



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

**I Background Information:**

**A 510(k) Number**

K254166

**B Applicant**

Streck

**C Proprietary and Established Names**

MDx-Chex for BCN

**D Regulatory Information**

Product Code(s)	Classification	Regulation Section	Panel
PMN	Class II	866.3920	MI

**II Submission/Device Overview:**

**A Purpose for Submission:**

To obtain a substantial equivalence determination for the MDx-Chex for BCN.

**B Measurand:**

Multi-analyte external quality control materials for microbiology NAAT assays.

**C Type of Test:**

The MDx-Chex for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes by the DiaSorin LIAISON PLEX Gram-Negative Blood Culture assay on the LIAISON PLEX System. MDx-Chex for BCN Control 1 and Control 2 are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 1: Gram-negative bacteria: *Acinetobacter baumannii*, *Haemophilus influenzae*, *Neisseria meningitidis*, *Pseudomonas aeruginosa*, *Stenotrophomonas*

*maltophilia*; genus: *Acinetobacter* spp., *Pseudomonas* spp.; antimicrobial resistance genes: KPC, NDM, and VIM. Control 2: Gram-negative bacteria: *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Klebsiella variicola*, *Morganella morganii*, *Serratia marcescens*; family/genus: *Enterobacteriaceae*/*Morganellaceae*, *Citrobacter* spp., *Enterobacter* spp., *Proteus* spp., *Salmonella* spp.; antimicrobial resistance genes: CTX-M, IMP, MCR, OXA, and SME. This product is not intended to replace manufacturer controls provided with the device.

### III Intended Use/Indications for Use:

#### A Intended Use(s):

See Indications for Use below.

#### B Indication(s) for Use:

MDx-Chex for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the DiaSorin LIAISON PLEX Gram-Negative Blood Culture assay on the LIAISON PLEX System. MDx-Chex for BCN Control 1 and Control 2 are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 1: Gram-negative bacteria: *Acinetobacter baumannii*, *Haemophilus influenzae*, *Neisseria meningitidis*, *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*; genus: *Acinetobacter* spp., *Pseudomonas* spp.; antimicrobial resistance genes: KPC, NDM, and VIM. Control 2: Gram-negative bacteria: *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Klebsiella variicola*, *Morganella morganii*, *Serratia marcescens*; family/genus: *Enterobacteriaceae*/*Morganellaceae*, *Citrobacter* spp., *Enterobacter* spp., *Proteus* spp., *Salmonella* spp.; antimicrobial resistance genes: CTX-M, IMP, MCR, OXA, and SME. This product is not intended to replace manufacturer controls provided with the device.

#### C Special Conditions for Use Statement(s):

Rx – For Prescription Use Only

#### D Special Instrument Requirements:

LIAISON Analyzer

### IV Device/System Characteristics:

#### A Device Description:

MDx-Chex for BCN is a cellular-based external quality control containing stabilized blood components (erythrocytes and leukocytes), simulated blood culture media, inactivated microorganisms, and antimicrobial resistance gene targets. The control simulates positive and negative blood culture samples and is processed in "control mode" per the assay IFU. Use of full-process cellular controls enables evaluation of the entire analytical workflow for sample-to-

result tests, including lysis, nucleic acid isolation/purification, hybridization, detection, and analysis, and provides assessment of the impact of inhibitors and pre-analytical variables.

MDx-Chex for BCN is supplied as two controls packaged as follows:

- Control 1 (pink cap), 5 microtubes × 0.5 mL each, containing 300 µL per tube.
- Control 2 (black cap), 5 microtubes × 0.5 mL each, containing 300 µL per tube. Each tube contains sufficient volume for a single test.

The kit has two configurations:

- Package containing five Control 1 vials and five Control 2 vials
- Package containing 10 Control 1 vials and 10 Control 2 vials

The analyte composition for the Control set is described in Table 1, below.

