June 15, 2026

Diasorin Molecular, LLC
Kate Goscha
Senior Manager, Regulatory Affairs
11331 Valley View St.
Cypress, California 90630

Re: K260333
Trade/Device Name: LIAISON NES Group A Strep; LIAISON NES Group A Strep Control Swab Kit
Regulation Number: 21 CFR 21 CFR 866.2680
Regulation Name: Streptococcus spp. nucleic
Regulatory Class: Class II
Product Code: PGX, OOI
Dated: February 2, 2026
Received: February 2, 2026

Dear Kate Goscha:

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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 21 .9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 21 .9.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
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)*
K260333

Device Name
LIAISON NES Group A Strep ;
LIAISON NES Group A Strep Control Swab Kit

Indications for Use *(Describe)*

LIAISON NES Group A Strep :

LIAISON NES Group A Strep is a real-time PCR assay intended for use on the LIAISON NES instrument for the in vitro qualitative detection of Streptococcus pyogenes, Group A Streptococcus (GAS) bacterial nucleic acid in throat swab specimens freshly collected from human patients with signs and symptoms of pharyngitis. This test is intended for use as an aid in the rapid diagnosis of Group A Streptococcus bacterial infections.

LIAISON NES Group A Strep Control Swab Kit :

The LIAISON NES Group A Strep Control Swab Kit is intended to be used as positive and negative controls with the LIAISON NES Group A Strep assay for use on the LIAISON NES instrument. These controls are not intended for use with other assays or systems.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

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

A. 510(k) Number:

K260333

B. Purpose of Submission:

Dual 510(k) and
CLIA Waiver Application

C. Measurand:

Group A *Streptococcus* bacterial nucleic acid

D. Type of Test:

Qualitative Real Time Polymerase Chain Reaction (RT-PCR)

E. Applicant:

Kate Goscha
Diasorin Molecular LLC
11331 Valley View Street
Cypress, CA 90630

F. Proprietary and Established Names:

LIAISON NES® Group A Strep
LIAISON NES® Group A Strep Control Swab Kit

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
PGX	II	21 CFR 866.2680 – *Streptococcus* spp. nucleic acid-based assay	Microbiology
OOI	Class II	21 CFR 862.2570 – Instrumentation for clinical multiplex test systems	CH - Clinical Chemistry

H. Intended Use:

510(k) Summary

1. Intended Use(s):

LIAISON NES® Group A Strep is a real-time PCR assay intended for use on the LIAISON NES® instrument for the in vitro qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* (GAS) bacterial nucleic acid in throat swab specimens freshly collected from human patients with signs and symptoms of pharyngitis. This test is intended for use as an aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections.

The LIAISON NES® Group A Strep Control Swab Kit is intended to be used as positive and negative controls with the LIAISON NES® Group A Strep assay for use on the LIAISON NES® instrument. These controls are not intended for use with other assays or systems.

2. Indications for user:

Same as intended use.

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.

510(k) Summary

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® Group A Strep assay used on the LIAISON NES® instrument is a real-time PCR system that enables the direct amplification and detection of Group A *Streptococcus* bacterial nucleic acid in throat swab specimens.

The LIAISON NES® Group A Strep assay consists of the LIAISON NES® instrument, LIAISON NES® Group A Strep Cartridge containing all the required PCR reagents, NES Sample Vial containing working solution, and NES Swab for throat sample collection.

Following collection, the throat swab is placed into the NES Sample Vial. The sample is released into the working solution, and the entire contents of the vial are transferred into the LIAISON NES® Group A Strep Cartridge.

In the LIAISON NES® Group A Strep assay, dye-labeled fluorescent probes and primers amplify and detect Group A *Streptococcus* bacterial DNA and internal control (IC) DNA. Conserved regions of Group A *Streptococcus* genome are targeted to identify the bacteria in the specimen, while the internal control (IC) DNA is used to detect any PCR failures and/or inhibition.

J. Substanial Equivalence Information:

1. Predicate device name(s):

   Simplexa™ Group A Strep Direct

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

   K143651

3. Comparison with predicate:

   The following table compares the similarities and differences between the LIAISON® NES Group A Strep assay and the Simplexa™ Group A Strep Direct assay (K143651).

