



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K243013

B Applicant

Luminex Corporation

C Proprietary and Established Names

LIAISON PLEX Gram-Negative Blood Culture Assay

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
PEN	Class II	21 CFR 866.3365 - Multiplex Nucleic Acid Assay For Identification Of Microorganisms And Resistance Markers From Positive Blood Cultures	MI - Microbiology
NSU	Class II	21 CFR 862.2570 - Instrumentation for clinical multiplex test systems	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

To obtain substantial equivalence determination for the LIAISON PLEX Gram-Negative Blood Culture Assay

B Measurand:

Nucleic acid sequences from the following gram-negative bacteria and antibiotic resistance markers: *Enterobacteriaceae* / *Morganellaceae*, *Acinetobacter baumannii*, *Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella*

oxytoca, *Klebsiella pneumoniae*, *Klebsiella variicola*, *Morganella morganii*, *Neisseria meningitidis*, *Proteus* spp., *Pseudomonas aeruginosa*, *Pseudomonas* spp., *Salmonella* spp., *Serratia marcescens*, *Stenotrophomonas maltophilia*, CTX-M (*bla*CTX-M), IMP (*bla*IMP), KPC (*bla*KPC), NDM (*bla*NDM), OXA (*bla*OXA), VIM (*bla*VIM), MCR, and SME (*bla*SME).

C Type of Test:

A multiplexed nucleic acid test intended for use with the automated LIAISON PLEX instrument for the qualitative *in vitro* detection and identification of nucleic acid from gram-negative bacteria in a positive blood culture media sample that demonstrates the presence of gram-negative bacteria as determined by Gram stain.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay, performed using the automated, sample-to-result LIAISON PLEX System, is a qualitative multiplexed *in vitro* diagnostic test for the simultaneous detection and identification of selected gram-negative pathogens and/or selected genetic determinants associated with antimicrobial resistance in positive blood culture bottles. LIAISON PLEX BCN Assay is performed directly on blood culture media using blood culture bottles identified as positive by a continuous monitoring blood culture system which contain gram-negative bacteria as determined by Gram stain.

The BCN Assay detects and identifies the following:

Resistance Markers:

CTX-M (*bla*CTX-M)

IMP (*bla*IMP)

KPC (*bla*KPC)

NDM (*bla*NDM)

OXA (*bla*OXA)

VIM (*bla*VIM)

MCR

SME (*bla*SME)

Gram Negative Genera and Species:

Enterobacteriaceae / *Morganellaceae*

Acinetobacter baumannii

Acinetobacter spp.

Citrobacter spp.

Enterobacter spp. (1)

Escherichia coli (2)

Haemophilus influenzae

Klebsiella oxytoca

Klebsiella pneumoniae

Klebsiella variicola

Morganella morganii
Neisseria meningitidis
Proteus spp.
Pseudomonas aeruginosa
Pseudomonas spp.
Salmonella spp.
Serratia marcescens
Stenotrophomonas maltophilia

(1) Due to reclassification, *Klebsiella aerogenes* will be reported Enterobacter spp.

(2) LIAISON PLEX BCN Assay will not distinguish between *Escherichia coli* and *Shigella* spp. (*S. dysenteriae*, *S. boydii*, *S. flexneri* and *S. sonnei*).

LIAISON PLEX BCN Assay contains targets for the detection of genetic determinants associated with resistance to carbapenems (*bla*CTX-M, *bla*IMP, *bla*KPC, *bla*NDM, *bla*OXA48-like, *bla*VIM, *bla*SME) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant MCR, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to β -lactams and colistin exist.

LIAISON PLEX BCN Assay is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial bloodstream infections (BSI). LIAISON PLEX BCN Assay is not intended to monitor treatment of these infections. Sub-culturing of positive blood cultures is necessary to recover organisms for antimicrobial susceptibility testing (AST), for identification of organisms not detected by LIAISON PLEX BCN Assay, to detect mixed infections that may not be detected by LIAISON PLEX BCN Assay, for association of antimicrobial resistance marker genes to a specific organism, or for epidemiological typing.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

LIAISON PLEX Instrument and Software version 1.4

IV Device/System Characteristics:

A Device Description:

The LIAISON PLEX Gram Negative Blood Culture (BCN) Assay is an automated test for the detection and identification of nucleic acids from gram-negative bacteria in a positive blood culture sample. The LIAISON PLEX BCN Assay is performed directly on blood culture media using blood culture bottles identified as positive by a continuous monitoring blood culture system, and which contain gram-negative bacteria, as determined by Gram stain.

The LIAISON PLEX BCN Assay is performed on the LIAISON PLEX System. The LIAISON PLEX System is a fully automated, benchtop device that performs sample preparation and microarray-based hybridization for the detection of target-specific nucleic acids. The LIAISON PLEX BCN Assay components required to perform the test include the following single-use, disposables:

- LIAISON PLEX BCN Assay Cartridge
- LIAISON PLEX BCN Assay Transfer Pipettes

The test reagents are supplied in a single, disposable test cartridge.

The LIAISON PLEX BCN Assay has 33 different reportable targets. Reporting of these targets is based on detection of one or more of the nucleic acid targets. Results can be:

- reviewed by the user on the touchscreen;
- exported to a USB flash drive; and,
- printed, or submitted to a Laboratory Information System (LIS) for reporting.

The LIAISON PLEX System automates the BCN Assay sample analysis through the following steps: 1) Sample Preparation, 2) Hybridization, and 3) Signal Analysis. The image analysis of the microarray provides light signal intensities from the target-specific capture spots, as well as the negative control, background, and imaging control spots.

B Principle of Operation:

The assay workflow is as follows:

1. The user adds the sample into the BCN Assay Cartridge and closes the cartridge sample port.
2. The user creates a new order in the LIAISON PLEX System and scans the barcode ID or manually enters the sample ID.
3. The user scans the barcode with the hand-held barcode reader.
4. The user inserts the BCN Assay Cartridge into the open bay and then initiates the run. This is repeated, as needed, for up to six cartridges.
5. The system scans the barcode located on the top of the BCN Assay Cartridge and automatically performs the appropriate assay based on the unique barcode on the cartridge.

The following steps take place within the closed cartridge:

1. Sample Preparation – The sample is mixed with reagents and nucleic acid extraction occurs via mechanical and chemical cell lysis and magnetic bead-based nucleic acid isolation. The sample then goes through a series of washes to capture and purify the nucleic acid. The nucleic acid is then transferred into the hybridization unit.
2. Hybridization – Extracted nucleic acids hybridize to specific capture DNA probes arrayed on a glass slide in a microarray format and the bound target DNA, in turn, hybridizes with mediator and gold-nanoparticle probes. An image of the hybridization unit is taken and the LIAISON PLEX Software performs data analysis.
3. Signal Analysis – Gold nanoparticle probes bound specifically to target-containing spots in the microarray are silver-enhanced, and light scatter from the spots is measured and further analyzed to determine the presence (Detected) or absence (Not Detected) of a target.

The system completes all necessary steps for the assay. No user intervention is necessary once the run is initiated. Once the run is complete, the user removes the cartridge(s) and disposes of them in the appropriate waste container. Following a series of quality control checks a final call is made for the Target: Detected if the Target signal is above threshold and Not Detected otherwise. Failure of any quality control checks results in a “No Call” result.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Verigene Gram Negative Blood Culture Nucleic Acid Test (BC-GN)

B Predicate 510(k) Number(s):

K132843

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K243013</u> (Candidate device)	<u>K132843</u> (Predicate device)
Device Trade Name	LIASION PLEX Gram Negative Blood Culture (BCN) Assay	Verigene Gram Negative Blood Culture Nucleic Acid Test (BC-GN)
General Device Characteristic Similarities		
Intended Use/Indications For Use	The LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay, performed using the automated, sample-to-result LIAISON PLEX System, is a qualitative multiplexed <i>in vitro</i> diagnostic test for the simultaneous detection and identification of selected gram-negative pathogens and/or selected genetic determinants associated with antimicrobial resistance in positive blood culture bottles. LIAISON PLEX BCN Assay is performed directly on blood culture media using blood culture bottles identified as positive by a continuous monitoring blood culture system which contain gram-negative bacteria as determined by Gram stain. The BCN Assay detects and identifies the following: Resistance Markers: CTX-M (<i>bla</i>CTX-M) IMP (<i>bla</i>IMP) KPC (<i>bla</i>KPC) NDM (<i>bla</i>NDM) OXA (<i>bla</i>OXA) VIM (<i>bla</i>VIM) MCR SME (<i>bla</i>SME)	The Verigene Gram Negative Blood Culture Nucleic Acid Test (BC-GN), performed using the sample-to-result Verigene System, is a qualitative multiplexed <i>in vitro</i> diagnostic test for the simultaneous detection and identification of selected gram-negative bacteria and resistance markers. BC-GN is performed directly on blood culture media using blood culture bottles identified as positive by a continuous monitoring blood culture system and which contain gram-negative bacteria as determined by gram stain. BC-GN detects and identifies the following: Gram Negative Genera and Species: <i>Acinetobacter</i> spp. <i>Citrobacter</i> spp. <i>Enterobacter</i> spp. <i>Proteus</i> spp. <i>Escherichia coli</i> (1)

	Gram Negative Genera and Species: <i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Acinetobacter baumannii</i> <i>Acinetobacter</i> spp. <i>Citrobacter</i> spp. <i>Enterobacter</i> spp. (1) <i>Escherichia coli</i> (2) <i>Haemophilus influenzae</i> <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> <i>Klebsiella variicola</i> <i>Morganella morganii</i> <i>Neisseria meningitidis</i> <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Pseudomonas</i> spp. <i>Salmonella</i> spp. <i>Serratia marcescens</i> <i>Stenotrophomonas maltophilia</i> (1) Due to reclassification, <i>Klebsiella aerogenes</i> will be reported <i>Enterobacter</i> spp. (2) LIAISON PLEX BCN Assay will not distinguish between <i>Escherichia coli</i> and <i>Shigella</i> spp. (<i>S. dysenteriae</i>, <i>S. boydii</i>, <i>S. flexneri</i> and <i>S. sonnei</i>). LIAISON PLEX BCN Assay contains targets for the detection of genetic determinants associated with resistance to carbapenems (<i>bla</i>CTX-M, <i>bla</i>IMP, <i>bla</i>KPC, <i>bla</i>NDM, <i>bla</i>OXA48-like, <i>bla</i>VIM, <i>bla</i>SME) to aid in the identification of potentially antimicrobial-resistant organisms in positive blood culture samples. In addition, the panel includes an assay for the detection of the mobilized genetic determinant MCR, an emerging marker of public health importance. The antimicrobial resistance gene or marker detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance gene and marker assays do not indicate susceptibility, as multiple mechanisms of resistance to β-lactams and colistin exist. LIAISON PLEX BCN Assay is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial bloodstream infections (BSI). LIAISON PLEX BCN Assay is not intended to monitor treatment of these infections. Sub-culturing of positive blood cultures is necessary to recover organisms for antimicrobial susceptibility testing	<i>Klebsiella pneumoniae</i> <i>Klebsiella oxytoca</i> <i>Pseudomonas aeruginosa</i> (1) BC-GN will not distinguish <i>Escherichia coli</i> from <i>Shigella</i> spp. (<i>S. dysenteriae</i>, <i>S. flexneri</i>, <i>S. boydii</i>, and <i>S. sonnei</i>) Resistance Markers: CTX-M (<i>bla</i>CTX-M) IMP (<i>bla</i>IMP) KPC (<i>bla</i>KPC) NDM (<i>bla</i>NDM) OXA (<i>bla</i>OXA) VIM (<i>bla</i>VIM) BC-GN is indicated for use in conjunction with other clinical and laboratory findings to aid in the diagnosis of bacterial bloodstream infections; however, it is not used to monitor these infections. Sub-culturing of positive blood cultures is necessary to recover organisms for antimicrobial susceptibility testing (AST), for identification of organisms not detected by BC-GN, to detect mixed infections that may not be detected by BC-GN, for association of antimicrobial resistance marker genes to a specific organism, or for epidemiological typing.
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	(AST), for identification of organisms not detected by LIAISON PLEX BCN Assay, to detect mixed infections that may not be detected by LIAISON PLEX BCN Assay, for association of antimicrobial resistance marker genes to a specific organism, or for epidemiological typing.	
Measurand	Target DNA sequences of gram-negative bacteria and antimicrobial resistance markers	Same
Specimen Type	Positive blood culture (PBC) samples that contain gram-negative bacteria	Same
Test Principle	Qualitative, multiplexed nucleic acid hybridization test on a microarray format using capture and mediator oligonucleotides for gold nanoparticle probe-based endpoint detection	Same
Sample Extraction	Chemical and mechanical lysis followed by a chaotrope-based nucleic acid isolation procedure	Same
Quality Controls	Two internal processing controls (extraction and hybridization controls). External controls are recommended to be run.	Same
Test Interpretation Output	Detected/Not Detected	Same
General Device Characteristic Differences		
Organisms Detected	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Acinetobacter baumannii</i> <i>Acinetobacter</i> spp. <i>Citrobacter</i> spp. <i>Enterobacter</i> spp. <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> <i>Klebsiella variicola</i> <i>Morganella morganii</i> <i>Neisseria meningitidis</i> <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i> <i>Pseudomonas</i> spp.	<i>Acinetobacter</i> spp. <i>Citrobacter</i> spp. <i>Enterobacter</i> spp. <i>Escherichia coli</i> <i>Klebsiella oxytoca</i> <i>Klebsiella pneumoniae</i> <i>Proteus</i> spp. <i>Pseudomonas aeruginosa</i>

	<i>Salmonella</i> spp. <i>Serratia marcescens</i> <i>Stenotrophomonas maltophilia</i>	
Resistance Markers Detected	CTX-M (<i>bla</i> CTX-M) IMP (<i>bla</i> IMP) KPC (<i>bla</i> KPC) NDM (<i>bla</i> NDM) OXA (<i>bla</i> OXA) VIM (<i>bla</i> VIM) MCR SME (<i>bla</i> SME)	CTX-M (<i>bla</i> CTX-M) IMP (<i>bla</i> IMP) KPC (<i>bla</i> KPC) NDM (<i>bla</i> NDM) OXA (<i>bla</i> OXA) VIM (<i>bla</i> VIM)
Storage Requirements	15-30°C (for cartridges only)	2-8°C (for cartridges only)
Test Design	LIAISON PLEX BCN Assay Cartridge, LIAISON PLEX BCN Assay Transfer Pipettes	Verigene BC-GN Test Cartridge, Verigene BC-GN Extraction Tray (with Tip Holder Assembly), Verigene BC-GN Utility Kit
Required Equipment	LIAISON PLEX System	Verigene System, Reader and Processor SP
Time to Result	2.5 hours	~ 2 hours

VI Standards/Guidance Documents Referenced:

Document #	Title
Class II Special Controls Guideline	Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures; Class II Special Controls Guideline for Industry and Food and Drug Administration Staff (Issued May 27, 2015)
Guidance Document	Electronic Submission Template for Medical Device 510(k) Submissions; Guidance for Industry and Food and Drug Administration Staff (October 2023)
Guidance Document	Content of Premarket Submissions for Device Software Functions; Guidance for Industry and Food and Drug Administration Staff (June 2023)
Guidance Document	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff (Issued September 27, 2023)
CLSI EP07 3rd Edition	Interference Testing in Clinical Chemistry
CLSI EP12 3rd Edition	Evaluation of Qualitative Binary Output Examination Performance
CLSI EP17-A2	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition
CLSI EP24-A2	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline - Second Edition
CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline
ANSI AAMI ISO 14971:2019	Application of Risk Management to Medical Devices
ISO 15223-1 Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling). Part 1: Terms, definition and general requirements.

ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) Part 2: In vitro diagnostic reagents for professional use
ISO 18113-3:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) Part 3: In vitro diagnostic instruments for professional use
ISO 20916	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice. First edition. 2019.
ISO 23640	In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents
ISO 3864-1	Graphic Symbols - Safety Colors and Safety Signs - Part 1. Design Principles for Safety Signs and Safety Markings (2011)
IEC 60601-1-2 Edition 4.0	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests (2014-02)
IEC 61010-1 Edition 3.1, Consolidated Version	Safety Requirements for Electrical Equipment for Measurement Control and Laboratory Use - Part 1: General Requirements, Including Corrigendum 1. (2017-01)
IEC 61326-2-6 Edition 3.0	Electrical Equipment for Measurement Control and Laboratory Use - EMC Requirements - Part 2-6: Particular Requirements - In Vitro Diagnostic (IVD) Medical Equipment (2010-10)
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 62304:2006	Medical device software - Software life cycle processes
ISTA 3A	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less. (2018)
ISTA 7D	Temperature Test for Transport Packaging

VII Performance Characteristics (if/when applicable):

Analytical Performance:

1. Precision/Reproducibility:

Precision/reproducibility was conducted according to CLSI EP05-A3¹ and the Special Controls Guideline² to assess the performance of the LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay.

Site-to-Site

A site-to-site precision study was conducted at three sites (2 external, one internal). A total of 10 blood culture samples were tested: six representative on-panel organisms (*Haemophilus influenzae*, *Neisseria meningitidis*, *Acinetobacter baumannii* + OXA, *Escherichia coli* + MCR, *Klebsiella pneumoniae* + KPC, and *Serratia marcescens* + SME) individually cultured to ring positivity and to eight hours after ring positivity, one negative sample contrived with an off-panel organism (*Staphylococcus aureus*), and one negative blood culture matrix (NBM) sample. Testing was conducted on one lot of the candidate test. Ninety (90) data

¹ CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

² FDA Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures; Guideline for Industry and Food and Drug Administration Staff (Issued May 27, 2015)

points were generated for each on-panel member and culture timepoint (0, 8 hrs post-positivity): 3 replicates per run $\times$ 2 operators per day $\times$ 5 non-consecutive days $\times$ 3 sites = 90 data points. Acceptance criteria are $\geq 95\%$ agreement of positive and negative samples with expected results. Results are summarized in **Table 1** below.

Table 1. Summary Results of Site-to-Site Reproducibility

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Site 1	Site 2	Site 3	Overall	Lower	Upper
<i>A. baumannii</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
<i>K. pneumoniae</i>	Ring Positive	100% (30/30)	100% (31/31)	100% (30/30)	100% (91/91)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
<i>H. influenzae</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
<i>N. meningitidis</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
<i>E. coli</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
<i>S. marcescens</i>	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
<i>S. aureus</i>	Off-panel Negative	98.3% (59/60)	100% (60/60)	100% (60/60)	99.4% (179/180)	96.9%	99.9%
Negative Blood Culture	Off-panel Negative	100% (60/60)	100% (60/60)	100% (60/60)	100% (180/180)	97.9%	100%
Resistance Markers							
OXA	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
KPC	Ring Positive	100% (30/30)	100% (31/31)	100% (30/30)	100% (91/91)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
MCR	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
SME	Ring Positive	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%
	Ring Positive +8 Hours	100% (30/30)	100% (30/30)	100% (30/30)	100% (90/90)	95.9%	100%

Lot-to-Lot

A lot-to-lot precision study was conducted using one operator at one internal site. Testing was conducted over a minimum of five non-consecutive days across three lots of LIAISON PLEX BCN Assay cartridges and two LIAISON PLEX systems. Data from the cartridge lot for Operator 1 tested during site-to-site testing was leveraged for assessment of lot-to-lot precision. A total of 6 blood culture samples were tested: two representative on-panel organisms (*A. baumannii* + OXA and *K. pneumoniae* + KPC) individually cultured to ring positivity and to eight hours after ring positivity, one negative sample contrived with an off-panel organism (*Staphylococcus aureus*), and one negative blood culture matrix (NBM) sample. Ninety (90) data points were generated per lot: 3 replicates per run $\times$ 5 days $\times$ 6 panel members = 90 data points. Acceptance criteria are $\geq 95\%$ agreement of positive and negative samples with expected results. Results are summarized in **Table 2** below.