**Table 1. Analyte composition for Control 1 and Control 2**

<b>Gram-Negative Bacteria*</b>		
<b>Target</b>	<b>Control 1</b>	<b>Control 2</b>
Enterobacteriaceae/Morganellaceae	Not Detected	Detected
<i>Acinetobacter</i> spp.	Detected	Not Detected
<i>Acinetobacter baumannii</i>	Detected	Not Detected
<i>Citrobacter</i> spp.	Not Detected	Detected
<i>Enterobacter</i> spp.	Not Detected	Detected
<i>Escherichia coli</i>	Not Detected	Detected
<i>Haemophilus influenzae</i>	Detected	Not Detected
<i>Klebsiella oxytoca</i>	Not Detected	Detected
<i>Klebsiella pneumoniae</i>	Not Detected	Detected
<i>Klebsiella variicola</i>	Not Detected	Detected
<i>Morganella morganii</i>	Not Detected	Detected
<i>Neisseria meningitidis</i>	Detected	Not Detected
<i>Proteus</i> spp.	Not Detected	Detected
<i>Pseudomonas</i> spp.	Detected	Not Detected
<i>Pseudomonas aeruginosa</i>	Detected	Not Detected
<i>Salmonella</i> spp.	Not Detected	Detected
<i>Serratia marcescens</i>	Not Detected	Detected
<i>Stenotrophomonas maltophilia</i>	Detected	Not Detected
<b>Antimicrobial Resistance Genes*</b>		
<b>Gene</b>	<b>Control 1</b>	<b>Control 2</b>
CTX-M	Not Detected	Detected
IMP	Not Detected	Detected
KPC	Detected	Not Detected
MCR	Not Detected	Detected
NDM	Detected	Not Detected
OXA	Not Detected	Detected
SME	Not Reviewed	Detected
VIM	Detected	Not Detected

\*All bacteria analytes are sourced from ATCC, American Type Culture Collection

**B Principle of Operation:**

Not applicable.

**V Substantial Equivalence Information:**

**A Predicate Device Name(s):**

MDx-Chex for BC-GN

**B Predicate 510(k) Number(s):**

K231223

**C Comparison with Predicate(s):**

Device & Predicate Device(s):	<a href="#">K254166</a>	<a href="#">K231223</a>
Device Trade Name	MDx-Chex for BCN	MDx-Chex for BC-GN
General Device Characteristic Similarities		
Intended Use/Indications For Use	<p>MDx-Chex for BCN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the DiaSorin LIAISON PLEX Gram-Negative Blood Culture assay on the LIAISON PLEX System. MDx-Chex for BCN Control 1 and Control 2 are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Control 1: Gram-negative bacteria: <i>Acinetobacter baumannii</i>, <i>Haemophilus influenzae</i>, <i>Neisseria meningitidis</i>, <i>Pseudomonas aeruginosa</i>, <i>Stenotrophomonas maltophilia</i>; genus:</p>	<p>MDx-Chex for BC-GN is intended for use as an external positive and negative assayed control to monitor the performance of the qualitative detection of Gram-negative bacteria and associated antimicrobial resistance genes, by the Luminex VERIGENE Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) on Luminex VERIGENE systems. The MDx-Chex for BC- GN Positive and Negative Controls are composed of a buffered solution with stabilized erythrocytes and leukocytes in a matrix of blood culture media components. Positive Control: Gram-negative bacteria: <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Klebsiella oxytoca</i>, <i>Pseudomonas aeruginosa</i>; Species:</p>

	<p><i>Acinetobacter spp.</i>, <i>Pseudomonas spp.</i>; antimicrobial resistance genes: KPC, NDM, and VIM. Control 2: Gram-negative bacteria: <i>Escherichia coli</i>, <i>Klebsiella oxytoca</i>, <i>Klebsiella pneumoniae</i>, <i>Klebsiella variicola</i>, <i>Morganella morganii</i>, <i>Serratia marcescens</i>; family/genus: <i>Enterobacteriaceae</i>/ <i>Morganellaceae</i>, <i>Citrobacter spp.</i>, <i>Enterobacter spp.</i>, <i>Proteus spp.</i>, <i>Salmonella spp.</i>; antimicrobial resistance genes: CTX-M, IMP, MCR, OXA, and SME. This product is not intended to replace manufacturer controls provided with the device.</p>	<p><i>Acinetobacter spp.</i>, <i>Citrobacter spp.</i>, <i>Enterobacter spp.</i>, <i>Proteus spp.</i>; antimicrobial resistance genes: CTX-M, IMP, KPC, NDM, OXA, and VIM. Negative Control: buffered solution only. This product is not intended to replace manufacturer controls provided with the device.</p>
Physical Format	Same	Ready-to-Use Liquid
Indications for Use	Same	Process like a patient sample
Composition	Buffered solution with stabilized human erythrocytes and leukocytes, simulated blood culture media components, and inactivated microorganisms.	Intact inactivated bacteria, human erythrocytes and leukocytes, and relevant components of blood culture media
Assay Steps Monitored	Same	Lysis, nucleic acid isolation/purification/inhibitor removal, DNA hybridization, detection, identification/data reporting
<b>General Device Characteristic Differences</b>		
Number of targets monitored in one assay	Multiple, 26 targets 18 Gram-negative organisms 8 Resistance genes	Multiple, 14 targets 8 Gram-negative organisms 6 Resistance genes