Device & Predicate Device:	**Predicate Device: (K143651)**	**Device K260333**
Device Trade Name	Simplexa™ Group A Strep Direct and Simplexa Group A Strep Positive Control Pack	LIAISON NES® Group A Strep and LIAISON NES® Group A Strep Control Swb Kit
General Device Characteristic Similarities		

510(k) Summary

Intended Use/Indications for Use	The Focus Diagnostics Simplexa™ Group A Strep Direct assay is intended for use on the 3M Integrated Cycler for the in vitro qualitative detection of Group A Streptococcus (GAS) from throat swabs collected from human patients with signs and symptoms of pharyngitis, such as sore throat. This test is intended for use as an aid in the diagnosis of GAS infection. The assay is intended for use in hospital, reference, or state laboratory settings. The device is not intended for point-of-care use. Focus Diagnostics' Simplexa™ Group A Strep Positive Control Pack is intended to be used as a control with Simplexa™ Group A Strep Direct. This control is not intended for use with other assays or systems.	LIAISON NES® Group A Strep is a real-time PCR assay is intended for use on the LIAISON NES® instrument for the in vitro qualitative detection of *Streptococcus pyogenes*, Group A *Streptococcus* (GAS) bacterial nucleic acid in throat swab specimens freshly collected from human patients with signs and symptoms of bacterial pharyngitis. This test is intended for use as an aid in the rapid diagnosis of Group A *Streptococcus* bacterial infections. The LIAISON NES® Group A Strep Control Swab Kit is intended to be used as positive and negative controls with the LIAISON NES® Group A Strep assay for use on the LIAISON NES® instrument. These controls are not intended for use with other assays or systems.
Measurand	Nucleic acid from organism detected.	Same
Patient Population	Patients with signs and symptoms of pharyngitis.	Same
Organism detected	*Streptococcus pyogenes*	Same
Reporting Features	System software analyzes processed image data and provides test results	Same
Assay Software Functions	Defines target-specific parameters, instrument protocols and report requirements.	Same
General Device Characteristic Differences		
Sample Type	Throat Swab in Amies Medium	Dry Throat Swab
Time to Result	~ 60 minutes	~ 18 minutes
Instrumentation	3M Integrated Cyclear	LIAISON NES®
Technological Principle	Bi-functional fluorescent probe-primers used together with corresponding reverse primers amplify Group A Strep bacterial DNA and Internal Control (DNA IC). Utilizes one genetic target in GAS chromosome.	Dye-labeled fluorescent probes and primers amplify and detect Group A Strep bacterial DNA and internal control (IC) DNA. Utilizes two separate genetic targets in GAS chromosome.

510(k) Summary

Automated System (Sample to Answer)	Software automatically interprets and displays results.	Automated sample processing, amplification, and results interpretation and display.

K. Standards/Guidance Documents Referenced:

- 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. User Verification of Precision and Estimation of Bias; Approved Guideline – Third Edition. CLSI document EP15-A3. Wayne, PA: Clinical Laboratory Standards Institute; 2019.
- 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. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI document EP25-A. Wayne, PA: Clinical Laboratory Standards Institute; 2009.
- CLSI. Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures. 1st Ed. CLSI Document EP35. Wayne, PA: Clinical Laboratory Standards Institute; 2019.
- 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.
- IEC 62366-1 Edition 1.1 2020-06 Consolidated Version; Medical devices – Part 1: Application of usability engineering to medical devices
- 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

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

510(k) Summary

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® Group A Strep assay used on the LIAISON NES® instrument is a real-time PCR system that enables the direct amplification and detection of Group A Streptococcus bacterial nucleic acidin throat swab specimens.

The LIAISON NES® Group A Strep assay consists of the LIAISON NES® instrument, LIAISON NES® Group A Strep Cartridge containing all the required PCR reagents, NES Sample Vial containing working solution, and NES Swab for throat sample collection.

Following collection, the throat swab is placed into the NES Sample Vial. The sample is released into the working solution, and the entire contents of the vial are transferred into the LIAISON NES® Group A Strep Cartridge.

In the LIAISON NES® Group A Strep assay, dye-labeled fluorescent probes and primers amplify and detect Group A Streptococcus bacterial DNA and internal control (IC) DNA. Conserved regions of Group A Streptococcus genome are targeted to identify the bacteria in the specimen, while the internal control (IC) DNA is used to detect any PCR failures and/or inhibition.

M. Clinical Performance Characteristics:

The clinical performance of the LIAISON NES® Group A Strep assay was evaluated using clinical specimens prospectively collected between April 2025 and December 2025 from four 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 pharyngitis. Throat swabs were collected by a Healthcare Provider. All collection and testing was performed at CLIA-waived facilities, representative of the intended use, point-of-care environment.

510(k) Summary

A total of 1423 unique prospectively collected specimens, collected from four geographically diverse US sites that met the pre-determined inclusion criteria, were enrolled in the study. Clinical sample testing using the LIAISON NES® Group A Strep assay was performed using the LIAISON NES® instrument by untrained operators at all four collection sites.

Out of the 1423 specimens enrolled in the prospective arm of the study, 21 (1.5%) specimens were disqualified and removed from further analysis. After a single test of each specimen, 1380 specimens generated valid LIAISON NES® Group A Strep assay results for a final success rate of 98.4% (1380/1402).

