May 19, 2026

Luminex Corporation
Michael Treas
Senior Regulatory Affairs Associate
4088 Commercial Ave.
Northbrook, Illinois 60062

Re: K253722
Trade/Device Name: LIAISON PLEX Gastrointestinal Flex Assay
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal microorganism multiplex nucleic acid-based assay
Regulatory Class: Class II
Product Code: PCH, NSU
Dated: November 21, 2025
Received: November 24, 2025

Dear Michael Treas:

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

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

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

BRYAN M. GRABIAS -S
2026.05.19 11:14:39 -04'00'

Bryan Grabias, Ph.D.
Acting Branch Chief
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

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

510(k) Number *(if known)*
K253722

Device Name
LIAISON PLEX® Gastrointestinal Flex Assay

Indications for Use *(Describe)*
The LIAISON PLEX® Gastrointestinal Flex Assay is an automated and qualitative multiplexed test for simultaneous detection and identification of common pathogenic bacteria, viruses, and parasites from liquid or soft stool preserved in Cary-Blair or modified Cary-Blair medium and additionally for parasites, from liquid or soft stool preserved in alcohol-based formalin-free parasite fixative (e.g., EcoFix®, Total-Fix®) collected from individuals with signs and symptoms of gastrointestinal infection. The test is performed on the automated LIAISON PLEX® System utilizing reverse transcription (RT), polymerase chain reaction (PCR), and array hybridization to detect specific gastrointestinal microbial nucleic acid gene sequences associated with the pathogenic bacteria, viruses, and parasites:

Bacteria:
Campylobacter spp. (C. coli/C. jejuni/C. lari/C. upsaliensis)
Clostridioides difficile (tcdA/tcdB)
Enterotoxigenic Escherichia coli (ETEC) LT/ST
Plesiomonas shigelloides
Salmonella spp.
Shiga-like toxin-producing Escherichia coli (STEC) stx1
Shiga-like toxin-producing Escherichia coli (STEC) stx2
Shigella/Enteroinvasive Escherichia coli (EIEC)
Vibrio cholerae
Vibrio spp. (V. parahaemolyticus/V. vulnificus)
Yersinia enterocolitica

Viruses:
Adenovirus F40/41
Astrovirus
Norovirus GI/GII
Rotavirus A
Sapovirus I/II/IV/V

Parasites:
Blastocystis sp.
Cryptosporidium spp.
Cyclospora cayetanensis
Dientamoeba fragilis
Entamoeba histolytica
Giardia lamblia (also known as G. intestinalis and G. duodenalis)
Microsporidia (Encephalitozoon hellem/Encephalitozoon intestinalis/Enterocytozoon bieneusi)
Strongyloides stercoralis

The LIAISON PLEX Gastrointestinal Flex Assay is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological information; however, it is not to be used to monitor these infections.

Concomitant culture is necessary for organism recovery and further typing of bacterial agents.

This device is not intended to monitor C. difficile infection.

LIAISON PLEX Gastrointestinal Flex Assay results should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Confirmed positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive cause of patient illness. Negative LIAISON PLEX Gastrointestinal Flex Assay results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

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 CRF 807.92.

Preparation date: May 15, 2026

A. 510(k) Number:

K253722

B. Purpose of Submission:

Traditional 510(k), New Device

C. Measurand:

The measurand for the LIAISON PLEX® Gastrointestinal *Flex* Assay is the presence or absence of specific gastrointestinal microbial nucleic acid gene sequences (DNA or RNA) associated with pathogenic bacteria, viruses, and parasites in stool samples.

D. Type of Test:

This is a qualitative, multiplex nucleic acid amplification test (NAAT) that utilizes reverse transcription polymerase chain reaction (RT-PCR) and PCR technology combined with microarray-based hybridization for the simultaneous detection and identification of multiple gastrointestinal bacterial, viral, and parasitic nucleic acid targets in stool specimens.

E. Applicant:

Michael Treas
Luminex Corporation
4088 Commercial Ave.
Northbrook, IL 60062

F. Proprietary and Established Name:

LIAISON PLEX® Gastrointestinal *Flex* Assay

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
PCH	II	21 CFR 866.3990 – Gastrointestinal pathogen panel multiplex nucleic acid-based assay system	Microbiology

510(k) Summary

H. Intended Use(s):

a. LIAISON PLEX® Gastrointestinal *Flex* Assay —

The LIAISON PLEX® Gastrointestinal *Flex* Assay is an automated and qualitative multiplexed test for simultaneous detection and identification of common pathogenic bacteria, viruses, and parasites from liquid or soft stool preserved in Cary-Blair or modified Cary-Blair medium and additionally for parasites, from liquid or soft stool preserved in alcohol-based formalin-free parasite fixative (e.g., EcoFix®, Total-Fix®) collected from individuals with signs and symptoms of gastrointestinal infection. The test is performed on the automated LIAISON PLEX® System utilizing reverse transcription (RT), polymerase chain reaction (PCR), and array hybridization to detect specific gastrointestinal microbial nucleic acid gene sequences associated with the pathogenic bacteria, viruses, and parasites:

Bacteria:

- *Campylobacter* spp. *(C. coli/C. jejuni/C. lari/C. upsaliensis)*
- *Clostridioides difficile (tcdA/tcdB)*
- Enterotoxigenic *Escherichia coli* (ETEC) LT/ST
- *Plesiomonas shigelloides*
- *Salmonella* spp.
- Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1*
- Shiga-like toxin-producing *Escherichia coli* (STEC) *stx2*
- *Shigella*/Enteroinvasive *Escherichia coli* (EIEC)
- *Vibrio cholerae*
- *Vibrio* spp. *(V. parahaemolyticus/V. vulnificus*)
- *Yersinia enterocolitica*

Viruses:

- Adenovirus F40/41
- Astrovirus
- Norovirus GI/GII
- Rotavirus A
- Sapovirus I/II/IV/V

Parasites:

- *Blastocystis* sp.
- *Cryptosporidium* spp.
- *Cyclospora cayetanensis*
- *Dientamoeba fragilis*
- *Entamoeba histolytica*

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- *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*)
- Microsporidia (*Encephalitozoon hellem*/*Encephalitozoon intestinalis*/*Enterocytozoon bieneusi*)
- *Strongyloides stercoralis*

The LIAISON PLEX Gastrointestinal *Flex* Assay is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological information; however, it is not to be used to monitor these infections.

Concomitant culture is necessary for organism recovery and further typing of bacterial agents.

This device is not intended to monitor *C. difficile* infection.

LIAISON PLEX Gastrointestinal *Flex* Assay results should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Confirmed positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive cause of patient illness. Negative LIAISON PLEX Gastrointestinal *Flex* Assay results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

b. Indication(s) for use:

Same as intended use.

c. Special conditions for use statement(s):

For prescription use only.

For *in vitro* diagnostic use only

d. Special instrument requirements:

For use with LIAISON PLEX® Instrument.

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Device Description:

The LIAISON PLEX® Gastrointestinal *Flex* Assay is an automated test for the detection and identification of nucleic acids from enteric bacteria, viruses, and parasites in stool samples. The LIAISON PLEX Gastrointestinal *Flex* Assay is performed on the LIAISON PLEX® System. The LIAISON PLEX System is an automated platform that performs sample preparation and is capable of polymerase chain reaction (PCR) for the detection of target-specific nucleic acids.

The LIAISON PLEX System is a fully automated, bench-top "sample-to-answer" device that performs sample preparation and microarray-based hybridization for the detection of target-specific nucleic acids. The test reagents are supplied as a single, disposable test cartridge with a sample processing tube and a transfer pipette.

The system consists of an instrument and a single-use, disposable test cartridge. The user initiates the test protocol on the LIAISON PLEX® System by scanning the barcode ID located on the test cartridge and entering the specimen information. The user loads a pre-processed specimen into the specimen loading well of the test cartridge and inserts the test cartridge into one of the six processing modules in the LIAISON PLEX® System to initiate the test. The LIAISON PLEX® System contains the necessary parameters to run the test cartridge, analyze the data, and generate test results.

The LIAISON PLEX® System automates the LIAISON PLEX® Gastrointestinal *Flex* Assay specimen analysis through the following steps:

- Specimen Extraction: Nucleic acid extraction via mechanical cell lysis and magnetic bead-based nucleic acid isolation of prepared stool specimens obtained from patients.
- Target Amplification: Multiplex PCR- and RT-PCR- based amplification of the extracted nucleic acids to generate target-specific amplicons.
- Hybridization: Amplicon hybridization to target specific capture oligos in a microarray format followed by mediator and gold-nanoparticle oligo hybridization.
- Signal Generation & Analysis – gold nanoparticle probes bound specifically to target-containing spots in the microarray are silver-enhanced via nanoparticle deposition, and light scatter from the spots is measured and further analyzed to determine the presence (Detected) or absence (Not Detected) of a target.

The assay is intended for use by trained laboratory personnel in moderate to high complexity clinical laboratories. The system is validated for stability under various conditions and has been verified for transport and shipping stability for both domestic and international distribution.

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Substantial Equivalence Information:

This document presents a comprehensive comparative analysis between the LIAISON PLEX® Gastrointestinal *Flex* Assay and the Biofire® Filmarray® Gastrointestinal Panel (FDA 510(k) K242367). The analysis is structured to fulfill the predicate device comparison requirements of 21 CFR 807.92(a)(3). Table 1 contains a side-by-side technical comparison and rationale for each difference to ensure clarity, traceability, and regulatory alignment.

Table 1. Comparative Summary Table

Attribute	**Subject – LIAISON PLEX® GI *Flex* Assay**	**Predicate – BIOFIRE® FILMARRAY® GI Panel — K242367**	**Equivalent**
Manufacturer / System	Diasorin; LIAISON PLEX® System; single-use closed cartridge.	bioMérieux; FILMARRAY® 2.0 or TORCH; single use closed pouch.	Negligible differences
Product Code	PCH	PCH	Same
Subsequent Code	NSU		
Regulation	21 CFR 866.3990	21 CFR 866.3990	Same
Regulation Name	Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay	Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay	Same
Regulatory Class	II	II	Same
Measurand	Nucleic acid from Organisms detected	Nucleic acid from Organisms detected	Same
Intended use / indications	The LIAISON PLEX® Gastrointestinal *Flex* Assay is an automated and qualitative multiplexed test for simultaneous detection and identification of common pathogenic bacteria, viruses, and parasites from liquid or soft stool preserved in Cary-Blair or modified Cary-Blair medium and additionally for parasites, from liquid or soft stool preserved in alcohol-based formalin-free parasite fixative collected from individuals with	The BIOFIRE® FILMARRAY® Gastrointestinal (GI) Panel is a qualitative multiplexed nucleic acid-based *in vitro* diagnostic test intended for use with BIOFIRE® FILMARRAY® Systems. The BIOFIRE GI Panel is capable of the simultaneous detection and identification of nucleic acids from multiple bacteria, viruses, and parasites directly from stool samples in Cary-Blair transport media obtained from individuals with signs	Negligible differences

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Attribute	Subject – LIAISON PLEX® GI *Flex* Assay	Predicate – BIOFIRE® FILMARRAY® GI Panel — K242367	Equivalent
	signs and symptoms of gastrointestinal infection. The test is performed on the automated LIAISON PLEX® System utilizing reverse transcription (RT), polymerase chain reaction (PCR), and array hybridization to detect specific gastrointestinal microbial nucleic acid gene sequences associated with the pathogenic bacteria, viruses, and parasites: **Bacteria:** • *Campylobacter* spp. *(C. coli/C. jejuni/C. lari/C. upsaliensis)* • *Clostridioides difficile (tcdA/tcdB)* • Enterotoxigenic *Escherichia coli* (ETEC) LT/ST • *Plesiomonas shigelloides* • *Salmonella* spp. • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1* • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx2* • *Shigella*/Enteroinvasive *Escherichia coli* (EIEC) • *Vibrio cholerae* • *Vibrio* spp. *(V. parahaemolyticus/V. vulnificus*) • *Yersinia enterocolitica* **Viruses:** • Adenovirus F40/41 • Astrovirus • Norovirus GI/GII • Rotavirus A • Sapovirus I/II/IV/V	and/or symptoms of gastrointestinal infection. The following bacteria (including several diarrheagenic *E. coli/Shigella* pathotypes), parasites, and viruses are identified using the BIOFIRE GI Panel: • *Campylobacter* (*C. jejuni/C. coli/C. upsaliensis*) • *Clostridium difficile* (*C. difficile*) toxin A/B • *Plesiomonas shigelloides* • *Salmonella* • *Vibrio* (*V. parahaemolyticus/V. vulnificus/ V. cholerae*), including specific identification of *Vibrio cholerae* • *Yersinia enterocolitica* • Enteroaggregative *Escherichia coli* (EAEC) • Enteropathogenic *Escherichia coli* (EPEC) • Enterotoxigenic *Escherichia coli* (ETEC) LT/ST • Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1/stx2* (including specific identification of the *E. coli* O157 serogroup within STEC) • *Shigella*/ Enteroinvasive *Escherichia coli* (EIEC) • *Cryptosporidium* • *Cyclospora cayetanensis* • *Entamoeba histolytica* • *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*) • Adenovirus F 40/41 • Astrovirus • Norovirus GI/GII	

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Attribute	Subject – LIAISON PLEX® GI *Flex* Assay	Predicate – BIOFIRE® FILMARRAY® GI Panel — K242367	Equivalent
	Parasites: • *Blastocystis* sp. • *Cryptosporidium* spp. • *Cyclospora cayetanensis* • *Dientamoeba fragilis* • *Entamoeba histolytica* • *Giardia lamblia* (also known as *G. intestinalis* and *G. duodenalis*) • Microsporidia (*Encephalitozoon hellem*/*Encephalitozoon intestinalis*/*Enterocytozoon bieneusi*) • *Strongyloides stercoralis* The LIAISON PLEX Gastrointestinal *Flex* Assay is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness, in conjunction with other clinical, laboratory, and epidemiological information; however, it is not to be used to monitor these infections. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. This device is not intended to monitor *C. difficile* infection. LIAISON PLEX Gastrointestinal *Flex* Assay results should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Confirmed positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive cause of patient	• Rotavirus A • Sapovirus (Genogroups I, II, IV, and V) The BIOFIRE GI Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule out co-infection with organisms not included in the BIOFIRE GI Panel. The agent detected may not be the definite cause of the disease. Concomitant culture is necessary for organism recovery and further typing of bacterial agents. This device is not intended to monitor or guide treatment for *C. difficile* infection. Due to the small number of positive specimens collected for certain organisms during the prospective clinical study, performance characteristics for E. coli O157, Plesiomonas shigelloides, Yersinia enterocolitica, Astrovirus, and Rotavirus A were established primarily with retrospective clinical specimens. Performance characteristics for Entamoeba histolytica, and Vibrio (V. parahaemolyticus, V. vulnificus, and Vibrio cholerae) were established primarily	

510(k) Summary

Attribute	Subject – LIAISON PLEX® GI *Flex* Assay	Predicate – BIOFIRE® FILMARRAY® GI Panel — K242367	Equivalent
	illness. Negative LIAISON PLEX Gastrointestinal *Flex* Assay results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.	using contrived clinical specimens. Negative BIOFIRE GI Panel results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease. A gastrointestinal microorganism multiplex nucleic acid-based assay also aids in the detection and identification of acute gastroenteritis in the context of outbreaks.	
Technological Principles	RT-PCR/PCR with microarray hybridization (nanoparticle/silver enhancement).	Nested multiplex RT-PCR + high-resolution melt HRM; similar fundamental scientific technology.	Differences
Core detection chemistry	Multiplex RT-PCR/PCR → microarray hybridization with gold nanoparticle probe and silver enhancement; optical signal analysis.	Nested multiplex RT-PCR (PCR1) → single plex PCR2 array → HRM endpoint analysis; optical signal analysis.	Differences
Specimen matrices	Liquid or soft stool in Cary-Blair / modified Cary-Blair; parasite targets also from alcohol-based formalin-free fixative.	Stool in Cary-Blair only.	Negligible differences
Internal/process controls	Automated internal control for extraction/nucleic acid recovery/amplification/detection; synthetic DNA controls; hybridization control; results reported Pass/Fail/N/A. Internal control must pass or entire run invalid.	RNA Process Control and PCR2 Control; both must be positive or entire run invalid.	Negligible differences

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Attribute	Subject – LIAISON PLEX® GI *Flex* Assay	Predicate – BIOFIRE® FILMARRAY® GI Panel — K242367	Equivalent
Panel management / selective reporting	*Flex*™: selection/deselection of targets at run setup; post-run analysis for deselected targets using *Flex* Credits (no re-run).	Software option for selective reporting of *C. difficile* and/or Norovirus (regional availability).	Negligible differences
Result type / interpretation	Per-target Detected/Not Detected; internal control status (Pass/Fail/N/A).	Detected/Not Detected/Invalid; conditional N/A (e.g., EPEC suppressed when STEC detected).	Negligible differences
Risk / Safety Considerations	Closed cartridge workflow with internal controls and specific decontamination cautions; interference evaluated.	Closed pouch workflow; internal controls; invalid-run handling; cross-reactivity caveats	Negligible differences
System / Consumable Design	LIAISON PLEX bench-top system; closed, single-use cartridge with integrated reagents/tips and barcode; hazardous reagents noted (e.g., guanidinium thiocyanate).	BIOFIRE FILMARRAY 2.0 or Torch; closed, single-use pouch with hydration and sample injection vials; Torch adds stacked modules, horizontal loading, Ethernet communication, integrated touchscreen	Negligible differences
Carryover / Cross-contamination	Closed, single-use cartridge minimizes risk; No carryover/cross contamination observed within an instrument or when using the assay.	Closed pouch design minimizes risk; cross contamination and carryover sections present; invalid run handling defined.	Negligible differences
Interference / Analytical Specificity	No interference observed at claimed levels for listed substances and inhibitory microorganisms	Analytical specificity; ≥99% detection at LoD and >99% negative agreement. No interference or cross-reactivity identified.	Negligible differences
Reproducibility / Precision Across Platforms	Multi-site, multi-operator reproducibility ≥99.2% across matrices (Cary-Blair and parasite fixative).	K160459: ≥99% detection at 1× LoD across Torch systems (96 replicates/analyte); negative agreement >99%	Negligible differences

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Standards/Guidance Documents Referenced:

FDA Guidance – Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens

AAMI. Principles for medical device security – Risk Management. AAMI document TIR57:2016. Association for the Advancement of Medical Instrumentation; 2016.