## VI Standards/Guidance Documents Referenced:

Not applicable

**VII Performance Characteristics (if/when applicable):**

**A Analytical Performance:**

1. Reproducibility:

A multi-site reproducibility study was conducted for the MDx-Chex for BCN where testing was completed at three different sites, with three operators and consisted of ten Control 1 samples and ten Control 2 samples for each of three lots of MDx-Chex for BCN, for a total of 30 samples per control type (*i.e.*, Control 1 and Control 2) and 60 samples per lot. Both Control 1 and Control 2 were tested on different days (2 MDx-Chex for BCN control types x 1 lot x 1 day, for 10 days and 3 different sites) for a total of 180 runs (90 runs per MDx-Chex for BCN control type) generated for data analysis from all testing sites and all MDx-Chex for BCN sites.

All samples were prepared and analyzed using the LIAISON PLEX System per the controls Instructions for Use. This resulted in a positive percent agreement (PPA) of 99% (178/180) and a negative percent agreement (NPA) of 100% (180/180) for the MDx-Chex for BCN Control 1 and Control 2. Results are summarized in Table 2 and Table 3, below.

**Table 2. MDx-Chex for BCN: Positive Percent Agreement Multi-Site Reproducibility Summary**

Category	Site 1		Site 2		Site 3		Percent Agreement	95% CI
	Observed/Expected Results	PPA	Observed/Expected Results	PPA	Observed/Expected Results	PPA		
MDx-Chex for BC-GN Positive Control 1 and Control 2	58*/60	97%	60/60	100%	60/60	100%	99% (178/180)	96-100%

\* One Positive Control 1 and one Positive Control Level 2 produced unexpected results

**Table 3. MDx-Chex for BCN: Negative Percent Agreement Multi-Site Reproducibility Summary**

Category	Site 1		Site 2		Site 3		Percent Agreement	95% CI
	Observed/Expected Results	NPA	Observed/Expected Results	NPA	Observed/Expected Results	NPA		
MDx-Chex for BC-GN Negative Control 1 and Control 2	60/60	100%	60/60	100%	60/60	100%	100% (180/180)	98-100%

The results support the reproducibility of the MDx-Chex for BCN Controls 1 and 2 across three separately manufactured control lots, days, and operators when used with the DiaSorin LIAISON PLEX BCN panels on three different LIAISON PLEX Systems.

2. Repeatability:

An internal repeatability study was conducted to assess performance of MDx-Chex for BCN using at least two LIAISON PLEX Systems, three MDx-Chex for BCN lots, at least three LIAISON PLEX BCN test cartridge lots, and a minimum of two operators. Testing consisted of evaluating 20 samples per control type (Control 1 and Control 2), 40 samples per MDx-Chex for BCN lot, tested over 20 different days (2 MDx-Chex for BCN control types x 1 control type/day x 3 lots x 20 days), for a total of 120 replicates generated for data analysis.

Samples were prepared according to MDx-Chex for BCN control instructions, and tested using the LIAISON PLEX BCN system, per the Instructions for Use of the assay. This testing resulted in a PPA of 98% (118/120) for both MDx-Chex for BCN controls (Table 4) and a NPA of 100% (120/120) for both MDx-Chex for BCN controls (Table 5).