All clinical specimens were compared to culture followed by latex agglutination and positive confirmation by MALDI-TOF using an FDA-cleared IVD library. Comparator testing was performed at a single external reference lab. The diagnostic performance of the LIAISON NES® Group A Strep assay was determined using Sensitivity, Specificity, and Negative Predictive Value (NPV), along with the associated 95% confidence intervals. The overall (all sites combined) performance of the LIAISON NES® Group A Strep assay when compared to the reference culture method is summarized in **Table 1A**. Performance of the LIAISON NES® Group A Strep assay when compared to the reference culture method was also evaluated by sites, as shown in **Table 1B.**

Table 1 A. Clinical Performance of LIAISON NES Group A Strep

All sites combined		**Reference Culture Method**		
		Positive	**Negative**	**Total**
LIAISON NES Group A Strep	**Positive**	104	53†	157
	Negative	0	1223	1223
	Total	104	1276	1380

Sensitivity	100% (104/104)	95% CI (96.44% - 100%)
Specificity	95.85% (1223/1276)	95% CI (94.61% - 96.81%)
PPV	66.24% (104/157)	95% CI (58.54% - 73.17%)
NPV	100% (1223/1223)	95% CI (99.69% - 100%)

† Discordant result analysis showed that Strep A was detected in 51/53 False Positive specimens by at least one of three FDA-cleared molecular assays.

510(k) Summary

Table 1 B. Performance of the LIAISON NES Group A Strep Stratified by Sites

Site	Total	TP	FN	TN	FP	Sensitivity [95% CI]	Specificity [95% CI]
Site 1	330	21	0	296	13	100% (21/21) [84.54% - 100%]	95.79% (296/309) [92.94% - 97.53%]
Site 2	434	50	0	365	19	100% (50/50) [92.86% - 100%]	95.05% (365/384) [92.40% - 96.81%]
Site 3	379	20	0	347	12	100% (20/20) [83.89% - 100%]	96.66% (347/359) [94.25% - 98.08%]
Site 4	237	13	0	215	9	100% (13/13) [77.19% - 100%]	95.98% (215/224) [92.54% - 97.87%]
All Sites	1380	104	0	1223	53	100% (104/104) [96.44% - 100%]	95.85% (1223/1276) [94.61% - 96.81%]

TP = true positive, FN = false negative, TN = true negative, FP = false positive, CI = confidence interval

REPRODUCIBILITY

Site-to-site reproducibility of the LIAISON NES® Group A Strep assay was evaluated by testing LIAISON NES® Group A Strep assay cartridges with a reproducibility panel, blinded to operators, consisting of eight panel members including negative samples (simulated negative matrix (NTC)), positive control (PC) and six positive panel members. The six positive panel members consisted of contrived samples containing two strains of *Streptococcus pyogenes* individually. Each strain was spiked onto dry swabs at two different concentrations [Low Positive (LP) ~ 1x Limit of Detection (LoD), Moderate Positive (MP) ~ 3x LoD].

Each sample panel member was tested by two different operators at each testing site. Each operator tested each panel member in three replicates each day for a total of five testing days. A total of ninety replicates [three (3) replicates X two (2) operators X three (3) sites X five (5) days] were evaluated for each panel member. A total of fourteen LIAISON NES® instruments [at least two (2) per site] were used to evaluate the reproducibility study.

Table 2. Reproducibility Panel Member Details

Panel Member		Strain	Approximate Concentration	Replicates per day per operator	Total replicates per operator	Total replicates in study
1	*S. pyogenes* M1 LP	*S. pyogenes* M1 (ATCC 700294)	1X LoD	3	15	90
2	*S. pyogenes* M1 MP	*S. pyogenes* M1 (ATCC 700294)	3X LoD	3	15	90
3	*S. pyogenes* M3 LP	*S. pyogenes* M3 (ATCC BAA-595)	1X LoD	3	15	90

510(k) Summary

Panel Member		Strain	Approximate Concentration	Replicates per day per operator	Total replicates per operator	Total replicates in study
4	*S. pyogenes* M3 MP	*S. pyogenes* M3 (ATCC BAA-595)	3X LoD	3	15	90
5	Simulated Negative Matrix (NTC)	N/A	N/A	3	15	90
6	LIAISON NES Group A Strep (GAS) Positive Control (PC)	N/A	N/A	3	15	90
Total				**18**	**90**	**540**

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

Table 3. LIAISON NES® Group A Strep Reproducibility

	Site 1	Site 2	Site 3	All Sites
Panel Member	**Agreement with expected results**	**Agreement with expected results**	**Agreement with expected results**	**Agreement with expected results**
S. pyogenes M1 LP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
S. pyogenes M1 MP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
S. pyogenes M3 LP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
S. pyogenes M3 MP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
NTC	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
PC	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)

