LIAISON NES®

Diasorin

LIAISON NES® FLU A/B, RSV & COVID-19

Instructions for Use



REF NES4450

IVD

Rx Only

For In Vitro Diagnostic Use.

CLIA Complexity: WAIVED*

* This statement only applies to customers within the United States:

For use with anterior nasal swab specimens.

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA Waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA Waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.

Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

INTENDED USE

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.

SUMMARY AND EXPLANATION

The LIAISON NES® FLU A/B, RSV & COVID-19 assay is a real-time RT-PCR test used on the patented LIAISON NES® instrument to detect influenza A, influenza B, RSV, and SARS-CoV-2 viruses in dry anterior nasal swabs (ANS). The LIAISON NES® system is capable of processing biological samples and performing nucleic acid amplification, with fluorometric detection of the resulting amplified products.

Influenza A and B (flu A and B) are highly contagious, acute viral infections of the respiratory tract. The influenza viral pathogens are transmitted from person to person primarily by aerosolized virus-containing droplets. The influenza season typically spans from November through April in the Northern Hemisphere and from May to September in the Southern Hemisphere. Infections occur in all age groups and cause significant health and financial concerns worldwide. The duration of illness is typically 2-5 days, but symptoms may last for a week or longer.[1,2,3]

RSV infection is more prevalent in infants and toddlers and is a leading cause of hospitalization for this age group, but RSV also causes disease in adults that can be severe in certain populations. In

infants and young children, RSV disease can range from a cold-like illness, bronchitis or croup to lower respiratory infections such as bronchiolitis and pneumonia. In adults, symptomatic infection usually presents as an upper respiratory tract illness with a runny nose (rhinorrhea), sore throat (pharyngitis), and cough, with some patients also complaining of headache, fatigue, and fever. High-risk adults, such as those with certain chronic illnesses or immunosuppression, may have more severe diseases such as pneumonia.[4]

COVID-19 (coronavirus disease 2019) is a disease caused by the SARS-CoV-2 virus and was discovered in December 2019 in Wuhan, China. It is very contagious, causes severe respiratory illness with high rates of morbidity and mortality, and has quickly spread around the world, being consequently declared a pandemic by the World Health Organization (WHO).[5,6,7,8] Patients with COVID-19 suffer mild to severe respiratory illness with symptoms of fever, cough, shortness of breath, and complications including pneumonia.[9]

PRINCIPLES OF THE PROCEDURE

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 anterior nasal swabs. Anterior 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.

MATERIALS PROVIDED

The LIAISON NES® FLU A/B, RSV & COVID-19 (NES4450) assay box contains the following:

- (10) pouched LIAISON NES® FLU A/B, RSV & COVID-19 Cartridges (NES4451)
- (10) NES Swab tubes for sample collection (NES4001)
- (10) pouched NES Sample Vials, each containing one foil sealed vial with buffer and one cap (NES1502)
- (1) Printed copy of the Patient Test Quick Reference Guide
- (1) Printed copy of the Nasal swab self-collect Quick Reference Guide

MATERIALS REQUIRED BUT NOT PROVIDED

- LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit (NES4460) containing:
  - (10) LIAISON NES® FLU A/B, RSV & COVID-19 Positive Control Swab (NES4461)
  - (10) LIAISON NES® FLU A/B, RSV & COVID-19 Negative Control Swab (NES4462)
- Disposable, powder-free nitrile gloves
- Biohazard waste container
- LIAISON NES® instrument (NES1001)

ASSAY DESCRIPTION

The LIAISON NES® FLU A/B, RSV & COVID-19 assay contains 10 individually wrapped cartridges. Each Cartridge can be used to run a single test. Upon receipt, store all components at the temperature range indicated on the label. Each cartridge contains sufficient material for a single reaction. The cartridge must be used within 2 hours from the opening of the pouch.

