.83 (2.9%)	96.2% - 100%
PC Influenza B	100% (32/32)	29.4 ± 0.39 (1.3%)	100% (32/32)	29.4 ± 0.28 (0.9%)	100% (32/32)	28.6 ± 0.73 (2.6%)	100% (96/96)	29.1 ± 0.62 (2.1%)	96.2% - 100%
PC Sars-CoV-2	100% (32/32)	30.9 ± 1.21 (3.9%)	100% (32/32)	30.8 ± 0.29 (0.9%)	100% (32/32)	30.3 ± 1.08 (3.6%)	100% (96/96)	30.6 ± 0.97 (3.2%)	96.2% - 100%
PC RSV	100% (32/32)	29.8 ± 0.55 (1.8%)	100% (32/32)	29.8 ± 0.31 (1.0%)	100% (32/32)	30.4 ± 0.83 (2.7%)	100% (96/96)	30.0 ± 0.66 (2.2%)	96.2% - 100%
NTC	100% (32/32)	NA	100% (32/32)	NA	100% (32/32)	NA	100% (96/96)	NA	96.2% - 100%

Ct = Cycle threshold, SD= Standard Deviation, %CV = Percent Coefficient of Variation, LP = Low Positive, MP = Moderate Positive, NTC = No Template Control, PC = Positive Control
[a] One (1) Influenza B Low Positive replicate tested at Site 3 had an unexpected false negative ("Not Detected") result.

Table 5: LIAISON® NES FLU A/B, RSV & COVID-19 Internal Control Reproducibility

Sample	Site 1		Site 2		Site 3		All Sites		
	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 LP	100% (32/32)	25.0 ± 0.50 (2.0%)	100% (32/32)	24.7 ± 0.41 (1.7%)	100% (32/32)	24.5 ± 0.48 (2.0%)	100% (96/96)	24.8 ± 0.50 (2.0%)	96.2% - 100%
Influenza A MP	100% (32/32)	24.8 ± 0.48 (1.9%)	100% (32/32)	24.9 ± 0.40 (1.6%)	96.9% (31/32)[a]	24.8 ± 1.20 (4.8%)	99% (95/96)[a]	24.8 ± 0.77 (3.1%)	94.3% - 99.8%
Influenza B LP	100% (32/32)	24.9 ± 0.53 (2.1%)	100% (32/32)	24.6 ± 0.49 (2.0%)	100% (32/32)	24.7 ± 0.58 (2.4%)	100% (96/96)	24.7 ± 0.55 (2.2%)	96.2% - 100%
Influenza B MP	100% (32/32)	24.9 ± 0.79 (3.2%)	100% (32/32)	24.5 ± 0.58 (2.4%)	100% (32/32)	24.5 ± 0.54 (2.2%)	100% (96/96)	24.6 ± 0.66 (2.7%)	96.2% - 100%
SARS-CoV-2 LP	100% (32/32)	24.9 ± 0.64 (2.6%)	100% (32/32)	24.8 ± 0.49 (2.0%)	100% (32/32)	24.7 ± 0.49 (2.0%)	100% (96/96)	24.8 ± 0.55 (2.2%)	96.2% - 100%
SARS-CoV-2 MP	100% (32/32)	24.9 ± 0.59 (2.4%)	100% (32/32)	24.8 ± 0.45 (1.8%)	100% (32/32)	24.7 ± 0.59 (2.4%)	100% (96/96)	24.8 ± 0.55 (2.2%)	96.2% - 100%
RSV LP	100% (32/32)	24.9 ± 0.57 (2.3%)	100% (32/32)	24.6 ± 0.48 (1.9%)	100% (32/32)	24.6 ± 0.60 (2.4%)	100% (96/96)	24.7 ± 0.57 (2.3%)	96.2% - 100%
RSV MP	100% (32/32)	24.9 ± 0.54 (2.2%)	100% (32/32)	24.6 ± 0.41 (1.7%)	100% (32/32)	24.7 ± 0.57 (2.3%)	100% (96/96)	24.7 ± 0.53 (2.1%)	96.2% - 100%
PC	100% (32/32)	24.0 ± 0.52 (2.2%)	100% (32/32)	23.8 ± 0.36 (1.5%)	100% (32/32)	24.0 ± 0.88 (3.7%)	100% (96/96)	23.9 ± 0.62 (2.6%)	96.2% - 100%
NTC	100% (32/32)	25.0 ± 0.44 (1.8%)	100% (32/32)	24.6 ± 0.35 (1.4%)	100% (32/32)	24.5 ± 0.52 (2.1%)	100% (96/96)	24.7 ± 0.49 (2.0%)	96.2% - 100%

Ct = Cycle threshold, SD= Standard Deviation, %CV = Percent Coefficient of Variation, LP = Low Positive, MP = Moderate Positive, NTC = No Template Control, PC = Positive Control

[a] One (1) replicate of Influenza A MP at Site 3 had a "Not Detected" IC result.