AAMI. Principles for medical device security – Postmarket risk management for device manufacturers. AAMI document TIR97:2019. Association for the Advancement of Medical Instrumentation; 2019.

CLSI. Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard – Second Edition. CLSI document AUTO11-A2. Wayne, PA: Clinical Laboratory Standards Institute; 2014.

CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical Laboratory Standards Institute; 2019.

CLSI. Interference Testing in Clinical Chemistry. 3rd Ed. CLSI Document EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.

CLSI. Evaluation of Qualitative, Binary Output Examination Performance; Approved Guideline – Third Edition. CLSI document EP12. Wayne, PA: Clinical Laboratory Standards Institute; 2023.

CLSI. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. CLSI document EP17-A2. Wayne, PA: Clinical Laboratory Standards Institute; 2012.

CLSI. Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline – Second Edition. CLSI document EP24-A2. Wayne, PA: Clinical Laboratory Standards Institute; 2011.

CLSI. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI document EP25-A. Wayne, PA: Clinical Laboratory Standards Institute; 2009.

CLSI. Collection Transport Preparation and Storage of Specimens for Molecular Methods. 2nd Edition. CLSI Document MM13. Wayne, PA: Clinical Laboratory Standards Institute; 2020.

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CLSI. Verification and Validation of Multiplex Nucleic Acid Assays. 2nd Edition. CLSI Document MM17. Wayne, PA: Clinical Laboratory Standards Institute; 2018.

ISTA. Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less. ISTA Document 3A. International Safe Transit Association. 2018.

IEC 62366-1 Edition 1.1 2020-06 Consolidated Version; Medical devices – Part 1: Application of usability engineering to medical devices

IEC 61010-1 Edition 3.1 2017-01 Consolidated Version; Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version; Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 61326-1 Edition 3.0 2020-10; Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements IEC 61326-2 Edition 3.0 2020-10; Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

IEC 62304 Edition 1.1 2015-06 Consolidated Version; Medical device software – Software life cycle processes

IEC TR 60878 Ed. 4.0 2022-11; Graphical symbols for electrical equipment in medical practice [Including: Corrigendum 1 (2023)]

IEC TR 80001-2-2:2012. Application of risk management for IT Networks incorporating medical devices – Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls

IEC TR 80001-2-8 Edition 1.0 206-05; Application of risk management for IT – networks incorporating medical devices – Part 2-8: Application guidance – Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2

ISO 14971:2019 Medical Devices – Application of risk management to medical devices

ISO 15223-1: 2021-07 – Medical Devices- Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements

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UL ANSI 2900-1 First Edition 2017; Standard for Safety, Standard for Software Cybersecurity Network-Connectable Products, Part 1: General Requirements

UL ANSI 2900-2-1 First Edition 2017; Standard for Safety, Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

EN ISO 18113-1 2011; In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). In vitro diagnostic instruments for professional use

EN ISO 18113-2 2011; In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 2: In vitro diagnostic reagents for professional use

ISO 23640 2015; Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied. General requirements

CLSI MM13 2nd Edition, MM13Ed2E; Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods

CLSI MM17 2nd Edition, MM17Ed2E; Verification and Validation of Multiplex Nucleic Acid Assays

Test Principle:

The LIAISON PLEX® Gastrointestinal *Flex* Assay is an automated test for the detection and identification of nucleic acids from enteric bacteria, viruses, and parasites in stool samples. The LIAISON PLEX Gastrointestinal *Flex* Assay is performed on the LIAISON PLEX® System. The LIAISON PLEX System is an automated platform that performs sample preparation and is capable of reverse transcription (RT) and polymerase chain reaction (PCR) followed by microarray-based hybridization for the detection of target-specific nucleic acids. The test reagents are supplied as a single, disposable test cartridge with a sample processing tube and a transfer pipette.

Clinical Performance

Prospective and Pre-selected Clinical Evaluation

A multi-site clinical study established the diagnostic accuracy of the LIAISON PLEX® Gastrointestinal (GI) *Flex* Assay. The clinical performance of the LIAISON PLEX Gastrointestinal *Flex* Assay was evaluated using clinical specimens prospectively collected between January 2024 and July 2025 from seven geographically diverse clinical sites within the United States. The clinical study utilized residual, de-identified specimens collected from pediatric and adult patients exhibiting clinical signs and symptoms of gastrointestinal infection.

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All clinical specimens were compared to an FDA cleared molecular assay, PCR followed by bi-directional sequencing (BDS) assays, or a combination of the two according to the algorithm described in Table 2 below. In the case of Shiga-like toxin-producing *Escherichia coli* (STEC), PCR/BDS was also used to distinguish between *stx1* and *stx2*.

Table 2. Reference Method Algorithm

LIAISON PLEX® Gastrointestinal *Flex* Assay Target	Comparator Method
Bacteria	
Clostridioides difficile (*tcdA/tcdB*)	FDA-cleared molecular assay
Enterotoxigenic *Escherichia coli* (ETEC) LT/ST	FDA-cleared molecular assay with positive confirmation by PCR/BDS
Campylobacter spp. (*C. coli/C. jejuni/C.lari/C.upsaliensis*)	
Salmonella spp.	
Shiga-like toxin-producing *Escherichia coli* (STEC) *stx1*	
Shiga-like toxin-producing *Escherichia coli* (STEC) *stx2*	
Shigella/Enteroinvasive *Escherichia coli* (EIEC)	
Vibrio cholerae	
Plesiomonas shigelloides	PCR/BDS
Vibrio spp. (*V.parahaemolyticus/V.vulnificus*)	
Yersinia enterocolitica	
Viruses	
Adenovirus F (40/41)	FDA-cleared molecular assay with positive confirmation by PCR/BDS
Norovirus GI/GII	

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LIAISON PLEX® Gastrointestinal *Flex* Assay Target	Comparator Method
Rotavirus A	
Astrovirus	PCR/BDS
Sapovirus I/II/IV/V	
Parasites	
Cryptosporidium spp.	For Cary-Blair specimens: FDA-cleared molecular assay with positive confirmation by PCR/BDS For Fixative specimens: PCR/BDS
Entamoeba histolytica	
Giardia lamblia (also known as *G. intestinalis* and *G. duodenalis*)	
Blastocystis sp.	PCR/BDS
Cyclospora cayetanensis	
Dientamoeba fragilis	
Microsporidia (*Encephalitozoon hellem/Encephalitozoon intestinalis/Enterocytozoon bieneusi*)	
Strongyloides stercoralis	

A total of 2240 unique prospectively collected specimens, collected from seven geographically diverse US sites, that met the pre-defined inclusion criteria, were enrolled in the study. Clinical testing runs and re-runs were performed according to the Instructions for Use using the LIAISON PLEX Gastrointestinal *Flex* Assay on the LIAISON PLEX® System by trained operators at all sites.

Prospective specimen (Arm 1) testing occurred between August 2024 and July 2025. Of the 2240 specimens enrolled in the prospective arm of the study, 7 (0.3%) specimens were disqualified and removed from further analysis. Of the seven (7) specimens, four (4) specimens were duplicate patient specimens and three (3) specimens did not have comparator results available. Following exclusions, 2233 prospective specimens were included in the data analysis.

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For targets that exhibited low prevalence rates in the prospective study, the prospective specimen set was supplemented with 333 pre-selected remnant, de-identified specimens (Arm 2) sourced from 17 sites/vendors in the United States, one (1) vendor in France and one (1) vendor in Germany. The pre-selected specimens were identified by Standard of Care (SoC) results and confirmed by comparator method testing prior to enrollment in the study. To minimize bias, pre-selected specimens were tested in a randomized, blinded manner along with negative specimens at three (3) external and one (1) internal site. Pre-selected specimen collection dates ranged from September 2017 through February 2026, while (Arm 2) testing occurred between August 2025 and March 2026.

Targets such as *Blastocystis* sp., *Cryptosporidium* spp., *Cyclospora cayatanensis*, *Giardia lamblia*, *Dientamoeba fragilis*, *Plesiomonas shigelloides,* Shiga-like toxin-producing *E.coli* (STEC) *stx2, Vibrio cholerae, Vibrio* spp., *Entamoeba histolytica,* Microsporidia*, Strongyloides stercoralis,* and *Yersinia enterocolitica* exhibited low prevalence rates in the prospective study, and insufficient pre-selected specimens were available for enrollment in the study, necessitating the preparation and testing of contrived specimens. Additional specimens were contrived for the parasite targets as needed to ensure a sufficient number of specimens in both Cary-Blair and fixative media.

A total of 827 specimens were contrived and tested as part of Arm 3 (contrived specimens). To minimize bias, contrived specimens were blinded, randomized, and tested along with Arm 2 positive and/or negative clinical specimens at four (4) external testing sites and one (1) internal testing site from July 2025 to March 2026. Results from contrived specimens were analyzed separately from the prospective and pre-selected data sets.

The overall invalid rate across prospective, pre-selected, and contrived arms of testing was 3.8% (129/3393) after the initial run. Of the 129 specimens with initial invalid results, 128 (3.8%) specimens were retested, and 113 (3.3%) specimens generated valid LIAISON PLEX Gastrointestinal *Flex* Assay results after a single retest. Fifteen (15, 0.4%) specimens remained invalid on repeat, and one (1, 0.03%) specimen was not retested due to insufficient volume, resulting in an overall success rate of 99.5% (3377/3393).

For each target, the diagnostic performance of the LIAISON PLEX Gastrointestinal *Flex* Assay was determined using Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA), along with the associated Wilson score 95% confidence intervals (95% CI as compared to the reference method). The results for prospective and pre-selected specimen analysis are summarized in Table 3 through Table 5. The performance of the LIAISON PLEX Gastrointestinal *Flex* Assay for contrived specimens is presented separately in Table 6 and Table 7.

Discordant results for applicable targets were resolved by testing with assays not included in the comparator testing analysis. Methods of discordant analysis included PCR/BDS, an FDA-cleared molecular method , or standard of care results, as applicable. Results of discordant analyses are presented as footnotes to Table 3 to Table 5.

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Table 3. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of Prospective and Pre-Selected Data Sets (Arm 1 and Arm 2)

Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Bacteria							
Clostridioides difficile (tcdA/tcdB)	Prospective	40/41[1]	97.6%	87.4% - 99.6%	202/204[2]	99%	96.5% - 99.7%
	Pre-selected	0/0	N/A	N/A	0/0	N/A	N/A
***Campylobacter* spp.**	Prospective	36/40[3]	90%	76.9% - 96%	1400/1402[4]	99.9%	99.5% - 100%
	Pre-selected	8/8	100%	67.6% - 100%	290/291[5]	99.7%	98.1% - 99.9%
Enterotoxigenic *E. coli* (ETEC) LT/ST	Prospective	8/10[6]	80%	49% - 94.3%	1419/1431[7]	99.2%	98.5% - 99.5%
	Pre-selected	22/22	100%	85.1% - 100%	278/279[8]	99.6%	98% - 99.9%
Plesiomonas shigelloides	Prospective	6/6	100%	61% - 100%	1654/1654	100%	99.8% - 100%
	Pre-selected	10/10	100%	72.2% - 100%	292/292	100%	98.7% - 100%
***Salmonella* spp.**	Prospective	29/29	100%	88.3% - 100%	1405/1405	100%	99.7% - 100%
	Pre-selected	5/5	100%	56.6% - 100%	294/294	100%	98.7% - 100%
Shiga-like toxin-producing *E. coli* (STEC) *stx1*	Prospective	10/10	100%	72.2% - 100%	1429/1432[9]	99.8%	99.4% - 99.9%
	Pre-selected	21/21	100%	84.5% - 100%	279/279	100%	98.6% - 100%
Shiga-like toxin-producing *E. coli* (STEC) *stx2*	Prospective	4/4	100%	51% - 100%	1437/1438[10]	99.9%	99.6% - 100%
	Pre-selected	11/11	100%	74.1% - 100%	287/289[11]	99.3%	97.5% - 99.8%
***Shigella*/ Enteroinvasive *E. coli* (EIEC)**	Prospective	19/19	100%	83.2% - 100%	1423/1423	100%	99.7% - 100%
	Pre-selected	15/15	100%	79.6% - 100%	284/284	100%	98.7% - 100%
Vibrio cholerae	Prospective	0/0	N/A	N/A	1440/1441[12]	99.9%	99.6% - 100%
	Pre-selected	0/0	N/A	N/A	299/299	100%	98.7% - 100%
***Vibrio* spp.**	Prospective	0/0	N/A	N/A	1659/1660[13]	99.9%	99.7% - 100%
	Pre-selected	7/8[14]	87.5%	52.9% - 97.8%	294/294	100%	98.7% - 100%
Yersinia enterocolitica	Prospective	5/8[15]	62.5%	30.6% - 86.3%	1649/1652[16]	99.8%	99.5% - 99.9%
	Pre-selected	38/39[17]	97.4%	86.8% - 99.5%	263/263	100%	98.6% - 100%