LP = Low Positive, MP = Medium Positive, PC = Positive Control, NTC = No Template Control

Table 4. LIAISON NES® Group A Strep Internal Control Reproducibility

	Site 1	Site 2	Site 3	All Sites
Panel Member	**Agreement with expected results**	**Agreement with expected results**	**Agreement with expected results**	**Agreement with expected results**
S. pyogenes M1 LP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
S. pyogenes M1 MP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
S. pyogenes M3 LP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
S. pyogenes M3 MP	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
NTC	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)

510(k) Summary

	Site 1	Site 2	Site 3	All Sites
Panel Member	**Agreement with expected results**	**Agreement with expected results**	**Agreement with expected results**	**Agreement with expected results**
PC	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)

LP = Low Positive, MP = Medium Positive, NTC = No Template Control, PC = Positive Control

N. Analytical Performance Characteristics:

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION

The LoD of the LIAISON NES® Group A Strep assay was determined to be the lowest detectable concentration of verified (re-grown and re-titered) bacterial stock (CFU/swab) at which ≥ 95% of all replicates were detected. Two (2) serotypes of *S. pyogenes* were serially diluted in human negative matrix and spiked onto NES swab to determine the LoD. The LoD results are shown in 5.

Table 5. LIAISON NES® Group A Strep Assay Limit of Detection

Bacterial Serotype	LoD (CFU) [1]	LoD (CFU/ml)[2]
S. pyogenes serotype M1 ATCC 700294	90.7	129.6 CFU/ml
S. pyogenes serotype M3 ATCC BAA-595	29.7	42.4 CFU/ml

[1]Number of organisms (colony forming units) applied to swab prior to placing it into the NES Sample Vial.

[2] Final concentration of organisms after 10 uL of bacterial dilution is spiked onto the dry swab and released in 700 uL of working solution contained in NES Sample Vial (assuming 100% recovery of bacteria).

ANALYTICAL REACTIVITY/CROSS REACTIVITY

Analytical Reactivity

The analytical reactivity of the LIAISON NES® Group A Strep assay was evaluated. A total of fifteen (15) strains were tested. Verified (re-grown and re-titered) bacterial material was diluted in simulated negative matrix and spiked onto NES swab at the concentrations listed in Table 6 below (corresponding to 3X LoD or higher) and tested in triplicate. Each strain was tested initially in triplicate using 90 CFU/swab (i.e. 3 X LoD) level established for *S. pyogenes* strain M3 ATCC BAA-595). The study was designed such that the concentrations for each strain not detected at the initial 90 CFU/swab were increased until 100% detection was obtained. This additional testing was required for 8 of the 15 strains tested. Overall, seven (7) strains were detected at 100% at 3x LoD, four (4) strains were detected at 100% at 5x LoD and four (4) strains were detected at 100% at 8x LoD. The concentrations tested and results are shown in Table 6.

510(k) Summary

Table 6. LIAISON NES® Group A Strep Assay Analytical Reactivity

Target	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)
M2 (MGAS 10270)	90 CFU/swab	100% (3/3)
M4 (MGAS 10750 [FL01-86])	240 CFU/swab	100% (3/3)
M6 (MGAS 10394)	150 CFU/swab	100% (3/3)
Bruno [CIP 104226]	90 CFU/swab	100% (3/3)
M12 (MGAS 9429)	90 cps/swab	100% (3/3)
M18 (MGAS 8232)	90 cps/swab	100% (3/3)
M58 (CDC-SS-872 [R67/3884])	240 CFU/swab	100% (3/3)
6 (Typing strain S43 [Dochez and Avery S43 (Texas)])	90 CFU/swab	100% (3/3)
23 (Typing strain T23 [F. Griffith strain Barts 102])	150 CFU/swab	100% (3/3)
46 (C105 [20RS14])	90 CFU/swab	100% (3/3)
17 (Typing strain J17E [A. Coburn R9])	240 CFU/swab	100% (3/3)
26 (Typing Strain J17F [A. Coburn R17])	150 CFU/swab	100% (3/3)
40 (Typing strain C143 [C143])	90 CFU/swab	100% (3/3)
M-3 [DLS 88002, Weller]	150 CFU/swab	100% (3/3)
14 [P20080]	240 CFU/swab	100% (3/3)

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

An *in silico* inclusivity analysis of the assay oligo sequences in the LIAISON NES® Group A Strep assay was performed. All primer and probe sets were aligned against sequences available in the GenBank database (as of August 30, 2025). Specifically, a total of 930 *Streptococcus pyogenes* sequences with coverage of the assay's oligo sets were assessed in this analysis. Based on the *in silico* analysis, LIAISON NES® Group A Strep assay exhibits 100% inclusivity of the analyzed sequences available in the aforementioned database.