510(k) Summary

N. Analytical Performance Characteristics

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION

The LoD of the LIAISON® NES FLU A/B, RSV & COVID-19 assay on dry nasal swabs (NS) specimens was determined to be the lowest detectable concentration of quantitated titered viral stocks (copies/swab) at which ≥ 95% of all replicates were detected. Two (2) strains of influenza A, two (2) strains of influenza B, two (2) strains of RSV and two (2) strains of SARS-CoV-2 were serially diluted in pooled negative human nasal matrix and spiked onto dry NS to determine the LoD. The LoD results are shown in Table 6.

Table 6: LIAISON® NES FLU A/B, RSV & COVID-19 assay Limit of Detection

Virus strain/isolate	LoD (copies/swab)
Influenza A Victoria/4897/2022 (H1N1)	6000
Influenza A Darwin/9/21 (H3N2)	8000
Influenza B Austria/1359417/2021 (Victoria)	4000
Influenza B Phuket/3073/2013 (Yamagata)	5000
RSVA A Isolate 2006	8000
RSV B Isolate 12/2014	8000
SARS-CoV-2 USA/WA 1/2020	1000
SARS-CoV-2 USA/MDHP20874/2021 (B.1.1.529 Omicron)	1000

The LoD of the LIAISON® NES FLU A/B, RSV & COVID-19 assay using inactivated SARS-CoV-2 WHO International Standard viral particles on dry NS specimens was determined to be the lowest detectable concentration of quantitated titered viral stock (IU/swab) at which ≥ 95% of all replicates were detected. The Second WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 22/252) was serially diluted in pooled negative human nasal matrix and spiked onto dry NS to determine the LoD. The LoD results are shown in Table 7.

510(k) Summary

Table 7: LIAISON® NES FLU A/B, RSV & COVID-19 assay Limit of Detection for WHO International Standard for SARS-CoV-2 RNA

Virus strain	LoD (IU/swab)
Second WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 22/252)	400

ANALYTICAL REACTIVITY/CROSS REACTIVITY

Analytical Reactivity

The analytical reactivity of the LIAISON® NES FLU A/B, RSV & COVID-19 assay on dry NS specimens was evaluated. A total of thirty-six (36) influenza A strains, fourteen (14) influenza B strains, nine (9) RSV strains, and nineteen (19) SARS-CoV-2 strains were tested. Quantified viral material was diluted in pooled negative human nasal matrix and spiked onto dry NS at the concentrations listed in Tables 8-11 below (corresponding to 3X LoD) and tested in triplicate. The results are shown in Tables 8-11. All strains and subtypes were 100% detected with LIAISON® NES FLU A/B, RSV & COVID-19 assay at 3X LoD except for SARS-CoV-2 Isolate hCoV-19/USA/CA-Stanford -109_S21/2022 PANGO Lineage B.1.1.529 (XBB Omicron) which was detected at 4X LoD and influenza A/Hong Kong/8/68 (H3N2) which was detected at 5X LoD.

Table 8: LIAISON® NES FLU A/B, RSV & COVID-19 assay Analytical Reactivity – Influenza A

Influenza A Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
A/Michigan/45/2015 (H1N1)	18000	100% (3/3)
A/Brisbane/59/2007 (H1N1)	18000	100% (3/3)
A/NY/02/2009 (H1N1)	18000	100% (3/3)
A/Mexico/4108/2009 (H1N1)	18000	100% (3/3)
A/New York/18/2009 (H1N1)	18000	100% (3/3)
A/Taiwan/42/2006 (H1N1)	18000	100% (3/3)
A/Brisbane/02/2018 (H1N1)	18000	100% (3/3)
A/Wisconsin/588/2019 (H1N1)	18000	100% (3/3)