Component Name	REF	Number/Kit	Number Needed to Perform One Test
LIAISON NES® FLU A/B, RSV & COVID-19 Cartridge	NES4451	10	1
NES Sample Vial	NES1502	10	1
NES Swab	NES4001	10	1

COMPONENT DESCRIPTION

Assay Component	Content
LIAISON NES® FLU A/B, RSV & COVID-19 Cartridge	DNA polymerase, reverse transcriptase, RNase inhibitor, buffers, dNTPs, encapsulated RNA (internal control) template, dye-labeled fluorescent probes and primers specific for influenza A, influenza B, SARS-CoV-2, RSV, and RNA internal control detection.
NES Sample Vial	Working solution containing rinsing buffer (≥0.1mM of salts diluted in approximately 1xTE buffer)
NES Swab	Sterile swab

REAGENT HANDLING AND STORAGE

1. Store LIAISON NES® FLU A/B, RSV & COVID-19 assay box containing test cartridges, nasal swab tubes, and sample vials at the temperature range indicated on the label.
2. Store the assay box away from sunlight.
3. Do not refrigerate or freeze the test cartridges, nasal swabs, and/or sample vials.
4. Do not use assay or test cartridges beyond their expiration dates.
5. After opening the test cartridge from the pouch, use it within 2 hours (120 minutes). Perform the test immediately after preparing the cartridge.

WARNINGS AND PRECAUTIONS

1. Do not open the cartridge pouch until ready to use.
2. Consult the LIAISON NES® User Manual for additional warnings, precautions, and procedures related to the operation of the LIAISON NES® instrument.
3. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents and equipment. Thoroughly wash your hands after completing the test.
4. Treat all human specimens and cartridges as potentially capable of transmitting infectious agents.
5. Do not smoke, drink, eat, handle contact lenses, or apply make-up in areas where kit reagents and/or human specimens are handled.
6. Dispose of used test cartridges, used sample vials, used swabs, and other collected specimens according to local, state, and federal regulations.
7. Contamination of patient samples or reagents can produce erroneous results. Handle samples and reagents according to standard laboratory practices.[10,11]
8. The test should be performed at room temperature (Store all components at the temperature range indicated on the label).
9. Avoid touching, scratching, or tampering with the underside foil on the cartridge. Avoid scratching or tampering with the cartridge wells and reagents located on the bottom of the cartridge. Only open the cap to input the specimen. Do not attempt to break open the cartridge.
10. Before inserting a prepared cartridge (with sample loaded) into the instrument, fully close the cartridge cap.
11. Upon inhalation or skin contact with the reagents, first aid measures should be taken.
12. Refer to the Safety Data Sheet (SDS) of the product for additional information regarding emergency response and exposure measures.
13. Use only the intended sample vial provided in the kit to dispense specimen into the cartridge sample port.
14. Do not use kit or contents if kit packaging or contents appear broken or damaged. Contact our technical support team at (800) 838-4548.

15. Viral culture should not be attempted in cases of positive results for SARS-CoV-2 and/or any similar microbial agents unless a facility with an appropriate level of biosafety (e.g., BSL-3 and BSL-3+, etc.) is available to receive and culture specimens.

INSTRUCTIONS FOR USE

To run a patient sample, please follow Instructions A and B as detailed below.

To run Quality Controls, please follow Instruction C.

In case of the first use of this device, Quality Controls (**positive and negative controls**) must be run as a first step, before proceeding with the test of a patient sample.

A. Sample Collection, Storage, and Transportation

Nasal swab must be collected using the NES Swab provided with the kit. The nasal swab can either be professionally collected by a healthcare provider or self-collected by the patient under the supervision of a healthcare provider. Follow the CDC Guidelines[12] for collection of an anterior nasal swab specimen or follow the instructions provided below.

⚠ *Read the entire LIAISON NES® FLU A/B, RSV & COVID-19 instructions for use (this document) before starting patient sample collection.*

Sample Collection:

1. Disinfect the surface where the procedure will be performed. Remove and lay out the contents of the LIAISON NES® FLU A/B, RSV & COVID-19 Kit.
2. Wash hands with soap and water. If soap and water are unavailable, use hand sanitizer to disinfect hands.
3. When collecting the sample from a patient, wear powder-free nitrile gloves.
4. Remove the NES Swab from the package. Ensure swab head does not come into contact with gloves or work surfaces.
5. Carefully insert the nasal swab head into the patient's nostril approximately 1 inch.
6. Gently rotate the swab five (5) times against the nasal wall for approximately 15 seconds.
7. Using the same swab, repeat steps 5 – 6 in the other nostril.

Sample Storage:

The sample, once collected, can be stored inside the swab tube at room temperature. Samples must be processed within 2 hours from collection.

Sample Transportation:

The sample can be transported inside the swab tube at room temperature.

B. Test Procedure *(refer to the quick reference guide provided with the kit for a pictorial depiction of the test procedure).*

1. Take a LIAISON NES® cartridge from a single test box and open the sample port.
2. Take a NES pre-filled sample vial from a single test box and remove the foil seal to open it.