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Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Viruses							
Astrovirus	Prospective	26/27[18]	96.3%	81.7% - 99.3%	1633/1633	100%	99.8% - 100%
	Pre-selected	7/7	100%	64.6% - 100%	294/295[19]	99.7%	98.1% - 99.9%
Adenovirus F (40/41)	Prospective	9/9	100%	70.1% - 100%	1430/1435[20]	99.7%	99.2% - 99.9%
	Pre-selected	21/21	100%	84.5% - 100%	276/278[21]	99.3%	97.4% - 99.8%
Norovirus GI/GII	Prospective	117/117	100%	96.8% - 100%	1307/1333[22]	98%	97.2% - 98.7%
	Pre-selected	2/2	100%	34.2% - 100%	297/297	100%	98.7% - 100%
Rotavirus A	Prospective	26/26	100%	87.1% - 100%	1411/1417[23]	99.6%	99.1% - 99.8%
	Pre-selected	6/6	100%	61% - 100%	293/293	100%	98.7% - 100%
Sapovirus I/II/IV/V	Prospective	21/29[24]	72.4%	54.3% - 85.3%	1621/1631[25]	99.4%	98.9% - 99.7%
	Pre-selected	11/11	100%	74.1% - 100%	281/290[26]	96.9%	94.2% - 98.4%
Parasites							
***Blastocystis* sp.**	Prospective	45/47[27]	95.7%	85.8% - 98.8%	2083/2173[28]	95.9%	94.9% - 96.6%
	Pre-selected	10/10	100%	72.2% - 100%	292/316[29]	92.4%	88.9% - 94.8%
***Cryptosporidium* spp.**	Prospective	13/17[30]	76.5	52.7% - 90.4%	1985/1985	100%	99.8% - 100%
	Pre-selected	29/29	100%	88.3% - 100%	294/294	100%	98.7% - 100%
Cyclospora cayetanensis	Prospective	2/2	100%	34.2% - 100%	2217/2218[31]	100%	99.7% - 100%
	Pre-selected	27/30[32]	90%	74.4% - 96.5%	295/296[33]	99.7%	98.1% - 99.9%
Dientamoeba fragilis	Prospective	14/16[34]	87.5%	64% - 96.5%	2203/2204[34]	100%	99.7% - 100%
	Pre-selected	13/14[34]	92.9%	68.5% - 98.7%	311/312[34]	99.7%	98.2% - 99.9%
Entamoeba histolytica	Prospective	2/2	100%	34.2% - 100%	1998/1998	100%	99.8% - 100%
	Pre-selected	1/1	100%	20.7% - 100%	322/322	100%	98.8% - 100%
Giardia lamblia	Prospective	9/9	100%	70.1% - 100%	1996/1998[35]	99.9%	99.6% - 100%
	Pre-selected	20/21[36]	95.2%	77.3% - 99.2%	302/302	100%	98.7% - 100%
Microsporidia	Prospective	4/5[37]	80%	37.6% - 96.4%	2214/2215[37]	100%	99.7% - 100%

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Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
	Pre-selected	8/8	100%	67.6% - 100%	318/318	100%	98.8% - 100%
Strongyloides stercoralis	Prospective	0/0	N/A	N/A	2220/2220	100%	99.8% - 100%
	Pre-selected	9/10[38]	90%	59.6% - 98.2%	316/316	100%	98.8% - 100%

[1]The prospective *Clostridioides difficile* False Negative specimen was negative by the Standard of Care molecular panel.
[2]The two prospective *Clostridioides difficile* False Positive specimens were negative by the Standard of Care molecular panel.
[3]One of the four prospective *Campylobacter* spp. False Negative specimens was negative by the Standard of Care molecular panel. An additional two specimens were negative by Standard of Care culture. The remaining specimen was negative when tested with an FDA-cleared molecular panel.
[4]One of the two prospective *Campylobacter* spp. False Positive specimens was positive by the Standard of Care molecular panel. The other prospective specimen was negative when tested with an FDA-cleared molecular panel.
[5]The pre-selected *Campylobacter* spp. False Positive specimen was positive when tested with an FDA-cleared molecular panel.
[6]One of the two prospective Enterotoxigenic *E. coli* (ETEC) LT/ST False Negative specimens was negative by Standard of Care FDA-cleared molecular panel. Both specimens were positive when tested with a second FDA-cleared molecular panel.
[7]Two of the twelve prospective Enterotoxigenic *E. coli* (ETEC) LT/ST False Positive specimens were positive by the Standard of Care molecular panel, and nine additional specimens were positive when tested with an FDA-cleared molecular panel.
[8]The pre-selected Enterotoxigenic *E. coli* (ETEC) LT/ST False Positive specimen was negative by the Standard of Care molecular panel.
[9]The three prospective Shiga-like toxin-producing *E. coli* (STEC) *stx1* False Positive specimens were *stx1/2* positive when tested with an FDA-cleared molecular panel and *stx1* positive by PCR/BDS.
[10]The prospective Shiga-like toxin-producing *E. coli* (STEC) *stx2* False Positive specimen was *stx1/2* positive when tested with an FDA-cleared molecular panel and *stx1* positive by PCR/BDS.
[11]One of the two pre-selected Shiga-like toxin-producing *E. coli* (STEC) *stx2* False Positive specimens was *stx1/2* positive when tested with an FDA-cleared molecular panel. The remaining specimen was *stx1/2* negative by Standard of Care molecular panel.
[12]The prospective *Vibrio cholerae* False Positive specimen was positive by PCR/BDS.
[13]The prospective *Vibrio* spp. False Positive specimen was positive when tested with an FDA-cleared molecular panel.
[14]The pre-selected *Vibrio* spp. False Negative specimen was negative when tested with an FDA-cleared molecular panel.
[15]One of the three prospective *Yersinia enterocolitica* False Negative specimens was negative by the Standard of Care molecular panel. Another was negative by Standard of Care culture and positive when tested with an FDA-cleared molecular panel. No evaluation of discordant results was performed for the third specimen.
[16]One of the three prospective *Yersinia enterocolitica* False Positive specimens was positive by the Standard of Care molecular panel. Another specimen was positive when tested with an FDA-cleared molecular panel. The third was negative by Standard of Care culture and when tested with an FDA-cleared molecular panel.
[17]No evaluation of discordant results was performed for the pre-selected *Yersinia enterocolitica* False Negative specimen.
[18]The prospective Astrovirus False Negative specimen was negative when tested with an FDA-cleared molecular panel.
[19]The pre-selected Astrovirus False Positive specimen was negative by Standard of Care molecular panel.
[20]The five prospective Adenovirus False Positive specimens were negative by PCR/BDS.
[21]The two pre-selected Adenovirus False Positive specimens were negative when tested with an FDA-cleared molecular panel.
[22]Eight of the twenty-six prospective Norovirus GI/GII False Positive specimens were positive by PCR/BDS. Two additional specimens were positive by the Standard of Care molecular panel. Six additional specimens were positive when tested with an FDA-cleared molecular panel. The remaining ten specimens were negative by PCR/BDS.
[23]Two of the six Rotavirus False Positive specimens were positive by PCR/BDS. An additional three specimens were positive when tested with an FDA-cleared molecular panel. The remaining specimen was negative by PCR/BDS.
[24]Three of the eight prospective Sapovirus I/II/IV/V False Negative specimens were negative when tested with an FDA-cleared molecular panel and one was negative by the Standard of Care molecular panel. Two additional specimens were positive by the Standard of Care molecular panel. The remaining two specimens were positive when tested with an FDA-cleared molecular panel.
[25]One of the ten prospective Sapovirus I/II/IV/V False Positive specimens was positive by the Standard of Care molecular panel. An additional five specimens were positive when tested with an FDA-cleared molecular panel. One specimen was negative by the Standard of Care molecular panel and one additional specimen was negative when tested with an FDA-cleared molecular panel. No evaluation of discordant results was performed for the remaining two specimens.
[26]Two of the nine pre-selected Sapovirus I/II/IV/V False Positive specimens were positive when tested with an FDA-cleared molecular panel. Two additional specimens were negative by Standard of Care molecular panel, four were negative when tested with an FDA-cleared molecular panel and no evaluation of discordant results was performed for the remaining specimen.
[27]No evaluation of discordant results was performed for the prospective *Blastocystis* sp. False Negative specimens.

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[28]Twenty-seven prospective Blastocystis spp. False Positive specimens were negative by Standard of Care O&P testing. No evaluation of discordant results was performed for the remaining sixty-three prospective *Blastocystis* sp. False Positive specimens.
[29]Two pre-selected Blastocystis sp. False Positive specimens were negative by Standard of Care O&P testing. No evaluation of discordant results was performed for the remaining twenty-two pre-selected *Blastocystis* sp. False Positive specimens.
[30]Two of the four prospective *Cryptosporidium* spp. False Negative specimens were negative by the Standard of Care molecular panel, one additional specimen was negative by Standard of Care O&P testing and the remaining specimen was positive by Standard of Care O&P testing and an FDA-cleared molecular panel.
[31]The prospective *Cyclospora cayetanensis* False Positive specimen was positive by Standard of Care molecular panel.
[32]One of the three pre-selected *Cyclospora cayetanensis* False Negative specimens was positive by Standard of Care molecular panel, and the remaining two were positive by Standard of Care O&P testing.
[33]The pre-selected *Cyclospora cayetanensis* False Positive specimen was positive by Standard of Care O&P testing.
[34]No evaluation of discordant results was performed for *Dientamoeba fragilis*.
[35]Both prospective *Giardia lamblia* False Positive specimens were negative by PCR/BDS.
[36]No evaluation of discordant results was performed for the pre-selected *Giardia lamblia* False Negative specimen.
[37]No evaluation of discordant results was performed for *Microsporidia*.
[38]No evaluation of discordant results was performed for *Strongyloides stercoralis*.

Table 4. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of Parasite Targets by Media Type of Prospective Data Set (Arm 1)

Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
Analyte	**Media Type**	**TP / (TP+FN)**	**PPA (%)**	**95% CI**	**TN / (TN+FP)**	**NPA (%)**	**95% CI**
***Blastocystis* sp.**	Cary-Blair	31/33	93.9%	80.4% - 98.3%	1561/1627	95.9%	94.9% - 96.8%
	Fixative	14/14	100%	78.5% - 100%	522/546	95.6%	93.5% - 97%
	Combined	**45/47[1]**	**95.7%**	**85.8% - 98.8%**	**2083/2173[2]**	**95.9%**	**94.9% - 96.6%**
***Cryptosporidium* spp.**	Cary-Blair	10/11	90.9%	62.3% - 98.4%	1431/1431	100%	99.7% - 100%
	Fixative	3/6	50%	18.8% - 81.2%	554/554	100%	99.3% - 100%
	Combined	**13/17[3]**	**76.5%**	**52.7% - 90.4%**	**1985/1985**	**100%**	**99.8% - 100%**
Cyclospora cayetanensis	Cary-Blair	1/1	100%	20.7% - 100%	1659/1659	100%	99.8% - 100%
	Fixative	1/1	100%	20.7% - 100%	558/559	99.8%	99% - 100%
	Combined	**2/2**	**100%**	**34.2% - 100%**	**2217/2218[4]**	**100%**	**99.7% - 100%**
Dientamoeba fragilis	Cary-Blair	10/12	83.3%	55.2% - 95.3%	1647/1648	99.9%	99.7% - 100%
	Fixative	4/4	100%	51% - 100%	556/556	100%	99.3% - 100%
	Combined	**14/16[5]**	**87.5%**	**64% - 96.5%**	**2203/2204[5]**	**100%**	**99.7% - 100%**
Entamoeba histolytica	Cary-Blair	1/1	100%	20.7% - 100%	1439/1439	100%	99.7% - 100%
	Fixative	1/1	100%	20.7% - 100%	559/559	100%	99.3% - 100%
	Combined	**2/2**	**100%**	**34.2% - 100%**	**1998/1998**	**100%**	**99.8% - 100%**
Giardia lamblia	Cary-Blair	7/7	100%	64.6% - 100%	1439/1440	99.9%	99.6% - 100%
	Fixative	2/2	100%	34.2% - 100%	557/558	99.8%	99% - 100%
	Combined	**9/9**	**100%**	**70.1% - 100%**	**1996/1998[6]**	**99.9%**	**99.6% - 100%**
Microsporidia	Cary-Blair	3/4	75%	30.1% - 95.4%	1655/1656	99.9%	99.7% - 100%
	Fixative	1/1	100%	20.7% - 100%	559/559	100%	99.3% - 100%
	Combined	**4/5[7]**	**80%**	**37.6% - 96.4%**	**2214/2215[7]**	**100%**	**99.7% - 100%**

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Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
Analyte	**Media Type**	**TP / (TP+FN)**	**PPA (%)**	**95% CI**	**TN / (TN+FP)**	**NPA (%)**	**95% CI**
Strongyloides stercoralis	Cary-Blair	0/0	N/A	N/A	1660/1660	100%	99.8% - 100%
	Fixative	0/0	N/A	N/A	560/560	100%	99.3% - 100%
	Combined	**0/0**	**N/A**	**N/A**	**2220/2220**	**100%**	**99.8% - 100%**

[1]No evaluation of discordant results was performed for Blastocystis sp. False Negative specimens.
[2]Twenty-seven prospective Blastocystis spp. False Positive specimens were negative by Standard of Care O&P testing. No evaluation of discordant results was performed for the remaining sixty-three prospective *Blastocystis* sp. False Positive specimens.
[3]Two of the four prospective *Cryptosporidium* spp. False Negative specimens were negative by the Standard of Care molecular panel, one additional specimen was negative by Standard of Care O&P testing and the remaining specimen was positive by Standard of Care O&P testing and an FDA-cleared molecular panel.
[4]The prospective *Cyclospora cayetanensis* False Positive specimen was positive by Standard of Care molecular panel.
[5]No evaluation of discordant results was performed for *Dientamoeba fragilis*.
[6]Both prospective *Giardia lamblia* False Positive specimens were negative by PCR/BDS..
[7]No evaluation of discordant results was performed for *Microsporidia*.

Table 5. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of Parasite Targets by Media Type of Pre-selected Data Set (Arm 2)

Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
Analyte	**Media Type**	**TP / (TP+FN)**	**PPA (%)**	**95% CI**	**TN / (TN+FP)**	**NPA (%)**	**95% CI**
***Blastocystis* sp.**	Cary-Blair	6/6	100%	61% - 100%	273/296	92.2%	88.6% - 94.8%
	Fixative	4/4	100%	51% - 100%	19/20	95%	76.4% - 99.1%
	Combined	**10/10**	**100%**	**72.2% - 100%**	**292/316[1]**	**92.4%**	**88.9% - 94.8%**
***Cryptosporidium* spp.**	Cary-Blair	29/29	100%	88.3% - 100%	270/270	100%	98.6% - 100%
	Fixative	0/0	N/A	N/A	24/24	100%	86.2% - 100%
	Combined	**29/29**	**100%**	**88.3% - 100%**	**294/294**	**100%**	**98.7% - 100%**
Cyclospora cayetanensis	Cary-Blair	19/21	90.5%	71.1% - 97.3%	281/281	100%	98.7% - 100%
	Fixative	8/9	88.9%	56.5% - 98%	14/15	93.3%	70.2% - 98.8%
	Combined	**27/30[2]**	**90%**	**74.4% - 96.5%**	**295/296[3]**	**99.7%**	**98.1% - 99.9%**
Dientamoeba fragilis	Cary-Blair	12/13	92.3%	66.7% - 98.6%	288/289	99.7%	98.1% - 99.9%
	Fixative	1/1	100%	20.7% - 100%	23/23	100%	85.7% - 100%
	Combined	**13/14[4]**	**92.9%**	**68.5% - 98.7%**	**311/312[4]**	**99.7%**	**98.2% - 99.9%**
Entamoeba histolytica	Cary-Blair	1/1	100%	20.7% - 100%	298/298	100%	98.7% - 100%
	Fixative	0/0	N/A	N/A	24/24	100%	86.2% - 100%
	Combined	**1/1**	**100%**	**20.7% - 100%**	**322/322**	**100%**	**98.8% - 100%**
Giardia lamblia	Cary-Blair	20/21	95.2%	77.3% - 99.2%	278/278	100%	98.6% - 100%
	Fixative	0/0	N/A	N/A	24/24	100%	86.2% - 100%
	Combined	**20/21[5]**	**95.2%**	**77.3% - 99.2%**	**302/302**	**100%**	**98.7% - 100%**

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Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
Analyte	**Media Type**	**TP / (TP+FN)**	**PPA (%)**	**95% CI**	**TN / (TN+FP)**	**NPA (%)**	**95% CI**
Microsporidia	Cary-Blair	8/8	100%	67.6% - 100%	294/294	100%	98.7% - 100%
	Fixative	0/0	N/A	N/A	24/24	100%	86.2% - 100%
	Combined	**8/8**	**100%**	**67.6% - 100%**	**318/318**	**100%**	**98.8% - 100%**
Strongyloides stercoralis	Cary-Blair	2/3	66.7%	20.8% - 93.9%	299/299	100%	98.7% - 100%
	Fixative	7/7	100%	64.6% - 100%	17/17	100%	81.6% - 100%
	Combined	**9/10[6]**	**90%**	**59.6% - 98.2%**	**316/316**	**100%**	**98.8% - 100%**

[1]Two pre-selected Blastocystis sp. False Positive specimens were negative by Standard of Care O&P testing. No evaluation of discordant results was performed for the remaining twenty-two pre-selected *Blastocystis* sp. False Positive specimens.
[2]One of the three pre-selected *Cyclospora cayetanensis* False Negative specimens was positive by Standard of Care molecular panel, and the remaining two were positive by Standard of Care O&P testing.
[3]The pre-selected *Cyclospora cayetanensis* False Positive specimen was positive by Standard of Care O&P testing.
[4]No evaluation of discordant results was performed for *Dientamoeba fragilis*.
[5]No evaluation of discordant results was performed for the pre-selected *Giardia lamblia* False Negative specimen.
[6]No evaluation of discordant results was performed for *Strongyloides stercoralis*.