Table 2. Summary Results of Lot-to-Lot Reproducibility

Organism	Target Type	Agreement with Expected Results				95% C.I.	
		Lot 1	Lot 2	Lot 3	Overall	Lower	Upper
<i>A. baumannii</i>	Ring Positive	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
	Ring Positive +8 Hours	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
<i>K. pneumoniae</i>	Ring Positive	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
	Ring Positive +8 Hours	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
<i>S. aureus</i>	Off-panel Negative	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
Negative Blood Culture	Off-panel Negative	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
Resistance Markers							
OXA	Ring Positive	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
	Ring Positive +8 Hours	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
KPC	Ring Positive	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%
	Ring Positive +8 Hours	100% (15/15)	100% (15/15)	100% (15/15)	100% (45/45)	92.1%	100%

Repeatability and Within-Laboratory Precision

Within-lab precision/repeatability was assessed using site-to-site precision study data. Results from site-to-site testing are stratified according to operator in **Table 3** below.

Table 3. Summary Results of Within-Lab/Repeatability Stratified by Operator

Organism	Target Type	Agreement with Expected Results	
		Site 1	
		Operator 1	Operator 2
<i>A. baumannii</i>	Ring Positive	100% 15/15	100% 15/15
	Ring Positive +8 Hours	100% 15/15	100% 15/15
<i>K. pneumoniae</i>	Ring Positive	100% 15/15	100% 15/15
	Ring Positive +8 Hours	100% 15/15	100% 15/15
<i>H. influenzae</i>	Ring Positive	100% 15/15	100% 15/15
	Ring Positive +8 Hours	100% 15/15	100% 15/15
<i>N. meningitidis</i>	Ring Positive	100% 15/15	100% 15/15
	Ring Positive +8 Hours	100% 15/15	100% 15/15

Organism	Target Type	Agreement with Expected Results	
		Site 1	
		Operator 1	Operator 2
<i>E. coli</i>	Ring Positive	100% 15/15	100% 15/15
	Ring Positive +8 Hours	100% 15/15	100% 15/15
<i>S. marcescens</i>	Ring Positive	100% 15/15	100% 15/15
	Ring Positive +8 Hours	100% 15/15	100% 15/15
<i>S. aureus</i>	Off-panel Negative	100% 30/30	96.7% 29/30
Negative Blood Culture	Off-panel Negative	100% 30/30	100% 30/30

2. Linearity:

This study is not applicable as the test device is a qualitative assay.

3. Analytical Specificity/Interference:

The LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay was evaluated for analytical specificity/cross-reactivity and interference.

Cross-Reactivity

The LIAISON PLEX BCN Assay was evaluated for microbial cross-reactivity. A total of 113 “off-panel” organisms, including those phylogenetically related to the on-panel organisms and organisms likely to be present in clinical blood culture samples but not detected by the LIAISON PLEX BCN Assay. Each potentially cross-reacting organism was spiked into negative blood matrix and tested in triplicate. All species were tested at clinically relevant concentrations or the highest achievable concentration. **Table 4** lists the microorganisms tested and the results of microbial cross-reactivity testing.

Table 4. Summary Results of Microorganisms Evaluated for Cross-Reactivity

Organism	Positivity (%)	Organism	Positivity (%)
Gram Positive			
<i>Abitrophia defective</i>	0%	<i>Leuconostoc carnosum</i>	0%
<i>Aerococcus viridans</i>	0%	<i>Leuconostoc mesenteroids</i>	0%
<i>Arcanobacterium bernardiae</i>	0%	<i>Listeria grayi</i>	0%
<i>Arcanobacterium haemolyticum</i>	0%	<i>Listeria innocua</i>	0%
<i>Bacillus cereus</i>	0%	<i>Listeria ivanovii</i>	0%
<i>Bacillus licheniformis</i>	0%	<i>Listeria welshimeri</i>	0%
<i>Bacillus subtilis</i>	0%	<i>Micrococcus luteus</i>	0%
<i>Bacillus thuringiensis</i>	0%	<i>Micrococcus lylae</i>	0%
<i>Corynebacterium amycolatum</i>	0%	<i>Pediococcus acidilactici</i>	0%
<i>Corynebacterium diphtheriae</i>	0%	<i>Pediococcus pentosaceus</i>	0%
<i>Corynebacterium pseudodiphtheriticum</i>	0%	<i>Peptostreptococcus anaerobius</i>	0%
<i>Corynebacterium striatum</i>	0%	<i>Planococcus citreus</i>	0%
<i>Cutibacterium acnes</i>	0%	<i>Planococcus kocurii</i>	0%
<i>Cutibacterium avidum</i>	0%	<i>Rothia dentocariosa</i>	0%
<i>Propionibacterium freudenreichii</i>	0%	<i>Rothia (Stomatococcus) mucilaginosus</i>	0%
<i>Enterococcus avium</i>	0%	<i>Staphylococcus capitis</i>	0%
<i>Enterococcus casseliflavus</i> , VRE, vanC	0%	<i>Staphylococcus caprae</i>	0%
<i>Enterococcus dispar</i>	0%	<i>Staphylococcus cohnii</i>	0%
<i>Enterococcus durans</i>	0%	<i>Staphylococcus haemolyticus</i>	0%
<i>Enterococcus flavescens</i>	0%	<i>Staphylococcus hominis</i>	0%
<i>Enterococcus gallinarum</i> , vanC	0%	<i>Staphylococcus intermedius</i>	0%

Organism	Positivity (%)	Organism	Positivity (%)
<i>Enterococcus hirae</i>	0%	<i>Staphylococcus lugdunensis</i>	0%
<i>Enterococcus mundtii</i>	0%	<i>Streptococcus agalactiae</i>	0%
<i>Enterococcus raffinosus</i>	0%	<i>Streptococcus anginosus</i>	0%
<i>Erysipelothrix rhusiopathiae</i>	0%	<i>Streptococcus bovis</i>	0%
<i>Kocuria kristinae</i>	0%	<i>Streptococcus constellatus</i>	0%
<i>Kytococcus sedentarius</i> , Met R	0%	<i>Streptococcus equinus</i>	0%
<i>Lactobacillus acidophilus</i>	0%	<i>Streptococcus mitis</i>	0%
<i>Lactobacillus crispatus</i>	0%	<i>Streptococcus pneumoniae</i>	0%
<i>Lactobacillus rhamnosus</i>	0%	<i>Streptococcus pyogenes</i>	0%
<i>Corynebacterium frankenforstense</i>	0%		
Gram Negative			
<i>Aggregatibacter aphrophilus</i>	0%	<i>Fusobacterium nucleatum</i>	0%
<i>Bacteroides fragilis</i>	0%	<i>Haemophilus haemolyticus</i>	0%
<i>Brevundimonas diminuta</i>	0%	<i>Herbaspirillum huttiense</i>	0%
<i>Burkholderia cepacian</i>	0%	<i>Kingella kingae</i>	0%
<i>Capnocytophaga ochracea</i>	0%	<i>Moraxella catarrhalis</i>	0%
<i>Cardiobacterium hominis</i>	0%	<i>Neisseria lactamica</i>	0%
<i>Comamonas testosterone</i>	0%	<i>Neisseria mucosa</i>	0%
<i>Delftia acidovorans</i>	0%	<i>Neisseria sicca</i>	0%
<i>Eikenella corrodens</i>	0%	<i>Parabacteroides distasonis</i>	0%
<i>Elizabethkingia meningoseptica</i>	0%	<i>Pasteurella aerogenes</i>	0%
<i>Fusobacterium necrophorum</i>	0%	<i>Prevotella bivia</i>	0%
<i>Aeromonas hydrophila</i>	0%	<i>Klebsiella quasivariicola</i>	100%
<i>Haemophilus parainfluenzae</i>	0%	<i>Providencia rustigiani</i>	100%
<i>Haemophilus parahaemolyticus</i>	33%	<i>Providencia vermicola</i>	100%
<i>Enterobacter kobei</i>	100%	<i>Pseudomonas paraeruginosa</i>	100%
<i>Haemophilus aegyptius</i>	100%	<i>Serratia entomophila</i>	100%
<i>Klebsiella grimontii</i>	100%	<i>Serratia nevei</i>	100%
<i>Klebsiella huaxiensis</i>	100%	<i>Serratia odorifera</i>	100%
<i>Klebsiella michiganensis</i>	100%	<i>Serratia quinivorans</i>	100%
<i>Klebsiella quasipneumoniae</i>	100%	<i>Serratia ureilytica</i>	100%
<i>Lelliottia amnigena</i>	100%		
Yeast/Fungi			
<i>Aspergillus fumigatus</i>	0%	<i>Candida tropicalis</i>	0%
<i>Candida albicans</i>	0%	<i>Cryptococcus neoformans</i>	0%
<i>Candida famata</i>	0%	<i>Kluyveromyces lactis</i>	0%
<i>Candida glabrata</i>	0%	<i>Saccharomyces cerevisiae</i>	0%
<i>Candida krusei</i>	0%	<i>Schizosaccharomyces pombe</i>	0%
<i>Candida parapsilosis</i>	0%		

Of the off-panel organisms tested, 17 species generated positive results for *Enterobacteriaceae* / *Morganellaceae*, and of those 17, 11 had an additional positive result that was found to be cross-reactive. **Table 5** lists the microorganisms shown to cross-react and the false target calls made on the LIAISON PLEX BCN Assay. The observed cross-reactivity is noted in the device labeling.

Table 5. Summary Results of Cross-Reactive Organisms

Organism	Positivity (%)	Results	
<i>Lelliottia amnigena</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Enterobacter</i> spp.

<i>Pseudomonas paraeruginosa</i>	100%	<i>Pseudomonas</i> spp.	<i>Pseudomonas aeruginosa</i>
<i>Serratia nevei</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>
<i>Serratia entomophila</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>
<i>Serratia ureilytica</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>
<i>Klebsiella quasivariicola</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella pneumoniae</i>
<i>Haemophilus aegyptius</i>	100%	None	<i>Haemophilus influenzae</i>
<i>Klebsiella michiganensis</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella oxytoca</i>
<i>Klebsiella grimontii</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella oxytoca</i>
<i>Klebsiella quasipneumoniae</i>	100%	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella pneumoniae</i>
<i>Haemophilus parahaemolyticus</i>	33%	None	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>

In Silico Inclusivity/Exclusivity

In silico analyses were conducted for potentially cross-reactive organisms that could not be obtained for wet testing to predict potential cross-reactivity of the assay oligos through a BLAST comparison of the oligo sequences to the GenBank nucleotide (nt) sequence database residing locally on company servers. To ensure that all potential cross-reactivity is assessed, this analysis was performed with all capture and mediator probes in the assay's oligo mix, including the internal control oligos. **Table 6** lists the microorganisms for which sequences were subjected to *in silico* analysis to predict potential cross-reactivity.

Table 6. Potential Cross-Reactive Organisms Tested in *In Silico* Analysis

On-Panel Organisms	Off-Panel Organisms			
	Gram-Positive Bacteria	Gram-Negative Bacteria	Resistance Markers	Yeasts / Viruses / Parasites
<i>Acinetobacter baumannii</i>	<i>Actinomyces israelii</i>	<i>Actinobacillus hominis</i>	AmpC	<i>Aspergillus flavus</i>
<i>Acinetobacter</i> spp.	<i>Actinomyces naeslundii</i>	<i>Actinobacillus ureae</i>	CMY	<i>Aspergillus fumigatus</i>
<i>Citrobacter</i> spp.	<i>Actinomyces odontolyticus</i>	<i>Aeromonas caviae</i>	<i>mecA</i>	<i>Aspergillus niger</i>
<i>Enterobacter</i> spp.	<i>Aerococcus sanguinicola</i>	<i>Aeromonas hydrophila</i>	<i>mecC</i>	<i>Aspergillus terreus</i>
<i>Enterobacteriaceae</i>	<i>Aerococcus urinae</i>	<i>Aeromonas sobria</i>	<i>ompK36</i>	<i>Blastomyces dermatitidis</i>
<i>Escherichia coli</i> / <i>Shigella</i> spp.	<i>Aerococcus viridans</i>	<i>Aggregatibacter actinomycetemcomitans</i>	RAHN	<i>Candida albicans</i>
<i>Haemophilus influenzae</i>	<i>Arcanobacterium bernardiae</i>	<i>Aggregatibacter aphrophilus</i>	SHV	<i>Candida auris</i>
<i>Klebsiella oxytoca</i>	<i>Arcanobacterium haemolyticum</i>	<i>Bacteroides caccae</i>	SPM	<i>Candida dubliniensis</i>
<i>Klebsiella pneumoniae</i>	<i>Arthrobacter psychrolactophilus</i>	<i>Bacteroides fragilis</i>	TEM	<i>Candida duobushaemulonii</i>
<i>Klebsiella variicola</i>	<i>Bacillus</i> spp.	<i>Bacteroides ovatus</i>	<i>vanA</i>	<i>Candida famata</i>
<i>Morganella morganii</i>	<i>Brochothrix thermosphacta</i>	<i>Bacteroides thetaiotaomicron</i>	<i>vanB</i>	<i>Candida glabrata</i>
<i>Morganellaceae</i>	<i>Carnobacterium divergens</i>	<i>Bacteroides uniformis</i>	<i>vanC</i>	<i>Candida guilliermondii</i>
<i>Neisseria meningitidis</i>	<i>Carnobacterium maltaromaticum</i>	<i>Bacteroides vulgatus</i>	<i>vanD</i>	<i>Candida haemulonii</i>

On-Panel Organisms	Off-Panel Organisms			
	Gram-Positive Bacteria	Gram-Negative Bacteria	Resistance Markers	Yeasts / Viruses / Parasites
<i>Proteus</i> spp.	<i>Cellulomonas turbata</i>	<i>Bacteroides xylanisolvens</i>	vanM	<i>Candida inconspicua</i>
<i>Pseudomonas aeruginosa</i>	<i>Cellulosimicrobium cellulans</i>	<i>Bordetella bronchiseptica</i>		<i>Candida kefyr</i>
<i>Pseudomonas</i> spp.	<i>Clostridioides difficile</i>	<i>Bordetella parapertussis</i>		<i>Candida krusei</i>
<i>Salmonella</i> spp.	<i>Clostridium bifermentans</i>	<i>Bordetella pertussis</i>		<i>Candida lipolytica</i>
<i>Serratia marcescens</i>	<i>Clostridium clostridioforme</i>	<i>Brevundimonas diminuta</i>		<i>Candida lusitanae</i>
<i>Stenotrophomonas maltophilia</i>	<i>Clostridium perfringens</i>	<i>Brevundimonas vesicularis</i>		<i>Candida metapsilosis</i>
CTX-M	<i>Clostridium ramosum</i> (<i>Thomasclavelia ramosa</i>)	<i>Burkholderia cepacia</i>		<i>Candida multis-gemmis</i>
IMP	<i>Clostridium septicum</i>	<i>Burkholderia mallei</i>		<i>Candida nivariensis</i>
KPC	<i>Clostridium tertium</i>	<i>Burkholderia multivorans</i>		<i>Candida norvegensis</i>
MCR (MCR-1, MCR-2, MCR-3)	<i>Clostridium tetani</i>	<i>Burkholderia pseudomallei</i>		<i>Candida orthopsilosis</i>
NDM	<i>Corynebacterium</i> spp.	<i>Campylobacter hominis</i>		<i>Candida parapsilosis</i>
OXA (OXA-23, OXA-24/40/143, OXA-48, OXA-58)	<i>Cutibacterium acnes</i>	<i>Capnocytophaga ochracea</i>		<i>Candida sojae</i>
SME	<i>Cutibacterium avidum</i>	<i>Cardiobacterium hominis</i>		<i>Candida tropicalis</i>
VIM	<i>Cutibacterium granulosum</i>	<i>Chlamydia trachomatis</i>		<i>Candida viswanathii</i>
	<i>Enterococcus avium</i>	<i>Chlamydophila pneumoniae</i>		<i>Coccidioides immitis</i>
	<i>Enterococcus casseliflavus</i>	<i>Chromobacterium violaceum</i>		<i>Coccidioides posadasii</i>
	<i>Enterococcus cecorum</i>	<i>Comamonas testosteroni</i>		<i>Cryptococcus amyloletus</i>
	<i>Enterococcus dispar</i>	<i>Delftia acidovorans</i>		<i>Cryptococcus gattii</i>
	<i>Enterococcus durans</i>	<i>Eikenella corrodens</i>		<i>Cryptococcus neoformans</i>
	<i>Enterococcus faecalis</i>	<i>Elizabethkingia meningoseptica</i>		<i>Cryptococcus uniguttulatus</i>
	<i>Enterococcus faecium</i>	<i>Fusobacterium necrophorum</i>		<i>Cutaneotrichosporon curvatum</i>
	<i>Enterococcus flavescens</i>	<i>Fusobacterium nucleatum</i>		<i>Cyberlindnera fabianii</i>
	<i>Enterococcus gallinarum</i>	<i>Haemophilus aegyptius</i>		<i>Geotrichum capitatum</i> (<i>Magnusiomyces capitatus</i>)
	<i>Enterococcus hirae</i>	<i>Haemophilus ducreyi</i>		<i>Histoplasma capsulatum</i>
	<i>Enterococcus mundtii</i>	<i>Haemophilus haemolyticus</i>		<i>Kluyveromyces lactis</i>
	<i>Enterococcus raffinosus</i>	<i>Haemophilus parahaemolyticus</i>		<i>Kodamaea ohmeri</i>
	<i>Erysipelothrix rhusiopathiae</i>	<i>Haemophilus parainfluenzae</i>		<i>Lodderomyces elongisporus</i>
	<i>Finegoldia magna</i>	<i>Haemophilus parasuis</i>		<i>Magnusiomyces capitatus</i>
	<i>Gemella haemolysans</i>	<i>Haemophilus quentini</i>		<i>Milleromyces farinosa</i>
	<i>Gemella morbillorum</i>	<i>Haemophilus sputorum</i>		<i>Naganishia albida</i>
	<i>Granulicatella adiacens</i>	<i>Herbaspirillum huttiense</i>		<i>Papiliotrema laurentii</i>
	<i>Granulicatella elegans</i>	<i>Kingella denitrificans</i>		<i>Penicillium chrysogenum</i>
	<i>Kocuria kristinae</i>	<i>Kingella kingae</i>		<i>Rhodotorula mucilaginosa</i>
	<i>Kocuria rhizophila</i>	<i>Kingella negevensis</i>		<i>Saccharomyces cerevisiae</i>
	<i>Kytococcus sedentarius</i>	<i>Kingella oralis</i>		<i>Schizosaccharomyces pombe</i>