510(k) Summary

Influenza A Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
A/California/07/2009 (H1N1)	18000	100% (3/3)
A/New Caledonia/20/1999 (H1N1)	18000	100% (3/3)
A/Guangdong-Moanan/SWL1536/2019 (H1N1)	18000	100% (3/3)
A/Puerto Rico/8/1934 (H1N1)	18000	100% (3/3)
A/Victoria/2570/2019 (H1N1)	18000	100% (3/3)
A/Nebraska/14/2018 (H1N1)	18000	100% (3/3)
A/Sydney/05/2021 (H1N1)	18000	100% (3/3)
A/Switzerland/9715293/2013 (H3N2)	24000	100% (3/3)
A/Hong Kong/4801/2014 (H3N2)	24000	100% (3/3)
A/Singapore/INFIMH-16-0019/2016 (H3N2)	24000	100% (3/3)
A/Perth/16/2009 (H3N2)	24000	100% (3/3)
A/Hong Kong/2671/2019 (H3N2)	24000	100% (3/3)
A/Hong Kong/8/1968 (H3N2)	24000 (3x LoD)	67% (2/3)
	32000 (4x LoD)	67% (2/3)
	40000 (5x LoD)	100% (3/3)
A/Cambodia/E0826360/2020 (H3N2)	24000	100% (3/3)
A/Kansas/14/2017 (H3N2)	24000	100% (3/3)
A/Port Chalmers/1/1973 (H3N2)	24000	100% (3/3)
A/Darwin/6/2021 (H3N2)	24000	100% (3/3)
A/Tasmania/503/2020 (H3N2)	24000	100% (3/3)
A/Thailand/08/2022 (H3N2)	24000	100% (3/3)

510(k) Summary

Influenza A Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
A/Texas/50/2012 (H3N2)	24000	100% (3/3)
A/Massachusetts/18/2022 (H3N2)	24000	100% (3/3)
A/swine/Ohio/09SW1484E/2009 (Extracted RNA) (H1N2)	18000	100% (3/3)
A/Anhui/01/2005 (H5N1)	18000	100% (3/3)
A/Egypt/N03072/2010 (H5N1)	18000	100% (3/3)
A/Hubei/1/2010 (H5N1)	18000	100% (3/3)
A/Mallard/Netherlands/12/2000 (H7N7)	18000	100% (3/3)
A/Hong Kong/33982/2009 (H9N2)	18000	100% (3/3)
A/bovine/Ohio.B24OSU-439/2024 gRNA (H5N1)	18000	100% (3/3)

Table 9: LIAISON® NES FLU A/B, RSV & COVID-19 assay Analytical Reactivity – Influenza B

Influenza B Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
B/Brisbane/60/2008 (Victoria)	12000	100% (3/3)
B/Brisbane/33/2008 (Victoria)	12000	100% (3/3)
B/Washington/02/2019 (Victoria)	12000	100% (3/3)
B/Colorado/06/2017 (Victoria)	12000	100% (3/3)
B/Florida/02/2006 (Victoria)	12000	100% (3/3)
B/Malaysia/2506/2004 (Victoria)	12000	100% (3/3)
B/Texas/2/2013 (Victoria)	12000	100% (3/3)
B/Maryland/1/1959 (Lineage unknown)	12000	100% (3/3)

510(k) Summary

Influenza B Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
B/Massachusetts/02/2012 (Yamagata)	15000	100% (3/3)
B/Wisconsin/1/2010 (Yamagata)	15000	100% (3/3)
B/Florida/07/2004 (Yamagata)	15000	100% (3/3)
B/Florida/04/2006 (Yamagata)	15000	100% (3/3)
B/Panama/45/1990 (Yamagata)	15000	100% (3/3)
B/Utah/9/2014 (Yamagata)	15000	100% (3/3)

Table 10: LIAISON® NES FLU A/B, RSV & COVID-19 assay Analytical Reactivity – RSV

RSV Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
RSV-A 1/2015 Isolate 1	24000	100% (3/3)
RSV-A2	24000	100% (3/3)
RSV-A 3/2015 Isolate 3	24000	100% (3/3)
RSV-A 4/2015 Isolate 1	24000	100% (3/3)
RSV-B 9320	24000	100% (3/3)
RSV-B CH93(18)-18	24000	100% (3/3)
RSV-B 3/2015 Isolate 1	24000	100% (3/3)
RSV-B1	24000	100% (3/3)
RSV-B 3/2015 Isolate 2	24000	100% (3/3)

510(k) Summary

Table 11: LIAISON® NES FLU A/B, RSV & COVID-19 assay Analytical Reactivity – SARS-CoV-2