Cross-Reactivity (Analytical Specificity)

Cross-reactivity of the LIAISON NES® Group A Strep assay was evaluated by testing forty-seven (47) whole microorganisms including related bacteria, high-prevalence pathogenic microorganisms or normal flora that are reasonably likely to be present in the clinical sample.

Specimens were prepared by diluting cultured or inactivated organisms, in simulated negative matrix and spiked onto NES swab. Cross-reactivity was determined based on three replicates. Results from cross-reactivity testing are summarized in Table **7**7. No cross-reactivity was observed with any of the microorganisms tested.

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Table 7: LIAISON NES® Group A Strep Assay Cross-Reactivity (Analytical Specificity)

Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
Adenovirus Type 1	10^5 $TCID_{50}$/mL	0% (0/3)
Arcanobacterium haemolyticum	10^6 CFU/mL	0% (0/3)
Bacillus cereus	10^6 CFU/mL	0% (0/3)
Bordetella pertussis	10^6 CFU/mL	0% (0/3)
Burkholderia cepacia	10^6 CFU/mL	0% (0/3)
Campylobacter rectus	10^6 CFU/mL	0% (0/3)
Candida albicans	10^6CFU/mL	0% (0/3)
Corynebacterium diphtheriae	10^6CFU/mL	0% (0/3)
Enterococcus faecalis	10^6CFU/mL	0% (0/3)
Escherichia coli	10^6CFU/mL	0% (0/3)
Fusobacterium necrophorum	10^6FU/mL	0% (0/3)
Haemophilus influenzae	10^6CFU/mL	0% (0/3)
Human Influenza virus A	10^5 $TCID_{50}$/mL	0% (0/3)
Human Influenza virus B	10^5 $TCID_{50}$/mL	0% (0/3)
Human metapneumovirus-9	10^5 $TCID_{50}$/mL	0% (0/3)
Klebsiella pneumoniae	10^6 CFU/mL	0% (0/3)
Lactobacillus acidophilus	10^6CFU/mL	0% (0/3)
Lactococcus lactis	10^6 CFU/mL	0% (0/3)
Legionella longbeachae	10^6FU/mL	0% (0/3)
Moraxella catarrhalis	$10^6$6 CFU/mL	0% (0/3)
Mycoplasma pneumoniae	10^6 cps/mL	0% (0/3)
Neisseria gonorrhoeae	10^6CFU/mL	0% (0/3)
Parainfluenza Type 3	10^5 $TCID_{50}$/mL	0% (0/3)
Peptostreptococcus micros	10^6 CFU/mL	0% (0/3)
Pseudomonas aeruginosa	10^6 CFU/mL	0% (0/3)
Respiratory syncytial virus Type B-9320	10^5 $TCID_{50}$/mL	0% (0/3)
Rhinovirus 1A	10^5 $TCID_{50}$/mL	0% (0/3)
Saccharomyces cerevisiae	10^6CFU/mL	0% (0/3)
Staphylococcus epidermidis	10^6 CFU/mL	0% (0/3)
Stenotrophomonas maltophilia	10^6FU/mL	0% (0/3)
Streptococcus agalactiae	10^6 CFU/mL	0% (0/3)
Streptococcus anginosus	10^6 CFU/mL	0% (0/3)
Streptococcus bovis	10^6 CFU/mL	0% (0/3)

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Organism	Tested Concentration	Agreement with Expected Results: % Detection (#Detected/#Total)
Streptococcus constellatus subsp. Pharyngis	10^6 CFU/mL	0% (0/3)
Streptococcus dysgalactiae subsp. Equisimilis	10^6CFU/mL	0% (0/3)
Streptococcus gallolyticus	10^6CFU/mL	0% (0/3)
Streptococcus intermedius	10^6 CFU/mL	0% (0/3)
Streptococcus mitis	10^6FU/mL	0% (0/3)
Streptococcus mutans	10^6CFU/mL	0% (0/3)
Streptococcus oralis	10^6 CFU/mL	0% (0/3)
Streptococcus pneumoniae	10^6 CFU/mL	0% (0/3)
Streptococcus salivarius	10^6FU/mL	0% (0/3)
Streptococcus sanguinis	10^6FU/mL	0% (0/3)
Treponema denticola	10^6CFU/mL	0% (0/3)
Veillonella parvula	$10^6$6 CFU/mL	0% (0/3)
Hoylesella oralis	10^6FU/mL	0% (0/3)
Streptococcus canis	10^6CFU/mL	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® Group A Strep assay was further evaluated with an *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 October 18, 2025, the assay oligos are predicted to have no potential cross-reactivity to any of the analyzed organisms.

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 simulated negative matrix and *S. pyogenes* (M1 ATCC 700294 or M3 ATCC BAA-595 serotype) at 3xLoD and 2) diluting each potentially interfering substance into a baseline sample consisting of simulated negative matrix. Prepared test samples were spiked onto NES swab and interference based on three replicates was determined. The results are shown in Table 8 and Table 9.