**Table 4. MDx-Chex for BCN: Positive Percent Agreement Repeatability Summary**

Category	Observed/Expected Results	PPA	95% CI
MDx-Chex for BCN Positive Control 1 and Control 2	118/120*	98%	94% - 100%

\*One Positive Control 1 and one Positive Control 2 produced unexpected results.

**Table 5. MDx-Chex for BCN: Negative Percent Agreement Repeatability Summary**

Category	Observed/Expected Results	NPA	95% CI
MDx-Chex for BCN Negative Control 1 and Control 2	120/120	100%	97% - 100%

The results support the repeatability of the MDx-Chex for BCN across three separately manufactured control lots when used with the Luminex BCN panels on the LIAISON PLEX system.

3. Lot-to-Lot Reproducibility

A lot-to-lot reproducibility study assessed the performance of the MDx-Chex for BCN across three lots. Ten Control 1 and 10 Control 2 tubes were tested per lot, for three lots, using one lot of LIAISON PLEX BCN testing cartridge lot, for a total of 60 replicates (30 per lot per control type). Samples were prepared per the control Instructions for Use (IFU) prior to testing. The study resulted in 100% PPA and 100% NPA for both Control 1 and Control 2 MDx-Chex for BCN, as shown in Table 6 and Table 7 below.

**Table 6. MDx-Chex for BCN: Positive Percent Agreement Lot-to-Lot Reproducibility Summary**

Category	MDx-Chex for BC-GN	Observed/Expected Results	PPA	95% CI
MDx-Chex for BCN Positive Control 1 and Control 2	5202	20/20	100%	83% – 100%
	5209	20/20	100%	83% – 100%
	5223	20/20	100%	83% – 100%

**Table 7. MDx-Chex for BCN: Negative Percent Agreement Lot-to-Lot Reproducibility Summary**

Category	MDx-Chex for BC-GN	Observed/Expected Results	NPA	95% CI
MDx-Chex for BCN Negative Control 1 and Control 2	5202	20/20	100%	83% – 100%
	5209	20/20	100%	83% – 100%
	5223	20/20	100%	83% – 100%

The results support lot-to-lot reproducibility of the MDx-Chex for BCN across three separately manufactured lots when used with the LIAISON PLEX BCN panel.

4. Linearity:

Not applicable

5. Analytical Specificity/Interference:

Not applicable

6. Detection Limit and Assay Reportable Range:

Not applicable

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

*a. Closed vial Stability*

A closed-vial stability study was conducted using three lots of MDx-Chex for BCN with the LIAISON PLEX BCN using the LIAISON PLEX system. Twenty Control 1 and 20 Control 2 samples representing three different lots of MDx-Chex for BCN were stored at room (25 °C) and refrigerated temperatures (2 °C) and collected at different timepoints for testing. Samples were tested at day zero (ship date) and at day 75 for each lot and storage condition. Samples were prepared and analyzed on the LIAISON PLEX BCN system per MDx-Chex for BCN Instructions for Use. The results of the closed vial stability testing are presented in Tables 8 and 9 below.

**Table 8. Closed-vial stability of MDx-Chex for BCN Control 1 and Control 2 - Positive Percent Agreement**

	Storage Temperature	# Lot	Observed/Expected Results	PPA	95% Confidence Interval
Day 0	NA	5202	39/40*	98%	87% - 100%
		5209	40/40	100%	91% - 100%
		5223	39/40*	98%	87% - 100%
Day 75 <sup>+</sup>	2 - 8°C	5202	40/40	100%	91% - 100%
		5209	40/40	100%	91% - 100%
		5223	40/40	100%	91% - 100%
	20 - 25°C	5202	40/40	100%	91% - 100%
		5209	40/40	100%	91% - 100%
		5223	40/40	100%	91% - 100%

<sup>+</sup> Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (Control 1: 82 days, Control 2: 83 Days), Lot 5209 (Control 1: 80 days, Control 2: 83 Days), Lot 5223 (Control 1: 84 days, Control 2: 85 Days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (Control 1: 82 days, Control 2: 83 Days), Lot 5209 (Control 1: 83 days, Control 2: 84 Days), Lot 5223 (Control 1: 85 days, Control 2: 88 Days).