SARS-CoV-2 Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
SARS-CoV-2 Isolate hCoV-19/USA/PHC658/2021 B.1.617.2 (Delta)	3000	100% (3/3)
SARS-CoV-2 Isolate Hong Kong/VM20001061/2020	3000	100% (3/3)
SARS-CoV-2 Isolate hCoV-19/Japan/TY7-503/2021 (Gamma Variant)	3000	100% (3/3)
SARS-CoV-2 Isolate USA/MD-HP24556/2022 BA.2.3 (Omicron)	3000	100% (3/3)
SARS-CoV-2 Isolate South Africa/KRISP-EC-K005325/2020 (B.1.351 South Africa variant)	3000	100% (3/3)
SARS-CoV-2 Isolate England/204820464/2020 B.1.1.7 (UK variant)	3000	100% (3/3)
SARS-CoV-2 USA/CA-Stanford-15_S02/2021 B.1.617.1 (Kappa Variant)	3000	100% (3/3)
SARS-CoV-2 USA/NY-Wadsworth-21025952-01/2021 B.1.526_2021 (Iota Variant)	3000	100% (3/3)
SARS-CoV-2 USA-WI 1/2020 (Lineage B)	3000	100% (3/3)
SARS-CoV-2 NY-Wadsworth-21006055-01/2021 Lineage P2_2021 (Zeta Variant)	3000	100% (3/3)
SARS-Related Coronavirus 2 Isolate hCoV-19/USA/New York/PV96109/2023 (Omicron Variant JN.1)	3000	100% (3/3)
SARS-CoV-2 Isolate USA-CA3/2020	3000	100% (3/3)
SARS-CoV-2 Isolate Germany/BavPat1/2020 (Lineage B)	3000	100% (3/3)
SARS-CoV-2 Isolate USA/CA/VRLC014/2021 PANGO Lineage B.1.429 (Epsilon)	3000	100% (3/3)
SARS-CoV-2 Isolate hCoV-1 9/USA/VA-FBCH_675/2021 PANGO Lineage AY4.2	3000	100% (3/3)
SARS-CoV-2 Isolate SARS-CoV-2 Peru/un-CDC-2-4069945/2021 PANGO Lineage C.37 (Lambda)	3000	100% (3/3)
SARS-CoV-2 isolate hCoV-191 USA/MD-HP38861/2022 PANGO Lineage B.1.1.529, BQ.1.1 (Omicron)	3000	100% (3/3)
	3000 (3x LoD)	67% (2/3)

510(k) Summary

SARS-CoV-2 Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
SARS-CoV-2 Isolate hCoV-19/USA/CA-Stanford-109_S21/2022 PANGO Lineage B.1.1.529, (XBB Omicron)	4000 (4x LoD)	100% (3/3)
SARS-CoV-2 Lineage JN.1.4 Omicron Variant USA/NY-Wadsworth-23068107-01/2023	3000	100% (3/3)

***In silico* Analytical Reactivity/Inclusivity**

An *in silico* inclusivity analysis of the assay oligo sequences in the LIAISON® NES FLU A/B, RSV & COVID-19 assay was performed. All primer and probe sets were aligned against sequences available in the GISAID EpiCoV (as of May 5, 2025), EpiFlu (between January 1, 2012 and May 4, 2025) or EpiRSV (as of May 4, 2025) databases depending on the target. Specifically, 5,641,034 sequences of SARS-CoV-2, 230093 sequences of influenza A, 54413 sequences of influenza B and 22929 sequences of Respiratory Syncytial Virus were aligned. Based on the *in silico* analysis, the LIAISON® NES FLU A/B, RSV & COVID-19 assay exhibits ~100% inclusivity to influenza A, influenza B, SARS-CoV-2 and RSV sequences available in the aforementioned databases.

Cross-Reactivity (Analytical Specificity)

Cross-reactivity of the LIAISON® NES FLU A/B, RSV & COVID-19 assay was evaluated by testing whole microorganisms (or purified nucleic acid from microorganisms) that are closely related, cause similar clinical symptoms, or may be present in the same sample type.

Specimens were prepared by diluting cultured isolates, inactivated organisms, or purified nucleic acids (whole genome) in pooled negative human nasal matrix and spiked onto dry NS. Cross-reactivity was determined based on three replicates. For microorganisms not titered in CFU/mL, copies/mL or $TCID_{50}$/mL, the maximum volume possible was used. Results from cross-reactivity testing are summarized in Table 12. No cross-reactivity was observed with any of the microorganisms tested.