No substances tested in Table showed any interference with the detection of *S. pyogenes* at the concentrations tested. No interference was observed for negative samples.

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Table 8: LIAISON NES® Group A Strep Assay Interference for Positive Sample

Potentially Interfering Substances	Active Ingredient	Tested Concentration	*S. pyogenes* M1 % Detection (#Detected/ #Tested)	*S. pyogenes* M3 % Detection (#Detected/ #Tested)
Blood (Human)	N/A	4% (v/v)	100% (3/3)	100% (3/3)
Chloraseptic® Max Sore Throat Spray	Phenol, Glycerin	8% (v/v)	100% (3/3)	100% (3/3)
Robitussin Maximum Strength Severe Multi-Symptom Cough + Flu	Acetaminophen, Dextromethorphan Guaifenesin	8% (v/v)	100% (3/3)	100% (3/3)
Cool Mint Listerine antiseptic mouthwash	Eucalyptol, Menthol, Methyl Salicylate, Thymol	8% (v/v)	100% (3/3)	100% (3/3)
Crest Pro-Health	Stannous Fluoride	8% (v/v)	100% (3/3)	100% (3/3)
Halls	Menthol	8% (v/v)	100% (3/3)	100% (3/3)
Advil Liqui-Gels	Ibuprofen	8% (v/v)	100% (3/3)	100% (3/3)
Food Dye Blue 1	N/A	8% (v/v)	100% (3/3)	100% (3/3)
Food Dye Yellow 5 (Tartrazina)	N/A	8% (v/v)	100% (3/3)	100% (3/3)
Orange Juice	N/A	8% (v/v)	100% (3/3)	100% (3/3)
Cepacol® Extra Strength Sore Throat Lozenges	Benzocaine, Menthol	0.024% Benzocaine (w/v), 0.0058% Menthol (w/v)	100% (3/3)	100% (3/3)
Sucrets® Sore Throat & Cough	Dyclonine Hydrochloride, Menthol, Pectin	0.0048% Dyclonine Hydrochloride (w/v), 0.012% Menthol (w/v), Pectin 0.014% (w/v)	100% (3/3)	100% (3/3)
Miralax	Polyethylene Glycol	2.43% (w/v)	100% (3/3)	100% (3/3)
Tums Ultra Strength	Calcium Carbonate	2.4 mg/ml	100% (3/3)	100% (3/3)
Penicillin G	Penicillin G Sodium Salt	0.8% (w/v)	100% (3/3)	100% (3/3)
Cephalexin	Cephalexin	0.2% (w/v)	100% (3/3)	100% (3/3)

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Potentially Interfering Substances	Active Ingredient	Tested Concentration	*S. pyogenes* M1 % Detection (#Detected/ #Tested)	*S. pyogenes* M3 % Detection (#Detected/ #Tested)
Mucin: porcine stomach Type II	Purified mucin protein	0.8% (w/v)	100% (3/3)	100% (3/3)
Amoxicillin	Amoxicillin	0.8% (w/v)	100% (3/3)	100% (3/3)
Aspirin	Acetylsalicylic acid	0.62 mg/ml	100% (3/3)	100% (3/3)

mg/mL = Milligrams/milliliter
v/v = Volume/Volume
w/v = Weight/Volume

Table 9: LIAISON NES® Group A Strep Assay Interference for Negative Sample

Potentially Interfering Substances	Active Ingredient	Tested Concentration	*S. pyogenes* % Detection (#Detected/ #Tested)	IC % Detection (#Detected/ #Tested)
Blood (Human)	N/A	4% (v/v)	0% (0/3)	100% (3/3)
Chloraseptic® Max Sore Throat Spray	Phenol, Glycerin	8% (v/v)	0% (0/3)	100% (3/3)
Robitussin Maximum Strength Severe Multi-Symptom Cough + Flu	Acetaminophen, Dextromethorphan Guaifenesin	8% (v/v)	0% (0/3)	100% (3/3)
Cool Mint Listerine antiseptic mouthwash	Eucalyptol, Menthol, Methyl Salicylate, Thymol	8% (v/v)	0% (0/3)	100% (3/3)
Crest Pro-Health	Stannous Fluoride	8% (v/v)	0% (0/3)	100% (3/3)
Halls	Menthol	8% (v/v)	0% (0/3)	100% (3/3)
Advil Liqui-Gels	Ibuprofen	8% (v/v)	0% (0/3)	100% (3/3)
Food Dye Blue 1	N/A	8% (v/v)	0% (0/3)	100% (3/3)
Food Dye Yellow 5 (Tartrazina)	N/A	8% (v/v)	0% (0/3)	100% (3/3)
Orange Juice	N/A	8% (v/v)	0% (0/3)	100% (3/3)
Cepacol® Extra Strength Sore Throat Lozenges	Benzocaine, Menthol	0.024% Benzocaine (w/v),	0% (0/3)	100% (3/3)