Table 6. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of Contrived Data Set (Arm 3) Bacterial Targets

Pathogen Target	Positive Percent Agreement			Negative Percent Agreement		
Analyte	**TP / (TP+FN)**	**PPA (%)**	**95% CI**	**TN / (TN+FP)**	**NPA (%)**	**95% CI**
Plesiomonas shigelloides	47/48	97.9%	89.1% - 99.6%	428/428	100%	99.1% - 100%
Shiga-like toxin-producing *E. coli* (STEC) *stx2*	50/50	100%	92.9% - 100%	426/426	100%	99.1% - 100%
Vibrio cholerae	49/50	98%	89.5% - 99.6%	426/426	100%	99.1% - 100%
Vibrio spp.	48/50	96%	86.5% - 98.9%	426/426	100%	99.1% - 100%
Yersinia enterocolitica	49/50	98%	89.5% - 99.6%	426/426	100%	99.1% - 100%

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Table 7. Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) of Contrived Data Set (Arm 3) Parasite Targets

Pathogen Target		Positive Percent Agreement			Negative Percent Agreement		
Analyte	**Media Type**	**TP / (TP+FN)**	**PPA (%)**	**95% CI**	**TN / (TN+FP)**	**NPA (%)**	**95% CI**
***Blastocystis* sp.**	Cary-Blair	0/0	N/A	N/A	470/476	98.7%	97.3% - 99.4%
	Fixative	50/50	100%	92.9% - 100%	294/298	98.7%	96.6% - 99.5%
	Combined	**50/50**	**100%**	**92.9% - 100%**	**741/751**	**98.7%**	**96.6% - 99.5%**
***Cryptosporidium* spp.**	Cary-Blair	0/0	N/A	N/A	476/476	100%	99.2% - 100%
	Fixative	49/50	98%	89.5% - 99.6%	298/298	100%	98.7% - 100%
	Combined	49/50	98%	89.5% - 99.6%	**774/774**	**100%**	**99.5% - 100%**
Cyclospora cayatanensis	Cary-Blair	29/29	100%	88.3% - 100%	447/447	100%	99.1% - 100%
	Fixative	27/30	90%	74.4% - 96.5%	318/318	100%	98.8% - 100%
	Combined	**56/59**	**94.9%**	**86.1% - 98.3%**	**765/765**	**100%**	**99.5% - 100%**
Dientamoeba fragilis	Cary-Blair	30/30	100%	88.6% - 100%	446/446	100%	99.1% - 100%
	Fixative	30/30	100%	88.6% - 100%	318/318	100%	98.8% - 100%
	Combined	**60/60**	**100%**	**94% - 100%**	**764/764**	**100%**	**99.5% - 100%**
Entamoeba histolytica	Cary-Blair	30/30	100%	88.6% - 100%	446/446	100%	99.1% - 100%
	Fixative	57/60	95%	86.3% - 98.3%	288/288	100%	98.7% - 100%
	Combined	**87/90**	**96.7%**	**90.7% - 98.9%**	**734/734**	**100%**	**99.5% - 100%**
Giardia lamblia	Cary-Blair	30/30	100%	88.6% - 100%	446/446	100%	99.1% - 100%
	Fixative	29/30	96.7%	83.3% - 99.4%	317/318	99.7%	98.2% - 99.9%
	Combined	**59/60**	**98.3%**	**91.1% - 99.7%**	**763/764**	**99.9%**	**99.3% - 100%**
Microsporidia	Cary-Blair	29/30	96.7%	83.3% - 99.4%	446/446/	100%	99.1% - 100%
	Fixative	30/30	100%	88.6% - 100%	318/318	100%	98.8% - 100%
	Combined	**59/60**	**98.3%**	**91.1% - 99.7%**	**764/764**	**100%**	**99.5% - 100%**
Strongyloides stercoralis	Cary-Blair	25/25	100%	86.7% - 100%	451/451	100%	99.2% - 100%
	Fixative	50/50	100%	92.9% - 100%	298/298	100%	98.7% - 100%
	Combined	**75/75**	**100%**	**95.1% - 100%**	**749/749**	**100%**	**99.5% - 100%**

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Analytical Performance

Limit of Detection

A limit of detection (LoD) study was performed to evaluate the analytical sensitivity of the LIAISON PLEX® Gastrointestinal *Flex* Assay. The limit of detection was performed in two stages for every assay target – an initial determination stage followed by a final confirmation step. The LoD was investigated for all assay targets in Cary-Blair stool matrix. Parasite targets included in the assay were additionally investigated in two parasite fixative stool matrices.

The LoD determination step was performed for each strain/sample using a 3-fold dilution series and four replicates per dilution (concentration). In this step, the 'determined LoD' was identified as the lowest concentration where a 100% detection rate was observed.

LoD confirmation for each strain was performed by testing serial concentrations beginning at the determined LoD, with subsequent increases or decreases in three-fold increments, until the lowest concentration demonstrating ≥95% detection across replicates was established as the 'confirmed LoD'. Confirmation phase testing of each concentration was executed across a minimum of three test days; across 3 assay kit lots, and included at least 20 valid replicates.

The limit of detection for each strain/sample tested is listed in Table 8. Where multiple strains or samples per assay target call were tested, the highest LoD defined the LoD claim for the target. The limit of detection for each assay target is listed in Table 9.

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Table 8: LIAISON PLEX® Gastrointestinal Flex Assay Limit of Detection Summary by Strain/Sample

LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
Bacterial Targets						
***Campylobacter* spp.**	*Campylobacter coli*	ATCC 43482	Cary-Blair	5.65E+00 CFU/mL	95% (19/20)	4.57E+02 CFU/mL
	Campylobacter jejuni subsp. *jejuni*	ATCC 29428	Cary-Blair	4.57E+02 CFU/mL	100% (20/20)	
	Campylobacter lari	ATCC 35222	Cary-Blair	1.69E+01 CFU/mL	100% (20/20)	
	Campylobacter upsaliensis	ATCC 43953	Cary-Blair	5.08E+01 CFU/mL	100% (20/20)	
***Clostridioides difficile* (*tcdA/tcdB*)**	*Clostridioides difficile*	ATCC 43255	Cary-Blair	1.88E+00 CFU/mL	100% (20/20)	5.65E+00 CFU/mL
	Clostridioides difficile	ATCC BAA-1805	Cary-Blair	5.65E+00 CFU/mL	95% (19/20)	
Enterotoxigenic *E.coli* (ETEC) LT/ST	*Escherichia coli* (LT+, ST1A+, ST1B+)	ATCC 35401	Cary-Blair	4.57E+02 CFU/mL	100% (20/20)	4.57E+02 CFU/mL
	Escherichia coli (ST1B+)	ATCC 43896	Cary-Blair	4.57E+02 CFU/mL	100% (20/20)	

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LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
Plesiomonas shigelloides	*Plesiomonas shigelloides*	ATCC 51903	Cary-Blair	1.37E+03 CFU/mL	100% (20/20)	4.12E+03 CFU/mL
	Plesiomonas shigelloides	ATCC 14029	Cary-Blair	4.12E+03 CFU/mL	100% (20/20)	
***Salmonella* spp.**	*Salmonella enterica* subsp. *enterica* serovar Typhimurium	ATCC 13311	Cary-Blair	1.37E+03 CFU/mL	100% (20/20)	1.37E+03 CFU/mL
	Salmonella enterica subsp. *arizonae*	ATCC 13314	Cary-Blair	1.37E+03 CFU/mL	100% (20/20)	
Shiga-like toxin-producing *E.coli* (STEC) *stx1*	*Escherichia coli* (O157:H7), *STX1*	ATCC 43890	Cary-Blair	1.37E+03 CFU/mL	100% (20/20)	1.37E+03 CFU/mL
Shiga-like toxin-producing *E.coli* (STEC) *stx2*	*Escherichia coli* (O104:H4), *STX2*	ATCC BAA-2326	Cary-Blair	4.57E+02 CFU/mL	100% (20/20)	4.57E+02 CFU/mL
***Shigella*/Enteroinvasive *E.coli* (EIEC)**	*Shigella boydii*	ATCC 25930	Cary-Blair	1.52E+02 CFU/mL	95% (19/20)	4.57E+02 CFU/mL
	Shigella flexneri	ATCC 25929	Cary-Blair	4.57E+02 CFU/mL	100% (20/20)	
Vibrio cholerae	*Vibrio cholerae* (O:1)	ATCC 39315	Cary-Blair	4.12E+03 CFU/mL	100% (20/20)	4.12E+03 CFU/mL

510(k) Summary

LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
	Vibrio cholerae (O:139)	ATCC 51394	Cary-Blair	4.12E+03 CFU/mL	100% (20/20)	
***Vibrio* spp.**	*Vibrio parahaemolyticus*	ATCC 49398	Cary-Blair	1.37E+03 CFU/mL	100% (20/20)	1.37E+03 CFU/mL
	Vibrio vulnificus	ATCC 27562	Cary-Blair	4.57E+02 CFU/mL	100% (20/20)	
Yersinia enterocolitica	*Yersinia enterocolitica*	ATCC 23715	Cary-Blair	1.37E+03 CFU/mL	95% (19/20)	1.37E+03 CFU/mL
	Yersinia enterocolitica	ATCC 700822	Cary-Blair	1.37E+03 CFU/mL	100% (20/20)	
Viral Targets						
Adenovirus F40/41	Human adenovirus 40	ATCC VR-931	Cary-Blair	4.57E+02 copies/mL	95% (19/20)	4.57E+02 copies/mL
	Human adenovirus 41	ATCC VR-930	Cary-Blair	4.57E+02 copies/mL	100% (20/20)	
Astrovirus	Astrovirus Type 1	ATCC VR-1936	Cary-Blair	1.00E+06 copies/mL	100% (20/20)	1.00E+06 copies/mL
	Astrovirus Type 2	ATCC VR-1943	Cary-Blair	1.11E+05 copies/mL	100% (20/20)	
Norovirus GI/GII	Norovirus GI	Zeptometrix 0830086CFL	Cary-Blair	2.75E+04 copies/mL	100% (20/20)	3.70E+04 copies/mL

510(k) Summary

LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
	Norovirus GII	Zeptometrix 0830087CFL	Cary-Blair	3.70E+04 copies/mL	100% (20/20)	
Rotavirus A	Rotavirus A	ATCC VR-2550	Cary-Blair	1.23E+04 copies/mL	100% (20/20)	1.23E+04 copies/mL
	Rotavirus A	ATCC VR-2551	Cary-Blair	4.57E+02 copies/mL	100% (20/20)	
Sapovirus I/II/IV/V	Sapovirus GI	Clinical Specimen LMNX-2829	Cary-Blair	1.23E+04 copies/mL	100% (20/20)	1.23E+04 copies/mL
	Sapovirus GII	Clinical Specimen LMNX-2964	Cary-Blair	1.23E+04 copies/mL	95% (19/20)	
Parasitic Targets						
***Blastocystis* sp.**	*Blastocystis hominis*	ATCC 50177	Cary-Blair	1.69E+01 cells/mL	100% (20/20)	Cary-Blair: 4.57E+02 cells/mL EcoFix: 1.52E+02 cells/mL Total-Fix: 5.08E+01 cells/mL
			EcoFix	1.52E+02 cells/mL	100% (20/20)	
			Total-Fix	5.65E+00 cells/mL	95% (19/20)	
	Blastocystis hominis	ATCC 50608	Cary-Blair	4.57E+02 cells/mL	100% (20/20)	
			EcoFix	1.52E+02 cells/mL	100% (20/20)	
			Total-Fix	5.08E+01 cells/mL	100% (20/20)	
***Cryptosporidium* spp.**	*Cryptosporidium parvum*	Waterborne P102C	Cary-Blair	1.37E+03 oocysts/mL	100% (20/20)	Cary-Blair: 4.12E+03 oocysts/mL EcoFix: 4.12E+03 oocysts/mL
			EcoFix	4.12E+03 oocysts/mL	100% (20/20)	

510(k) Summary

LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
			Total-Fix	1.37E+03 oocysts/mL	95% (19/20)	Total-Fix: 4.12E+03 oocysts/mL
	Cryptosporidium meleagridis	TU1867	Cary-Blair	4.12E+03 oocysts/mL	100% (20/20)	
			EcoFix	1.37E+03 oocysts/mL	100% (20/20)	
			Total-Fix	4.12E+03 oocysts/mL	100% (20/20)	
	Cryptosporidium muris	Waterborne P104	Cary-Blair	4.12E+03 oocysts/mL	100% (20/20)	
			EcoFix	1.37E+03 oocysts/mL	100% (20/20)	
			Total-Fix	4.12E+03 oocysts/mL	100% (20/20)	
Cyclospora cayetanensis	*Cyclospora cayetanensis*	Clinical Specimen LMNX-3415	Cary-Blair	4.12E+03 copies/mL	100% (20/20)	Cary-Blair: 4.12E+03 copies/mL EcoFix: 9.95E+02 copies/mL Total-Fix: 9.95E+02 copies/mL
	Cyclospora cayetanensis	Clinical Specimen LMNX-3862	Cary-Blair	7.57E+02 copies/mL	100% (20/20)	
		Clinical Specimen LMNX-4486	EcoFix	9.95E+02 copies/mL	95% (19/20)	
			Total-Fix	9.95E+02 copies/mL	100% (20/20)	
Dientamoeba fragilis	*Dientamoeba fragilis*	D.fragilis-1	Cary-Blair	1.52E+02 copies/mL	100% (20/20)	Cary-Blair: 4.57E+02 copies/mL EcoFix: 4.57E+02 copies/mL
			EcoFix	1.52E+02 copies/mL	100% (20/20)	

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LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
			Total-Fix	1.52E+02 copies/mL	100% (20/20)	Total-Fix: 4.57E+02 copies/mL
	Dientamoeba fragilis	D.fragilis-2	Cary-Blair	4.57E+02 copies/mL	100% (20/20)	
			EcoFix	4.57E+02 copies/mL	100% (20/20)	
			Total-Fix	4.57E+02 copies/mL	100% (20/20)	
Entamoeba histolytica	*Entamoeba histolytica*	ATCC 30459	Cary-Blair	6.97E-02 cells/mL	100% (20/20)	Cary-Blair: 1.88E+00 cells/mL EcoFix: 1.88E+00 cells/mL Total-Fix: 1.88E+00 cells/mL
			EcoFix	6.97E-02 cells/mL	100% (20/20)	
			Total-Fix	6.97E-02 cells/mL	95% (19/20)	
	Entamoeba histolytica	ATCC 50524	Cary-Blair	1.88E+00 cells/mL	100% (20/20)	
			EcoFix	1.88E+00 cells/mL	100% (20/20)	
			Total-Fix	1.88E+00 cells/mL	100% (20/20)	
Giardia lamblia	*Giardia intestinalis*	ATCC 30888	Cary-Blair	5.08E+01 cells/mL	95% (19/20)	Cary-Blair: 1.52E+02 cells/mL EcoFix: 1.52E+02 cells/mL Total-Fix: 1.52E+02 cells/mL
			EcoFix	1.52E+02 cells/mL	95% (19/20)	
			Total-Fix	5.08E+01 cells/mL	95% (19/20)	