Table 12: LIAISON® NES FLU A/B, RSV & COVID-19 Assay Cross-Reactivity (Analytical Specificity)

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
Bordetella parapertussis	1E6 CFU/mL	0% (0/3)
Bordetella pertussis	1E6 CFU/mL	0% (0/3)
Candida albicans	1E6 CFU/mL	0% (0/3)
Corynebacterium diphtheriae	1E6 CFU/mL	0% (0/3)

510(k) Summary

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
Escherichia coli	1E6 CFU/mL	0% (0/3)
Fusobacterium necrophorum	1E6 CFU/mL	0% (0/3)
Haemophilus influenzae	1E6 CFU/mL	0% (0/3)
Lactobacillus casei	1E6 CFU/mL	0% (0/3)
Legionella pneumophila	1E6 CFU/mL	0% (0/3)
Leptospira interrogans	Quantification not provided by the manufacturer. Maximum testable volume used.	0% (0/3)
Moraxella catarrhalis	1E6 CFU/mL	0% (0/3)
Neisseria elongata	1E6 CFU/mL	0% (0/3)
Neisseria gonorrhoeae	1E6 CFU/mL	0% (0/3)
Neisseria meningitidis	1E6 CFU/mL	0% (0/3)
Pneumocystis jirovecii	1E6 CFU/mL	0% (0/3)
Pseudomonas aeruginosa	1E6 CFU/mL	0% (0/3)
Staphylococcus aureus	1E6 CFU/mL	0% (0/3)
Staphylococcus epidermidis BAA-3171	1E6 CFU/mL	0% (0/3)
Streptococcus pneumoniae	1E6 CFU/mL	0% (0/3)
Streptococcus pyogenes M1	1E6 CFU/mL	0% (0/3)
Streptococcus salivarius	1E6 CFU/mL	0% (0/3)
Aspergillus fumigatus	1E6 copies/mL	0% (0/3)
Chlamydia pneumoniae	1E6 copies/mL	0% (0/3)
Mycobacterium tuberculosis (genomic DNA)	1E6 copies/mL	0% (0/3)
Mycoplasma genitalium	1E6 copies/mL	0% (0/3)

510(k) Summary

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
Mycoplasma pneumoniae	1E6 copies/mL	0% (0/3)
Adenovirus 7A	1E5 $TCID_{50}$/mL	0% (0/3)
Adenovirus Type 31	1E5 $TCID_{50}$/mL	0% (0/3)
CMV AD-169	1E5 $TCID_{50}$/mL	0% (0/3)
Coronavirus 229E	1E5 $TCID_{50}$/mL	0% (0/3)
Coronavirus HKU1 (synthetic RNA)	1E5 genome copies/mL	0% (0/3)
Coronavirus NL63	1E5 $TCID_{50}$/mL	0% (0/3)
Coronavirus OC43	1E5 $TCID_{50}$/mL	0% (0/3)
EBV	1E5 cps/mL	0% (0/3)
Enterovirus Type 68	1E5 $TCID_{50}$/mL	0% (0/3)
hMPV 9	1E5 $TCID_{50}$/mL	0% (0/3)
Influenza C SendaiITU2IO8	1E5 $TCID_{50}$/mL	0% (0/3)
Measles virus	1E5 $TCID_{50}$/mL	0% (0/3)
MERS Coronavirus (Florida/USA-2_Saudi Arabia_2014)	1E5 cps/mL	0% (0/3)
Mumps virus	1E5 $TCID_{50}$/mL	0% (0/3)
Parainfluenza virus Type 1	1E5 $TCID_{50}$/mL	0% (0/3)
Parainfluenza virus Type 2	1E5 $TCID_{50}$/mL	0% (0/3)
Parainfluenza virus Type 3	1E5 $TCID_{50}$/mL	0% (0/3)
Parainfluenza virus Type 4A	1E5 $TCID_{50}$/mL	0% (0/3)
Parechovirus Type 1	1E5 $TCID_{50}$/mL	0% (0/3)
Rhinovirus Type 1A	1E5 $TCID_{50}$/mL	0% (0/3)
SARS Coronavirus	Quantification not provided by the manufacturer. Maximum testable volume used.	0% (0/3)

510(k) Summary

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
Pooled human nasal wash	10%	0% (0/3)

CFU/mL= colony forming units/milliliter

copies/mL= copies/milliliter

$TCID_{50}$/mL= tissue culture infectious dose/milliliter

In silico Cross Reactivity/Exclusivity

The analytical specificity of the LIAISON® NES FLU A/B, RSV & COVID-19 assay was further evaluated with an extended *in silico* analysis to predict potential cross-reactivity of the assay oligos through a BLAST comparison of all primers and probes in the assay to the human reference genome and the GenBank nt sequence database. Based on the *in silico* exclusivity analysis, the assay oligos are predicted to have no cross reactivity to human genome sequences from the *Homo sapiens* reference genome GRCh38.p14. *In silico* assessment of the analyzed potential cross-reactive organisms, with sequences available in the GenBank nt database as of May 3, 2025, predicts potential cross-reactivity for assay oligos of SARS-CoV-2 to some bat coronavirus and bat SARS-like coronavirus strains.