   ⚠ *If any liquid spills or if a vial is leaking – DO NOT USE. Use a new sample vial.*

3. Insert the NES Swab used to collect the patient's sample into the sample vial and rotate the swab **ten (10) times while squeezing** the swab head.
4. After rotation, break the swab shaft at the red mark by snapping along the rim of the sample vial. *(Refer to the quick reference provided with the kit for a pictorial depiction.)*
5. Twist the blue cap onto the sample vial with the swab head inside.

   ⚠ *Dispose swab handle into biohazardous waste.*

6. Unscrew the clear nozzle cap of the sample vial.

   ⚠ *Place the cartridge on a hard, flat surface and keep level*.

7. Insert tip of the sample vial into the LIAISON NES® Cartridge sample port.
8. Firmly squeeze the sample vial to dispense ALL the liquid.

   ⚠ *Failure to transfer ALL the liquid into the cartridge can cause invalid results.*

9. Carefully remove the sample vial and close the cartridge securely.

   ⚠ *Dispose sample vial and clear nozzle cap into biohazard waste*.

   ⚠ *Keep cartridge upright - do not tilt or shake. Perform the test immediately.*

10. Log into the LIAISON NES® instrument.
11. Scan the patient ID barcode using the 'Barcode Scanning Window' on the LIAISON NES® instrument, or, alternatively, enter the patient's information manually. The door will open automatically.
12. Ensure the cartridge is labeled with the sample ID.
13. Insert the LIAISON NES® test cartridge fully into the LIAISON NES® instrument with specimen port facing outwards. *(Refer to the quick reference guide provided with this kit for a pictorial depiction.)*
14. Fully close the LIAISON NES® instrument door.
15. Run the test following on-screen instructions.
16. The door will automatically open when the test run is completed. Remove and dispose of the cartridge into the biohazard waste.
17. Close the door to view the test results.

C. Run Positive and Negative Quality Controls

LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit (Part Number: NES4460) is needed to perform a quality control test.

1. The LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit contains positive and negative control swabs. Follow the test procedure (instructions B described above) by using the positive or negative control swab instead of the NES Swab to successfully complete a quality control test.
2. Refer to the instructions for use documentation provided with the LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit.

RESULT INTERPRETATION

Upon completion of a test run, results will display automatically.

Results	Interpretation
Positive	Result indicates the presence of Flu A and/or Flu B and/or RSV and/or SARS-CoV-2 in the patient sample.
Negative	Result indicates the absence of Flu A and/or Flu B and/or RSV and/or SARS-CoV-2 in the patient sample.
Invalid	Result indicates an inability to conclusively determine the presence or absence of Flu A and/or Flu B and/or RSV and/or SARS-CoV-2 in the patient sample. Collect a fresh sample and re-test with a new test cartridge from the same kit or a new kit. If the problem persists, contact our Technical Support Team at our toll-free number (800) 838-4548.

The results are automatically uploaded to the Diasorin cloud (if connected), LIS (if connected), or can be saved as a pdf on the USB key. Refer to the LIAISON NES® User Manual for additional details.

Results can be wirelessly printed to any printer connected within the network. Consult the LIAISON NES® User Manual to set up a printer.

INSTRUMENT ERRORS

In case of instrument errors, please refer to the LIAISON NES® instrument User Manual.

LIMITATIONS

1. For in vitro diagnostic use only.
2. For prescription use only.
3. This product can be used only with the LIAISON NES® System.