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LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
	Giardia lamblia	ATCC PRA-254	Cary-Blair	1.52E+02 cells/mL	100% (20/20)	
			EcoFix	1.52E+02 cells/mL	100% (20/20)	
			Total-Fix	1.52E+02 cells/mL	100% (20/20)	
Microsporidia	*Encephalitozoon hellem*	ATCC 50451	Cary-Blair	2.08E+03 copies/mL	95% (19/20)	Cary-Blair: 2.08E+03 copies/mL EcoFix: 1.87E+04 copies/mL Total-Fix: 6.25E+03 copies/mL
			EcoFix	1.87E+04 copies/mL	100% (20/20)	
			Total-Fix	6.25E+03 copies/mL	100% (20/20)	
	Encephalitozoon intestinalis	ATCC 50651	Cary-Blair	3.97E+02 copies/mL	95% (19/20)	
			EcoFix	3.57E+03 copies/mL	100% (20/20)	
			Total-Fix	1.19E+03 copies/mL	100% (20/20)	
	Enterocytozoon bieneusi	Clinical Specimen LMNX-2885	Cary-Blair	1.37E+03 copies/mL	100% (20/20)	
	Enterocytozoon bieneusi	Clinical Specimen LMNX-4140	Cary-Blair	1.37E+03 copies/mL	100% (20/20)	
			EcoFix	4.12E+03 copies/mL	100% (20/20)	
			Total-Fix	1.37E+03 copies/mL	100% (20/20)	

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LIAISON PLEX GI Assay Target	Organism	Isolate ID	Media	Concentration at LoD per Strain	Percent Positivity at LoD	Concentration at LoD per Target
Strongyloides stercoralis	*Strongyloides stercoralis*	Clinical Specimen LMNX-3433	Cary-Blair	2.02E+04 copies/mL	95% (19/20)	Cary-Blair: 2.02E+04 copies/mL EcoFix: 2.72E+04 copies/mL Total-Fix: 2.16E+04 copies/mL
			EcoFix	2.72E+04 copies/mL	95% (19/20)	
			Total-Fix	2.16E+04 copies/mL	100% (20/20)	

510(k) Summary

Table 9: LIAISON PLEX® Gastrointestinal Flex Assay Limit of Detection by Target

LIAISON PLEX Gastrointestinal Flex Assay Target	Limit of Detection in Cary-Blair	Limit of Detection in EcoFix	Limit of Detection in Total-Fix
Bacterial Targets			
Campylobacter spp.	4.57E+02 CFU/mL	N/A	N/A
Clostridioides difficile (*tcdA/tcdB*)	5.65E+00 CFU/mL	N/A	N/A
Enterotoxigenic *E.coli* (ETEC) LT/ST	4.57E+02 CFU/mL	N/A	N/A
Plesiomonas shigelloides	4.12E+03 CFU/mL	N/A	N/A
Salmonella spp.	1.37E+03 CFU/mL	N/A	N/A
Shiga-like toxin-producing *E.coli* (STEC) *stx1*	1.37E+03 CFU/mL	N/A	N/A
Shiga-like toxin-producing *E.coli* (STEC) *stx2*	4.57E+02 CFU/mL	N/A	N/A
Shigella/Enteroinvasive *E.coli* (EIEC)	4.57E+02 CFU/mL	N/A	N/A
Vibrio cholerae	4.12E+03 CFU/mL	N/A	N/A
Vibrio spp.	1.37E+03 CFU/mL	N/A	N/A
Yersinia enterocolitica	1.37E+03 CFU/mL	N/A	N/A
Viral Targets			
Adenovirus F40/41	4.57E+02 copies/mL	N/A	N/A
Astrovirus	1.00E+06 copies/mL	N/A	N/A
Norovirus GI/GII	3.70E+04 copies/mL	N/A	N/A
Rotavirus A	1.23E+04 copies/mL	N/A	N/A
Sapovirus I/II/IV/V	1.23E+04 copies/mL	N/A	N/A
Parasitic Targets			
Blastocystis sp.	4.57E+02 cells/mL	1.52E+02 cells/mL	5.08E+01 cells/mL
Cryptosporidium spp.	4.12E+03 oocysts/mL	4.12E+03 oocysts/mL	4.12E+03 oocysts/mL
Cyclospora cayetanensis	4.12E+03 copies/mL	9.95E+02 copies/mL	9.95E+02 copies/mL
Dientamoeba fragilis	4.57E+02 copies/mL	4.57E+02 copies/mL	4.57E+02 copies/mL
Entamoeba histolytica	1.88E+00 cells/mL	1.88E+00 cells/mL	1.88E+00 cells/mL
Giardia lamblia	1.52E+02 cells/mL	1.52E+02 cells/mL	1.52E+02 cells/mL
Microsporidia	2.08E+03 copies/mL	1.87E+04 copies/mL	6.25E+03 copies/mL
Strongyloides stercoralis	2.02E+04 copies/mL	2.72E+04 copies/mL	2.16E+04 copies/mL

510(k) Summary

Analytical Reactivity (Inclusivity)

Analytical Reactivity (Inclusivity) of the LIAISON PLEX® Gastrointestinal *Flex* Assay was evaluated with a collection of 243 culture isolates and clinical samples, representing the genetic diversity of the analytes targeted in the LIAISON PLEX Gastrointestinal *Flex* Assay. Fifty (50/243) of the culture isolates and clinical samples, referenced in this study, were used to determine Limit of Detection (LoD) for each assay target. The remaining 193 (193/243) strains were diluted in Cary-Blair Negative Stool Matrix to a final concentration of 3x LoD or the highest available concentration where stock concentration was limiting. Each diluted strain was tested in triplicate. In cases where 100% positivity was not achieved at 3x LoD, higher titers of the strain, up to 1000x LoD, were tested until 100% positivity was achieved.

Of the 243 strains tested, four strains had unknown concentrations. All four of these strains demonstrated 100% positivity in wet testing. Of the 239 strains with known concentrations, fifty strains demonstrated ≥95% positivity at 1x LoD. Of the remaining 189 strains, 168 strains demonstrated 100% positivity at ≤3x LoD, five (5) strains demonstrated 100% positivity at 10x LoD, thirteen (13) strains demonstrated 100% positivity at 100x LoD, and three (3) strains demonstrated 100% positivity at 1000x LoD.

Results of analytical reactivity testing are shown in Table 10 through Table 13.

Table 10: Summary of Analytical Reactivity Testing Results

	Number of Strains						
	Total Tested	**≥95% Positivity at 1x LoD**	**100% Positivity at ≤3x LoD**	**100% Positivity at 10x LoD**	**100% Positivity at 100x LoD**	**100% Positivity at 1000x LoD**	**100% Positivity at Unknown Concentration**
Bacteria	147	22	111	3	11	---	---
Viruses	55	10	39	2	2	1	1[1,2]
Parasites	41	18	18	---	---	2	3[2]
Total	243	50	168	5	13	3	4

[1]Sample tested neat

[2]Sample concentration unknown

510(k) Summary

Table 11: Analytical Reactivity (Inclusivity) Bacterial Strains

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
Campylobacter spp.	*Campylobacter coli*	N/A	N/A	**ATCC 43482**	1x	5.65E+00	95% (19/20)
	Campylobacter coli			ATCC 43488	100x	5.65E+02	100% (3/3)
	Campylobacter coli			ATCC 43483	100x	5.65E+02	100% (3/3)
	Campylobacter coli			ATCC BAA-371	100x	5.65E+02	100% (3/3)
	Campylobacter coli			ATCC 43489	100x	5.65E+02	100% (3/3)
	Campylobacter jejuni (Including subsp.*jejuni and* subsp.*doylei)*			ATCC 49349	3x	1.37E+03	100% (3/3)
	Campylobacter jejuni (Including subsp.*jejuni and* subsp.*doylei)*			**ATCC 29428**	1x	4.57E+02	100% (20/20)
	Campylobacter jejuni (Including subsp.*jejuni and* subsp.*doylei)*			ATCC 43479	3x	1.37E+03	100% (3/3)
	Campylobacter jejuni (Including subsp.*jejuni and* subsp.*doylei)*			ATCC 43474	3x	1.37E+03	100% (3/3)
	Campylobacter jejuni (Including subsp.*jejuni and* subsp.*doylei)*			ATCC 43465	3x	1.37E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Campylobacter upsaliensis			ATCC 43954	100x	5.08E+03	100% (3/3)
	Campylobacter upsaliensis			ATCC BAA-1059	3x	1.52E+02	100% (3/3)
	Campylobacter upsaliensis			**ATCC 43953**	1x	5.08E+01	100% (20/20)
	Campylobacter upsaliensis			ATCC 49816	3x	1.52E+02	100% (3/3)
	Campylobacter upsaliensis			ATCC 49815	3x	1.52E+02	100% (3/3)
	Campylobacter lari			**ATCC 35222**	1x	1.69E+01	100% (20/20)
	Campylobacter lari			ATCC 43675	100x	1.69E+03	100% (3/3)
	Campylobacter lari			ATCC 35223	100x	1.69E+03	100% (3/3)
	Campylobacter lari			ATCC BAA-1060	100x	1.69E+03	100% (3/3)
	Campylobacter lari			ATCC 35221	100x	1.69E+03	100% (3/3)
Clostridioides difficile (*tcdA/tcdB*)	*Clostridioides difficile*	0, A+, B+		**ATCC 43255 (CCUG19126, VPI 10463)**	1x	1.88E+00	100% (20/20)
	Clostridioides difficile	0, A+, B+		ATCC 9689 (90556-M6S)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 700792 (14797-2)	3x	1.70E+01	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Clostridioides difficile	0, A+, B+		ATCC 17858 (1253)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	IIIb, A+, B+		**ATCC BAA-1805 (NAP I strain)**	1x	5.65E+00	95% (19/20)
	Clostridioides difficile	0, A+, B+		ATCC BAA-1382 (630)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 51695 (BDMS 18 AN)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 43600 (2149)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 43599 (2022)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 43596 (545)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 43594 (W1194)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	0, A+, B+		ATCC 17857 (870)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	VIII, A-, B+		ATCC 43598 (1470)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	X, A-, B+		CCUG 20309 (Also known as CCUG 8864)	3x	1.70E+01	100% (3/3)
	Clostridioides difficile	N/A		ATCC 43597	100x	5.65E+02	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Clostridioides difficile			ATCC BAA-1803	3x	1.70E+01	100% (3/3)
	Clostridioides difficile			ATCC BAA-1875	3x	1.70E+01	100% (3/3)
	Clostridioides difficile			ATCC BAA-1814	3x	1.70E+01	100% (3/3)
	Clostridioides difficile			ATCC BAA-1870	3x	1.70E+01	100% (3/3)
	Clostridioides difficile			ATCC BAA-1812	3x	1.70E+01	100% (3/3)
	Clostridioides difficile			ATCC BAA-1808	3x	1.70E+01	100% (3/3)
	Clostridioides difficile			ATCC BAA-1874	3x	1.70E+01	100% (3/3)
Enterotoxigenic *E.coli* (ETEC) LT/ST	Enterotoxigenic *Escherichia coli* (ETEC, LT/ST)	LT+, ST1A+, ST1B+		**ATCC 35401**	1x	4.57E+02	100% (20/20)
	Enterotoxigenic *Escherichia coli* (ETEC, LT/ST)	LT+, ST1A+		CI Penn State 14.1385	3x	1.37E+03	100% (3/3)
	Enterotoxigenic *Escherichia coli* (ETEC, LT/ST)	ST1A+		CI Penn State 10.0049	3x	1.37E+03	100% (3/3)
	Enterotoxigenic *Escherichia coli* (ETEC, LT/ST)	ST1B+		**ATCC 43896**	1x	4.57E+02	100% (20/20)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Enterotoxigenic *Escherichia coli* (ETEC, LT/ST)	LT+		ATCC 43886	3x	1.37E+03	100% (3/3)
Plesiomonas shigelloides	*Plesiomonas shigelloides*	N/A		ATCC 51572	3x	1.24E+04	100% (3/3)
	Plesiomonas shigelloides			Zeptometrix 0801899	3x	1.24E+04	100% (3/3)
	Plesiomonas shigelloides			**ATCC 51903**	1x	1.37E+03	100% (20/20)
	Plesiomonas shigelloides			**ATCC 14029**	1x	4.12E+03	100% (20/20)
	Plesiomonas shigelloides			CI OSUPS-1	3x	1.24E+04	100% (3/3)
Salmonella spp.	*Salmonella enterica* subsp. *enterica*	I	*Agona*	ATCC 51957	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Anatum*	ATCC 9270	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Bareilly*	ATCC 9115	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Berta*	ATCC 8392	3x	4.11E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Salmonella enterica subsp. *enterica*		*Braenderup*	ATCC BAA-664	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Enteritidis*	ATCC 13076	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Heidelberg*	ATCC 8326	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*I 4,[5],12:i:-*	ATCC 700720	10x	1.37E+04	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Infantis*	ATCC 51741	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Javiana*	ATCC BAA-1593	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Mississippi*	ATCC BAA-2739	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Montevideo*	ATCC 8387	10x	1.37E+04	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Muenchen*	ATCC BAA-1594	3x	4.11E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Salmonella enterica subsp. *enterica*		*Newport*	ATCC 27869	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Oranienburg*	ATCC 9239	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Paratyphi B*	ATCC 10719	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Saintpaul*	ATCC 9712	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Thompson*	ATCC BAA-3141	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Typhi*	ATCC 9993	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Typhimurium*	**ATCC 13311**	1x	1.37E+03	100% (20/20)
	Salmonella enterica subsp. *enterica*		*Choleraesuis*	ATCC 7001	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *enterica*		*Dublin*	ATCC 39184	3x	4.11E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Salmonella enterica subsp. *enterica*		*Paratyphi A*	ATCC 11511	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *salamae*	II	N/A	ATCC 700148	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *arizonae*	IIIa		**ATCC 13314**	1x	1.37E+03	100% (20/20)
	Salmonella enterica subsp. *diarizonae*	IIIb		ATCC 12325	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *houtenae*	IV		ATCC 43974	3x	4.11E+03	100% (3/3)
	Salmonella enterica subsp. *Indica*	VI		ATCC 43976	3x	4.11E+03	100% (3/3)
	Salmonella bongori	N/A		ATCC 43975	3x	4.11E+03	100% (3/3)
Shiga-like toxin-producing *E. coli* (STEC) *stx1*	*Escherichia coli,* O157	O157:H7		**ATCC 43890**	1x	1.37E+03	100% (20/20)
	Escherichia coli, Non-O157	O26:H11		CI MSU DEC10C	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O26:NM		CI MSU TW07948	3x	4.11E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Escherichia coli, Non-O157	O45:H2		CI MSU TW10121	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O103:H2		CI TW08101	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O111:H8		ATCC BAA-184	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O118:H2		CI CDC 2009C-4091	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O145:NM		ATCC BAA-2130	3x	4.11E+03	100% (3/3)
Shiga-like toxin-producing *E. coli* (STEC) *stx1/stx2*	*Escherichia coli,* O157	O157:H7		ATCC 43894	3x	4.11E+03	100% (3/3)
	Escherichia coli, O157	O157:H7		ATCC 35150	3x	4.11E+03	100% (3/3)
	Escherichia coli, O157	O157:H7		ATCC 43895	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O26:H11		ATCC BAA-2196	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O111:H8		ATCC BAA-179	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O111:NM		CI TN DOH N10E001241	3x	4.11E+03	100% (3/3)
	Escherichia coli, Non-O157	O113:H21		ATCC BAA-177	3x	4.11E+03	100% (3/3)
	Escherichia coli, O157	O157:NM		CI TN DOH 61361	3x	1.37E+03	100% (3/3)
	Escherichia coli, Non-O157	O104:H21		ATCC BAA-178	3x	1.37E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
Shiga-like toxin-producing *E. coli* (STEC) *stx2*	*Escherichia coli,* Non-O157	O104:H4		**ATCC BAA-2326**	1x	4.57E+02	100% (20/20)
	Escherichia coli, Non-O157	O111:H2		CI TW06296	3x	1.37E+03	100% (3/3)
	Escherichia coli, Non-O157	O121:H19		ATCC BAA-2219	3x	1.37E+03	100% (3/3)
Shigella/ Enteroinvasive *E.coli* (EIEC)	*Shigella boydii*	N/A		ATCC 12031	3x	4.56E+02	100% (3/3)
	Shigella boydii			ATCC 12028	3x	4.56E+02	100% (3/3)
	Shigella boydii			ATCC 12030	10x	1.52E+03	100% (3/3)
	Shigella boydii			ATCC 12035	3x	4.56E+02	100% (3/3)
	Shigella boydii			**ATCC 25930**	1x	1.52E+02	95% (19/20)
	Shigella dysenteriae			ATCC 9361	3x	1.37E+03	100% (3/3)
	Shigella dysenteriae			ATCC 12037	3x	1.37E+03	100% (3/3)
	Shigella dysenteriae			ATCC 49549	3x	1.37E+03	100% (3/3)
	Shigella dysenteriae			ATCC 49556	3x	1.37E+03	100% (3/3)
	Shigella dysenteriae			ATCC 29027	3x	1.37E+03	100% (3/3)
	Shigella flexneri			ATCC 12022	3x	1.37E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Shigella flexneri			**ATCC 25929**	1x	4.57E+02	100% (20/20)
	Shigella flexneri			ATCC 29903	3x	1.37E+03	100% (3/3)
	Shigella flexneri			ATCC 49070	3x	1.37E+03	100% (3/3)
	Shigella flexneri			ATCC 700930	3x	1.37E+03	100% (3/3)
	Shigella sonnei			ATCC 9290	3x	1.37E+03	100% (3/3)
	Shigella sonnei			ATCC 25931	3x	1.37E+03	100% (3/3)
	Shigella sonnei			ATCC 29029	3x	1.37E+03	100% (3/3)
	Shigella sonnei			ATCC 29030	3x	1.37E+03	100% (3/3)
	Shigella sonnei			ATCC 11060	3x	1.37E+03	100% (3/3)
	Enteroinvasive *Escherichia coli* (EIEC)			ATCC 43892	3x	1.37E+03	100% (3/3)
	Enteroinvasive *Escherichia coli* (EIEC)			ATCC 43893	3x	1.37E+03	100% (3/3)
	Enteroinvasive *Escherichia coli* (EIEC)			CI Penn State 86.0937	3x	1.37E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Enteroinvasive *Escherichia coli* (EIEC)			CI Penn State 85.1797	3x	1.37E+03	100% (3/3)
	Enteroinvasive *Escherichia coli* (EIEC)			CI Penn State 85.1792	3x	1.37E+03	100% (3/3)
Vibrio cholerae	*Vibrio cholerae*	O1		ATCC 14100	3x	1.24E+04	100% (3/3)
	Vibrio cholerae			ATCC 25870	3x	1.24E+04	100% (3/3)
	Vibrio cholerae			**ATCC 39315**	1x	4.12E+03	100% (20/20)
	Vibrio cholerae	O139		**ATCC 51394**	1x	4.12E+03	100% (20/20)
	Vibrio cholerae	Non-O1/ Non-O139		ATCC 25874	3x	1.24E+04	100% (3/3)
Vibrio spp.	*Vibrio parahaemolyticus*	N/A		ATCC 17802	3x	4.11E+03	100% (3/3)
	Vibrio parahaemolyticus			ATCC 35118	3x	4.11E+03	100% (3/3)
	Vibrio parahaemolyticus			**ATCC 49398**	1x	1.37E+03	100% (20/20)
	Vibrio parahaemolyticus			ATCC 49529	3x	4.11E+03	100% (3/3)
	Vibrio parahaemolyticus			ATCC BAA-238	3x	4.11E+03	100% (3/3)