INTERFERING SUBSTANCES

Potentially interfering substances from respiratory specimens were tested for the ability to generate false positive or false negative results. Samples were prepared by: 1) diluting each potentially interfering substance into a baseline sample consisting of pooled negative human nasal matrix and influenza A Darwin/9/21 (H3N2), influenza B Phuket 3073/2013 (Yamagata), SARS-CoV-2 USA/WA 1/2020 or RSV B Isolate 12/2014 at 3X LoD and 2) diluting each potentially interfering substance into a baseline sample consisting of pooled negative human nasal matrix. Prepared test samples were spiked onto dry NS and interference based on three replicates was determined. The results are shown in Table 13 and Table 14.

Remdesivir at a concentration of 0.1 mg/mL showed a negative result in one out of the three replicates for RSV. The replicates were retested at a lower concentration of 0.05 mg/mL and no interference was observed for RSV. No other substances tested in Table 12 showed any interference with the detection of SARS-CoV-2, influenza A or influenza B at the concentrations tested. No interference was observed for negative samples.

510(k) Summary

Table 13: LIAISON® NES FLU A/B, RSV & COVID-19 assay Interference for Positive Sample

Potentially Interfering Substances	Active Ingredient	Interferent Concentration	Influenza A	Influenza B	SARS-CoV-2	RSV
			% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)
Afrin Nasal Spray	Oxymetazoline	15% (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Antibacterial, systemic	Tobramycin	0.004 mg/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Antibiotic, nasal ointment	Mupirocin	6.6 mg/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Blood	N/A	2% (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Purified Mucin Protein	Bovine submaxillary gland mucin, type I-S	5 mg/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Nasal corticosteroid (Beconase AQ)	Beclomethasone	5% (w/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
	Dexamethasone	5% (w/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
	Mometasone	5% (w/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Nasal corticosteroid (Fluticasone)	Fluticasone	5% (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Tamiflu Antiviral drug	Oseltamivir	0.001 mM	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Zicam Nasal Gel	*Luffa operculata*, *Galphimia glauca*, histaminum hydrochloricum	5 % (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Budesonide	Budesonide	5% (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Flunisolide	Flunisolide	5% (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Relenza Antiviral Drug	Zanamivir	3.3 mg/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Throat lozenges	*Avena sativa,* Zinc gluconate, *Sambucus nigra*, Echinacea, Rose hips, Licorice root	1.25% (w/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Remdesivir	Remdesivir	0.1 mg/mL	100% (3/3)	100% (3/3)	100% (3/3)	67% (2/3)
		0.05 mg/mL	N/A	N/A	N/A	100% (3/3)
Neo-Synephrine nasal spray	Phenylephrine hydrochloride	15% (v/v)	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)

mg/mL= milligram/milliliter
v/v= volume *per* volume
w/v= weight *per* volume
mM= millimolar

510(k) Summary

Table 14: LIAISON® NES FLU A/B, RSV & COVID-19 Assay Interference for Negative Sample

Potentially Interfering Substances	Active Ingredient	Interferent Concentration	Influenza A	Influenza B	SARS-CoV-2	RSV	IC
			% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)
Afrin Nasal Spray	Oxymetazoline	15% (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Antibacterial, systemic	Tobramycin	0.004 mg/mL	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Antibiotic, nasal ointment	Mupirocin	6.6 mg/mL	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Blood	N/A	2% (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Purified Mucin Protein	Bovine submaxillary gland mucin, type I-S	5 mg/mL	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Nasal corticosteroid (Beconase AQ)	Beclomethasone	5% (w/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
	Dexamethasone	5% (w/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
	Mometasone	5% (w/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Nasal corticosteroid (Fluticasone)	Fluticasone	5% (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Tamiflu Antiviral drug	Oseltamivir	0.001 mM	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Zicam Nasal Gel	*Luffa operculata*, *Galphimia glauca*, histaminum hydrochloricum	5 % (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Budesonide	Budesonide	5% (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Flunisolide	Flunisolide	5% (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Relenza Antiviral Drug	Zanamivir	3.3 mg/mL	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Throat lozenges	*Avena sativa,* Zinc gluconate, *Sambucus nigra*, Echinacea, Rose hips, Licorice root	1.25% (w/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Remdesivir	Remdesivir	0.1 mg/mL	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
		0.05 mg/mL	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)
Neo-Synephrine nasal spray	Phenylephrine hydrochloride	15% (v/v)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	100% (3/3)

mg/mL= milligram/milliliter
v/v= volume *per* volume
w/v= weight *per* volume
mM= millimolar
IC = Internal Control