On-Panel Organisms	Off-Panel Organisms			
	Gram-Positive Bacteria	Gram-Negative Bacteria	Resistance Markers	Yeasts / Viruses / Parasites
	<i>Lactobacillus acidophilus</i>	<i>Legionella pneumophila</i>		<i>Talaromyces marneffeii</i>
	<i>Lactobacillus crispatus</i>	<i>Leptospira interrogans</i>		<i>Trichosporon asahii</i>
	<i>Lactobacillus rhamnosus</i>	<i>Moraxella catarrhalis</i>		<i>Wickerhamomyces anomalus</i>
	<i>Lactococcus garvieae</i>	<i>Moraxella osloensis</i>		BK Virus
	<i>Lactococcus lactis</i>	<i>Mycobacterium tuberculosis</i>		Chikungunya Virus
	<i>Leuconostoc carnosum</i>	<i>Neisseria gonorrhoeae</i>		Cytomegalovirus
	<i>Leuconostoc citreum</i>	<i>Neisseria lactamica</i>		Dengue Virus
	<i>Leuconostoc mesenteroides</i>	<i>Neisseria mucosa</i>		Enterovirus
	<i>Listeria spp.</i>	<i>Neisseria sicca</i>		Epstein Barr Virus
	<i>Macrococcus caseolyticus</i>	<i>Parabacteroides distasonis</i>		Hepatitis A virus
	<i>Micrococcus luteus</i>	<i>Parabacteroides merdae</i>		Hepatitis B virus
	<i>Mycobacterium avium complex (MAC)</i>	<i>Pasteurella aerogenes</i>		Hepatitis C virus
	<i>Mycobacterium fortuitum</i>	<i>Pasteurella canis</i>		Human alphaherpesvirus 1
	<i>Mycobacterium mucogenicum</i>	<i>Pasteurella multocida</i>		Human alphaherpesvirus 2
	<i>Mycoplasma hominis</i>	<i>Pasteurella stomatis</i>		Human betaherpesvirus 6
	<i>Mycoplasma pneumoniae</i>	<i>Prevotella bivia</i>		Human betaherpesvirus 7
	<i>Nocardia farcinica</i>	<i>Prevotella buccae</i>		Human Immunodeficiency Virus
	<i>Parvimonas micra</i>	<i>Prevotella denticola</i>		JC Virus
	<i>Pediococcus acidilactici</i>	<i>Prevotella melaninogenica</i>		Measles Virus
	<i>Pediococcus pentosaceus</i>	<i>Prevotella oralis</i>		Mumps Virus
	<i>Peptostreptococcus anaerobius</i>	<i>Psychrobacter cryohalolentis</i>		Parvovirus B19
	<i>Planococcus citreus</i>	<i>Psychrobacter immobilis</i>		Rubella Virus
	<i>Planococcus kocurii</i>	<i>Ralstonia mannitolilytica</i>		Varicella Zoster Virus
	<i>Propionibacterium freudenreichii</i>	<i>Ralstonia pickettii</i>		West Nile Virus
	<i>Propionibacterium propionicum (Arachnia propionica)</i>	<i>Serratia spp.</i>		Zika Virus
	<i>Rhodococcus equi</i>	<i>Stenotrophomonas acidaminiphila</i>		<i>Plasmodium falciparum</i>
	<i>Rothia dentocariosa</i>	<i>Stenotrophomonas nitritireducens</i>		<i>Trypanosoma cruzi</i>
	<i>Rothia mucilaginosa</i>	<i>Stenotrophomonas rhizophila</i>		
	<i>Sarcina ventriculi</i>	<i>Treponema pallidum</i>		
	<i>Solibacillus silvestris</i>	<i>Veillonella parvula</i>		
	<i>Staphylococcus spp.</i>	<i>Vibrio alginolyticus</i>		
	<i>Streptococcus spp.</i>	<i>Vibrio parahaemolyticus</i>		
	<i>Ureaplasma parvum</i>	<i>Vibrio vulnificus</i>		
	<i>Ureaplasma urealyticum</i>			
	<i>Vagococcus fluvialis</i>			
	<i>Weissella paramesenteroides</i>			

In silico analyses of potential non-specific amplification and detection predicts the following potential cross-reactivity against organisms listed in **Table 6**. The predicted cross-reactivity is noted in the device labeling.

- *Acinetobacter baumannii* oligo designs are predicted to detect some strains of *Acinetobacter pittii* and *Klebsiella pneumoniae*.
- Some strains of *Escherichia* species (*E. albertii*, *E. coli*, *E. fergusonii*, *E. marmotae*), *Raoultella terrigena* and *Shigella* species (*S. boydii*, *S. dysenteriae*, *S. flexneri*, *S. sonnei*) are predicted to produce false positive *Citrobacter* spp. results.
- *Enterobacter* spp. oligo designs are predicted to detect some strains of *Klebsiella huaxiensis*, *Leclercia adecarboxylata* and *Lelliottia* species (*Lelliottia amnigena*, *Lelliottia nimipressuralis*).
- Some strains of *Aeromonas hydrophila*, *Aggregatibacter aphrophilus*, *Corynebacterium frankenforstense*, *Haemophilus parahaemolyticus*, *Haemophilus parainfluenzae* and *Pseudomonas wenzhouensis* are predicted to produce false positive *Enterobacteriaceae* / *Morganellaceae* results.
- *Escherichia coli* oligo designs are predicted to detect some strains of *Escherichia albertii* and *Escherichia marmotae*.
- *Haemophilus influenzae* oligo designs are predicted to detect some strains of *Haemophilus aegyptius*.
- Some strains of *Cedecea* species (*C. davisae*, *C. lapagei*, *C. neteri*), *Enterobacter* species (*E. kobei*, *E. mori*), *Escherichia coli*, *Klebsiella* species (*K. aerogenes*, *K. electrica*, *K. grimontii*, *K. huaxiensis*, *K. michiganensis*, *K. pasteurii*, *K. pneumoniae*, *K. variicola*), *Kluyvera* species (*K. ascorbate*, *K. cryocrescens*), *Raoultella* species (*R. ornithinolytica*, *R. planticola*) and unspecified *Superficieibacter* species are predicted to produce false positive *Klebsiella oxytoca* results.
- *Klebsiella pneumoniae* oligo designs are predicted to detect some strains of *Enterobacteriaceae* and *Klebsiella* species (*K. africana*, *K. grimontii*, *K. quasipneumoniae*, *K. quasivariicola*, *K. variicola*).
- Some strains of *Cronobacter muytjensii*, *Klebsiella pneumoniae* and *Klebsiella quasipneumoniae* are predicted to produce false positive *Klebsiella variicola* results.
- Some strains of *Arsenophonus* species (*A. apicola*, *A. endosymbiont*, *A. nasoniae*), *Haemophilus parahaemolyticus*, *Leclercia adecarboxylata*, *Morganella psychrotolerans*, *Providencia* species (*P. hangzhouensis*, *P. heimbachae*, *P. huaxiensis*, *P. manganoxydans*, *P. rettgeri*, *P. rustigianii*, *P. stuartii*, *P. vermicola*), *Serratia* species (*S. grimesii*, *S. proteamaculans*, *S. quinivorans*) and *Xenorhabdus* species (*X. bovienii*, *X. budapestensis*, *X. griffiniae*, *X. hominickii*, *X. poinarii*) are predicted to produce false positive *Proteus* spp. results.
- *Pseudomonas aeruginosa* oligo designs are predicted to detect some strains of *Pseudomonas paraaeruginosa* and *Pseudomonas fluorescens*.
- *Salmonella* spp. oligo designs are predicted to detect one strain of *Enterobacteriaceae*.
- Some strains of *Serratia* species (*S. bockelmannii*, *S. entomophila*, *S. ficaria*, *S. fonticola*, *S. grimesii*, *S. inhibens*, *S. liquefaciens*, *S. nematodiphila*, *S. nevei*, *S. odorifera*, *S. proteamaculans*, *S. quinivorans*, *S. rhizosphaerae*, *S. rubidaea*, *S. surfactantfaciens*, *S. symbiotica*, *S. ureilytica*) are predicted to produce false positive *Serratia marcescens* results.

- *Stenotrophomonas maltophilia* oligo designs are predicted to detect some strains of *Enterobacter cloacae* and other *Stenotrophomonas* species (*S. acidaminiphila*, *S. nitritireducens*, *S. rhizophila*).
- Some strains of *Serratia liquefaciens* are predicted to produce false positive *Serratia marcescens* and CTX-M results.
- Some strains of *Serratia liquefaciens* and *Serratia nevei* are predicted to produce false positive *Serratia marcescens* and IMP results.
- Some strains of *Serratia nevei* are predicted to produce false positive *Serratia marcescens* and OXA results.

Microbial Interference and Competitive Inhibition

A microbial interference and competitive inhibition study was conducted to evaluate performance of the LIAISON PLEX BCN Assay to detect on-panel organisms in the presence of highly concentrated, potentially interfering microorganisms. To evaluate competitive inhibition, a set of ten representative pairwise combinations of a lower concentration on-panel target strain (ring positive) and a second on-panel target at high concentration (ring positive + 8 hours) were evaluated to assess dual target detection. To determine if non-target organisms can interfere with detection of on-panel organisms in the same sample, a microbial interference study was conducted. The study evaluated a set of ten representative pairwise combinations of a lower concentration on-panel target strains (ring positive) mixed with seven potentially interfering off-panel organisms at high concentration (~1.0E+08 CFU/mL). The on-panel pairwise strain mixtures were chosen to be representative of clinically relevant, polymicrobial bloodstream infections and were each tested in triplicate. Results of the microbial interference study and competitive inhibition studies are presented in **Tables 7 and 8**, respectively. Interference was not observed for the LIAISON PLEX BCN Assay when low concentration on-panel organisms are tested in the presence of high concentration interfering microbes and other on-panel organisms.

Table 7. Summary Results of Competitive Inhibition Study

On-Panel High Concentration Target	Positivity	On-Panel Low Concentration Target	Positivity
<i>Acinetobacter baumannii</i>	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
	100%	<i>Proteus mirabilis</i>	100%
<i>Citrobacter freundii</i>	100%	<i>Pseudomonas aeruginosa</i>	100%
	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
<i>Enterobacter cloacae</i>	100%	<i>Proteus mirabilis</i>	100%
	100%	<i>Pseudomonas aeruginosa</i>	100%
<i>Enterobacter cloacae</i>	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%

On-Panel High Concentration Target	Positivity	On-Panel Low Concentration Target	Positivity
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
	100%	<i>Proteus mirabilis</i>	100%
	100%	<i>Pseudomonas aeruginosa</i>	100%
<i>Escherichia coli</i>	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
	100%	<i>Proteus mirabilis</i>	100%
<i>Haemophilus influenzae</i>	100%	<i>Pseudomonas aeruginosa</i>	100%
	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
<i>Klebsiella oxytoca</i>	100%	<i>Proteus mirabilis</i>	100%
	100%	<i>Pseudomonas aeruginosa</i>	100%
	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
<i>Klebsiella pneumoniae</i>	100%	<i>Neisseria meningitidis</i>	100%
	100%	<i>Proteus mirabilis</i>	100%
	100%	<i>Pseudomonas aeruginosa</i>	100%
	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
<i>Neisseria meningitidis</i>	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Proteus mirabilis</i>	100%
	100%	<i>Pseudomonas aeruginosa</i>	100%
	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
<i>Proteus mirabilis</i>	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Citrobacter freundii</i>	100%

On-Panel High Concentration Target	Positivity	On-Panel Low Concentration Target	Positivity
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
	100%	<i>Pseudomonas aeruginosa</i>	100%
<i>Pseudomonas aeruginosa</i>	100%	<i>Acinetobacter baumannii</i>	100%
	100%	<i>Citrobacter freundii</i>	100%
	100%	<i>Enterobacter cloacae</i>	100%
	100%	<i>Escherichia coli</i>	100%
	100%	<i>Haemophilus influenzae</i>	100%
	100%	<i>Klebsiella oxytoca</i>	100%
	100%	<i>Klebsiella pneumoniae</i>	100%
	100%	<i>Neisseria meningitidis</i>	100%
	100%	<i>Proteus mirabilis</i>	100%

Table 8. Summary Results of Microbial Interference Study

On-Panel Low Concentration Target	Positivity	Off-Panel High Concentration Target	Positivity
<i>Acinetobacter baumannii</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Citrobacter freundii</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Enterobacter cloacae</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Escherichia coli</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Haemophilus influenzae</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%

On-Panel Low Concentration Target	Positivity	Off-Panel High Concentration Target	Positivity
	100%	<i>Streptococcus mitis</i>	0%
<i>Klebsiella oxytoca</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Klebsiella pneumoniae</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Neisseria meningitidis</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Proteus mirabilis</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%
<i>Pseudomonas aeruginosa</i>	100%	<i>Bacillus cereus</i>	0%
	100%	<i>Clostridium perfringens</i>	0%
	100%	<i>Corynebacterium striatum</i>	0%
	100%	<i>Cutibacterium (Propionibacterium) acnes</i>	0%
	100%	<i>Staphylococcus aureus</i>	0%
	100%	<i>Staphylococcus epidermidis</i>	0%
	100%	<i>Streptococcus mitis</i>	0%

Endogenous/Exogenous Interference

An interfering substances study was conducted to assess the performance of the LIAISON PLEX BCN Assay in the presence of potentially interfering substances that may be present in blood culture specimens. A set of four representative on-panel target organisms were tested in the presence of six interfering substances across five replicates. A panel containing negative blood matrix was also tested to assess the risk of false positive results in the presence of potentially interfering substances. No interference was observed (**Table 9**).

Table 9. Summary Results of Interfering Substances Study

Interfering Substance	Concentration	Target	Positivity
Unconjugated Bilirubin	20 mg/dL	<i>Acinetobacter baumannii</i>	100%
		<i>Escherichia coli</i>	100%
		<i>Haemophilus influenzae</i>	100%
		<i>Neisseria meningitidis</i>	100%
		Negative Control	0%

Conjugated Bilirubin	20 mg/dL	<i>Acinetobacter baumannii</i>	100%
		<i>Escherichia coli</i>	100%
		<i>Haemophilus influenzae</i>	100%
		<i>Neisseria meningitidis</i>	100%
		Negative Control	0%
Hemoglobin	14 g/L	<i>Acinetobacter baumannii</i>	100%
		<i>Escherichia coli</i>	100%
		<i>Haemophilus influenzae</i>	100%
		<i>Neisseria meningitidis</i>	100%
		Negative Control	0%
Intralipid	3000 mg/dL	<i>Acinetobacter baumannii</i>	100%
		<i>Escherichia coli</i>	100%
		<i>Haemophilus influenzae</i>	100%
		<i>Neisseria meningitidis</i>	100%
		Negative Control	0%
γ -globulin	6 g/dL	<i>Acinetobacter baumannii</i>	100%
		<i>Escherichia coli</i>	100%
		<i>Haemophilus influenzae</i>	100%
		<i>Neisseria meningitidis</i>	100%
		Negative Control	0%
Sodium polyanetholsulfonate (SPS)	0.25% w/v	<i>Acinetobacter baumannii</i>	100%
		<i>Escherichia coli</i>	100%
		<i>Haemophilus influenzae</i>	100%
		<i>Neisseria meningitidis</i>	100%
		Negative Control	0%

4. Assay Reportable Range:

This study is not applicable as the test device is a qualitative assay.

5. Traceability, Stability and Expected Values (Controls, Calibrators, or Methods):

Quality Controls

Each BCN Assay Cartridge includes internal controls to ensure performance of sample preparation and detection. The internal extraction control is present in the lysis tube when the sample is added. Sample preparation is initiated, and the extraction control assesses extraction, nucleic acid recovery, and detection. A post-extraction hybridization control serves as an indicator of successful hybridization. Internal control results are reported as Pass or Fail on the printed reports. Internal controls must generate a signal above threshold in each internal reaction for the system to report a valid test result. Positive and negative external controls are not provided but are recommended to be tested with each new lot or shipment of reagents, or monthly (whichever occurs first). Negative blood matrix can be used as the negative control. Previously characterized positive samples or verified negative blood matrix spiked with well characterized organisms may be used as the external positive control. External controls should be used in accordance with laboratory protocols and in accordance with local, state, and federal accrediting organizations, as applicable.

Sample Stability

A sample stability study was performed to establish the recommended storage conditions for positive blood cultures prior to testing with the LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay. A representative panel of four on-panel organisms as well as a negative blood matrix control were tested. Fresh samples (ring positive and ring positive + 8

hours) were stored at various conditions, refrigerated (2° to 8°C) and room temperature (15°C to 30°C), and tested over various timepoints. Results of the sample stability study are presented in **Tables 10 and 11** below.

Table 10. Summary Results of Sample Stability (Refrigerated, 2° to 8°C)

Organism/Resistance Marker	Condition	% Positivity At Timepoints			
		T0	T1 (24 hours)	T2 (72 hours)	T3 (7 days)
<i>Haemophilus influenzae</i>	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Acinetobacter baumannii</i> + OXA	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Escherichia coli</i> + MCR	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Neisseria meningitidis</i>	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
Negative Blood Matrix	NA	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)

Table 11. Summary Results of Sample Stability (RT, 15°C to 30°C)

Organism/Resistance Marker	Condition	% Positivity At Timepoints			
		T0	T1 (24 hours)	T2 (72 hours)	T3 (7 days)
<i>Haemophilus influenzae</i>	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Acinetobacter baumannii</i> + OXA	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Escherichia coli</i> + MCR	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Neisseria meningitidis</i>	Ring Positive	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (20/20)	100% (10/10)	100% (10/10)	100% (10/10)
Negative Blood Matrix	NA	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)

Fresh Versus Frozen Study

The performance of the LIAISON PLEX BCN Assay with fresh and frozen samples was evaluated by testing four on-panel organisms (ring positive and ring positive + 8 hours) as

well as a negative blood matrix control under five conditions: Initial testing of fresh samples (T0), 1 freeze-thaw cycle (T1), 2 freeze-thaw cycles (T2), 1 freeze-thaw cycle after 1 month of frozen storage (T3), and 2 freeze-thaw cycles after 1 month of frozen storage (T4). Samples were stored frozen for a minimum of 8 hours in between each freeze-thaw cycle. For the 1-month testing, material was frozen for at least 34 days prior to the first freeze-thaw. All samples demonstrated 100% agreement with the fresh sample (**Table 12**).

Table 12. Summary Results of Fresh Versus Frozen Study

Representative Organisms	Condition	Initial Testing			1-Month Testing	
		Fresh T(0)	1 st Freeze-thaw T(1)	2 nd Freeze-thaw T(2)	1 st Freeze-thaw T(3)	2 nd Freeze-thaw T(4)
<i>Acinetobacter baumannii</i>	Ring Positive	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Escherichia coli</i>	Ring Positive	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Haemophilus influenzae</i>	Ring Positive	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
<i>Neisseria meningitidis</i>	Ring Positive	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
	Ring Positive +8hr	100% (12/12)	100% (10/10)	100% (10/10)	100% (10/10)	100% (10/10)
Negative Blood Matrix	Ring Negative	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)	0% (0/3)

6. Detection Limit:

Growth and Detection Study

A growth and detection study was conducted to establish the range of expected organism concentrations present in incubated blood cultures at bottle positivity (i.e., ring positive) and eight hours after ring positive. Seventeen (17) organisms representing the LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay reportable targets were cultivated to ring positive and eight hours after ring positivity using a continuous monitoring blood culture system. Three unique blood bottles were tested in triplicate to assess ring positive growth and ring positive + eight hours for a total of nine bottles per organism. In addition, CFU/mL quantitation was done for each bottle. One negative blood bottle was also grown for at least five days. Results from the growth and detection study are presented in **Table 13**.