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Potentially Interfering Substances	Active Ingredient	Tested Concentration	*S. pyogenes*	IC
			% Detection (#Detected/ #Tested)	% Detection (#Detected/ #Tested)
		0.0058% Menthol (w/v)		
Sucrets® Sore Throat & Cough	Dyclonine Hydrochloride, Menthol, Pectin	0.0048% Dyclonine Hydrochloride (w/v), 0.012% Menthol (w/v), Pectin 0.014% (w/v)	0% (0/3)	100% (3/3)
Miralax	Polyethylene Glycol	2.43% (w/v)	0% (0/3)	100% (3/3)
Tums Ultra Strength	Calcium Carbonate	2.4 mg/ml	0% (0/3)	100% (3/3)
Penicillin G	Penicillin G Sodium Salt	0.8% (w/v)	0% (0/3)	100% (3/3)
Cephalexin	Cephalexin	0.2% (w/v)	0% (0/3)	100% (3/3)
Mucin: porcine stomach Type II	Purified mucin protein	0.8% (w/v)	0% (0/3)	100% (3/3)
Amoxicillin	Amoxicillin	0.8% (w/v)	0% (0/3)	100% (3/3)
Aspirin	Acetylsalicylic acid	0.62 mg/ml	0% (0/3)	100% (3/3)

mg/mL = Milligrams/milliliter
v/v = Volume/Volume
w/v = Weight/Volume

INHIBITION BY OTHER MICROORGANISMS

The LIAISON NES® Group A Strep assay was evaluated by testing the ability to detect a low concentration of *S. pyogenes* when other potentially inhibitory microorganisms were present. Specimens were prepared by diluting the potentially inhibitory cultured isolates or inactivated organisms into simulated negative matrix in the presence of a low concentration (3X LoD) of either *S. pyogenes* M1 ATCC 700294 or M3 ATCC BAA-595 serotype. Forty-seven (47) potentially inhibitory microorganisms were individually spiked on NES swab and tested in triplicate.

No inhibition by any organisms was observed for *S. pyogenes* at the concentrations indicated in Table 10.

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Table 10: LIAISON NES® Group A Strep Assay Microbial Inhibition

Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)	
		***S. pyogenes* M1**	***S. pyogenes* M1**
Adenovirus Type 1	10^5 TCID50/mL	100% (3/3)	100% (3/3)
Arcanobacterium haemolyticum	10^6 CFU/mL	100% (3/3)	100% (3/3)
Bacillus cereus	10^6 CFU/mL	100% (3/3)	100% (3/3)
Bordetella pertussis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Burkholderia cepacia	10^6 CFU/mL	100% (3/3)	100% (3/3)
Campylobacter rectus	10^6 CFU/mL	100% (3/3)	100% (3/3)
Candida albicans	10^6 CFU/mL	100% (3/3)	100% (3/3)
Corynebacterium diphtheriae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Enterococcus faecalis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Escherichia coli	10^6 CFU/mL	100% (3/3)	100% (3/3)
Fusobacterium necrophorum	10^6 CFU/mL	100% (3/3)	100% (3/3)
Haemophilus influenzae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Hoylesella oralis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Human Influenza virus A	10^5 TCID50/mL	100% (3/3)	100% (3/3)
Human Influenza virus B	10^5 TCID50/mL	100% (3/3)	100% (3/3)
Human metapneumovirus-9	10^5 TCID50/mL	100% (3/3)	100% (3/3)
Klebsiella pneumoniae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Lactobacillus acidophilus	10^6 CFU/mL	100% (3/3)	100% (3/3)
Lactococcus lactis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Legionella longbeachae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Moraxella catarrhalis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Mycoplasma pneumoniae	10^6 cps/mL	100% (3/3)	100% (3/3)
Neisseria gonorrhoeae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Parainfluenza Type 3	10^5 TCID50/mL	100% (3/3)	100% (3/3)
Peptostreptococcus micros	10^6 CFU/mL	100% (3/3)	100% (3/3)
Pseudomonas aeruginosa	10^6 CFU/mL	100% (3/3)	100% (3/3)
Respiratory syncytial virus Type B-9320	10^5 TCID50/mL	100% (3/3)	100% (3/3)