510(k) Summary

COMPETITIVE INTERFERENCE

Competitive Interference was performed to assess the ability of the assay to detect a low concentration of one (1) target analyte in the presence of a high concentration of another target analyte. Samples were prepared by diluting one (1) assay target analyte at a low concentration (3X LoD) into pooled negative human nasal matrix in the presence of a high concentration (1000X LoD) of one (1) of the other three (3) assay target analytes. Prepared specimens were spiked onto dry NS and tested in triplicate. The results are shown in Table 15. All the combinations tested showed no competitive interference for the detection of low concentrations of influenza A, influenza B, SARS-CoV-2 or RSV in the presence of high concentrations of another assay target analyte.

Table 15: LIAISON® NES FLU A/B, RSV & COVID-19 Assay Competitive Interference

Low Positive Baseline Sample		Competitive Interferent		Agreement with Expected Results: % Detection (#Detected/#Total)			
Strain	Copies/ swab	Strain	Copies/ swab	Influenza A	Influenza B	SARS-CoV-2	RSV
Influenza A Victoria/4897/2022	18000	Influenza B Austria/1359417/2021	4E6	100% (3/3)	100% (3/3)	0% (0/3)	0% (0/3)
		SARS-CoV-2 USA/MDHP20874/2021	1E6	100% (3/3)	0% (0/3)	100% (3/3)	0% (0/3)
		Respiratory Syncytial Virus A 2006 Isolate	8E6	100% (3/3)	0% (0/3)	0% (0/3)	100% (3/3)
Influenza B Austria/1359417/ 2021	12000	Influenza A Victoria/4897/2022	6E6	100% (3/3)	100% (3/3)	0% (0/3)	0% (0/3)
		SARS-CoV-2 USA/MDHP20874/2021	1E6	0% (0/3)	100% (3/3)	100% (3/3)	0% (0/3)
		Respiratory Syncytial Virus A 2006 Isolate	8E6	0% (0/3)	100% (3/3)	0% (0/3)	100% (3/3)
SARS-CoV-2 USA/MDHP20874/ 2021	3000	Influenza A Victoria/4897/2022	6E6	100% (3/3)	0% (0/3)	100% (3/3)	0% (0/3)
		Influenza B Austria/1359417/2021	4E6	0% (0/3)	100% (3/3)	100% (3/3)	0% (0/3)
		Respiratory Syncytial Virus A 2006 Isolate	8E6	0% (0/3)	0% (0/3)	100% (3/3)	100% (3/3)
Respiratory Syncytial Virus A 2006 Isolate	24000	Influenza A Victoria/4897/2022	6E6	100% (3/3)	0% (0/3)	0% (0/3)	100% (3/3)
		Influenza B Austria/1359417/2021	4E6	0% (0/3)	100% (3/3)	0% (0/3)	100% (3/3)
		SARS-CoV-2 USA/MDHP20874/2021	1E6	0% (0/3)	0% (0/3)	100% (3/3)	100% (3/3)

510(k) Summary

INHIBITION BY OTHER MICROORGANISMS

The LIAISON® NES FLU A/B, RSV & COVID-19 assay was evaluated by testing the ability to detect a low concentration of SARS-CoV-2, influenza A, influenza B, and RSV when other potentially inhibitory microorganisms were present. Specimens were prepared by diluting the potentially inhibitory cultured isolates, inactivated organisms or purified nucleic acids (whole genome) into pooled negative human nasal matrix in the presence of a low concentration (3X LoD) of either influenza A Darwin/9/21 (H3N2), influenza B Phuket 3073/2013 (Yamagata), RSV B Isolate 12/2014 or SARS-CoV-2 USA/WA 1/2020. Forty-eight (48) potentially inhibitory microorganisms were individually spiked and tested in triplicate. For organisms not titered in CFU/mL or $TCID_{50}$/mL, the maximum volume possible was used.