Table 13. Summary Results for Growth and Detection Study

Organism	Assay Targets Reported	At Positivity		8 Hours After Positivity	
		Mean Bottle Concentration (CFU/mL)	Agreement / Total (%) Detected)	Mean Bottle Concentration (CFU/mL)	Agreement / Total (%) Detected)
<i>Acinetobacter baumannii</i> [OXA] IHMA 128307	<i>Acinetobacter baumannii</i> <i>Acinetobacter</i> spp.	2.06E+08	9/9 (100%)	1.63E+08	9/9 (100%)

Organism	Assay Targets Reported	At Positivity		8 Hours After Positivity	
		Mean Bottle Concentration (CFU/mL)	Agreement / Total (%) Detected	Mean Bottle Concentration (CFU/mL)	Agreement / Total (%) Detected
	OXA				
<i>Citrobacter freundii</i> [VIM] IHMA 549813	<i>Citrobacter</i> spp. <i>Enterobacteriaceae</i> / <i>Morganellaceae</i> VIM	1.28E+09	9/9 (100%)	1.87E+09	9/9 (100%)
<i>Enterobacter cloacae</i> ATCC 35030	<i>Enterobacter</i> spp. <i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	1.58E+09	9/9 (100%)	2.04E+09	9/9 (100%)
<i>Escherichia coli</i> [MCR] NCTC 13846	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Escherichia coli</i> MCR	1.87E+09	9/9 (100%)	1.65E+09	9/9 (100%)
<i>Klebsiella oxytoca</i> [CTX-M] IHMA 683079	CTX-M <i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Klebsiella oxytoca</i>	9.69E+08	9/9 (100%)	3.41E+08	9/9 (100%)
<i>Klebsiella pneumoniae</i> [KPC] IHMA 629630	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> KPC <i>Klebsiella pneumoniae</i>	1.56E+09	9/9 (100%)	1.58E+09	9/9 (100%)
<i>Klebsiella variicola</i> ATCC BAA-830	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Klebsiella variicola</i>	1.75E+09	9/9 (100%)	2.06E+09	9/9 (100%)
<i>Salmonella enteritidis</i> ATCC 13076	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Salmonella</i> spp.	2.56E+08	9/9 (100%)	1.85E+09	9/9 (100%)
<i>Serratia marcescens</i> [SME] NCTC 13920	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> SME <i>Serratia marcescens</i>	2.38E+08	9/9 (100%)	1.47E+09	12/12 ¹ (100%)
<i>Morganella morganii</i> [NDM] IHMA 605873	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Morganella morganii</i> NDM	1.68E+09	9/9 (100%)	2.71E+09	9/9 (100%)
<i>Pseudomonas aeruginosa</i> [IMP] IHMA 576602	IMP <i>Pseudomonas aeruginosa</i> <i>Pseudomonas</i> spp.	7.99E+08	9/9 (100%)	1.26E+09	9/9 (100%)
<i>Stenotrophomonas maltophilia</i> ATCC 13636	<i>Stenotrophomonas maltophilia</i>	4.48E+08	9/9 (100%)	1.00E+09	9/9 (100%)
<i>Proteus mirabilis</i> ATCC 12453	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> <i>Proteus</i> spp.	2.26E+09	9/9 (100%)	2.12E+09	9/9 (100%)
<i>Haemophilus influenzae</i> ATCC 9007	<i>Haemophilus influenzae</i>	2.13E+09	9/9 (100%)	1.70E+09	9/9 (100%)
<i>Neisseria meningitidis</i> ATCC 43744	<i>Neisseria meningitidis</i>	1.88E+08	9/9 (100%)	2.87E+08	9/9 (100%)
Organism	Assay Targets Reported	Mean Bottle Concentration (CFU/mL)		Agreement / Total (%) Detected	
Negative Blood	None	0.00E+00		0/3 (0%)	

¹ One OXA false positive was observed in initial testing. An additional set of replicates was tested resulting in 12 total replicates.

Analytical Reactivity

An analytical reactivity study was performed to evaluate the inclusivity of the LIAISON PLEX BCN Assay through testing of multiple strains representing on-panel reportable targets. All on-panel organisms (n = 246) were tested in triplicate. A summary of organism results is listed in **Table 14**. A summary of results for resistance markers is listed in **Table 15**. One hundred percent (100%) positivity was noted for all targets.

Table 14. Summary Results of Inclusivity Study for Target Organisms

Reportable Target (Family)	Reportable Target (Genus)	Reportable Target (Species)	Organism	# Strains	% Detected
N/A	<i>Acinetobacter</i> spp.	N/A	<i>Acinetobacter guillouiae</i>	1	100%
			<i>Acinetobacter radioresistens</i>	2	100%
			<i>Acinetobacter baylyi</i>	1	100%
			<i>Acinetobacter bereziniae</i>	1	100%
			<i>Acinetobacter calcoaceticus</i>	1	100%
			<i>Acinetobacter haemolyticus</i>	1	100%
			<i>Acinetobacter indicus</i>	1	100%
			<i>Acinetobacter johnsonii</i>	1	100%
			<i>Acinetobacter junii</i>	1	100%
			<i>Acinetobacter lwoffii</i>	1	100%
			<i>Acinetobacter nosocomialis</i>	1	100%
			<i>Acinetobacter pittii</i>	1	100%
			<i>Acinetobacter schindleri</i>	1	100%
			<i>Acinetobacter ursingii</i>	1	100%
	<i>Acinetobacter</i> spp.	<i>Acinetobacter baumannii</i>	<i>Acinetobacter baumannii</i>	5	100%
Enterobacteriaceae / Morganellaceae	<i>Citrobacter</i> spp.	N/A	<i>Citrobacter amalonaticus</i>	2	100%
			<i>Citrobacter braakii</i>	2	100%
			<i>Citrobacter farmeri</i>	1	100%
			<i>Citrobacter freundii</i>	4	100%
			<i>Citrobacter gillenii</i>	1	100%
			<i>Citrobacter koseri</i>	5	100%
			<i>Citrobacter murlinae</i>	1	100%
			<i>Citrobacter rodentium</i>	1	100%
			<i>Citrobacter sedlakii</i>	1	100%
			<i>Citrobacter werkmanii</i>	1	100%
			<i>Citrobacter youngae</i>	1	100%
Enterobacteriaceae / Morganellaceae	<i>Enterobacter</i> spp.	N/A	<i>Enterobacter cloacae</i>	10	100%
			<i>Enterobacter aerogenes</i>	5	100%
			<i>Enterobacter amnigenus</i>	1	100%
			<i>Enterobacter asburiae</i>	1	100%
			<i>Enterobacter bugandensis</i>	1	100%
			<i>Enterobacter cancerogenus</i>	1	100%
			<i>Enterobacter hormaechei</i>	2	100%
			<i>Enterobacter ludwigii</i>	1	100%
Enterobacteriaceae / Morganellaceae	N/A	<i>Escherichia coli</i>	<i>Escherichia coli</i>	21	100%
			<i>Shigella boydii</i>	2	100%
			<i>Shigella dysenteriae</i>	2	100%
			<i>Shigella flexneri</i>	2	100%
			<i>Shigella sonnei</i>	2	100%
Enterobacteriaceae / Morganellaceae	N/A	<i>Klebsiella oxytoca</i>	<i>Klebsiella oxytoca</i>	5	100%

Reportable Target (Family)	Reportable Target (Genus)	Reportable Target (Species)	Organism	# Strains	% Detected
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	<i>Klebsiella pneumoniae</i>	<i>Klebsiella pneumoniae</i>	26	100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	<i>Klebsiella variicola</i>	<i>Klebsiella variicola</i>	5	100%
N/A	N/A	<i>Haemophilus influenzae</i>	<i>Haemophilus influenzae</i>	6	100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	<i>Morganella morganii</i>	<i>Morganella morganii</i>	5	100%
N/A	N/A	<i>Neisseria meningitidis</i>	<i>Neisseria meningitidis</i>	10	100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Proteus</i> spp.	N/A	<i>Proteus hauseri</i>	1	100%
			<i>Proteus mirabilis</i>	5	100%
			<i>Proteus myxofaciens</i>	1	100%
			<i>Proteus penneri</i>	1	100%
			<i>Proteus vulgaris</i>	2	100%
N/A	<i>Pseudomonas</i> spp.	N/A	<i>Pseudomonas alcaligenes</i>	1	100%
			<i>Pseudomonas chlororaphis</i>	1	100%
			<i>Pseudomonas fluorescens</i>	1	100%
			<i>Pseudomonas luteola</i>	1	100%
			<i>Pseudomonas mendocina</i>	1	100%
			<i>Pseudomonas monteilii</i>	1	100%
			<i>Pseudomonas mosselii</i>	1	100%
			<i>Pseudomonas mucidolens</i>	1	100%
			<i>Pseudomonas oryzae</i>	1	100%
			<i>Pseudomonas pseudoalcaligenes</i>	1	100%
			<i>Pseudomonas putida</i>	1	100%
			<i>Pseudomonas resinovorans</i>	1	100%
			<i>Pseudomonas stutzeri</i>	1	100%
			<i>Pseudomonas veronii</i>	1	100%
		<i>Pseudomonas aeruginosa</i>	<i>Pseudomonas aeruginosa</i>	4	100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Salmonella</i> spp.	N/A	<i>Salmonella bongori</i>	1	100%
			<i>Salmonella enterica</i>	12	100%
			<i>Salmonella enterica</i> subsp. <i>Arizonae</i>	1	100%
			<i>Salmonella enterica</i> subsp. <i>diarizonae</i>	1	100%
			<i>Salmonella enterica</i> subsp. <i>houstenae</i>	1	100%
			<i>Salmonella enterica</i> subsp. <i>indica</i>	1	100%
N/A	N/A	<i>Stenotrophomonas maltophilia</i>	<i>Stenotrophomonas maltophilia</i>	5	100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	<i>Serratia marcescens</i>	<i>Serratia marcescens</i>	6	100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	N/A	<i>Cedecea davisae</i>	2	100% [^]
			<i>Cedecea lapagei</i>	1	100% [^]
			<i>Cedecea neteri</i>	1	100%
			<i>Cronobacter muytjensii</i>	1	100%
			<i>Cronobacter sakazakii</i>	2	100%
			Enteric group 137	1	100%
			<i>Escherichia albertii</i>	1	100% [^]
			<i>Escherichia fergusonii</i>	1	100%

Reportable Target (Family)	Reportable Target (Genus)	Reportable Target (Species)	Organism	# Strains	% Detected
			<i>Escherichia hermanii</i>	1	100%
			<i>Edwardsiella tarda</i>	1	100%
			<i>Hafnia alvei</i>	1	100%
			<i>Hafnia alvei</i>	1	100%
			<i>Kluyvera ascorbata</i>	1	100%^
			<i>Kluyvera cryocrescens</i>	1	100%
			<i>Kluyvera georgiana</i>	1	100%
			<i>Kluyvera intermedia</i>	1	100%
			<i>Leclercia adecarboxylata</i>	1	100%^
			<i>Lelliottia nimipressuralis</i>	1	100%^
			<i>Pantoea agglomerans</i>	1	100%
			<i>Plesiomonas shigelloides</i>	1	100%
			<i>Pluralibacter gergoviae</i>	1	100%
			<i>Providencia acalifaciens</i>	1	100%
			<i>Providencia heimbachae</i>	1	100%
			<i>Providencia rettigeri</i>	1	100%^
			<i>Providencia stuartii</i>	1	100%^
			<i>Rahnella aquatilis</i>	1	100%
			<i>Raoultella ornithinolytica</i>	1	100%^
			<i>Raoultella planticola</i>	1	100%^
			<i>Raoultella terrigena</i>	1	100%^
			<i>Serratia plymuthica</i>	1	100%
			<i>Serratia grimesii</i>	1	100%^
			<i>Xenorhabdus bovienii</i>	1	100%^
			<i>Xenorhabdus poinarii</i>	1	100%
			<i>Yersinia enterocolitica</i>	1	100%
			<i>Yokenella regensburgei</i>	1	100%
			<i>Serratia ficaria</i>	1	100%^
			<i>Serratia fonticola</i>	1	100%^
			<i>Serratia liquefaciens</i>	1	100%^
			<i>Serratia proteamaculans</i>	1	0%^
			<i>Serratia rubidaea</i>	1	100%^

^ Tested strain gave expected target call and additional cross-reactive target call. See Table 16.

Table 15. Summary Results of Inclusivity Study for Target Resistance Markers

Reportable Target (Resistance Marker)	Organism	# Strains	% Detected
CTX-M	<i>Citrobacter freundii</i>	1	100%
	<i>Enterobacter cloacae</i>	5	100%
	<i>Escherichia coli</i>	14	100%
	<i>Klebsiella oxytoca</i>	2	100%
	<i>Klebsiella pneumoniae</i>	16	100%
	<i>Kluyvera ascorbata</i>	1	100%
	<i>Kluyvera georgiana</i>	1	100%
	<i>Morganella morganii</i>	1	100%
IMP	<i>Salmonella enterica</i>	1	100%
	<i>Escherichia coli</i>	1	100%
	<i>Klebsiella pneumoniae</i>	2	100%
	<i>Proteus mirabilis</i>	1	100%
KPC	<i>Pseudomonas aeruginosa</i>	1	100%
	<i>Citrobacter freundii</i>	2	100%
	<i>Enterobacter cloacae</i>	1	100%
	<i>Enterobacter hormaechei</i>	1	100%
	<i>Klebsiella pneumoniae</i>	3	100%

	<i>Morganella morganii</i>	1	100%
MCR	<i>Enterobacter cloacae</i>	2	100%
	<i>Escherichia coli</i>	5	100%
	<i>Klebsiella pneumoniae</i>	4	100%
	<i>Salmonella enterica</i>	2	100%
NDM	<i>Enterobacter cloacae</i>	1	100%
	<i>Escherichia coli</i>	4	100%
	<i>Klebsiella pneumoniae</i>	1	100%
	<i>Morganella morganii</i>	1	100%
OXA	<i>Acinetobacter baumannii</i>	5	100%
	<i>Acinetobacter radioresistens</i>	2	100%
	<i>Acinetobacter indicus</i>	1	100%
	<i>Escherichia coli</i>	2	100%
	<i>Klebsiella pneumoniae</i>	5	100%
SME	<i>Serratia marcescens</i>	6	100%
VIM	<i>Enterobacter cloacae</i>	1	100%
	<i>Klebsiella pneumoniae</i>	2	100%
	<i>Pseudomonas aeruginosa</i>	3	100%

Of the 246 on-panel organisms tested, 17 organisms generated additional target calls that align with known cross-reactivity based on *in silico* analysis, or design features. Additionally, one on-panel organism (*S. proteamaculans*) only generated the known cross-reactivity target call, not the expected target call. The 18 cross-reactive organisms are highlighted in **Table 16** and the observed cross-reactivity is noted in the device labeling.

Table 16. List of Tested Strains Demonstrating Cross-Reactivity

Cross-Reactive Organism	Expected Target	Additional Target Detected	# Detected
<i>Cedecea davisae</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella oxytoca</i>	1/3
<i>Cedecea lapagei</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella oxytoca</i>	1/3
<i>Escherichia albertii</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Escherichia coli</i>	2/3
<i>Kluyvera ascorbata</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i> CTX- M	<i>Klebsiella oxytoca</i>	3/3
<i>Leclercia adecarboxylata</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Enterobacter</i> spp.	3/3
<i>Lelliottia nimipressuralis</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Enterobacter</i> spp.	3/3
<i>Providencia rettigeri</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Proteus</i> spp.	1/3
<i>Providencia stuartii</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Proteus</i> spp.	1/3
<i>Raoultella ornithinolytica</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella oxytoca</i>	3/3
<i>Raoultella planticola</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Klebsiella oxytoca</i>	3/3
<i>Raoultella terrigena</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Citrobacter</i> spp.	3/3
<i>Serratia ficaria</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>	3/3
<i>Serratia fonticola</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>	3/3
<i>Serratia grimesii</i>	<i>Enterobacteriaceae</i> /	<i>Proteus</i> spp.	2/3

	<i>Morganellaceae</i>		
<i>Serratia liquefaciens</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>	3/3
<i>Serratia proteamaculans</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>	3/3
<i>Serratia rubidaea</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Serratia marcescens</i>	3/3
<i>Xenorhabdus bovienii</i>	<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	<i>Proteus</i> spp.	2/3

Comparison Studies:

1. Method Comparison with Predicate Device:

Please refer to Section VI.C (Clinical Studies) below for the clinical validation.

2. Matrix Comparison:

A matrix equivalency study was conducted to evaluate equivalence of 12 different blood culture bottle matrices from three different blood culture systems on the LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay. BacT/ALERT FA Plus blood culture bottles were not tested as performance was established in other analytical and clinical studies. **Table 17** lists the tested organisms. A minimum of two lots per media bottle type were used. For on-panel targets, at least 20 independent bottle growths per bottle type were cultured. Study results are presented in **Table 18**. All on-panel targets tested gave expected results in all bottle types, 100% detection. For off-panel targets, one replicate of *S. bongori* in VersaTREK REDOX 2 EZ Draw Media generated a false positive for the resistance marker OXA. Negative blood culture matrix gave expected results, 0% positivity.

Table 17. List of Tested Organisms and Mean Concentrations

Gram-Negative (On- panel) Organism	Strain ID	Mean Concentration (CFU/mL)
<i>Acinetobacter baumannii</i>	IHMA 128307	3.03E+08
<i>Acinetobacter lwoffii</i>	ATCC 15309	2.05E+08
<i>Citrobacter freundii</i>	IHMA 549813	1.03E+09
<i>Citrobacter amalonaticus</i>	ATCC 25405	9.87E+09
<i>Enterobacter cloacae</i>	ATCC 35030	1.16E+09
<i>Enterobacter aerogenes</i>	ATCC 35029	9.50E+09
<i>Proteus mirabilis</i>	ATCC 12453	6.64E+08
<i>Proteus vulgaris</i>	ATCC 29905	4.54E+08
<i>Salmonella bongori</i>	ATCC 43975	1.42E+09
<i>Salmonella enterica</i> subsp. <i>arizonae</i>	ATCC 13314	1.67E+09
<i>Pseudomonas aeruginosa</i>	IHMA 576602	4.88E+08
<i>Pseudomonas mendocina</i>	ATCC 25411	5.24E+08
<i>Klebsiella oxytoca</i>	IHMA 683079	7.29E+08
<i>Klebsiella pneumoniae</i>	IHMA 629630	6.61E+08
<i>Klebsiella variicola</i>	Clinical Isolate V0512	1.28E+09
<i>Escherichia coli</i>	NCTC 13846	1.17E+09
<i>Serratia marcescens</i>	IHMA 1642209	1.34E+09
<i>Morganella morganii</i>	IHMA 605873	1.28E+09
<i>Haemophilus influenzae</i>	ATCC 9007	6.70E+08
<i>Neisseria meningitidis</i>	ATCC 43744	3.07E+08
<i>Stenotrophomonas maltophilia</i>	ATCC 700269	4.18E+08
Gram-Positive (Off- panel) Organism	Strain	Mean Concentration (CFU/mL)
<i>Enterococcus faecalis</i>	ATCC 51575	7.51E+08
<i>Enterococcus faecium</i>	ATCC 700221	4.12E+08

Gram-Negative (On- panel) Organism	Strain ID	Mean Concentration (CFU/mL)
<i>Staphylococcus aureus</i> (MRSA)	ATCC BAA-2312	2.07E+08
<i>Staphylococcus epidermidis</i> (MRSE)	ATCC 35984	2.26E+08
<i>Streptococcus agalactiae</i>	ATCC 12386	7.50E+08
<i>Streptococcus constellatus</i>	ATCC 27823	5.25E+08
<i>Bacillus subtilis</i>	ATCC 19659	8.50E+07
<i>Bacillus cereus</i> ^a	ATCC 10702	4.40E+08
<i>Corynebacterium diphtheriae</i>	ATCC 27010	3.74E+08
<i>Corynebacterium striatum</i>	ATCC 43735	3.48E+08
<i>Listeria monocytogenes</i>	ATCC 15313	7.58E+08

^a Concentration of *Bacillus cereus* representing single blood bottle culture in VersaTREK REDOX2 EZ Draw Media.