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Organism	Tested Concentration	Agreement with Expected Results: %Detection (#Detected/#Total)	
		***S. pyogenes* M1**	***S. pyogenes* M1**
Rhinovirus 1A	10^5 TCID50/mL	100% (3/3)	100% (3/3)
Saccharomyces cerevisiae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Staphylococcus epidermidis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Stenotrophomonas maltophilia	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus agalactiae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus anginosus	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus bovisg	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus canis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus constellatus subsp. pharyngis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus dysgalactiae subsp. equisimilis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus gallolyticus	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus intermedius	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus mitis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus mutans	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus oralis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus pneumoniae	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus salivarius	10^6 CFU/mL	100% (3/3)	100% (3/3)
Streptococcus sanguinis	10^6 CFU/mL	100% (3/3)	100% (3/3)
Treponema denticola	10^6 CFU/mL	100% (3/3)	100% (3/3)
Veillonella parvula	10^6 CFU/mL	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® Group A Strep 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 *S. pyogenes* M3 serotype **(**ATCC BAA-595) into simulated negative matrix and then spiked on the NES swab at a final concentration of 10^6 CFU/swab. Simulated negative

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matrix onto NES swab was used as negative sample. The same alternating order was maintained when loading the corresponding cartridges into the instruments. No evidence of carry-over or cross-contamination was observed.

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Matrix Comparison

Equivalency in terms of performance between two (2) different matrices, Human Negative Matrix (HNM) and Simulated Negative Matrix (SNM) using the LIAISON NES® Group A Strep (NES2850) Assay were evaluated.

Simulated Negative Matrix (SNM) consisted of IDTE buffer with mucin, NaCl, and Human Genome DNA. Human Negative Matrix (HNM) was prepared by pooling throat swabs collected from healthy donors, negative for Group A *Streptococcus* (GAS). Both matrices were previously screened to ensure they were negative for Group A *Streptococcus* (GAS) bacteria.

Each matrix was contrived with two (2) *Streptococcus pyogenes* serotypes, M1 (ATCC 700294) and M3 (ATCC BAA-595) at the following concentrations:

- thirty (30) replicates at a low positive concentration (2x LoD)
- ten (10) replicates at a moderate positive concentration (5x LoD)
- five (5) replicates at a high positive concentration (10x LoD)

In addition, ten (10) replicates of both matrices without adding the target were tested as negative samples.

The doses for contrived samples are based on the declared LoD in CFU/swab defined in the LoD Verification study.

A total of forty (40) replicates of negative matrix, one hundred and twenty (120) low positive replicates (2x LoD), forty (40) moderate positive replicates (5x LoD) and twenty (20) high positive replicates (10x LoD) were tested by two (2) different operators over the course of two (2) non-consecutive days using one (1) lot of LIAISON NES® Group A Strep Cartridge (NES2851-MP), one (1) lot of NES Sample Vial (NES1502) and one (1) lot of NES Swab Tubes (NES4001). The results are summarized in **Table 11**.

The equivalency between the two (2) different matrix types has been confirmed since:

- a detection rate of 0% with a valid Internal Control is observed for negative samples in both matrices
- a detection rate of ≥95% is observed for low positive samples (2x LoD), for all *S. pyogenes* serotypes in both matrices
- a detection rate of 100% is observed for moderate (5x LoD) and high (10x LoD) positive samples for all *S. pyogenes* serotypes in both matrices
- the difference between the average Ct of detection of the target diluted (at the same concentration, 2xLoD, 5xLoD and 10xLoD) in both matrices (SNM and HNM) is ≤10%.

Table 11 Matrix Equivalence of LIAISON NES Group A Strep

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Target (Concentration)	Matrix	GAS (FAM)	IC (Q705)
		% Detection (#Detected/#Tested)	% Detection (#Detected/#Tested)
Negative (N/A)	SNM	0% (0/10)	100% (10/10)
	HNM	0% (0/10)	100% (10/10)
S. *pyogenes* M1 (2x LoD)	SNM	100% (30/30)	100% (30/30)
	HNM	100% (30/30)	100% (30/30)
S. *pyogenes* M1 (5x LoD)	SNM	100% (10/10)	100% (10/10)
	HNM	100% (10/10)	100% (10/10)
S. *pyogenes* M1 (10x LoD)	SNM	100% (5/5)	100% (5/5)
	HNM	100% (5/5)	100% (5/5)
Negative (N/A)	SNM	0% (0/10)	100% (10/10)
	HNM	0% (0/10)	100% (10/10)
S. *pyogenes* M3 (2x LoD)	SNM	100% (30/30)	100% (30/30)
	HNM	100% (30/30)	100% (30/30)
S. *pyogenes* M3 (5x LoD)	SNM	100% (10/10)	100% (10/10)
	HNM	100% (10/10)	100% (10/10)
S. *pyogenes* M3 (10x LoD)	SNM	100% (5/5)	100% (5/5)
	HNM	100% (5/5)	100% (5/5)

HNM = Human Negative Matrix; SNM = Simulated Negative Matrix

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 support a substantial equivalence decision.