510(k) Summary

Target Call	Species/ Species Type	Serotype / Toxin	Source / Strain	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration (CFU/mL)	% Positivity
	Vibrio vulnificus			**ATCC 27562**	1x	4.57E+02	100% (20/20)
	Vibrio vulnificus			ATCC 29307	3x	1.37E+03	100% (3/3)
	Vibrio vulnificus			ATCC 29306	3x	1.37E+03	100% (3/3)
	Vibrio vulnificus			ATCC 33817	3x	1.37E+03	100% (3/3)
	Vibrio vulnificus			ATCC BAA-86	100x	4.57E+04	100% (3/3)
Yersinia enterocolitica	*Yersinia enterocolitica*	O:3		**ATCC 700822**	1x	1.37E+03	100% (20/20)
	Yersinia enterocolitica	O:5,27		CI CDC B5725	3x	4.11E+03	100% (3/3)
	Yersinia enterocolitica	O:8		ATCC 9610	3x	4.11E+03	100% (3/3)
	Yersinia enterocolitica			**ATCC 23715**	1x	1.37E+03	95% (19/20)
	Yersinia enterocolitica	O:9		ATCC 700823	3x	4.11E+03	100% (3/3)
	Yersinia enterocolitica	N/A		ATCC 49397	3x	4.11E+03	100% (3/3)

510(k) Summary

Table 12: Analytical Reactivity (Inclusivity) Viral Strains

Target Call	Species/Species Type	Serotype / Toxin	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
Adenovirus F40/41	Adenovirus 40	N/A	**ATCC VR-931**	1x	4.57E+02 copies/mL	100% (20/20)
	Adenovirus 40		Zeptometrix 0810084CF	3x	1.37E+03 copies/mL	100% (3/3)
	Adenovirus 40		Virapur Tak 40	10x	4.57E+03 copies/mL	100% (3/3)
	Adenovirus 41		**ATCC VR-930**	1x	4.57E+02 copies/mL	95% (19/20)
	Adenovirus 41		Zeptometrix 0810085CF	3x	1.37E+03 copies/mL	100% (3/3)
	Adenovirus 41		Virapur Tak 41	3x	1.37E+03 copies/mL	100% (3/3)
	Adenovirus 41		LMNX-2729	3x	1.37E+03 copies/mL	100% (3/3)
	Adenovirus 41		LMNX-2734	3x	1.37E+03 copies/mL	100% (3/3)
Astrovirus	Astrovirus, Type 1	Type 1	**ATCC VR-1936**	1x	1.00E+06 copies/mL	100% (20/20)
	Astrovirus, Type 2	Type 2	**ATCC VR-1943**	1x	1.11E+05 copies/mL	100% (20/20)
	Astrovirus, Type 3	Type 3	ATCC VR-1944	3x	3.00E+06 copies/mL	100% (3/3)
	Astrovirus, Type 4	Type 4	ATCC VR-1945	3x	3.00E+06 copies/mL	100% (3/3)

510(k) Summary

Target Call	Species/Species Type	Serotype / Toxin	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Astrovirus, Type 5	Type 5	ATCC VR-1947	3x	3.00E+06 copies/mL	100% (3/3)
	Astrovirus, Type 6	Type 6	ATCC VR-1948	3x	3.00E+06 copies/mL	100% (3/3)
	Astrovirus, Type 7	Type 7	ATCC VR-1949	3x	3.00E+06 copies/mL	100% (3/3)
	Astrovirus, Type 8	Type 8	Zeptometrix 0810277CF	3x	4.20E+04 TCID50/mL	100% (3/3)
Norovirus GI/GII	Norovirus GI	GI.1	LMNX-3117	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GI	GI.2	PGI01-0263	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GI	GI.3	LMNX-3229	100x	2.75E+06 copies/mL	100% (3/3)
	Norovirus GI	GI.5	LMNX-2947	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GI	GI.6	PGI02-0617	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GI	GI.7	LMNX-3000	1000x	2.75E+07 copies/mL	100% (3/3)
	Norovirus GI	N/A	**Zeptometrix 0830086CFL**	1x	2.75E+04 copies/mL	100% (20/20)
	Norovirus GII	GII.1	LMNX-916	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.2	LMNX-2951	3x	1.11E+05 copies/mL	100% (3/3)

510(k) Summary

Target Call	Species/Species Type	Serotype / Toxin	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Norovirus GII	GII.3	PGI05-0019	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.4	LMNX-928	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII		LMNX-1151	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII		LMNX-2936	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII		LMNX-3509	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.6	LMNX-915	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.7	LMNX-704	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.8	LMNX-3005	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.9	LMNX-3582	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.12	LMNX-2963	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	GII.17	PGI01-0570	3x	1.11E+05 copies/mL	100% (3/3)
	Norovirus GII	N/A	**Zeptometrix 0830087CFL**	1x	3.70E+04 copies/mL	100% (20/20)
Rotavirus A	Rotavirus Group A		**ATCC VR-2550**	1x	1.23E+04 copies/mL	100% (20/20)

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Target Call	Species/Species Type	Serotype / Toxin	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Rotavirus Group A	N/A	**ATCC VR-2551**	1x	4.57E+02 copies/mL	100% (20/20)
	Rotavirus Group A		ATCC VR-2272	3x	3.69E+04 copies/mL	100% (3/3)
	Rotavirus Group A		ATCC VR-2104	3x	3.69E+04 copies/mL	100% (3/3)
	Rotavirus Group A		CI MCRI G6P5 #476	3x	3.69E+04 copies/mL	100% (3/3)
	Rotavirus Group A		CI MCRI G8P10 #475	3x	3.69E+04 copies/mL	100% (3/3)
	Rotavirus Group A		CI MCRI G12P4 #262	3x	3.69E+04 copies/mL	100% (3/3)
Sapovirus I/II/IV/V	Sapovirus, GI	GI.1	**LMNX-2829**	1x	1.23E+04 copies/mL	100% (20/20)
	Sapovirus, GI	GI.2	LMNX-3419	100x	1.23E+06 copies/mL	100% (3/3)
	Sapovirus, GI	GI.3	LMNX-746	Neat	Unknown	100% (3/3)
	Sapovirus, GI	GI.6	LMNXC-1747	3x	3.69E+04 copies/mL	100% (3/3)
	Sapovirus, GII	GII.1	**LMNX-2964**	1x	1.23E+04 copies/mL	95% (19/20)
	Sapovirus, GII	GII.2	LMNX-2945	3x	3.69E+04 copies/mL	100% (3/3)
	Sapovirus, GII	GII.3	LMNX-080	3x	3.69E+04 copies/mL	100% (3/3)

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Target Call	Species/Species Type	Serotype / Toxin	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Sapovirus, GII	GII.5	LMNX-2967	3x	3.69E+04 copies/mL	100% (3/3)
	Sapovirus, GIV	GIV.1	LMNX-155	3x	3.69E+04 copies/mL	100% (3/3)
	Sapovirus, GV	GV.1	LMNX-3118	3x	3.69E+04 copies/mL	100% (3/3)
	Sapovirus, GV	GV.1	LMNX-3206	10x	1.23E+05 copies/mL	100% (3/3)

Table 13: Analytical Reactivity (Inclusivity) Parasite Strains

Target Call	Species/ Species Type	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
Blastocystis sp.	*Blastocystis hominis*	**ATCC 50177**	1x	1.69E+01 cells/mL	100% (20/20)
	Blastocystis hominis	**ATCC 50608**	1x	4.57E+02 cells/mL	100% (20/20)
	Blastocystis hominis	ATCC 50587	3x	1.37E+03 copies/mL	100% (3/3)
	Blastocystis hominis	ATCC 50754	3x	1.37E+03 copies/mL	100% (3/3)

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Target Call	Species/ Species Type	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Blastocystis hominis	ATCC 50609	3x	1.37E+03 copies/mL	100% (3/3)
Cryptosporidium spp.	*Cryptosporidium parvum*	**Waterborne P102C**	1x	1.37E+03 oocysts/mL	100% (20/20)
	Cryptosporidium parvum	UA180108	3x	4.11E+03 oocysts/mL	100% (3/3)
	Cryptosporidium parvum	ATCC 87760	Unknown	2.00E-01 relative to stock	100% (3/3)
	Cryptosporidium parvum	ATCC 87762	Unknown	2.00E-01 relative to stock	100% (3/3)
	Cryptosporidium parvum	ATCC 87765	Unknown	1.00E-01 relative to stock	100% (3/3)
	Cryptosporidium hominis	TU502	3x	1.24E+04 oocysts/mL	100% (3/3)
	Cryptosporidium muris	**Waterborne P104**	1x	4.12E+03 oocysts/mL	100% (20/20)
	Cryptosporidium meleagridis	**TU1867**	1x	4.12E+03 oocysts/mL	100% (20/20)
Cyclospora cayetanensis	*Cyclospora cayetanensis*	**LMNX-3415**	1x	4.12E+03 copies/mL	100% (20/20)
	Cyclospora cayetanensis	**LMNX-3862**	1x	7.57E+02 copies/mL	100% (20/20)
	Cyclospora cayetanensis	LMNX-2562	1.2x Neat	4.81E+03 copies/mL	100% (3/3)
Dientamoeba fragilis	*Dientamoeba fragilis*	**D.fragilis-1**	1x	1.52E+02 copies/mL	100% (20/20)

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Target Call	Species/ Species Type	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Dientamoeba fragilis	**D.fragilis-2**	1x	4.57E+02 copies/mL	100% (20/20)
	Dientamoeba fragilis	LMNX-2693	3x	1.37E+03 copies/mL	100% (3/3)
	Dientamoeba fragilis	LMNX-2896	3x	1.37E+03 copies/mL	100% (3/3)
	Dientamoeba fragilis	LMNX-3679	3x	1.37E+03 copies/mL	100% (3/3)
Entamoeba histolytica	*Entamoeba histolytica*	ATCC 30015	3x	5.65E+00 cells/mL	100% (3/3)
	Entamoeba histolytica	**ATCC 30459**	1x	6.97E-02 cells/mL	100% (20/20)
	Entamoeba histolytica	ATCC 30458	3x	5.65E+00 cells/mL	100% (3/3)
	Entamoeba histolytica	ATCC 50412	3x	5.65E+00 cells/mL	100% (3/3)
	Entamoeba histolytica	**ATCC 50524**	1x	1.88E+00 cells/mL	100% (20/20)
Giardia lamblia	*Giardia lamblia/ Giardia duodenalis/ Giardia intestinalis*	ATCC 30957	3x	1.52E+03 cells/mL	100% (3/3)
	Giardia lamblia/ Giardia duodenalis/ Giardia intestinalis	**ATCC 30888**	1x	5.08E+01 cells/mL	95% (19/20)
	Giardia lamblia/ Giardia duodenalis/ Giardia intestinalis	ATCC 50582	3x	1.52E+03 cells/mL	100% (3/3)
	Giardia lamblia/ Giardia duodenalis/ Giardia intestinalis	ATCC PRA-242	3x	1.52E+03 cells/mL	100% (3/3)

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Target Call	Species/ Species Type	Isolate ID (LoD strains are in bold font)	Test Level (xLoD)	Test Concentration	% Positivity
	Giardia lamblia/ Giardia duodenalis/ Giardia intestinalis	**ATCC PRA-254**	1x	1.52E+02 cells/mL	100% (20/20)
Microsporidia	*Encephalitozoon hellem*	**ATCC 50451**	1x	1.52E+02 cells/mL	95% (19/20)
	Encephalitozoon hellem	ATCC 50504	3x	4.56E+02 cells/mL	100% (3/3)
	Encephalitozoon hellem	Waterborne P103H	1000x	1.52E+05 spores/mL	100% (3/3)
	Encephalitozoon intestinalis	**ATCC 50651**	1x	5.08E+01 cells/mL	95% (19/20)
	Encephalitozoon intestinalis	Waterborne P103I	1000x	5.08E+04 spores/mL	100% (3/3)
	Enterocytozoon bieneusi	**LMNX-2885**	1x	1.37E+03 copies/mL	100% (20/20)
	Enterocytozoon bieneusi	**LMNX-4140**	1x	1.37E+03 copies/mL	100% (20/20)
	Enterocytozoon bieneusi	LUM-920-240	3x	4.11E+03 copies/mL	100% (3/3)
Strongyloides stercoralis	*Strongyloides stercoralis*	**LMNX-3433**	1x	1.23E+04 copies/mL	100% (20/20)
	Strongyloides stercoralis	GI_FLEX-012	3x	3.69E+04 copies/mL	100% (3/3)

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Analytical Specificity (Cross-Reactivity)

Analytical specificity (Cross-reactivity) of the LIAISON PLEX® Gastrointestinal *Flex* Assay was assessed through wet testing of off-panel organisms, specifically including those phylogenetically related to the on-panel organisms as well as organisms typically present in stool samples.

Cross reactivity organisms (CROs) of interest were contrived in Cary-Blair Negative Stool Matrix at the highest available concentration. Samples were tested in triplicate with the LIAISON PLEX Gastrointestinal *Flex* Assay. When a non-specific positive result was observed, six (6) additional replicates from a new preparation were tested to confirm potential cross-reactivity.

Whole organisms and gBlocks representing targets with no observed cross-reactivity in wet testing are listed in Table 14. Whole organisms and gBlocks representing targets with observed cross-reactivity in wet testing are listed in Table 15. Organisms where cross-reactivity was predicted by *in silico* analysis performed in January 2025, but that were not wet tested are reported in Table 16.