Table 18. Performance Summary of Blood Culture Bottles

Blood Culture Bottle Manufacturer	Blood Culture Bottle Type	Number of Inoculated Bottles		Negative Blood Matrix (Negative Detection)
		Gram-Negative Bacteria (Positive Detection)	Gram-positive Bacteria (Negative Detection)	
bioMérieux BACT/ALERT 3D or VIRTUO	BacT/ALERT SA Standard Aerobic	21/21	10/10	2/2
	BacT/ALERT SN Standard Anaerobic	58/58	10/10	2/2
	BACT/ALERT FN Plus (Anaerobic)	21/21	10/10	2/2
	BACT/ALERT PF Plus (Pediatric)	63/63	10/10	2/2
Becton Dickinson BACTEC^a	BD BACTEC Standard Aerobic	21/21	10/10	2/2
	BD BACTEC Plus Aerobic	21/21	10/10	2/2
	BD BACTEC Standard Anaerobic	50/50	10/10	2/2
	BD BACTEC Plus Anaerobic	58/58	10/10	2/2
	BACTEC Peds Plus (Pediatric)	63/63	10/10	2/2
	BD BACTEC Lytic Anaerobic	20/20	10/10	2/2
Thermo Scientific VersaTREK^{a,b}	REDOX 1 EZ Draw (Aerobic)	60/60	10/10	2/2
	REDOX 2 EZ Draw (Anaerobic)	50/50	10/10	2/2
TOTAL		506/506 (100%)	120/120 (100%)	24/24 (100%)
		650/650 (100%)		

^a For gram-negative blood culture preparation, BACTEC and VersaTREK systems were not available and corresponding media bottles were placed in a standard laboratory incubator with a shaker for growth. For gram-positive blood culture growth, VersaTREK bottles were placed in a standard laboratory incubator with a shaker; BACT/ALERT and BACTEC blood bottles were grown using corresponding automated blood culture systems up to bottle ring positivity.

^b Negative Blood Matrix (NBM) was tested using two independent blood inoculations per bottle type and each NBM sample was tested in replicates of three (total six replicates per bottle type) per study design; 72 total runs from 24 total bottle inoculations.

Clinical Studies:

1. Prospective Clinical Study:

Clinical performance of the LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay to detect and identify target gram-negative bacterial pathogens from blood samples identified as 1) positive by a continuous monitoring blood culture system, and 2) gram-negative organisms by Gram stain, was assessed in a multi-site study using prospective samples from four geographically diverse clinical sites within the U.S. (Arm 1). The clinical study utilized

remnant, de-identified blood culture specimens. Samples were stored either refrigerated (2-8°C) if tested within 24 hours, or frozen ($\leq -70^{\circ}\text{C}$) if not tested within 24 hours of collection. A total of 1762 clinical specimens were prospectively collected between March 2024 and June 2024. Of these, 381 prospective specimens that met inclusion criteria, i.e., positive by a continuous monitoring blood culture system and removed within 12 hours of positive identification and exhibiting gram-negative morphology following Gram stain, were enrolled in the study. A total of 30 prospective specimens were excluded from the analysis (one duplicate patient enrollment, and 29 with incomplete reference testing results due to mixed growth, insufficient growth, or no growth). Patient demographic information for the 351 prospective samples included in the performance analysis is presented in **Table 19**.

Table 19. Demographic Data for Prospectively Collected Specimens

Gender	Site 01	Site 02	Site 03	Site 04	All Sites
Male	81 (54.4%)	50 (49.0%)	28 (48.3%)	22 (52.4%)	181 (51.6%)
Female	68 (45.6%)	52 (51.0%)	30 (51.7%)	20 (47.6%)	170 (48.4%)
Total	149 (100.0%)	102 (100.0%)	58 (100.0%)	42 (100.0%)	351 (100.0%)
Age (years)					
0-1	3 (2.0%)	3 (2.9%)	0 (0.0%)	4 (9.5%)	10 (2.8%)
>1-5	0 (0.0%)	2 (2.0%)	1 (1.7%)	0 (0.0%)	3 (0.9%)
>5-21	1 (0.7%)	4 (3.9%)	5 (8.6%)	0 (0.0%)	10 (2.8%)
>21-65	64 (43.0%)	46 (45.1%)	18 (31.0%)	14 (33.3%)	142 (40.5%)
>65	81 (54.4%)	42 (41.2%)	34 (58.6%)	24 (57.1%)	181 (51.6%)
Age Unknown	0 (0.0%)	5 (4.9%)	0 (0.0%)	0 (0.0%)	5 (1.4%)
Total	149 (100.0%)	102 (100.0%)	58 (100.0%)	42 (100.0%)	351 (100.0%)
Subject Status					
Emergency Room	0 (0.0%)	25 (24.5%)	43 (74.1%)	0 (0.0%)	68 (19.4%)
Hospitalized	134 (89.9%)	73 (71.6%)	15 (25.9%)	40 (95.2%)	262 (74.6%)
Long-Term Care	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.8%)	2 (0.6%)
Outpatient	0 (0.0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	1 (0.3%)
Status Unknown	15 (10.1%)	3 (2.9%)	0 (0.0%)	0 (0.0%)	18 (5.1%)
Total	149 (100.0%)	102 (100.0%)	58 (100.0%)	42 (100.0%)	351 (100.0%)
Blood Culture Bottle type					
BacT/ALERT FA Plus	72 (48.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	72 (20.5%)
BacT/ALERT FN Plus	77 (51.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	77 (21.9%)
BacT/ALERT PF Plus	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (7.1%)	3 (0.9%)
BacT/ALERT SA Standard Aerobic	0 (0.0%)	0 (0.0%)	0 (0.0%)	22 (52.4%)	22 (6.3%)
BacT/ALERT SN Standard Anaerobic	0 (0.0%)	0 (0.0%)	0 (0.0%)	16 (38.1%)	16 (4.6%)
BD BACTEC Lytic Anaerobic	0 (0.0%)	50 (49.0%)	15 (25.9%)	0 (0.0%)	65 (18.5%)
BD BACTEC Peds Plus	0 (0.0%)	5 (4.9%)	5 (8.6%)	0 (0.0%)	10 (2.8%)
BD BACTEC Plus Aerobic	0 (0.0%)	47 (46.1%)	14 (24.1%)	0 (0.0%)	61 (17.4%)
BD BACTEC Plus Anaerobic	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	1 (0.3%)
BD BACTEC Standard Aerobic	0 (0.0%)	0 (0.0%)	18 (31.0%)	1 (2.4%)	19 (5.4%)
BD BACTEC Standard Anaerobic	0 (0.0%)	0 (0.0%)	5 (8.6%)	0 (0.0%)	5 (1.4%)
Bottle Type Total	149 (100.0%)	102 (100.0%)	58 (100.0%)	42 (100.0%)	351 (100.0%)

Results of the LIAISON PLEX BCN Assay were compared to culture followed by automated microbiological/biochemical identification using VITEK 2, PCR followed by bidirectional sequencing (BDS), or both. The reference method algorithm is elaborated in the table below.

Table 20. Comparator Methods for the LIAISON PLEX BCN Assay Clinical Evaluation

LIAISON PLEX BCN Assay Target	Comparator Method
<i>Acinetobacter</i> spp.	Culture followed by Automated microbiological/biochemical identification using VITEK 2
<i>Citrobacter</i> spp.	
<i>Enterobacter</i> spp.	
<i>Enterobacteriaceae/Morganellaceae</i>	
<i>Escherichia coli</i>	
<i>Haemophilus influenzae</i>	
<i>Morganella morganii</i>	
<i>Neisseria meningitidis</i>	
<i>Proteus</i> spp.	
<i>Pseudomonas aeruginosa</i>	
<i>Pseudomonas</i> spp.	
<i>Salmonella</i> spp.	
<i>Serratia marcescens</i>	
<i>Stenotrophomonas maltophilia</i>	
<i>Acinetobacter baumannii</i>	Culture followed by Automated microbiological/biochemical identification using VITEK 2 with positive confirmation of the clinical isolate by PCR/BDS
<i>Klebsiella oxytoca</i>	
<i>Klebsiella pneumoniae</i>	
<i>Klebsiella variicola</i>	PCR followed by bi-directional sequencing
CTX-M (<i>bla</i> CTX-M)	
IMP (<i>bla</i> IMP)	
KPC (<i>bla</i> KPC)	
NDM (<i>bla</i> NDM)	
OXA (<i>bla</i> OXA)	
VIM (<i>bla</i> VIM)	
MCR	
SME	

Positive percent agreement (PPA) was calculated by dividing the number of true positive (TP) results by the sum of TP and false negative (FN) results, while negative percent agreement (NPA) was calculated by dividing the number of true negative (TN) results by the sum of TN and false positive (FP) results. The two-sided 95% confidence interval was also calculated. **Table 21** provides a summary of LIAISON PLEX BCN Assay prospective clinical study performance. Discordant results analysis was performed by PCR/BDS or an FDA-cleared molecular assay testing and reported as footnotes in the clinical performance tables. There were 21 specimens (6.0%) with an invalid result on the initial run, with 20 (5.7%) of those specimens generating valid BCN results upon retesting for a final success rate of 99.7% (350/351). The LIAISON PLEX BCN Assay reported multiple organism detections in two (2) prospective specimens representing 0.6% (2/351) of all prospective specimens. Both co-infections contained two organisms. Of those, 50% (1/2) were concordant with the reference method and 50% (1/2) contained one organism that was not detected by the reference method.

Table 21. Prospective Clinical Performance of the LIAISON PLEX BCN Assay

Target	Positive Percent Agreement				Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Organisms							
<i>Acinetobacter baumannii</i>	Fresh	0/0	0%	0%-0%	271/271	100%	98.6%-100%
	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	0/0	0%	0%-0%	350/350	100%	98.9%-100%
<i>Acinetobacter</i> spp.	Fresh	2/4	50%	15%-85%	267/267	100%	98.6%-100%
	Frozen	1/1	100%	20.7%-100%	78/78	100%	95.3%-100%
	Combined	3/5¹	60%	23.1%-88.2%	345/345	100%	98.9%-100%
<i>Citrobacter</i> spp.	Fresh	5/5	100%	56.6%-100%	266/266	100%	98.6%-100%
	Frozen	1/1	100%	20.7%-100%	78/78	100%	95.3%-100%
	Combined	6/6	100%	61%-100%	344/344	100%	98.9%-100%
<i>Enterobacter</i> spp.	Fresh	13/13	100%	77.2%-100%	258/258	100%	98.5%-100%
	Frozen	7/7	100%	64.6%-100%	72/72	100%	94.9%-100%
	Combined	20/20	100%	83.9%-100%	330/330	100%	98.8%-100%
<i>Enterobacteriaceae/</i> <i>Morganellaceae</i>	Fresh	237/237	100%	98.4%-100%	34/34	100%	89.8%-100%
	Frozen	68/69	98.6%	92.2%-99.7%	10/10	100%	72.2%-100%
	Combined	305/306	99.7%	98.2%-99.9%	44/44	100%	92%-100%
<i>Escherichia coli</i>	Fresh	144/145	99.3%	96.2%-99.9%	124/126	98.4%	94.4%-99.6%
	Frozen	34/34	100%	89.8%-100%	45/45	100%	92.1%-100%
	Combined	178/179	99.4%	96.9%-99.9%	169/171²	98.8%	95.8%-99.7%
<i>Haemophilus influenzae</i>	Fresh	6/6	100%	61%-100%	265/265	100%	98.6%-100%
	Frozen	2/2	100%	34.2%-100%	77/77	100%	95.2%-100%
	Combined	8/8	100%	67.6%-100%	342/342	100%	98.9%-100%
<i>Klebsiella oxytoca</i>	Fresh	5/5	100%	56.6%-100%	266/266	100%	98.6%-100%
	Frozen	4/4	100%	51%-100%	74/75	98.7%	92.8%-99.8%
	Combined	9/9	100%	70.1%-100%	340/341³	99.7%	98.4%-99.9%
<i>Klebsiella pneumoniae</i>	Fresh	29/30	96.7%	83.3%-99.4%	240/241	99.6%	97.7%-99.9%
	Frozen	15/15	100%	79.6%-100%	64/64	100%	94.3%-100%
	Combined	44/45	97.8%	88.4%-99.6%	304/305⁴	99.7%	98.2%-99.9%
<i>Klebsiella variicola</i>	Fresh	8/8	100%	67.6%-100%	262/262	100%	98.6%-100%
	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	8/8	100%	67.6%-100%	341/341	100%	98.9%-100%
<i>Morganella morganii</i>	Fresh	3/3	100%	43.9%-100%	268/268	100%	98.6%-100%
	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	3/3	100%	43.9%-100%	347/347	100%	98.9%-100%
<i>Neisseria meningitidis</i>	Fresh	0/0	0%	0%-0%	271/271	100%	98.6%-100%
	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	0/0	0%	0%-0%	350/350	100%	98.9%-100%
<i>Proteus</i> spp.	Fresh	16/16	100%	80.6%-100%	255/255	100%	98.5%-100%
	Frozen	7/7	100%	64.6%-100%	72/72	100%	94.9%-100%
	Combined	23/23	100%	85.7%-100%	327/327	100%	98.8%-100%
<i>Pseudomonas aeruginosa</i>	Fresh	21/22	95.5%	78.2%-99.2%	249/249	100%	98.5%-100%
	Frozen	7/7	100%	64.6%-100%	72/72	100%	94.9%-100%
	Combined	28/29	96.6%	82.8%-99.4%	321/321	100%	98.8%-100%
<i>Pseudomonas</i> spp.	Fresh	22/23	95.7%	79%-99.2%	248/248	100%	98.5%-100%
	Frozen	7/7	100%	64.6%-100%	72/72	100%	94.9%-100%
	Combined	29/30	96.7%	83.3%-99.4%	320/320	100%	98.8%-100%
<i>Salmonella</i>	Fresh	1/1	100%	20.7%-100%	270/270	100%	98.6%-100%

Target	Positive Percent Agreement				Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
spp.	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	1/1	100%	20.7%-100%	349/349	100%	98.9%-100%
<i>Serratia marcescens</i>	Fresh	9/9	100%	70.1%-100%	261/262	99.6%	97.9%-99.9%
	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	9/9	100%	70.1%-100%	340/341	99.7%	98.4%-99.9%
<i>Stenotrophomonas maltophilia</i>	Fresh	1/1	100%	20.7%-100%	270/270	100%	98.6%-100%
	Frozen	0/0	0%	0%-0%	79/79	100%	95.4%-100%
	Combined	1/1	100%	20.7%-100%	349/349	100%	98.9%-100%
Resistance Marker Genes⁵							
CTX-M (<i>bla</i> CTX-M)	Fresh	33/34	97.1%	85.1%-99.5%	225/227	99.1%	96.8%-99.8%
	Frozen	7/7	100%	64.6%-100%	70/70	100%	94.8%-100%
	Combined	40/41	97.6%	87.4%-99.6%	295/297	99.3%	97.6%-99.8%
IMP (<i>bla</i> IMP)	Fresh	0/0	0%	0%-0%	261/261	100%	98.5%-100%
	Frozen	0/0	0%	0%-0%	77/77	100%	95.2%-100%
	Combined	0/0	0%	0%-0%	338/338	100%	98.9%-100%
KPC (<i>bla</i> KPC)	Fresh	1/1	100%	20.7%-100%	259/259	100%	98.5%-100%
	Frozen	0/0	0%	0%-0%	77/77	100%	95.2%-100%
	Combined	1/1	100%	20.7%-100%	336/336	100%	98.9%-100%
NDM (<i>bla</i> NDM)	Fresh	0/0	0%	0%-0%	261/261	100%	98.5%-100%
	Frozen	0/0	0%	0%-0%	77/77	100%	95.2%-100%
	Combined	0/0	0%	0%-0%	338/338	100%	98.9%-100%
OXA (<i>bla</i> OXA)	Fresh	0/0	0%	0%-0%	256/260	98.5%	96.1%-99.4%
	Frozen	0/0	0%	0%-0%	76/77	98.7%	93%-99.8%
	Combined	0/0	0%	0%-0%	332/337	98.5%	96.6%-99.4%
VIM (<i>bla</i> VIM)	Fresh	0/0	0%	0%-0%	261/261	100%	98.5%-100%
	Frozen	0/0	0%	0%-0%	77/77	100%	95.2%-100%
	Combined	0/0	0%	0%-0%	338/338	100%	98.9%-100%
MCR	Fresh	0/0	0%	0%-0%	258/258	100%	98.5%-100%
	Frozen	0/0	0%	0%-0%	76/76	100%	95.2%-100%
	Combined	0/0	0%	0%-0%	334/334	100%	98.9%-100%
SME	Fresh	0/0	0%	0%-0%	10/10	100%	72.2%-100%
	Frozen	0/0	0%	0%-0%	0/0	0%	0%-0%
	Combined	0/0	0%	0%-0%	10/10	100%	72.2%-100%

¹The clinical isolate from one of the two *Acinetobacter* spp. FN specimens was negative for *Acinetobacter* spp. by BDS.

²The clinical isolate from one of the two *Escherichia coli* FP specimens was positive for *Escherichia coli* by BDS.

³The *Klebsiella oxytoca* FP specimen was positive for *Klebsiella oxytoca* by Standard of Care.

⁴The *Klebsiella pneumoniae* FP specimen was positive for *Klebsiella pneumoniae* by Standard of Care.

⁵The LIAISON PLEX BCN assay will report the presence or absence of resistance markers only if an applicable organism is also detected, therefore the total number of evaluable samples for each resistance marker is dependent on the number of applicable organisms enrolled.

2. Retrospective Sample Evaluation:

For targets that exhibited low prevalence rates or were not encountered in the prospective study, the prospective specimen set was supplemented with 231 pre-selected (Arm 2) and 746 contrived specimens (Arm 3), yielding a total of 1328 specimens enrolled in the entire study. Pre-selected (archived, frozen) specimens were collected from September 2019 to May 2024, while testing occurred during May 2024 to August 2024. A summary of the demographic information available for retrospective samples is presented in **Table 22**.

Table 22. Demographic Data for Retrospective Samples

Gender	# Specimens (%)
Male	136 (58.9%)
Female	91 (39.4%)
Gender Unknown	4 (1.7%)
Total	231 (100.0%)
Age (years)	
0-1	13 (5.6%)
>1-5	2 (0.9%)
>5-21	4 (1.7%)
>21-65	90 (39.0%)
>65	107 (46.3%)
Age Unknown	15 (6.5%)
Total	231 (100.0%)
Subject Status	
Emergency Room	2 (0.9%)
Hospitalized	18 (7.8%)
Long-Term Care	0 (0.0%)
Status Unknown	211 (91.3%)
Total	231 (100.0%)
Blood Culture Bottle Type	
BD BACTEC Lytic Anaerobic	8 (3.5%)
BD BACTEC Peds Plus	1 (0.4%)
BD BACTEC Plus Aerobic	20 (8.7%)
BD BACTEC Standard Aerobic	89 (38.5%)
BD BACTEC (Unknown Aerobic)	5 (2.2%)
BD BACTEC (Unknown Anaerobic)	3 (1.3%)
BD BACTEC (Unknown)	15 (6.5%)
BacT/ALERT FA Plus	29 (12.6%)
BacT/ALERT FN Plus	26 (11.3%)
Unknown Aerobic	4 (1.7%)
Unknown Anaerobic	1 (0.4%)
Bottle Type Unknown	30 (13.0%)
Total	231 (100.0%)

The pre-selected specimens included remnant, de-identified specimens sourced from seven (7) different sites/vendors in the U.S. and one site in Italy. The pre-selected specimens were identified by Standard of Care (SoC) testing and confirmed as positive by VITEK 2 and/or PCR/BDS according to the reference method algorithm prior to enrollment in the study. Clinical runs and re-runs using the LIAISON PLEX BCN Assay were tested on the LIAISON PLEX System by trained operators at four external and one internal site. Pre-selected specimens were blinded, randomized, and tested along with unique negative clinical specimens to minimize bias. Five (5) specimens (2.2%) yielded an invalid result on the initial run, with four (1.7%) of those specimens generating valid BCN results upon retesting for a final success rate of 99.6% (230/231). Performance is summarized in **Table 23**.