4. The detection of viral nucleic acid is dependent upon proper sample collection, transport, handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
5. A negative test does not preclude the possibility of infection. False-negative results may occur if the viruses are present at a level that is below the analytical sensitivity of the assay or if the virus has genomic mutations, insertions, deletions, or rearrangements or if the test is performed very early in the course of illness.
6. This test is a qualitative test and does not provide the quantitative value of detected virus present.
7. This test has been designed to detect influenza A, influenza B, RSV, and SARS-CoV-2. This test does not detect other viral, fungal, or bacterial pathogens.
8. The test results should be interpreted in conjunction with other clinical and laboratory data available to the clinician.
9. The performance of this test has not been established for immunocompromised individuals.
10. The performance of this test has not been established for patients without symptoms of viral respiratory tract infection.
11. The performance of this test has not been established for monitoring the treatment of influenza A, influenza B, RSV, or SARS-CoV-2 infection.
12. The performance of this test has not been established for individuals who have received an inhaled influenza vaccine.
13. The performance of this test has not been established for use in donor screening tests.
14. This test is designed for use with freshly collected anterior nasal swab samples.
15. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2, influenza A, influenza B and RSV and their prevalence, which change over time.
16. The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described may lead to erroneous results.
17. The performance of this test has not been established for screening blood or blood products for the presence of influenza A, influenza B, RSV, or SARS-CoV-2 or for use with samples other than anterior nasal swab (ANS) specimens.
18. Inhibition of Flu B detection was observed with *Staphylococcus aureus* tested at 1E6 CFU/mL. No inhibition was observed when a lower concentration of 3.13E5 CFU/mL was tested.
19. Inhibition of Flu B detection was observed with Parainfluenza Virus Type 1 tested at 1E5 TCID50/mL. No inhibition was observed when a lower concentration of 3.31E4 TCID50/mL was tested.
20. Positive and negative predictive values are highly dependent on prevalence. The likelihood of a negative result being false is higher during peak activity when prevalence of disease is high. The likelihood of a positive result being false is higher during periods when prevalence is moderate to low.
21. Performance characteristics for Influenza A were established during the 2024-2025 influenza seasons when Influenza A/H1 and A/H3 were predominant. When other influenza A viruses are emerging, performance characteristics may differ.
22. This test does not differentiate influenza A subtypes (i.e., H1N1, H3N2); additional testing is required to differentiate any specific influenza A subtypes or strains, in consultation with local public health departments.

23. This test is not intended for the detection of influenza C virus infections.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

LIAISON NES® FLU A/B, RSV & COVID-19 Assay positive results (expected values) for each individual target are summarized for specimens included in the prospective study analysis per site and per age group in Table 1 and Table 2.

Table 1. Expected Values for Prospective Specimens by site (N=1571)

	Site 1 (N = 355)		Site 2 (N = 301)		Site 3 (N = 189)		Site 4 (N = 75)		Site 5 (N = 213)		Site 6 (N = 205)		Site 13 (N = 233)		Total (N = 1571)	
Target	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**
Influenza A	78	22.0% (78/355)	58	19.3% (58/301)	81	42.9% (81/189)	10	13.3% (10/75)	76	35.7% (76/213)	57	27.8% (57/205)	57	24.5% (57/233)	417	26.5% (417/1571)
Influenza B	7	2.0% (7/355)	18	6.0% (18/301)	2	1.1% (2/189)	0	0.0% (0/75)	3	1.4% (3/213)	5	2.4% (5/205)	4	1.7% (4/233)	39	2.5% (39/1571)
RSV	35	9.9% (35/355)	14	4.7% (14/301)	12	6.3% (12/189)	2	2.7% (2/75)	6	2.8% (6/213)	16	7.8% (16/205)	20	8.6% (20/233)	105	6.7% (105/1571)
COVID-19	4	1.1% (4/355)	14	4.7% (14/301)	10	5.3% (10/189)	9	12.0% (9/75)	9	4.2% (9/213)	15	7.3% (15/205)	11	4.7% (11/233)	72	4.6% (72/1571)

Table 2. Expected Values for Prospective Specimens by age (N=1571)

	0-1 Years (N=145)		2-5 Years (N=246)		6-21 Years (N=679)		22-65 Years (N=439)		>65 Years (N=62)		Overall (N=1571)	
Target	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**	**#Pos**	**(%)**
Influenza A	31	21.4% (31/145)	81	32.9% (81/246)	184	27.1% (184/679)	106	24.1% (106/439)	15	24.2% (15/62)	417	26.5% (417/1571)
Influenza B	0	0.0% (0/145)	4	1.6% (4/246)	29	4.3% (29/679)	6	1.4% (6/439)	0	0.0% (0/62)	39	2.5% (39/1571)
RSV	23	15.9% (23/145)	41	16.7% (41/246)	29	4.3% (29/679)	6	1.4% (6/439)	6	9.7% (6/62)	105	6.7% (105/1571)
COVID-19	8	5.5% (8/145)	4	1.6% (4/246)	23	3.4% (23/679)	30	6.8% (30/439)	7	11.3% (7/62)	72	4.6% (72/1571)

LIAISON NES® FLU A/B, RSV & COVID-19 Assay reported multiple virus detections in a total of 10 prospective specimens. This represents 1.6% (10/623) of positive prospective specimens and 0.6% (10/1571) of all prospective specimens. All coinfections (100%, 10/10) contained two viruses. Of the 10 specimens with multiple virus detections, 50% (5/10) were concordant with the reference methods and 50% (5/10) contained one or more viruses that were not detected by the reference/comparator methods.