Table 14: Organisms with No Observed Cross-Reactivity to LIAISON PLEX® Gastrointestinal Flex Assay in Wet Testing

Organism	Concentration Tested	Organism	Concentration Tested
Bacteria			
Abiotrophia defectiva	5.70E+06 CFU/mL	*Fusobacterium varium*	1.31E+08 CFU/mL
Acinetobacter baumannii	3.16E+08 CFU/mL	*Helicobacter fennelliae*	5.00E+04 CFU/mL
Acinetobacter lwoffii	6.30E+07 CFU/mL	*Helicobacter pylori*	4.98E+06 CFU/mL
Aeromonas hydrophila	1.76E+08 CFU/mL	*Klebsiella oxytoca*	2.69E+08 CFU/mL
Alcaligenes faecalis subsp. *faecalis*	1.09E+09 CFU/mL	*Klebsiella pneumoniae*	2.66E+08 CFU/mL
Bacillus cereus	2.41E+07 CFU/mL	*Lactobacillus acidophilus*	4.83E+07 CFU/mL
Bacteroides caccae	4.47E+08 CFU/mL	*Lactobacillus reuteri*	1.09E+08 CFU/mL
Bacteroides fragilis	7.60+E08 CFU/mL	*Lactococcus lactis*	3.02E+08 CFU/mL
Bacteroides stercoris	2.35E+08 CFU/mL	*Leminorella grimontii*	2.35E+08 CFU/mL
Bifidobacterium bifidum	1.91E+07 CFU/mL	*Listeria grayi*	2.90E+07 CFU/mL
Campylobacter concisus	1.40E+05 CFU/mL	*Listeria monocytogenes*	3.43E+08 CFU/mL
Campylobacter curvus	3.05E+06 CFU/mL	*Morganella morganii*	2.44E+08 CFU/mL
Campylobacter fetus	2.30E+08 CFU/mL	*Peptoniphilus asaccharolyticus*	8.35E+07 CFU/mL
Campylobacter gracilis	2.85E+05 CFU/mL	*Peptostreptococcus anaerobius*	3.15E+05 CFU/mL
Campylobacter hominis	2.25E+05 CFU/mL	*Porphyromonas asaccharolytica*	2.30E+06 CFU/mL
Campylobacter rectus	1.81E+07 CFU/mL	*Prevotella bivia*	1.14E+08 CFU/mL

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Organism	Concentration Tested	Organism	Concentration Tested
Campylobacter showae	1.70E+06 CFU/mL	*Prevotella melaninogenica*	2.32E+07 CFU/mL
Candida albicans	1.21E+07 CFU/mL	*Prevotella (Hoylesella) oralis*	1.70E+07 CFU/mL
Cedecea davisae	1.40E+07 CFU/mL	*Proteus mirabilis*	3.24E+08 CFU/mL
Citrobacter amalonaticus	3.57E+08 CFU/mL	*Proteus penneri*	6.95E+07 CFU/mL
Citrobacter freundii	1.30E+08 CFU/mL	*Proteus vulgaris*	1.69E+08 CFU/mL
Citrobacter sedlakii	2.55E+07 CFU/mL	*Providencia alcalifaciens*	1.74E+08 CFU/mL
Clostridium bifermentans	6.05E+06 CFU/mL	*Providencia stuartii*	3.42E+08 CFU/mL
Clostridium bolteae	5.20E+05 CFU/mL	*Providencia rettgeri*	2.91E+08 CFU/mL
Clostridium butyricum	1.14E+07 CFU/mL	*Pseudomonas aeruginosa*	4.36E+08 CFU/mL
Clostridium difficile (Non-toxigenic)	3.19E+06 CFU/mL	*Pseudomonas putida*	8.45E+06 CFU/mL
Clostridium haemolyticum	2.60E+05 CFU/mL	*Ruminococcus bromii*	5.00E+05 CFU/mL
Clostridium methylpentosum	7.90E+06 CFU/mL	*Serratia liquefaciens*	4.93E+08 CFU/mL
Clostridium nexile	1.28E+06 CFU/mL	*Serratia marcescens*	1.82E+08 CFU/mL
Clostridium novyi	9.65E+05 CFU/mL	*Staphylococcus aureus*	2.71E+08 CFU/mL
Clostridium perfringens	1.77E+06 CFU/mL	*Staphylococcus epidermidis*	4.54E+08 CFU/mL
Clostridium scindens	1.20E+07 CFU/mL	*Streptococcus dysgalactiae*	6.75E+07 CFU/mL
Clostridium septicum	2.54E+06 CFU/mL	*Vibrio alginolyticus*	9.00E+06 CFU/mL
Clostridium sordellii	2.86E+06 CFU/mL	*Vibrio fluvialis*	3.60E+07 CFU/mL
Clostridium sporogenes	1.14E+07 CFU/mL	*Vibrio furnissii*	4.65E+07 CFU/mL
Desulfovibrio piger	1.50E+05 CFU/mL	*Vibrio harveyi*	3.80E+06 CFU/mL
Edwardsiella tarda	5.95E+08 CFU/mL	*Vibrio metschnikovii*	5.60E+06 CFU/mL
Enterobacter (Klebsiella) aerogenes	3.95E+07 CFU/mL	*Vibrio mimicus*	3.40E+07 CFU/mL
Enterobacter cloacae	5.70E+08 CFU/mL	*Vibrio natriegens*[1]	1.29E+07 CFU/mL
Enterococcus faecalis	2.09E+08 CFU/mL	*Yersinia bercovieri*	4.70E+07 CFU/mL
Enterococcus faecium	1.43E+08 CFU/mL	*Yersinia kristensenii* (gBlock)	1.50E+07 copies/mL
Escherichia coli	1.36E+08 CFU/mL	*Yersinia pseudotuberculosis*	2.84E+08 CFU/mL
Escherichia coli (EAEC)	4.47E+08 CFU/mL	*Yersinia rochesterensis* (gBlock)	1.50E+07 copies/mL
Escherichia coli (EPEC)	6.10E+08 CFU/mL	*Yersinia rohdei*	1.01E+07 CFU/mL
Escherichia fergusonii	2.95E+08 CFU/mL	*Yersinia ruckeri*	3.50E+07 CFU/mL

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Organism	Concentration Tested	Organism	Concentration Tested
Escherichia hermannii	2.79E+08 CFU/mL		
Viruses			
Human adenovirus 31 (gBlock)	1.50E+07 copies/mL	Cytomegalovirus, AD-169	1.35E+03 TCID50/mL
Adenovirus Type 7A, Species B	9.75E+05 TCID50/mL	Echovirus Type 11	2.95E+06 TCID50/mL
Human mastadenovirus B (gBlock)	1.50E+07 copies/mL	Enterovirus Type 68, 09/2014 Isolate 4	1.23E+04 TCID50/mL
Adenovirus Type 4, Species E	8.50E+03 TCID50/mL	Hepatitis A virus, HM-175 (clone 1)	4.45E+05 TCID50/mL
Coxsackie virus Type A16	2.04E+06 TCID50/mL	Human mastadenovirus C (gBlock)	1.50E+07 copies/mL
Coxsackie virus B3	2.04E+06 TCID50/mL	Human mastadenovirus G (gBlock)	1.50E+07 copies/mL
Parasites			
Entamoeba dispar	1.25E+04 cells/mL	*Pentatrichomonas hominis*	1.30E+06 cells/mL
Entamoeba dispar (gBlock)	1.50E+07 copies/mL	*Pentatrichomonas hominis* (gBlock)	1.50E+07 copies/mL
Entamoeba moshkovskii	8.50E+04 cells/mL	*Trichomonas tenax*	1.10E+06 cells/mL
Cyclospora colobi (gBlock)	1.50E+07 copies/mL	*Trichomonas tenax* (gBlock)	1.50E+07 copies/mL

[1]*Vibrio cincinnatiensis* was unavailable, *Vibrio natriegens* was used as a replacement

Table 15: Organisms with Observed Cross-Reactivity to LIAISON PLEX® Gastrointestinal Flex Assay in Wet Testing

Reportable Target	Organism	Lowest Test Concentration with Positivity
Adenovirus F40/41	Adenovirus Type 31, Species A[1]	8.50E+03 TCID50/mL
	Adenovirus Type 26, Species D	5.85E+02 TCID50/mL
***Blastocystis* sp.**	*Cystoisospora belli* (gBlock)	1.50E+07 copies/mL
	Toxoplasma gondii	7.70E+04 cells/mL
Entamoeba histolytica	*Entamoeba nuttalli* (gBlock)[2]	1.50E+07 copies/mL
Giardia lamblia	*Giardia ardeae* (gBlock)[3]	1.50E+07 copies/mL
	Giardia cricetidarum (gBlock)[4]	1.50E+07 copies/mL
	Giardia microti (gBlock)[4]	1.50E+07 copies/mL

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Reportable Target	Organism	Lowest Test Concentration with Positivity
	Giardia muris[4]	6.25E+03 cysts/mL
	Giardia psittaci (gBlock)[3]	1.50E+07 copies/mL
Shiga-like toxin-producing *E.coli* (STEC) *stx1*	Adenovirus Type 1, Species C[1]	2.09E+05 TCID50/mL

[1] Organism was wet tested and tested positive, however, the organism was not predicted to cross-react by *in silico* analysis performed in January 2025. The associated gBlock did not cross-react, suggesting that the cross-reacting area of the organism genome is not encompassed by the gBlock fragment or the organism was mis-labeled from the vendor or contaminated.
[2] Primate pathogen which shows homology to *Entamoeba histolytica*.
[3] Avian pathogen which shows homology to *Giardia lamblia*.
[4] Rodent pathogen which shows homology to *Giardia lamblia*.

Table 16: Organisms Not Wet Tested but Predicted by in silico Analysis (January 2025) to Cross-React with LIAISON PLEX® Gastrointestinal Flex Assay

Reportable Target	Predicted Cross-Reaction
Astrovirus	Strains of canine, feline, porcine/swine and California sea lion astroviruses
Rotavirus A	Strains of porcine rotavirus
Strongyloides stercoralis	*Strongyloides callosciureus* *Strongyloides cebus* *Strongyloides fuelleborni* *Strongyloides myopotami* *Strongyloides papillosus* *Strongyloides procyonis* *Strongyloides ransomi* *Strongyloides ratti* *Strongyloides robustus* *Strongyloides venezuelensis*
Vibrio cholerae	*Vibrio tarriae* (accession CP022353.1)[1]

[1] Per Islam et al. (2022), *Vibrio tarriae* is considered a novel member of the Cholerae clade

Competitive Inhibition/Co-Infection

Competitive inhibition (co-infection) of the LIAISON PLEX® Gastrointestinal *Flex* Assay was assessed by testing Cary-Blair Negative Stool Matrix (CB-NSM) with prevalent co-infection targets where one target is at a low concentration (three times its reported Limit of Detection) and the other target is at a high concentration (100 times its reported Limit of Detection) and vice versa. Each combination was tested in three replicates.

The Percent Positivity was 100% for all targets in each co-infection combination tested. The study demonstrated no competitive inhibition between any co-infection combinations tested.

Percent Positivity results for each pair of Competitive Inhibition targets tested are detailed in

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Table

Table 17: Percent Positivity of Each Target in Prevalent Co-Infection Combinations

Co-infection Combination	Target at 100x LoD	Target at 3x LoD	% Positivity of Target at 100x LoD	% Positivity of Target at 3x LoD
CI-01-A	Adenovirus F40/41	Rotavirus A	100.0% (3/3)	100.0% (3/3)
CI-01-B	Rotavirus A	Adenovirus F40/41	100.0% (3/3)	100.0% (3/3)
CI-02-A	*Blastocystis* sp.	*Salmonella* spp.	100.0% (3/3)	100.0% (3/3)
CI-02-B	*Salmonella* spp.	*Blastocystis* sp.	100.0% (3/3)	100.0% (3/3)
CI-03-A	*Campylobacter* spp.	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	100.0% (3/3)	100.0% (3/3)
CI-03-B	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	*Campylobacter* spp.	100.0% (3/3)	100.0% (3/3)
CI-04-A	*Clostridioides difficile (tcdA/tcdB)*	*Blastocystis* sp.	100.0% (3/3)	100.0% (3/3)
CI-04-B	*Blastocystis* sp.	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-05-A	*Clostridioides difficile (tcdA/tcdB)*	*Campylobacter* spp.	100.0% (3/3)	100.0% (3/3)
CI-05-B	*Campylobacter* spp.	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-06-A	*Clostridioides difficile (tcdA/tcdB)*	Enterotoxigenic *E. coli* (ETEC) LT/ST	100.0% (3/3)	100.0% (3/3)
CI-06-B	Enterotoxigenic *E. coli* (ETEC) LT/ST	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-07-A	*Clostridioides difficile (tcdA/tcdB)*	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-07-B	Norovirus GI/GII	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-08-A	*Clostridioides difficile (tcdA/tcdB)*	*Salmonella* spp.	100.0% (3/3)	100.0% (3/3)
CI-08-B	*Salmonella* spp.	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-09-A	*Clostridioides difficile (tcdA/tcdB)*	Sapovirus I/II/IV/V	100.0% (3/3)	100.0% (3/3)
CI-09-B	Sapovirus I/II/IV/V	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)

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Co-infection Combination	Target at 100x LoD	Target at 3x LoD	% Positivity of Target at 100x LoD	% Positivity of Target at 3x LoD
CI-10-A	*Clostridioides difficile (tcdA/tcdB)*	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	100.0% (3/3)	100.0% (3/3)
CI-10-B	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-11-A	*Clostridioides difficile (tcdA/tcdB)*	*Vibrio cholerae*	100.0% (3/3)	100.0% (3/3)
CI-11-B	*Vibrio cholerae*	*Clostridioides difficile (tcdA/tcdB)*	100.0% (3/3)	100.0% (3/3)
CI-12-A	*Giardia lamblia*	*Cryptosporidium* spp.	100.0% (3/3)	100.0% (3/3)
CI-12-B	*Cryptosporidium* spp.	*Giardia lamblia*	100.0% (3/3)	100.0% (3/3)
CI-13-A	Norovirus GI/GII	Adenovirus F40/41	100.0% (3/3)	100.0% (3/3)
CI-13-B	Adenovirus F40/41	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-14-A	Norovirus GI/GII	Astrovirus	100.0% (3/3)	100.0% (3/3)
CI-14-B	Astrovirus	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-15-A	Norovirus GI/GII	Rotavirus A	100.0% (3/3)	100.0% (3/3)
CI-15-B	Rotavirus A	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-16-A	Norovirus GI/GII	*Salmonella* spp.	100.0% (3/3)	100.0% (3/3)
CI-16-B	*Salmonella* spp.	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-17-A	Norovirus GI/GII	Sapovirus I/II/IV/V	100.0% (3/3)	100.0% (3/3)
CI-17-B	Sapovirus I/II/IV/V	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-18-A	Norovirus GI/GII	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	100.0% (3/3)	100.0% (3/3)
CI-18-B	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	Norovirus GI/GII	100.0% (3/3)	100.0% (3/3)
CI-19-A	Rotavirus A	Enterotoxigenic *E. coli* (ETEC) LT/ST	100.0% (3/3)	100.0% (3/3)

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Co-infection Combination	Target at 100x LoD	Target at 3x LoD	% Positivity of Target at 100x LoD	% Positivity of Target at 3x LoD
CI-19-B	Enterotoxigenic *E. coli* (ETEC) LT/ST	Rotavirus A	100.0% (3/3)	100.0% (3/3)
CI-20-A	Rotavirus A	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	100.0% (3/3)	100.0% (3/3)
CI-20-B	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	Rotavirus A	100.0% (3/3)	100.0% (3/3)
CI-21-A	*Salmonella* spp.	*Campylobacter* spp.	100.0% (3/3)	100.0% (3/3)
CI-21-B	*Campylobacter* spp.	*Salmonella* spp.	100.0% (3/3)	100.0% (3/3)
CI-22-A	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	*Shigella*/Enteroinvasive *E. coli* (EIEC)	100.0% (3/3)	100.0% (3/3)
CI-22-B	*Shigella*/Enteroinvasive *E. coli* (EIEC)	Shiga-like toxin-producing *E. coli* (STEC) *stx1*	100.0% (3/3)	100.0% (3/3)
CI-23-A	*Shigella*/Enteroinvasive *E. coli* (EIEC)	*Salmonella* spp.	100.0% (3/3)	100.0% (3/3)
CI-23-B	*Salmonella* spp.	*Shigella*/Enteroinvasive *E. coli* (EIEC)	100.0% (3/3)	100.0% (3/3)

Interfering Substances

The potential inhibitory effect of nineteen (19) endogenous and exogenous substances expected to be found in stool samples or introduced during sample collection were evaluated for the LIAISON PLEX® Gastrointestinal *Flex* Assay.