Table 23. Retrospective Clinical Performance of the LIAISON PLEX BCN Assay

Target	Positive Percent Agreement			Negative Percent Agreement		
	TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Organisms						
<i>Acinetobacter baumannii</i>	30/31	96.8%	83.8%-99.4%	199/199	100%	98.1%-100%

Target	Positive Percent Agreement			Negative Percent Agreement		
	TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
<i>Acinetobacter</i> spp.	33/35	94.3%	81.4%-98.4%	195/195	100%	98.1%-100%
<i>Citrobacter</i> spp.	23/24	95.8%	79.8%-99.3%	206/206	100%	98.2%-100%
<i>Enterobacter</i> spp.	9/10	90%	59.6%-98.2%	220/220	100%	98.3%-100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	123/123	100%	97%-100%	106/107	99.1%	94.9%-99.8%
<i>Escherichia coli</i>	1/1	100%	20.7%-100%	229/229	100%	98.4%-100%
<i>Haemophilus influenzae</i>	24/24	100%	86.2%-100%	206/206	100%	98.2%-100%
<i>Klebsiella oxytoca</i>	26/27	96.3%	81.7%-99.3%	203/203	100%	98.1%-100%
<i>Klebsiella pneumoniae</i>	1/1	100%	20.7%-100%	227/229	99.1%	96.9%-99.8%
<i>Klebsiella variicola</i>	4/4	100%	51%-100%	197/197	100%	98.1%-100%
<i>Morganella morganii</i>	5/5	100%	56.6%-100%	225/225	100%	98.3%-100%
<i>Neisseria meningitidis</i>	1/3	33.3%	6.1%-79.2%	227/227	100%	98.3%-100%
<i>Proteus</i> spp.	14/14	100%	78.5%-100%	216/216	100%	98.3%-100%
<i>Pseudomonas aeruginosa</i>	6/6	100%	61%-100%	224/224	100%	98.3%-100%
<i>Pseudomonas</i> spp.	7/7	100%	64.6%-100%	223/223	100%	98.3%-100%
<i>Salmonella</i> spp.	16/16	100%	80.6%-100%	214/214	100%	98.2%-100%
<i>Serratia marcescens</i>	20/20	100%	83.9%-100%	209/210	99.5%	97.4%-99.9%
<i>Stenotrophomonas maltophilia</i>	10/10	100%	72.2%-100%	219/220	99.5%	97.5%-99.9%
Resistance Marker Genes						
CTX-M (<i>bla</i> CTX-M)	5/5	100%	56.6%-100%	169/169	100%	97.8%-100%
IMP (<i>bla</i> IMP)	0/0	0%	0%-0%	174/174	100%	97.8%-100%
KPC (<i>bla</i> KPC)	0/0	0%	0%-0%	164/164	100%	97.7%-100%
NDM (<i>bla</i> NDM)	1/1	100%	20.7%-100%	173/173	100%	97.8%-100%
OXA (<i>bla</i> OXA)	26/26	100%	87.1%-100%	137/138	99.3%	96%-99.9%
VIM (<i>bla</i> VIM)	0/0	0%	0%-0%	174/174	100%	97.8%-100%
MCR	0/0	0%	0%-0%	131/131	100%	97.2%-100%
SME	0/0	0%	0%-0%	21/21	100%	84.5%-100%

3. Contrived Sample Evaluation:

Clinical evaluation was supplemented with contrived specimens for low prevalence gram-negative bacterial targets, prepared by inoculating cultured pathogens into blood bottles containing sterile blood and placed on a continuous monitoring system until identified as positive. A minimum of 50 contrived specimens were prepared for each target that did not reach 30 positive specimens in the combined prospective and pre-selected arms of the study. Samples were collected within eight hours of ring positivity and stored frozen until testing. A total of 746 contrived specimens including 91 negatives were tested in a randomized, blinded manner at five clinical sites. A summary of contrived specimens is provided in **Table 24**.

Table 24. List of Contrived Specimens Tested

Organism	Resistance Marker(s)	Strain	# Specimens Tested
<i>Acinetobacter baumannii</i>	CTX-M-15 OXA-68	NR-52181	5
	IMP-16 OXA-120	NR-52206	5
	OXA-94 NDM-1	NR-52200	5
	OXA-24 OXA-40	IHMA 132584	10
<i>Acinetobacter baumannii</i> Total			25
<i>Acinetobacter indicus</i>	OXA-164 (Grp. 58)	ATCC 17976	10

Organism	Resistance Marker(s)	Strain	# Specimens Tested
<i>Acinetobacter lwoffii</i>	N/A	ATCC 15309	10
<i>Acinetobacter</i> spp. Total			20
<i>Citrobacter freundii</i>	CTX-M NDM-1 OXA-9	AR-0157	5
	CTX-M-9	IHMA 484282	5
	KPC-3	IHMA 569351	5
	VIM-1	IHMA 549813	17
<i>Citrobacter</i> spp. Total			32
<i>Enterobacter cloacae</i> complex	CTX-M-12A - Grp. 1	IHMA 600078	5
	IMP-8	AR-0502	5
	KPC	ATCC BAA- 2082	3
	KPC	IHMA 550287	3
	MCR	IHMA 952508	18
	NDM-1 CTX-M Grp. 1	IHMA 449297	5
	OXA-1	AR-0838	5
	VIM-1	IHMA 584208	10
<i>Enterobacter</i> spp. Total			54
<i>Escherichia coli</i>	IMP-1 CTX-M Grp.1	IHMA 449334	10
	KPC-4	AR-0104	6
	MCR	IHMA 1256822	10
	OXA 48 CTX-M-117 Grp. 1	NRZ-00176	10
	NDM-4 CTX-M-61	IHMA 581817	5
<i>Escherichia coli</i> Total			41
<i>Klebsiella oxytoca</i>	CTX-M-31 (Grp. 2)	IHMA 583882	4
	CTX-M-34 (Grp. 1)	IHMA 549508	6
	IMP-4	AR-0837	5
	KPC-3	AR-0147	5
<i>Klebsiella oxytoca</i> Total			20
<i>Klebsiella pneumoniae</i>	IMP-26 CTX-M-15 (Grp. 1)	IHMA 600486	9
	KPC-11	IHMA 520285	5
	MCR	IHMA 974642	10
	NDM CTX- M-117 Grp.1	ATCC BAA- 2146	5
	NDM-1 CTX-M-15	AR-0505	5
	VIM-27	IHMA 468881	12
<i>Klebsiella pneumoniae</i> Total			46
<i>Klebsiella variicola</i>	NA	Clinical Isolate V0348	10
	NA	Clinical Isolate V0512	10
	NA	Clinical Isolate V0527	10
	NA	Clinical Isolate V0780	10
	NA	Clinical Isolate V0808	10
<i>Klebsiella variicola</i> Total			50
<i>Morganella morganii</i>	CTX-M-15 NDM-1 OXA-1	AR-0057	12
	KPC-2	AR-0133	20
	NA	ATCC 25829	10
	NA	ATCC 25830	10
	NA	OSU CS-273	10
<i>Morganella morganii</i> Total			62
<i>Neisseria meningitidis</i>	NA	ATCC 13077	8
	NA	ATCC 13090	11
	NA	ATCC 13113	9
	NA	ATCC 35561	10
	NA	ATCC 6250	1
	NA	NCTC 10790	11

Organism	Resistance Marker(s)	Strain	# Specimens Tested
<i>Neisseria meningitidis</i> Total			50
<i>Proteus mirabilis</i>	IMP-27	Creighton PM CB1	10
	KPC-6	AR-0155	5
	KPC-2 OXA-10	AR-0156	5
	NDM-1	AR-0159	10
<i>Proteus</i> spp. Total			30
<i>Pseudomonas aeruginosa</i>	IMP-7	Creighton PS315	10
	KPC-5	AR-0231	5
	NA	AR-0238	5
	NDM-1	AR-0246	5
	VIM-2	IHMA 589519	11
<i>Pseudomonas aeruginosa</i> Total			36
<i>Pseudomonas putida</i>	NA	ATCC 12633	22
<i>Pseudomonas</i> spp. Total			22
<i>Salmonella enterica</i> subsp. <i>enterica</i> serotype <i>Braenderup</i>	NA	ATCC 700136	8
<i>Salmonella enterica</i> subsp. <i>salamae</i>	NA	ATCC 700148	8
<i>Salmonella enterica</i> subsp. <i>Enterica</i> serotype <i>Typhimurium</i>	NA	AR-0635	12
<i>Salmonella enterica</i> subsp. <i>enterica</i> serotype <i>Typhimurium</i>	OXA-48	NCTC 13954	5
<i>Salmonella enterica</i> subsp. <i>enterica</i> serotype <i>Infantis</i>	CTX-M-65	AR-0919	5
<i>Salmonella enterica</i> subsp. <i>enterica</i>	NA	ATCC 10721	10
<i>Salmonella enterica</i> subsp. <i>enterica</i> serotype <i>Enteritidis</i>	MCR-1	AR-0496	12
<i>Salmonella enterica</i> subsp. <i>enterica</i> serotype <i>Senftenberg</i>	NDM	AR-0127	10
<i>Salmonella</i> spp. Total			70
<i>Serratia marcescens</i>	CTX-M KPC-3 OXA-1	AR-0517	5
	SME	AR-0121	50
<i>Serratia marcescens</i> Total			55
<i>Stenotrophomonas maltophilia</i>	NA	ATCC 13637	12
	NA	ATCC 17666	10
	NA	ATCC 700269	8
	NA	ATCC BAA 85	10
	NA	MSI-6	10
<i>Stenotrophomonas maltophilia</i> Total			50

Of the 746 contrived samples evaluated, 717 (96.1%) generated valid LIAISON PLEX BCN Assay results on the first attempt; 29 (3.9%) samples generated an invalid result. Twenty-eight of these samples generated a valid result upon retesting for a final success rate of 99.9% (745/746). The results of contrived sample testing are presented in **Table 25**.

Table 25. Contrived Sample Clinical Performance of the LIAISON PLEX BCN Assay

Target	Positive Percent Agreement			Negative Percent Agreement		
	TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Organisms						
<i>Acinetobacter baumannii</i>	25/25	100%	86.7%-100%	720/720	100%	99.5%-100%
<i>Acinetobacter</i> spp.	45/45	100%	92.1%-100%	700/700	100%	99.5%-100%
<i>Citrobacter</i> spp.	32/32	100%	89.3%-100%	713/713	100%	99.5%-100%
<i>Enterobacter</i> spp.	54/54	100%	93.4%-100%	691/691	100%	99.4%-100%
<i>Enterobacteriaceae</i> /	460/460	100%	99.2%-100%	284/285	99.6%	98%-99.9%

<i>Morganellaceae</i>						
<i>Escherichia coli</i>	41/41	100%	91.4%-100%	704/704	100%	99.5%-100%
<i>Haemophilus influenzae</i>	0/0	0%	0%-0%	745/745	100%	99.5%-100%
<i>Klebsiella oxytoca</i>	20/20	100%	83.9%-100%	725/725	100%	99.5%-100%
<i>Klebsiella pneumoniae</i>	46/46	100%	92.3%-100%	698/699	99.9%	99.2%-100%
<i>Klebsiella variicola</i>	50/50	100%	92.9%-100%	695/695	100%	99.5%-100%
<i>Morganella morganii</i>	62/62	100%	94.2%-100%	683/683	100%	99.4%-100%
<i>Neisseria meningitidis</i>	50/50	100%	92.9%-100%	695/695	100%	99.5%-100%
<i>Proteus</i> spp.	30/30	100%	88.6%-100%	715/715	100%	99.5%-100%
<i>Pseudomonas aeruginosa</i>	35/36	97.2%	85.8%-99.5%	709/709	100%	99.5%-100%
<i>Pseudomonas</i> spp.	57/58	98.3%	90.9%-99.7%	687/687	100%	99.4%-100%
<i>Salmonella</i> spp.	70/70	100%	94.8%-100%	675/675	100%	99.4%-100%
<i>Serratia marcescens</i>	55/55	100%	93.5%-100%	690/690	100%	99.4%-100%
<i>Stenotrophomonas maltophilia</i>	49/49	100%	92.7%-100%	696/696	100%	99.5%-100%
Resistance Marker Genes¹						
CTX-M (<i>bla</i> CTX-M)	105/105	100%	96.5%-100%	305/306	99.7%	98.2%-99.9%
IMP (<i>bla</i> IMP)	54/54	100%	93.4%-100%	357/357	100%	98.9%-100%
KPC (<i>bla</i> KPC)	61/61	100%	94.1%-100%	350/350	100%	98.9%-100%
NDM (<i>bla</i> NDM)	67/67	100%	94.6%-100%	344/344	100%	98.9%-100%
OXA (<i>bla</i> OXA)	35/35	100%	90.1%-100%	375/376	99.7%	98.5%-100%
VIM (<i>bla</i> VIM)	50/50	100%	92.9%-100%	361/361	100%	98.9%-100%
MCR	50/50	100%	92.9%-100%	326/326	100%	98.8%-100%
SME	50/50	100%	92.9%-100%	5/5	100%	56.6%-100%

¹The LIAISON PLEX BCN assay will report the presence or absence of resistance markers only if an applicable organism is also detected, therefore the total number of evaluable samples for each resistance marker is dependent on the number of applicable organisms enrolled.

4. Combined Clinical Performance:

The combined prospective and retrospective performance is shown in **Table 26**.

Table 26. Combined Clinical Performance of the LIAISON PLEX BCN Assay

Target		Positive Percent Agreement			Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
Organisms							
<i>Acinetobacter baumannii</i>	Prospective	0/0	N/A	N/A	350/350	100%	98.9%-100%
	Pre-selected	30/31	96.8%	83.8%-99.4%	199/199	100%	98.1%-100%
	Combined	30/31	96.8%	83.8%-99.4%	549/549	100%	99.3%-100%
<i>Acinetobacter</i> spp.	Prospective	3/5	60%	23.1%-88.2%	345/345	100%	98.9%-100%
	Pre-selected	33/35	94.3%	81.4%-98.4%	195/195	100%	98.1%-100%
	Combined	36/40¹	90%	76.9%-96%	540/540	100%	99.3%-100%
<i>Citrobacter</i> spp.	Prospective	6/6	100%	61%-100%	344/344	100%	98.9%-100%
	Pre-selected	23/24	95.8%	79.8%-99.3%	206/206	100%	98.2%-100%
	Combined	29/30	96.7%	83.3%-99.4%	550/550	100%	99.3%-100%
<i>Enterobacter</i> spp.	Prospective	20/20	100%	83.9%-100%	330/330	100%	98.8%-100%
	Pre-selected	9/10	90%	59.6%-98.2%	220/220	100%	98.3%-100%
	Combined	29/30	96.7%	83.3%-99.4%	550/550	100%	99.3%-100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	Prospective	305/306	99.7%	98.2%-99.9%	44/44	100%	92%-100%
	Pre-selected	123/123	100%	97%-100%	106/107	99.1%	94.9%-99.8%
	Combined	428/429	99.8%	98.7%-100%	150/151	99.3%	96.3%-99.9%
<i>Escherichia coli</i>	Prospective	178/179	99.4%	96.9%-99.9%	169/171	98.8%	95.8%-99.7%
	Pre-selected	1/1	100%	20.7%-100%	229/229	100%	98.4%-100%

Target		Positive Percent Agreement			Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
	Combined	179/180	99.4%	96.9%-99.9%	398/400²	99.5%	98.2%-99.9%
<i>Haemophilus influenzae</i>	Prospective	8/8	100%	67.6%-100%	342/342	100%	98.9%-100%
	Pre-selected	24/24	100%	86.2%-100%	206/206	100%	98.2%-100%
	Combined	32/32	100%	89.3%-100%	548/548	100%	99.3%-100%
<i>Klebsiella oxytoca</i>	Prospective	9/9	100%	70.1%-100%	340/341	99.7%	98.4%-99.9%
	Pre-selected	26/27	96.3%	81.7%-99.3%	203/203	100%	98.1%-100%
	Combined	35/36	97.2%	85.8%-99.5%	543/544³	99.8%	99%-100%
<i>Klebsiella pneumoniae</i>	Prospective	44/45	97.8%	88.4%-99.6%	304/305	99.7%	98.2%-99.9%
	Pre-selected	1/1	100%	20.7%-100%	227/229	99.1%	96.9%-99.8%
	Combined	45/46	97.8%	88.7%-99.6%	531/534⁴	99.4%	98.4%-99.8%
<i>Klebsiella variicola</i>	Prospective	8/8	100%	67.6%-100%	341/341	100%	98.9%-100%
	Pre-selected	4/4	100%	51%-100%	197/197	100%	98.1%-100%
	Combined	12/12	100%	75.8%-100%	538/538	100%	99.3%-100%
<i>Morganella morganii</i>	Prospective	3/3	100%	43.9%-100%	347/347	100%	98.9%-100%
	Pre-selected	5/5	100%	56.6%-100%	225/225	100%	98.3%-100%
	Combined	8/8	100%	67.6%-100%	572/572	100%	99.3%-100%
<i>Neisseria meningitidis</i>	Prospective	0/0	N/A	N/A	350/350	100%	98.9%-100%
	Pre-selected	1/3	33.3%	6.1%-79.2%	227/227	100%	98.3%-100%
	Combined	1/3⁵	33.3%	6.1%-79.2%	577/577	100%	99.3%-100%
<i>Proteus</i> spp.	Prospective	23/23	100%	85.7%-100%	327/327	100%	98.8%-100%
	Pre-selected	14/14	100%	78.5%-100%	216/216	100%	98.3%-100%
	Combined	37/37	100%	90.6%-100%	543/543	100%	99.3%-100%
<i>Pseudomonas aeruginosa</i>	Prospective	28/29	96.6%	82.8%-99.4%	321/321	100%	98.8%-100%
	Pre-selected	6/6	100%	61%-100%	224/224	100%	98.3%-100%
	Combined	34/35	97.1%	85.5%-99.5%	545/545	100%	99.3%-100%
<i>Pseudomonas</i> spp.	Prospective	29/30	96.7%	83.3%-99.4%	320/320	100%	98.8%-100%
	Pre-selected	7/7	100%	64.6%-100%	223/223	100%	98.3%-100%
	Combined	36/37	97.3%	86.2%-99.5%	543/543	100%	99.3%-100%
<i>Salmonella</i> spp.	Prospective	1/1	100%	20.7%-100%	349/349	100%	98.9%-100%
	Pre-selected	16/16	100%	80.6%-100%	214/214	100%	98.2%-100%
	Combined	17/17	100%	81.6%-100%	563/563	100%	99.3%-100%
<i>Serratia marcescens</i>	Prospective	9/9	100%	70.1%-100%	340/341	99.7%	98.4%-99.9%
	Pre-selected	20/20	100%	83.9%-100%	209/210	99.5%	97.4%-99.9%
	Combined	29/29	100%	88.3%-100%	549/551	99.6%	98.7%-99.9%
<i>Stenotrophomonas maltophilia</i>	Prospective	1/1	100%	20.7%-100%	349/349	100%	98.9%-100%
	Pre-selected	10/10	100%	72.2%-100%	219/220	99.5%	97.5%-99.9%
	Combined	11/11	100%	74.1%-100%	568/569	99.8%	99%-100%
Resistance Marker Genes⁶							
CTX-M (<i>bla</i> CTX-M)	Prospective	40/41	97.6%	87.4%-99.6%	295/297	99.3%	97.6%-99.8%
	Pre-selected	5/5	100%	56.6%-100%	169/169	100%	97.8%-100%
	Combined	45/46	97.8%	88.7%-99.6%	464/466	99.6%	98.4%-99.9%
IMP (<i>bla</i> IMP)	Prospective	0/0	N/A	N/A	338/338	100%	98.9%-100%
	Pre-selected	0/0	N/A	N/A	174/174	100%	97.8%-100%
	Combined	0/0	N/A	N/A	512/512	100%	99.3%-100%
KPC (<i>bla</i> KPC)	Prospective	1/1	100%	20.7%-100%	336/336	100%	98.9%-100%
	Pre-selected	0/0	N/A	N/A	164/164	100%	97.7%-100%
	Combined	1/1	100%	20.7%-100%	500/500	100%	99.2%-100%
	Prospective	0/0	N/A	N/A	338/338	100%	98.9%-100%