\* One MDx-Chex for BCN Control 1 from Lot 5202 and one MDx-Chex for BCN Control 1 from Lot 5223 produced unexpected results.

**Table 9. Closed-vial stability of MDx-Chex for BCN Control 1 and Control 2 - Negative Percent Agreement**

	Storage Temperature	# Lot	Observed/Expected Results	NPA	95% Confidence Interval
Day 0	NA	5202	40/40	100%	91% - 100%
		5209	40/40	100%	91% - 100%
		5223	40/40	100%	91% - 100%
Day 75	2 - 8°C	5202	40/40	100%	91% - 100%
		5209	40/40	100%	91% - 100%
		5223	40/40	100%	91% - 100%
	20 - 25°C	5202	40/40	100%	91% - 100%
		5209	40/40	100%	91% - 100%
		5223	40/40	100%	91% - 100%

<sup>+</sup> Indicates that lots stored at 2-8°C were tested for at least 75 days; Lot 5202 (Control 1: 82 days, Control 2: 83 Days), Lot 5209 (Control 1: 80 days, Control 2: 83 Days), Lot 5223 (Control 1: 84 days, Control 2: 85 Days). Lots stored at 20-25°C were tested for at least 75 days; Lot 5202 (Control 1: 82 days, Control 2: 83 Days), Lot 5209 (Control 1: 83 days, Control 2: 84 Days), Lot 5223 (Control 1: 85 days, Control 2: 88 Days).

The data supports that MDx-Chex for BCN Control kit is stable for a minimum of 75 days for use with the LIAISON PLEX BCN panel, when stored at 2°C- 25°C.

*b. Shipping Stability*

A shipping stability study was performed to determine the stability of MDx-Chex for BCN during shipment. Twenty samples of each control type (Control 1 and Control 2) were prepared from one lot of the MDx-Chex for BCN and stored at both ends of the storage temperature recommendations (i.e., 2°C and 25°C). Control samples were then shipped under simulated winter and summer conditions for a period of five days (i.e., 120 hours). After the end of simulation period, the control samples were stored at the recommended temperatures, and data were then collected for each simulated shipping profile within the 75-day closed-vial stability testing period. Temperature stress conditions for summer and winter include a 120-hour exposure period with the following temperature profile, as presented in Table 10, below.

**Table 10. Temperature Stress conditions**

Intervals	Interval Time (h)	Summer		Winter	
		Initial Temperature	Final Temperature	Initial Temperature	Final Temperature
1	5	22	22	22	22
2	0	22	26	22	15
3	14	26	26	15	15
4	5.5	26	22	15	22
5	5.5	22	25	22	17
6	10	25	22	17	22
7	2	22	40	22	-10
8	7.5	40	29	-10	10
9	7.5	29	29	10	10
10	5	29	40	10	-10
11	9	40	26	-10	15
12	8.5	26	26	15	15
13	0	26	29	15	10
14	11.5	29	29	10	10
15	0	29	22	10	22
16	10	22	22	22	22
17	7.5	22	30	22	8
18	7.5	30	24	8	18
19	4	24	24	18	18

Samples at each storage temperature (2-8°C and 20-25°C) were exposed to winter and summer temperature extremes and then were stored back at each respective temperature for a week prior to being tested using LIAISON PLEX BCN panel. All results met the predefined acceptance criteria of PPA or NPA  $\geq 90\%$  and are presented in Table 11 and 12, below.

**Table 11. Shipping Study of MDx-Chex for BCN – Positive Percent Agreement**

Category	Storage Temperature <sup>1</sup>	Observed/Expected Results	PPA	95% CI
Summer	2-8°C	40/40	100%	91 – 100%
	20-25°C	40/40	100%	91 – 100%
Winter	2-8°C	39/40*	98%	87 – 100%
	20-25°C	40/40	100%	91 – 100%

<sup>1</sup> Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions and incubated back at each respective storage temperature prior to testing on the LIAISON PLEX system.

\* One Positive Control Level 1 had unexpected result.