Staphylococcus aureus and Parainfluenza Virus Type 1 at a high concentration of 1E6 CFU/mL and 1E5 $TCID_{50}$/mL, respectively, produced a negative result in one (1) out of three (3) replicates for influenza B. A lower concentration of these microorganisms (*Staphylococcus aureus* at 3.13E5 CFU/mL and Parainfluenza Virus Type 1 at 3.13E4 $TCID_{50}$/mL) were tested and no interference was observed. No inhibition by other organisms was observed for SARS-CoV-2, influenza A, influenza B or RSV at the concentrations indicated in Table 16.

Table 16: LIAISON® NES FLU A/B, RSV & COVID-19 Assay Microbial Inhibition

Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)			
		Influenza A	Influenza B	SARS-CoV-2	RSV
Bordetella parapertussis	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Bordetella pertussis	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Candida albicans	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Corynebacterium diphtheriae	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Escherichia coli	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Fusobacterium necrophorum	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Haemophilus influenzae	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Lactobacillus casei	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Legionella pneumophila	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Leptospira interrogans	Quantification not provided by the manufacturer.	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)

510(k) Summary

Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)			
		Influenza A	Influenza B	SARS-CoV-2	RSV
	Maximum testable volume used.				
Moraxella catarrhalis	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Neisseria elongata	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Neisseria gonorrhoeae	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Neisseria meningitidis	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Pneumocystis jirovecii	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Pseudomonas aeruginosa	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Staphylococcus aureus	1E6 CFU/mL	100% (3/3)	0% (0/3)	100% (3/3)	100% (3/3)
	3.13E5 CFU/mL	N/A	100% (3/3)	N/A	N/A
Staphylococcus epidermidis BAA-3171	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Streptococcus pneumoniae	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Streptococcus pyogenes M1	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Streptococcus salivarius	1E6 CFU/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Aspergillus fumigatus	1E6 copies/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Chlamydia pneumoniae	1E6 copies/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Mycobacterium tuberculosis (genomic DNA)	1E6 copies/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Mycoplasma genitalium	1E6 copies/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Mycoplasma pneumoniae	1E6 copies/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Adenovirus 7A	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Adenovirus Type 31	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
CMV AD-169	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)

510(k) Summary

Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)			
		Influenza A	Influenza B	SARS-CoV-2	RSV
Coronavirus 229E	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Coronavirus HKU1 (synthetic RNA)	1E5 genome copies/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Coronavirus NL63	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Coronavirus OC43	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
EBV	1E5 cps/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Enterovirus Type 68	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
hMPV 9	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Influenza C SendaiITU2IO8	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Measles virus	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
MERS Coronavirus (Florida/USA-2_Saudi Arabia_2014)	1E5 cps/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Mumps virus	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Parainfluenza virus Type 1	1E5 $TCID_{50}$/mL	100% (3/3)	33% (1/3)	100% (3/3)	100% (3/3)
	3.13E4 $TCID_{50}$/mL	N/A	100% (3/3)	N/A	N/A
Parainfluenza virus Type 2	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Parainfluenza virus Type 3	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Parainfluenza virus Type 4A	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Parechovirus Type 1	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
SARS Coronavirus	Quantification not provided by the manufacturer. Maximum testable volume used.	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)

510(k) Summary

Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)			
		Influenza A	Influenza B	SARS-CoV-2	RSV
Rhinovirus Type 1A	1E5 $TCID_{50}$/mL	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
Pooled human nasal wash	10%	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)

CFU/mL= colony forming units/milliliter

Cps/mL= copies/milliliter

$TCID_{50}$/mL= tissue culture infectious dose/milliliter

CARRY-OVER CONTAMINATION

Amplification carry-over and cross-contamination for the LIAISON® NES FLU A/B, RSV & COVID-19 assay has been assessed. The study was designed by processing the samples alternating between highly positive and negative samples. High Positive (HP) samples were formulated by spiking SARS-CoV-2 USA/MDHP20874/2021 in pooled negative human nasal matrix onto dry NS at a final concentration of 1000X LoD (1E8 copies/mL). Pooled negative nasal matrix onto dry NS was used as negative sample. The same alternating order was maintained when loading the corresponding cartridges into the instruments. No evidence of carry-over contamination was observed.

ASSAY CUT-OFF

For each channel, the respective target is detected if (1) the fluorescence signal crosses the fluorescence threshold, and (2) the cycle at which it crosses is at/before the last cycle (the Ct threshold, 45 cycles).

MATRIX COMPARISON

Not applicable

O. Proposed Labeling:

The labeling provided in the submission satisfies the requirements of 21 CFR 809.10.

P. Conclusion:

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