Target		Positive Percent Agreement			Negative Percent Agreement		
		TP / (TP+FN)	PPA (%)	95% CI	TN / (TN+FP)	NPA (%)	95% CI
NDM (<i>bla</i> NDM)	Pre-selected	1/1	100%	20.7%-100%	173/173	100%	97.8%-100%
	Combined	1/1	100%	20.7%-100%	511/511	100%	99.3%-100%
OXA (<i>bla</i> OXA)	Prospective	0/0	N/A	N/A	332/337	98.5%	96.6%-99.4%
	Pre-selected	26/26	100%	87.1%-100%	137/138	99.3%	96%-99.9%
	Combined	26/26	100%	87.1%-100%	469/475	98.7%	97.3%-99.4%
VIM (<i>bla</i> VIM)	Prospective	0/0	N/A	N/A	338/338	100%	98.9%-100%
	Pre-selected	0/0	N/A	N/A	174/174	100%	97.8%-100%
	Combined	0/0	N/A	N/A	512/512	100%	99.3%-100%
MCR	Prospective	0/0	N/A	N/A	334/334	100%	98.9%-100%
	Pre-selected	0/0	N/A	N/A	131/131	100%	97.2%-100%
	Combined	0/0	N/A	N/A	465/465	100%	99.2%-100%
SME	Prospective	0/0	N/A	N/A	10/10	100%	72.2%-100%
	Pre-selected	0/0	N/A	N/A	21/21	100%	84.5%-100%
	Combined	0/0	N/A	N/A	31/31	100%	89%-100%

¹Clinical isolates from two of the four *Acinetobacter* spp. FN specimens were negative for *Acinetobacter* spp. by BDS.

²The clinical isolate from one of the two *Escherichia coli* FP specimens was positive for *Escherichia coli* by BDS.

³The *Klebsiella oxytoca* FP specimen was positive for *Klebsiella oxytoca* by Standard of Care.

⁴Two of the three *Klebsiella pneumoniae* FP specimens were positive for *Klebsiella pneumoniae* by Standard of Care.

⁵Both *Neisseria meningitidis* FN specimens were positive by another FDA-cleared molecular assay.

⁶The LIAISON PLEX BCN assay will report the presence or absence of resistance markers only if an applicable organism is also detected, therefore the total number of evaluable samples for each resistance marker is dependent on the number of applicable organisms enrolled.

The LIAISON PLEX BCN Assay reports family-level results for *Enterobacteriaceae* / *Morganellaceae* and genus-level results for *Acinetobacter* spp., *Citrobacter* spp., *Enterobacter* spp., *Proteus* spp., *Pseudomonas* spp., and *Salmonella* spp. Positive percent agreement (PPA) for target organisms in all studies stratified at the species level is presented in **Table 27** below.

Table 27. PPA Summary Results for All Studies Stratified by Species

Organism	Prospective (Arm 1)		Pre-selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Enterobacteriaceae/Morganellaceae</i>						
<i>Enterobacteriaceae/Morganellaceae</i>	99.7% (305/306)	98.2%-99.9%	100% (123/123)	97%-100%	100% (460/460)	99.2%-100%
<i>Citrobacter</i> spp.	100% (6/6)	61%-100%	95.8% (23/24)	79.8%-99.3%	100% (32/32)	89.3%-100%
<i>Citrobacter amalonaticus</i>	N/A	N/A	100% (1/1)	20.7%-100%	N/A	N/A
<i>Citrobacter braakii</i>	100% (2/2)	34.2%-100%	N/A	N/A	N/A	N/A
<i>Citrobacter freundii</i>	N/A	N/A	100% (7/7)	64.6%-100%	100% (32/32)	89.3%-100%
<i>Citrobacter koseri</i>	100% (3/3)	43.9%-100%	91.7% (11/12)	64.6%-98.5%	N/A	N/A
<i>Citrobacter sedlakii</i>	N/A	N/A	100% (1/1)	20.7%-100%	N/A	N/A
<i>Citrobacter youngae</i>	100% (1/1)	20.7%-100%	N/A	N/A	N/A	N/A
<i>Citrobacter</i> spp. (unknown)	N/A	N/A	100% (3/3)	43.9%-100%	N/A	N/A
<i>Enterobacter</i> spp.	100% (20/20)	83.9%-100%	90.0% (9/10)	59.6%-98.2%	100% (54/54)	93.4%-100%
<i>Enterobacter cloacae</i> complex	100% (14/14)	78.5%-100%	90.0% (9/10)	59.6%-98.2%	100% (54/54)	93.4%-100%
<i>Klebsiella aerogenes</i> (fmr. <i>Enterobacter aerogenes</i>)	100% (6/6)	61%-100%	N/A	N/A	N/A	N/A

Organism	Prospective (Arm 1)		Pre-selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Proteus</i> spp.	100% (23/23)	85.7%-100%	100% (14/14)	78.5%-100%	100% (30/30)	88.6%-100%
<i>Proteus hauseri</i>	N/A	N/A	100% (1/1)	20.7%-100%	N/A	N/A
<i>Proteus mirabilis</i>	100% (21/21)	84.5%-100%	100% (13/13)	77.2%-100%	100% (30/30)	88.6%-100%
<i>Proteus vulgaris</i>	100% (1/1)	20.7%-100%	N/A	N/A	N/A	N/A
<i>Proteus</i> spp. (unknown)	100% (1/1)	20.7%-100%	N/A	N/A	N/A	N/A
<i>Salmonella</i> spp.	100% (1/1)	20.7%-100%	100% (16/16)	80.6%-100%	100% (70/70)	94.8%-100%
<i>Salmonella enterica</i>	N/A	N/A	100% (5/5)	56.6%-100%	100% (60/60)	94%-100%
<i>Salmonella</i> Senftenberg	N/A	N/A	N/A	N/A	100% (10/10)	72.2%-100%
<i>Salmonella</i> spp. (unknown)	100% (1/1)	20.7%-100%	100% (11/11)	74.1%-100%	N/A	N/A
<i>Escherichia coli</i>	100% (179/179)	97.9%-100%	100% (1/1)	20.7%-100%	100% (41/41)	91.4%-100%
<i>Shigella sonnei</i>	100% (1/1)	20.7%-100%	N/A	N/A	N/A	N/A
<i>Klebsiella oxytoca</i>	100% (10/10)	72.2%-100%	100% (28/28)	87.9%-100%	100% (20/20)	83.9%-100%
<i>Klebsiella</i> <i>pneumoniae</i>	100% (52/52)	93.1%-100%	100% (4/4)	51%-100%	100% (46/46)	92.3%-100%
<i>Klebsiella variicola</i>	N/A	N/A	N/A	N/A	100% (50/50)	92.9%-100%
<i>Morganella morganii</i>	100% (3/3)	43.9%-100%	100% (5/5)	56.6%-100%	100% (62/62)	94.2%-100%
<i>Pantoea</i> spp.	100% (1/1)	20.7%-100%	100% (1/1)	20.7%-100%	N/A	N/A
<i>Providencia stuartii</i>	100% (1/1)	20.7%-100%	N/A	N/A	N/A	N/A
<i>Raoultella planticola</i>	100% (2/2)	34.2%-100%	N/A	N/A	N/A	N/A
<i>Serratia liquefaciens</i>	100% (1/1)	20.7%-100%	N/A	N/A	N/A	N/A
<i>Serratia marcescens</i>	100% (9/9)	70.1%-100%	100% (20/20)	83.9%-100%	100% (55/55)	93.5%-100%
Non-Enterobacteriaceae/Morganellaceae						
<i>Acinetobacter</i> spp.	60% (3/5)	23.1%-88.2%	94.3% (33/35)	81.4%-98.4%	100% (45/45)	92.1%-100%
<i>Acinetobacter baumannii</i>	N/A	N/A	96.8% (30/31)	83.8%-99.4%	100% (25/25)	86.7%-100%
<i>Acinetobacter indicus</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2%-100%
<i>Acinetobacter lwoffii</i>	33.3% (1/3)	6.1%-79.2%	50.0% (1/2)	9.5%-90.5%	100% (10/10)	72.2%-100%
<i>Acinetobacter</i> spp. (unknown)	100% (2/2)	34.2%-100%	100% (2/2)	34.2%-100%	N/A	N/A
<i>Pseudomonas</i> spp.	96.7% (29/30)	83.3%-99.4%	100% (7/7)	64.6%-100%	98.3% (57/58)	90.9%-99.7%
<i>Pseudomonas aeruginosa</i>	96.6% (28/29)	82.8%-99.4%	100% (6/6)	61%-100%	97.2% (35/36)	85.8%-99.5%
<i>Pseudomonas putida</i>	N/A	N/A	N/A	N/A	100% (22/22)	85.1%-100%
<i>Pseudomonas stutzeri</i>	100% (1/1)	20.7%-100%	100% (1/1)	20.7%-100%	N/A	N/A

The LIAISON PLEX BCN assay reports the presence or absence of resistance markers only if an associated organism is also detected. PPA for each resistance marker stratified by eligible organism is listed in **Tables 28 to 35**.

Table 28. PPA Results for CTX-M Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Acinetobacter</i> spp.	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Citrobacter</i> spp.	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Enterobacter</i> spp.	100% (1/1)	20.7-100%	N/A	N/A	100% (10/10)	72.2-100%

<i>Enterobacteriaceae / Morganellaceae</i>	97.6% (40/41)	87.4-99.6%	100% (5/5)	56.6-100%	100% (100/100)	96.3-100%
<i>Escherichia coli</i>	100% (33/33)	89.6-100%	100% (1/1)	20.7-100%	100% (25/25)	86.7-100%
<i>Klebsiella oxytoca</i>	0%	0-0%	100% (2/2)	34.2-100%	100% (4/4)	51-100%
<i>Klebsiella pneumoniae</i>	83.3% (5/6)	43.6-97%	N/A	N/A	100% (29/29)	88.3-100%
<i>Klebsiella variicola</i>	100% (1/1)	20.7-100%	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	100% (12/12)	75.8-100%
<i>Proteus spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Pseudomonas spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Salmonella spp.</i>	N/A	N/A	100% (2/2)	34.2-100%	100% (5/5)	56.6-100%
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Stenotrophomonas maltophilia</i>	N/A	N/A	N/A	N/A	N/A	N/A
Overall	97.6% (40/41)	87.4-99.6%	100% (5/5)	56.6-100%	100% (105/105)	96.5-100%

Table 29. PPA Results for IMP(*bla*_{IMP}) Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Acinetobacter spp.</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Citrobacter spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Enterobacter spp.</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Enterobacteriaceae / Morganellaceae</i>	N/A	N/A	N/A	N/A	100% (39/39)	91-100%
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Klebsiella oxytoca</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Klebsiella pneumoniae</i>	N/A	N/A	N/A	N/A	100% (9/9)	70.1-100%
<i>Klebsiella variicola</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Proteus spp.</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Pseudomonas spp.</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Salmonella spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Stenotrophomonas maltophilia</i>	N/A	N/A	N/A	N/A	N/A	N/A
Overall	N/A	N/A	N/A	N/A	100% (54/54)	93.4-100%

Table 30. PPA Results for KPC(*bla*_{KPC}) Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Acinetobacter spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Citrobacter spp.</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Enterobacter spp.</i>	N/A	N/A	N/A	N/A	100% (6/6)	61-100%
<i>Enterobacteriaceae / Morganellaceae</i>	100% (1/1)	20.7-100%	N/A	N/A	100% (56/56)	93.6-100%
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	100% (6/6)	61-100%
<i>Klebsiella oxytoca</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Klebsiella pneumoniae</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%

<i>Klebsiella variicola</i>	100% (1/1)	20.7-100%	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	100% (19/19)	83.2-100%
<i>Proteus</i> spp.	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Pseudomonas</i> spp.	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Salmonella</i> spp.	N/A	N/A	N/A	N/A	0%	0-0%
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
Overall	100% (1/1)	20.7-100%	N/A	N/A	100% (61/61)	94.1-100%

Table 31. PPA Results for NDM(*bla*_{NDM}) Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Acinetobacter</i> spp.	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Citrobacter</i> spp.	N/A	N/A	100% (1/1)	20.7-100%	100% (5/5)	56.6-100%
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	N/A	100% (1/1)	20.7-100%	100% (57/57)	93.7-100%
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Klebsiella oxytoca</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella pneumoniae</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Klebsiella variicola</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	100% (12/12)	75.8-100%
<i>Proteus</i> spp.	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Pseudomonas</i> spp.	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%
<i>Salmonella</i> spp.	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Stenotrophomonas maltophilia</i>	N/A	N/A	N/A	N/A	N/A	N/A
Overall	N/A	N/A	100% (1/1)	20.7-100%	100% (67/67)	94.6-100%

Table 32. PPA Results for OXA(*bla*_{OXA}) Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	100% (26/26)	87.1-100%	100% (10/10)	72.2-100%
<i>Acinetobacter</i> spp.	N/A	N/A	100% (26/26)	87.1-100%	100% (20/20)	83.9-100%
<i>Citrobacter</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	N/A	N/A	N/A	100% (15/15)	79.6-100%
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Klebsiella oxytoca</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella pneumoniae</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella variicola</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Proteus</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Pseudomonas</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Salmonella</i> spp.	N/A	N/A	N/A	N/A	100% (5/5)	56.6-100%

<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	N/A	N/A
Overall	N/A	N/A	100% (26/26)	87.1-100%	100% (35/35)	90.1-100%

Table 33. PPA Results for VIM(*blavim*) Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Acinetobacter</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Citrobacter</i> spp.	N/A	N/A	N/A	N/A	100% (17/17)	81.6-100%
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	N/A	N/A	N/A	100% (39/39)	91-100%
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella oxytoca</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella pneumoniae</i>	N/A	N/A	N/A	N/A	100% (12/12)	75.8-100%
<i>Klebsiella variicola</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Proteus</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	100% (11/11)	74.1-100%
<i>Pseudomonas</i> spp.	N/A	N/A	N/A	N/A	100% (11/11)	74.1-100%
<i>Salmonella</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Stenotrophomonas maltophilia</i>	N/A	N/A	N/A	N/A	N/A	N/A
Overall	N/A	N/A	N/A	N/A	100% (50/50)	92.9-100%

Table 34. PPA Results for MCR Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Acinetobacter</i> spp.	N/A	N/A	N/A	N/A	100% (18/18)	82.4-100%
<i>Citrobacter</i> spp.	N/A	N/A	N/A	N/A	100% (50/50)	92.9-100%
<i>Enterobacter</i> spp.	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Escherichia coli</i>	N/A	N/A	N/A	N/A	100% (10/10)	72.2-100%
<i>Klebsiella oxytoca</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella pneumoniae</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella variicola</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Morganella morganii</i>	N/A	N/A	N/A	N/A	N/A	N/A
<i>Proteus</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Pseudomonas aeruginosa</i>	N/A	N/A	N/A	N/A	100% (12/12)	75.8-100%
<i>Pseudomonas</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Salmonella</i> spp.	N/A	N/A	N/A	N/A	N/A	N/A
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	100% (18/18)	82.4-100%
Overall	N/A	N/A	N/A	N/A	100% (50/50)	92.9-100%

Table 35. PPA Results for SME Stratified by Associated Host Organism

Organism	Prospective (Arm 1)		Pre - selected (Arm 2)		Contrived (Arm 3)	
	PPA	95% CI	PPA	95% CI	PPA	95% CI
<i>Serratia marcescens</i>	N/A	N/A	N/A	N/A	100% (50/50)	92.9-100%

Overall	N/A	N/A	N/A	N/A	100% (50/50)	92.9-100%
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A supplemental comparison of the performance of the CTX-M resistance marker compared to phenotypic antimicrobial susceptibility testing (AST) results for various β -lactam antibiotics, including cepheids (Cefazolin, Cefuroxime, Cefoxitin, Ceftazidime, Ceftriaxone, Cefepime), and Aztreonam by relevant organism is shown in **Table 36**. Note that antimicrobial resistance is known to occur via mechanisms other than presence of the CTX-M gene; conversely, the presence of the CTX-M gene may not always phenotypically confer antimicrobial resistance.