LIAISON NES® FLU A/B, RSV & COVID-19 Assay expected values for observed co-infection combinations are presented per age group in Table 3.

Table 3. Expected Values for Observed Co-infection Combinations 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 Years (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% (1/69)	1	0.23% (1/439)	1	1.61% (1/62)	6	0.38% (6/1571)

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).

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 4.

Table 4. 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 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.

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 5. Reproducibility Panel Member Details

Panel Member		Strain	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)	Darwin/9/21	2X LoD	2	32	96
2	Influenza B Low Positive (LP)	Phuket 3073/2013	2X LoD	2	32	96
3	RSV Low Positive (LP)	RSV B 12/2014 Isolate 1	2X LoD	2	32	96
4	SARS-CoV-2 Low Positive (LP)	USA/WA 1/2020	2X LoD	2	32	96
5	Influenza A Moderate Positive (MP)	Darwin/9/21	5X LoD	2	32	96
6	Influenza B Moderate Positive (MP)	Phuket 3073/2013	5X LoD	2	32	96
7	RSV Moderate Positive (MP)	RSV B 12/2014 Isolate 1	5X LoD	2	32	96
8	SARS-CoV-2 Moderate Positive (MP)	USA/WA 1/2020	5X LoD	2	32	96
9	NTC – Pooled Negative Human Nasal Matrix	NA	NA	2	32	96
10	PC - LIAISON NES® FLU A/B, RSV & COVID-19 Positive Control Swab (PC)	NA	5-10X LoD	2	32	96
				20	**320**	**960**

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

Table 6. 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%

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
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 7. 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

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 8.

Table 8. 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
RSV 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 9.

Table 9. 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 10-13 below (corresponding to 3X LoD) and tested in triplicate. The results are shown in Tables 10-13. 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 10. 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)
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)

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 11. 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)
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 12. 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)

Table 13. 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 Strain	Tested Concentration (copies/swab)	Agreement with Expected Results: %Detection (#Detected/#Total)
SARS-CoV-2 isolate hCoV-191 USA/MD-HP38861/2022 PANGO Lineage B.1.1.529, BQ.1.1 (Omicron)	3000	100% (3/3)
SARS-CoV-2 Isolate hCoV-19/USA/CA-Stanford - 109_S21/2022 PANGO Lineage B.1.1.529, (XBB Omicron)	3000 (3x LoD)	67% (2/3)
	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 14. No cross-reactivity was observed with any of the microorganisms tested.

Table 14: 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)
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)

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
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)
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)

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
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)
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 15 and Table 16.

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 15 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.

Table 15: 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

Table 16: 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)
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

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 17. 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 17: 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)

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 18.

Table 18: 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. Maximum testable volume used.	100% (3/3)	100% (3/3)	100% (3/3)	100% (3/3)
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)

Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)			
		Influenza A	Influenza B	SARS-CoV-2	RSV
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)
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)

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 AND CROSS-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.

FLEX STUDIES

Flex studies were performed to evaluate the robustness of the LIAISON NES® FLU A/B, RSV & COVID-19 assay. Variations in workflow and operating environment that may reasonably be expected to occur with untrained operators in the intended use CLIA-waived setting were evaluated. Results of the flex studies conducted demonstrate robust performance of the LIAISON NES® FLU A/B, RSV & COVID-19 assay under conditions of stress.

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GLOSSARY*

	Caution, consult accompanying documents		Telephone
	Consult instructions for use	IVD	In vitro diagnostic medical device
	Biological risk	REF	Catalog number
	Contains sufficient for <n> tests	MD	Medical Device
	Temperature limitation	LOT	Batch code
	Manufacturer	CONT	Kit contents
	Use by	Rx Only	Prescription only
	Do not reuse		Keep Dry
	Keep away from sunlight	STERILE EO	Sterilized using ethylene oxide
	Do not use if package is damaged		Do not resterilize
	Single sterile barrier system		Date of manufacture
SN	Serial number		

*ISO 15223-1

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If you experience any technical issues or concerns, please contact our Technical Support Team at our toll-free number (800) 838-4548.

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