Testing included using both negative and positive samples. The negative sample tested was negative stool matrix in either Cary-Blair or Parasite Fixative and tested the functionality of the assay to yield valid negative results in the presence of potentially interfering substances. A representative panel was designed in Cary-Blair Negative Stool Matrix to include analytes representative of each amplification pool and each target type included in the assay design (an RNA virus, a DNA virus, a gram-negative bacterium, a gram-positive bacterium, a toxin-producing bacterium, and a parasite). A representative panel was designed in Parasite Fixative Negative Stool Matrix to include analytes representative of parasite targets. Targets in the positive samples were prepared at 3x LoD to test the functionality of the entire sample to answer workflow to assess interference of the extraction, amplification, and detection reagents in the LIAISON PLEX Gastrointestinal *Flex* Assay cartridge in the presence of potentially interfering substances.

In each matrix, at least five replicates of positive and negative samples were tested in the presence of each Potentially Interfering Substance.

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No interference was observed for the potentially interfering substances listed in Table 18.

Table 18: Potentially Interfering Substances Tested with No Observed Interference

Interfering Substances with No Observed Adverse Effect on Performance	
Non-Microbial Interfering Substance	**Concentration Tested**
Triglyceride (Fecal Fat)	5% v/v
Cholesterol (Fecal Fat)	3% w/v
Human Hemoglobin	5% w/v
Human Whole Blood	25% v/v
Nystatin Suspension (Antifungal)	25% v/v
Phenylephrine (Preparation H)	10% w/v
Hydrocortisone (Preparation H)	12% w/v
Aluminum Hydroxide, Magnesium Hydroxide (Mylanta)	10% v/v
Mineral Oil	25% v/v
Sennosides (Ex-lax)	10% w/v
Bismuth subsalicylate (Pepto-Bismol)	10% v/v
Naproxen Sodium	2.1% w/v
Mucin	0.5% w/v
Benzalkonium Chloride	1% v/v
Ethanol	1% v/v

Calcium carbonate, Polymyxin B sulfate/Bacitracin zinc, and Loperamide Hydrochloride were identified as interfering substances at the initial concentration tested. When tested at the next lower input level, no interference was observed for any targets included in the assay. See results in Table 19.

Table 19: Potentially Interfering Substances Tested with Observed Interference

Product	**Active Ingredient**	**Concentration of Product with Observed Interference**		**Concentration of Product with No Observed Interference**	
		in Stool Collection Media	**Equivalent in Raw Stool**	**in Stool Collection Media**	**Equivalent in Raw Stool**
Tums Antacid	Calcium carbonate	10% w/v in Cary-Blair stool	40% w/v	5% w/v in Cary-Blair stool	20% w/v
Polysporin First Aid Antibiotic Ointment	Polymyxin B sulfate/Bacitracin zinc	10% w/v in Cary-Blair stool	40% w/v	5% w/v in Cary-Blair stool	20% w/v

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Product	Active Ingredient	Concentration of Product with Observed Interference		Concentration of Product with No Observed Interference	
		in Stool Collection Media	Equivalent in Raw Stool	in Stool Collection Media	Equivalent in Raw Stool
Imodium AD Anti-Diarrheal Oral Solution	Loperamide Hydrochloride	10% v/v in Parasite Fixative stool	40% v/v	5% v/v in Parasite Fixative stool	20% v/v

Microbial Inhibition

The impact of twelve (12) potentially inhibitory non-panel microorganisms that are commonly found in stool specimens was evaluated for the LIAISON PLEX® Gastrointestinal *Flex* Assay.

Testing included using both negative and positive samples. The negative sample tested was negative stool matrix in either Cary-Blair or Parasite Fixative and tested the functionality of the assay to yield valid negative results in the presence of potentially inhibitory microorganisms. A representative panel was designed in Cary-Blair Negative Stool Matrix to include analytes representative of each amplification pool and each target type included in the assay design (an RNA virus, a DNA virus, a gram-negative bacterium, a gram-positive bacterium, a toxin-producing bacterium, and a parasite). A representative panel was designed in Parasite Fixative Negative Stool Matrix to include analytes representative of parasite targets. Targets in the positive samples were prepared at 3x LoD to test the functionality of the entire sample to answer workflow to assess interference of the extraction, amplification, and detection reagents in the LIAISON PLEX Gastrointestinal *Flex* Assay cartridge in the presence of potentially inhibitory microorganisms.

In each matrix, at least five replicates of positive and negative samples were tested in the presence of each potentially inhibitory microorganism at ≥ 10^6 organisms/mL, or the highest available concentration.

No interference was observed for any of the potentially inhibitory microorganisms tested. The microorganisms tested are listed in Table 20.

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Table 20: Potentially Inhibitory Microorganisms Tested with No Observed Interference

Potentially Inhibitory Microorganisms Tested with No Observed Interference	
Bacteroides fragilis	*Escherichia coli*
Bifidobacterium bifidum	*Klebsiella pneumoniae*
Candida albicans	*Lactobacillus acidophilus*
Clostridium perfringens	*Prevotella bivia*
Klebsiella aerogenes	*Prevotella oralis*
Enterococcus faecalis	*Staphylococcus aureus*

Carry-over and Cross Contamination

The potential for carry-over between tests and cross contamination within an instrument when using the LIAISON PLEX® Gastrointestinal *Flex* Assay was assessed through testing of High Positive samples containing representative assay targets in an alternating series with Negative samples containing no targets (checkerboard design).

High Positive samples were tested in modules adjacent to those running Negative to evaluate possible cross contamination.

On each instrument, negative samples were tested immediately following testing of High Positive samples within the same module to evaluate possible carry-over.

This alternating series was continued across five valid rounds of testing performed by two operators, each using one of two LIAISON PLEX® Instruments with six modules each.

The Negative sample tested was Cary-Blair Negative Stool Matrix (CB-NSM). The High Positive sample tested was contrived in CB-NSM to contain *Salmonella enterica* (representative DNA target) at 10^6 CFU/mL and Rotavirus A (representative RNA target) at 10^6 copies/mL.

The expected result for the High Positive sample was 100% positivity of Rotavirus A and *Salmonella* spp. and 0% positivity for all other targets.

The expected result for the Negative sample was 0% positivity for all targets. No carry-over or cross contamination was observed.

Multi-Site Reproducibility

Site-to-site reproducibility of the LIAISON PLEX® Gastrointestinal *Flex* Assay was evaluated across three sites. A single lot of Assay Kits was tested by two operators at each of three sites. Testing included negative, low positive, and moderate positive samples in two sample matrices (Parasite Fixative Stool Matrix and Cary-Blair Stool Matrix). For each sample matrix, sample identities were randomized in sets of nine (three each of negatives, low positives, and moderate positives) and

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blinded to the operators. For each sample matrix, every operator at each site executed nine tests per study day over five non-consecutive days.

Negative Samples were either negative stool matrix in Cary-Blair media or Negative Stool Matrix in parasite fixative. Negative Stool Matrices were comprised of samples from multiple donors that had been pooled and confirmed negative for all targets on the LIAISON PLEX Gastrointestinal *Flex* Assay prior to use in this protocol. Negative samples tested site-to-site reproducibility of the assay's ability to yield negative results.

The positive Cary-Blair samples were designed to include analytes representative of each amplification pool and each target type included in the assay design (an RNA virus, a DNA virus, a gram-negative bacterium, a gram-positive bacterium, a toxin-producing bacterium, and a parasite).

The positive parasite fixative samples were designed to include analytes representative of the on-panel parasite targets.

Positive samples were prepared with targets at 1.5 times their LoD (low positive) and 3 times their LoD (moderate positive) to test the site-to-site reproducibility of the entire sample-to-answer workflow.

Site-to-site reproducibility of the LIAISON PLEX Gastrointestinal *Flex* Assay was demonstrated across sites with an Overall Percent Agreement of 99.7% for stool samples preserved in Cary-Blair and 99.2% for stool samples preserved in parasite fixative.

Results of the site-to-site reproducibility study are summarized in Table 21 and Table 22.

Table 21: Site-to Site Overall Percent Agreement for Cary-Blair Stool Matrix Samples

Panel Assay Target	Sample Type	% Agreement with Expected result			
		Site 1	Site 2	Site 3	All Sites (95% Confidence)
Adenovirus F40/41	**Low positive**	96.7% (29/30)	100% (30/30)	100% (30/30)	98.9% (89/90) (94.0% - 99.8%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90) (94.0% - 99.8%)
***Clostridioides difficile* (*tcdA/tcdB*)**	**Low positive**	100% (30/30)	96.7% (29/30)	96.7% (29/30)	97.8% (88/90) (92.3% - 99.4%)
	Moderate positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90) (94.0% - 99.8%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
***Cryptosporidium* spp.**		100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

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Panel Assay Target	Sample Type	% Agreement with Expected result			
		Site 1	Site 2	Site 3	All Sites (95% Confidence)
	Low positive				(95.9% - 100%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
Norovirus GI/GII	Low positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90)
					(94.0% - 99.8%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
Rotavirus A	Low positive	93.3% (28/30)	96.7% (29/30)	96.7% (29/30)	95.6% (86/90)
					(89.1% - 98.3%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
Shiga-like toxin-producing *E. coli* (STEC) *stx2*	Low positive	100% (30/30)	96.7% (29/30)	100% (30/30)	98.9% (89/90)
					(94.0% - 99.8%)
	Moderate positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90)
					(94.0% - 99.8%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
Shigella/Enteroinvasive *E. coli* (EIEC)	Low positive	90.0% (27/30)	100% (30/30)	93.3% (28/30)	94.4% (85/90)
					(87.6% - 97.6%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)
					(95.9% - 100%)
All Other Targets	Negative	100% (1530/1530)	100% (1530/1530)	100% (1530/1530)	100% (4590/4590)
					(99.9% - 100%)

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Table 22: Site-to-Site Overall Percent Agreement for Parasite Fixative Stool Matrix Samples

Panel Assay Target	Sample Type	% Agreement with Expected result			
		Site 1	Site 2	Site 3	All Sites (95% Confidence)
***Blastocystis* sp.**	Low positive	96.7% (29/30)	100% (30/30)	100% (30/30)	98.9% (89/90) (94.0% - 99.8%)
	Moderate positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90) (94.0% - 99.8%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
***Cryptosporidium* spp.**	Low positive	96.7% (29/30)	100% (30/30)	100% (30/30)	98.9% (89/90) (94.0% - 99.8%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
Dientamoeba fragilis	Low positive	96.7% (29/30)	100% (30/30)	93.3% (28/30)	96.7% (87/90) (90.7% - 98.9%)
	Moderate positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90) (94.0% - 99.8%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
Entamoeba histolytica	Low positive	93.3% (28/30)	96.7% (29/30)	93.3% (28/30)	94.4% (85/90) (87.6% - 97.6%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
Giardia lamblia	Low positive	100% (30/30)	100% (30/30)	93.3% (28/30)	97.8% (88/90) (92.3% - 99.4%)
	Moderate positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90) (95.9% - 100%)
Microsporidia	Low positive	93.3% (28/30)	100% (30/30)	100% (30/30)	97.8% (88/90) (92.3% - 99.4%)
	Moderate positive	100% (30/30)	100% (30/30)	96.7% (29/30)	98.9% (89/90) (94.0% - 99.8%)
	Negative	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)

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Panel Assay Target	Sample Type	% Agreement with Expected result			
		Site 1	Site 2	Site 3	All Sites (95% Confidence)
					(95.9% - 100%)
All Other Targets	Negative	100% (180/180)	100% (180/180)	100% (180/180)	100% (540/540)
					(99.3% - 100%)

Within-Laboratory Precision/Repeatability

Within-site precision and repeatability of the LIAISON PLEX® Gastrointestinal *Flex* Assay was evaluated across days, operators, and replicates. A single lot of Assay Kits was tested by two operators at one internal site. Testing included negative, low positive, and moderate positive samples in two separate sample matrices (Parasite Fixative Stool Matrix and Cary-Blair Stool Matrix). For each sample matrix, sample identities were randomized in sets of nine (three each of negatives, low positives, and moderate positives) and blinded to the operators. For each sample matrix, each operator executed nine tests per study day over five non-consecutive days.

Negative Samples tested were either negative stool matrix (NSM) in Cary-Blair media or Negative Stool Matrix (NSM) in parasite fixative. Negative Stool Matrices were comprised of samples from multiple donors that had been previously pooled and confirmed negative for all targets on the LIAISON PLEX Gastrointestinal *Flex* Assay. Negative samples tested the precision/repeatability of the assay's ability to yield negative test results.

The positive Cary-Blair samples were designed to include analytes representative of each amplification pool and each target type included in the assay design (an RNA virus, a DNA virus, a gram-negative bacterium, a gram-positive bacterium, a toxin-producing bacterium, and a parasite).

The positive parasite fixative samples were designed to include analytes representative of the on-panel parasite targets.

Positive samples were prepared with targets at 1.5 times their Limit of Detection (low positive) and 3 times their Limit of Detection (moderate positive) to test the precision and repeatability of the entire sample-to-answer workflow.

Precision and Repeatability of the LIAISON PLEX Gastrointestinal Assay was demonstrated across operators, days, and replicates. The percent agreement with the expected results in Cary-Blair Stool Matrix or Parasite Fixative Stool Matrix was > 95% for all analytes tested in negative and moderate positive samples. The percent agreement with the expected results in Cary-Blair Stool Matrix or Parasite Fixative Stool Matrix was > 90% for all analytes in low positive samples. Results of the Precision/Repeatability study are summarized in Table 23 and Table 24.

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Table 23: Overall Percent Agreement for Cary-Blair Stool Matrix Samples by Target

Panel Assay Target	% Agreement with Expected result		
	Low Positive	Moderate Positive	Negative
Adenovirus F40/41	96.7% (29/30)	100% (30/30)	100% (30/30)
Clostridioides difficile (tcdA/tcdB)	100% (30/30)	100% (30/30)	100% (30/30)
***Cryptosporidium* spp.**	100% (30/30)	100% (30/30)	100% (30/30)
Norovirus GI/GII	100% (30/30)	100% (30/30)	100% (30/30)
Rotavirus A	93.3% (28/30)	100% (30/30)	100% (30/30)
Shiga-like toxin-producing *E. coli* (STEC) *stx2*	100% (30/30)	100% (30/30)	100% (30/30)
***Shigella*/Enteroinvasive *E. coli* (EIEC)**	90.0% (27/30)	100% (30/30)	100% (30/30)
All Other Targets	100% (510/510)	100% (510/510)	100% (510/510)

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Table 24: Overall Percent Agreement for Parasite Fixative Stool Matrix Samples by Target

Panel Assay Target	% Agreement with Expected result		
	Low Positive	Moderate Positive	Negative
***Blastocystis* sp.**	96.7% (29/30)	100% (30/30)	100% (30/30)
***Cryptosporidium* spp.**	96.7% (29/30)	100% (30/30)	100% (30/30)
Dientamoeba fragilis	96.7% (29/30)	100% (30/30)	100% (30/30)
Entamoeba histolytica	93.3% (28/30)	100% (30/30)	100% (30/30)
Giardia lamblia	100% (30/30)	100% (30/30)	100% (30/30)
Microsporidia	93.3% (28/30)	100% (30/30)	100% (30/30)
All Other Targets	100% (60/60)	100% (60/60)	100% (60/60)

Proposed Labeling:

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

Conclusion:

The LIAISON PLEX® Gastrointestinal *Flex* Assay is substantially equivalent to the predicate device, Biofire® Filmarray® Gastrointestinal Panel (K242367). Despite differences in workflow and instrumentation, both assays share the same intended use, target analytes, and use RT-PCR amplification followed by analysis, and both assays demonstrate comparable analytical and clinical performance.