Table 36. Clinical Performance of CTX-M Compared to AST Results

On-Panel Organism	Ampicillin		Aztreonam		Cefazolin		Cefepime		Cefoxitin		Ceftazidime		Ceftriaxone		Cefuroxime	
	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)	TP (TP+F N) (%)	TN (TN+F P) (%)
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Acinetobacter</i> spp.	0/1 (0)	N/A	0/1 (0)	N/A	0/1 (0)	N/A	N/A	2/2 (100)	N/A	N/A	N/A	2/2 (100)	N/A	2/2 (100)	N/A	N/A
<i>Citrobacter</i> spp.	0/2 (0)	N/A	0/1 (0)	2/2 (100)	0/3 (0)	2/2 (100)	N/A	6/6 (100)	0/2 (0)	1/1 (100)	0/2 (0)	1/1 (100)	0/2 (0)	4/4 (100)	0/2 (0)	N/A
<i>Enterobacter</i> spp.	0/3 (0)	1/1 (100)	1/3 (33.3)	10/10 (100)	0/8 (0)	3/3 (100)	1/3 (33.3)	14/14 (100)	0/6 (0)	1/1 (100)	1/3 (33.3)	11/11 (100)	0/1 (0)	6/6 (100)	N/A	1/1 (100)
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	28/147 (19)	93/94 (98.9)	27/33 (81.8)	148/148 (100)	29/122 (23.8)	147/147 (100)	26/30 (86.7)	249/252 (98.8)	3/27 (11.1)	207/231 (89.6)	23/31 (74.2)	177/183 (96.7)	26/35 (74.3)	225/228 (98.7)	24/42 (57.1)	164/165 (99.4)
<i>Escherichia coli</i>	23/90 (25.6)	74/75 (98.7)	21/21 (100)	82/82 (100)	24/67 (35.8)	97/97 (100)	20/21 (95.2)	141/144 (97.9)	2/10 (20)	131/151 (86.8)	18/20 (90)	103/108 (95.4)	21/23 (91.3)	137/140 (97.9)	19/30 (63.3)	100/101 (99)
<i>Haemophilus influenzae</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella oxytoca</i>	0/8 (0)	1/1 (100)	N/A	8/8 (100)	0/6 (0)	2/2 (100)	N/A	9/9 (100)	N/A	10/10 (100)	N/A	10/10 (100)	0/1 (0)	9/9 (100)	0/1 (0)	7/7 (100)
<i>Klebsiella pneumoniae</i>	4/31 (12.9)	N/A	4/6 (66.7)	23/23 (100)	4/10 (40)	32/32 (100)	4/5 (80)	37/37 (100)	1/2 (50)	37/40 (92.5)	4/6 (66.7)	25/25 (100)	4/6 (66.7)	35/35 (100)	4/6 (66.7)	34/34 (100)
<i>Klebsiella variicola</i>	1/5 (20)	1/1 (100)	1/1 (100)	5/5 (100)	1/2 (50)	5/5 (100)	1/1 (100)	7/7 (100)	0/1 (0)	4/5 (80)	N/A	5/6 (83.3)	1/1 (100)	7/7 (100)	1/1 (100)	4/4 (100)
<i>Morganella morganii</i>	N/A	N/A	N/A	1/1 (100)	0/2 (0)	N/A	N/A	2/2 (100)	0/1 (0)	1/1 (100)	N/A	1/1 (100)	N/A	N/A	N/A	N/A
<i>Neisseria meningitidis</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Proteus</i> spp.	0/7 (0)	16/16 (100)	0/1 (0)	13/13 (100)	0/17 (0)	6/6 (100)	N/A	23/23 (100)	N/A	22/22 (100)	N/A	17/17 (100)	0/1 (0)	21/21 (100)	0/1 (0)	18/18 (100)
<i>Pseudomonas aeruginosa</i>	N/A	N/A	0/3 (0)	15/15 (100)	0/4 (0)	N/A	0/2 (0)	24/25 (96)	0/3 (0)	3/3 (100)	0/1 (0)	15/15 (100)	N/A	1/1 (100)	0/3 (0)	N/A
<i>Pseudomonas</i> spp.	N/A	N/A	0/3 (0)	16/16 (100)	0/4 (0)	N/A	0/2 (0)	25/26 (96.2)	0/3 (0)	3/3 (100)	0/1 (0)	15/15 (100)	N/A	2/2 (100)	0/3 (0)	N/A
<i>Salmonella</i> spp.	N/A	1/1 (100)	N/A	1/1 (100)	0/1 (0)	N/A	N/A	1/1 (100)	N/A	N/A	N/A	1/1 (100)	N/A	1/1 (100)	N/A	N/A
<i>Serratia marcescens</i>	0/2 (0)	N/A	N/A	5/5 (100)	0/7 (0)	N/A	N/A	10/10 (100)	0/6 (0)	N/A	N/A	5/5 (100)	N/A	5/5 (100)	0/1 (0)	N/A
<i>Stenotrophomonas maltophilia</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0/1 (0)	N/A	N/A	N/A	N/A	N/A

A supplemental comparison of carbapenemase resistance markers (OXA, KPC, IMP, NDM, VIM) compared to phenotypic AST results for carbapenem antibiotics (Ertapenem, Imipenem, Meropenem) by relevant organism is shown in **Table 37**. A similar supplemental comparison table of the SME resistance marker for *Serratia marcescens* is presented in **Table 38**. Note that antimicrobial resistance is known to occur via mechanisms other than presence of these resistance genes; conversely, the presence of these resistance genes may not always phenotypically confer antimicrobial resistance.

Table 37. Clinical Performance of OXA, KPC, IMP, NDM, VIM Compared to AST Results

On-Panel Organism	OXA		KPC		IMP		NDM		VIM	
	TP / (TP+FN) (%)	TN / (TN+FP) (%)	TP / (TP+FN) (%)	TN / (TN+FP) (%)	TP / (TP+FN) (%)	TN / (TN+FP) (%)	TP / (TP+FN) (%)	TN / (TN+FP) (%)	TP / (TP+FN) (%)	TN / (TN+FP) (%)
<i>Acinetobacter baumannii</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Acinetobacter</i> spp.	0/1 (0)	2/2 (100)	0/1 (0)	2/2 (100)	0/1 (0)	2/2 (100)	0/1 (0)	2/2 (100)	0/1 (0)	2/2 (100)
<i>Citrobacter</i> spp.	N/A	4/4 (100)	N/A	4/4 (100)	N/A	4/4 (100)	N/A	4/4 (100)	N/A	4/4 (100)
<i>Enterobacter</i> spp.	0/1 (0)	16/17 (94.1)	0/1 (0)	17/17 (100)	0/1 (0)	17/17 (100)	0/1 (0)	17/17 (100)	0/1 (0)	17/17 (100)
<i>Enterobacteriaceae/Morganellaceae</i>	0/4 (0)	282/287 (98.3)	1/4 (25)	287/287 (100)	0/4 (0)	287/287 (100)	1/4 (25)	287/287 (100)	1/4 (25)	287/287 (100)
<i>Escherichia coli</i>	0/1 (0)	171/175 (97.7)	0/1 (0)	175/175 (100)	0/1 (0)	175/175 (100)	0/1 (0)	175/175 (100)	0/1 (0)	175/175 (100)
<i>Haemophilus influenzae</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Klebsiella oxytoca</i>	N/A	10/10 (100)	N/A	10/10 (100)	N/A	10/10 (100)	N/A	10/10 (100)	N/A	10/10 (100)
<i>Klebsiella pneumoniae</i>	N/A	42/43 (97.7)	N/A	43/43 (100)	N/A	43/43 (100)	N/A	43/43 (100)	N/A	43/43 (100)
<i>Klebsiella variicola</i>	0/1 (0)	5/5 (100)	1/1 (100)	5/5 (100)	0/1 (0)	5/5 (100)	1/1 (100)	5/5 (100)	1/1 (100)	5/5 (100)
<i>Morganella morganii</i>	N/A	3/3 (100)	N/A	3/3 (100)	N/A	3/3 (100)	N/A	3/3 (100)	N/A	3/3 (100)
<i>Neisseria meningitidis</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
<i>Proteus</i> spp.	0/1 (0)	22/22 (100)	0/1 (0)	22/22 (100)	0/1 (0)	22/22 (100)	0/1 (0)	22/22 (100)	0/1 (0)	22/22 (100)
<i>Pseudomonas aeruginosa</i>	0/2 (0)	25/25 (100)	0/2 (0)	25/25 (100)	0/2 (0)	25/25 (100)	0/2 (0)	25/25 (100)	0/2 (0)	25/25 (100)
<i>Pseudomonas</i> spp.	0/2 (0)	26/26 (100)	0/2 (0)	26/26 (100)	0/2 (0)	26/26 (100)	0/2 (0)	26/26 (100)	0/2 (0)	26/26 (100)
<i>Salmonella</i> spp.	0 N/A	1/1 (100)	N/A	1/1 (100)	N/A	1/1 (100)	N/A	1/1 (100)	N/A	1/1 (100)
<i>Serratia marcescens</i>	N/A	9/9 (100)	N/A	9/9 (100)	N/A	9/9 (100)	N/A	9/9 (100)	N/A	9/9 (100)
<i>Stenotrophomonas maltophilia</i>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 38. Clinical Performance of SME Compared to AST Results

On-Panel Organism	SME	
	TP / (TP+FN) (%)	TN / (TN+FP) (%)
<i>Serratia marcescens</i>	N/A	9/9 (100%)

Clinical Cut-Off:

Not applicable.

Expected Values/Reference Range:

The LIAISON PLEX Gram-Negative Blood Culture (BCN) Assay prospective clinical study was conducted to evaluate clinical performance of the device using positive blood culture samples. The expected values of each target organism in the prospective samples are presented by site and age in **Tables 39 and 40**, respectively.

Table 39. Expected Values by Clinical Site (Prospective Samples)

Target	Site 01 (N=148)		Site 02 (N=102)		Site 03 (N=58)		Site 04 (N=42)		Total (N=351)	
	#Pos	(%)	#Pos	(%)	#Pos	(%)	#Pos	(%)	#Pos	(%)
Organisms										

<i>Acinetobacter baumannii</i>	0	0.0% (0/148)	0	0.0% (0/102)	0	0.0% (0/58)	0	0.0% (0/42)	0	0.0% (0/350)
<i>Acinetobacter</i> spp.	1	0.7% (1/148)	1	1.0% (1/102)	1	1.7% (1/58)	0	0.0% (0/42)	3	0.9% (3/350)
<i>Citrobacter</i> spp.	1	0.7% (1/148)	3	2.9% (3/102)	1	1.7% (1/58)	1	2.4% (1/42)	6	1.7% (6/350)
<i>Enterobacter</i> spp.	132	89.2% (132/148)	86	84.3% (86/102)	50	86.2% (50/58)	37	88.1% (37/42)	305	87.1% (305/350)
<i>Enterobacteriaceae/</i> <i>Morganellaceae</i>	11	7.4% (11/148)	6	5.9% (6/102)	2	3.4% (2/58)	1	2.4% (1/42)	20	5.7% (20/350)
<i>Escherichia coli</i>	72	48.6% (72/148)	49	48.0% (49/102)	31	53.4% (31/58)	28	66.7% (28/42)	180	51.4% (180/350)
<i>Haemophilus influenzae</i>	1	0.7% (1/148)	3	2.9% (3/102)	3	5.2% (3/58)	1	2.4% (1/42)	8	2.3% (8/350)
<i>Klebsiella oxytoca</i>	8	5.4% (8/148)	0	0.0% (0/102)	0	0.0% (0/58)	2	4.8% (2/42)	10	2.9% (10/350)
<i>Klebsiella pneumoniae</i>	24	16.2% (24/148)	12	11.8% (12/102)	7	12.1% (7/58)	2	4.8% (2/42)	45	12.9% (45/350)
<i>Klebsiella variicola</i>	3	2.0% (3/148)	2	2.0% (2/102)	3	5.2% (3/58)	0	0.0% (0/42)	8	2.3% (8/350)
<i>Morganella morganii</i>	1	0.7% (1/148)	2	2.0% (2/102)	0	0.0% (0/58)	0	0.0% (0/42)	3	0.9% (3/350)
<i>Neisseria meningitidis</i>	0	0.0% (0/148)	0	0.0% (0/102)	0	0.0% (0/58)	0	0.0% (0/42)	0	0.0% (0/350)
<i>Proteus</i> spp.	10	6.8% (10/148)	6	5.9% (6/102)	4	6.9% (4/58)	3	7.1% (3/42)	23	6.6% (23/350)
<i>Pseudomonas aeruginosa</i>	12	8.1% (12/148)	9	8.9% (9/101)	4	6.9% (4/58)	2	4.8% (2/42)	27	7.7% (27/349)
<i>Pseudomonas</i> spp.	12	8.1% (12/148)	11	10.8% (11/102)	4	6.9% (4/58)	2	4.8% (2/42)	29	8.3% (29/350)
<i>Salmonella</i> spp.	0	0.0% (0/148)	0	0.0% (0/102)	1	1.7% (1/58)	0	0.0% (0/42)	1	0.3% (1/350)
<i>Serratia marcescens</i>	3	2.0% (3/148)	5	4.9% (5/102)	2	3.4% (2/58)	0	0.0% (0/42)	10	2.9% (10/350)
<i>Stenotrophomonas maltophilia</i>	1	0.7% (1/148)	0	0.0% (0/102)	0	0.0% (0/58)	0	0.0% (0/42)	1	0.3% (1/350)
Resistance Marker Genes										
CTX-M (<i>bla</i> CTX-M)	22	15.0% (22/147)	12	12.4% (12/97)	5	9.1% (5/55)	3	7.7% (3/39)	42	12.4% (42/338)
IMP (<i>bla</i> IMP)	0	0.0% (0/147)	0	0.0% (0/97)	0	0.0% (0/55)	0	0.0% (0/39)	0	0.0% (0/338)
KPC (<i>bla</i> KPC)	1	0.7% (1/146)	0	0.0% (0/97)	0	0.0% (0/55)	0	0.0% (0/39)	1	0.3% (1/337)
NDM (<i>bla</i> NDM)	0	0.0% (0/147)	0	0.0% (0/97)	0	0.0% (0/55)	0	0.0% (0/39)	0	0.0% (0/338)
OXA (<i>bla</i> OXA)	5	3.4% (5/146)	0	0.0% (0/97)	0	0.0% (0/55)	0	0.0% (0/39)	5	1.5% (5/337)
VIM (<i>bla</i> VIM)	0	0.0% (0/147)	0	0.0% (0/97)	0	0.0% (0/55)	0	0.0% (0/39)	0	0.0% (0/338)
MCR	0	0.0% (0/145)	0	0.0% (0/96)	0	0.0% (0/54)	0	0.0% (0/39)	0	0.0% (0/334)
SME	0	0.0% (0/3)	0	0.0% (0/5)	0	0.0% (0/1)	0	0.0% (0/0)	0	0.0% (0/9)

Table 40. Expected Values by Age Group (Prospective Samples)

	0-1 year (N=10)		>2-5 years (N=3)		>6-21 years (N=10)		>22-65 years (N=142)		> 65 years (N=180)		Unknown years (N=5)		Overall (N=350)	
Target	#Pos	(%)	#Pos	(%)	#Pos	(%)	#Pos	(%)	#Pos	(%)	#Pos	(%)	#Pos	(%)
Organisms														
<i>Acinetobacter baumannii</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	0	0.0% (0/142)	0	0.0% (0/180)	0	0.0% (0/5)	0	0.0% (0/350)
<i>Acinetobacter</i> spp.	0	0.0% (0/10)	0	0.0% (0/3)	1	10.0% (1/10)	2	1.4% (2/142)	0	0.0% (0/180)	0	0.0% (0/5)	3	0.9% (3/350)

<i>Citrobacter</i> spp.	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	5	3.5% (5/142)	1	0.6% (1/180)	0	0.0% (0/5)	6	1.7% (6/350)
<i>Enterobacter</i> spp.	9	90.0% (9/10)	0	0.0% (0/3)	7	70.0% (7/10)	126	88.7% (126/142)	158	87.8% (158/180)	5	100.0% (5/5)	305	87.1% (305/350)
<i>Enterobacteriaceae</i> / <i>Morganellaceae</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	9	6.3% (9/142)	11	6.1% (11/180)	0	0.0% (0/5)	20	5.7% (20/350)
<i>Escherichia coli</i>	5	50.0% (5/10)	0	0.0% (0/3)	6	60.0% (6/10)	69	48.6% (69/142)	96	53.3% (96/180)	4	80.0% (4/5)	180	51.4% (180/350)
<i>Haemophilus</i> <i>influenzae</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	1	0.7% (1/142)	7	3.9% (7/180)	0	0.0% (0/5)	8	2.3% (8/350)
<i>Klebsiella oxytoca</i>	1	10.0% (1/10)	0	0.0% (0/3)	0	0.0% (0/10)	4	2.8% (4/142)	5	2.8% (5/180)	0	0.0% (0/5)	10	2.9% (10/350)
<i>Klebsiella pneumoniae</i>	1	10.0% (1/10)	0	0.0% (0/3)	1	10.0% (1/10)	22	15.5% (22/142)	21	11.7% (21/180)	0	0.0% (0/5)	45	12.9% (45/350)
<i>Klebsiella variicola</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	3	2.1% (3/142)	5	2.8% (5/180)	0	0.0% (0/5)	8	2.3% (8/350)
<i>Morganella morganii</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	2	1.4% (2/142)	1	0.6% (1/180)	0	0.0% (0/5)	3	0.9% (3/350)
<i>Neisseria meningitidis</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	0	0.0% (0/142)	0	0.0% (0/180)	0	0.0% (0/5)	0	0.0% (0/350)
<i>Proteus</i> spp.	1	10.0% (1/10)	0	0.0% (0/3)	0	0.0% (0/10)	7	4.9% (7/142)	14	7.8% (14/180)	1	20.0% (1/5)	23	6.6% (23/350)
<i>Pseudomonas aeruginosa</i>	1	10.0% (1/10)	2	66.7% (2/3)	2	20.0% (2/10)	9	6.4% (9/141)	13	7.2% (13/180)	0	0.0% (0/5)	27	7.7% (27/349)
<i>Pseudomonas</i> spp.	1	10.0% (1/10)	2	66.7% (2/3)	2	20.0% (2/10)	10	7.0% (10/142)	14	7.8% (14/180)	0	0.0% (0/5)	29	8.3% (29/350)
<i>Salmonella</i> spp.	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	1	0.7% (1/142)	0	0.0% (0/180)	0	0.0% (0/5)	1	0.3% (1/350)
<i>Serratia marcescens</i>	1	10.0% (1/10)	0	0.0% (0/3)	0	0.0% (0/10)	3	2.1% (3/142)	6	3.3% (6/180)	0	0.0% (0/5)	10	2.9% (10/350)
<i>Stenotrophomonas maltophilia</i>	0	0.0% (0/10)	0	0.0% (0/3)	0	0.0% (0/10)	1	0.7% (1/142)	0	0.0% (0/180)	0	0.0% (0/5)	1	0.3% (1/350)
Resistance Marker Genes														
CTX-M (<i>bla</i> CTX-M)	0	0.0% (0/10)	0	0.0% (0/2)	1	10.0% (1/10)	21	15.1% (21/139)	17	9.9% (17/172)	3	60.0% (3/5)	42	12.4% (42/338)
IMP (<i>bla</i> IMP)	0	0.0% (0/10)	0	0.0% (0/2)	0	0.0% (0/10)	0	0.0% (0/139)	0	0.0% (0/172)	0	0.0% (0/5)	0	0.0% (0/338)
KPC (<i>bla</i> KPC)	0	0.0% (0/10)	0	0.0% (0/2)	0	0.0% (0/10)	0	0.0% (0/138)	1	0.6% (1/172)	0	0.0% (0/5)	1	0.3% (1/337)
NDM (<i>bla</i> NDM)	0	0.0% (0/10)	0	0.0% (0/2)	0	0.0% (0/10)	0	0.0% (0/139)	0	0.0% (0/172)	0	0.0% (0/5)	0	0.0% (0/338)
OXA (<i>bla</i> OXA)	0	0.0% (0/10)	0	0.0% (0/2)	0	0.0% (0/10)	2	1.4% (2/138)	3	1.7% (3/172)	0	0.0% (0/5)	5	1.5% (5/337)
VIM (<i>bla</i> VIM)	0	0.0% (0/10)	0	0.0% (0/2)	0	0.0% (0/10)	0	0.0% (0/139)	0	0.0% (0/172)	0	0.0% (0/5)	0	0.0% (0/338)
MCR	0	0.0% (0/10)	0	0.0% (0/2)	0	0.0% (0/9)	0	0.0% (0/136)	0	0.0% (0/172)	0	0.0% (0/5)	0	0.0% (0/334)
SME	0	0.0% (0/1)	0	0.0% (0/0)	0	0.0% (0/0)	0	0.0% (0/3)	0	0.0% (0/5)	0	0.0% (0/0)	0	0.0% (0/9)
Mixed Infections														
<i>Enterobacter</i> spp. <i>Enterobacteriaceae</i> <i>Morganellaceae</i> <i>Escherichia coli</i> OXA	0	0.0% (0/0)	0	0.0% (0/0)	0	0.0% (0/0)	1	0.7% (1/142)	0	0.0% (0/180)	0	0.0% (0/0)	1	0.3% (1/350)
<i>Enterobacter</i> spp. <i>Enterobacteriaceae</i> <i>Morganellaceae</i> <i>Klebsiella variicola</i>	0	0.0% (0/0)	0	0.0% (0/0)	0	0.0% (0/0)	0	0.0% (0/0)	1	0.6% (1/180)	0	0.0% (0/0)	1	0.3% (1/350)

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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