**Table 12. Shipping Study of MDx-chex for BCN – Negative Percent Agreement**

Category	Storage Temperature <sup>1</sup>	Observed/Expected Results	PPA	95% CI
Summer	2-8°C	40/40	100%	91 – 100%
	20-25°C	40/40	100%	91 – 100%
Winter	2-8°C	40/40	100%	91 – 100%
	20-25°C	40/40	100%	91 – 100%

<sup>1</sup> Samples were stored at each respective temperature prior to exposure to simulated summer or winter conditions and incubated back at each respective storage temperature prior to testing on the LIAISON PLEX system.

Results demonstrate the MDx-Chex for BCN control kit is stable after exposure to summer and winter shipping temperature conditions.

8. Assay Cut-Off:

Not applicable

**B Comparison Studies:**

1. Method Comparison with Predicate Device:

Not applicable

2. Matrix Comparison:

The matrix of MDx-Chex for BCN contains stabilized blood components (erythrocytes and leukocytes) as well as components found in blood culture media. Since the matrix is not identical to that of the routine LIAISON PLEX BCN assay sample, blood culture media, a study was conducted to evaluate the effect of the matrix on the assay.

To demonstrate that the simulated blood culture matrix does not impact performance of the LIAISON PLEX BCN assay, *Escherichia coli* ( $3.0 \times 10^8$  cells/mL final concentration) was spiked into MDx-Chex for BCN matrix as well as into BD BACTEC Plus Aerobic/F culture medium supplemented with negative whole blood to simulate a clinical sample. These samples were then tested in triplicate using the LIAISON PLEX BCN assay. Three replicates of each simulated

matrix with no spike-in organism were also tested to serve as negative controls. The results presented in Table 13 and Table 14 showed PPA and NPA of 100%, respectively.

**Table 13. Matrix Equivalency Study Results for Control and Clinical Matrix Spiked with *E. coli***

Matrix type	Expected/Tested	PPA	95% CI
MDx-Chex for BCN matrix + <i>E. coli</i>	3/3	100%	29% - 100%
Clinical Matrix + <i>E. coli</i>	3/3	100%	29% - 100%

**Table 14. Matrix Equivalency Study Results for Unspiked Control and Clinical Matrix**

Matrix type	Expected/Tested	PPA	95% CI
MDx-Chex for Blood Culture GN matrix	3/3	100%	29% - 100%
Clinical Matrix	3/3	100%	29% - 100%

The results demonstrate that MDx-Chex for BCN matrix has no effect on target detection (no inhibition and/or false negative results) when tested with the LIAISON PLEX BCN panel.

**C Clinical Studies:**

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Clinical Cut-Off:

Not applicable

4. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

**D Expected Values/Reference Range:**

MDx-Chex for BCN is a qualitative control and the expected results are listed in Table 15, below.

**Table 15. Bacterial Pathogens and Antimicrobial Resistance Genes Detected by MDx-Chex for BCN Control Types**

<b>Gram-Negative Bacteria*</b>		
<b>Target</b>	<b>Control 1</b>	<b>Control 2</b>
Enterobacteriaceae/Morganellaceae	Not Detected	Detected
<i>Acinetobacter</i> spp.	Detected	Not Detected
<i>Acinetobacter baumannii</i>	Detected	Not Detected
<i>Citrobacter</i> spp.	Not Detected	Detected
<i>Enterobacter</i> spp.	Not Detected	Detected
<i>Escherichia coli</i>	Not Detected	Detected
<i>Haemophilus influenzae</i>	Detected	Not Detected
<i>Klebsiella oxytoca</i>	Not Detected	Detected
<i>Klebsiella pneumoniae</i>	Not Detected	Detected
<i>Klebsiella variicola</i>	Not Detected	Detected
<i>Morganella morganii</i>	Not Detected	Detected
<i>Neisseria meningitidis</i>	Detected	Not Detected
<i>Proteus</i> spp.	Not Detected	Detected
<i>Pseudomonas</i> spp.	Detected	Not Detected
<i>Pseudomonas aeruginosa</i>	Detected	Not Detected
<i>Salmonella</i> spp.	Not Detected	Detected
<i>Serratia marcescens</i>	Not Detected	Detected
<i>Stenotrophomonas maltophilia</i>	Detected	Not Detected
<b>Antimicrobial Resistance Genes*</b>		
<b>Gene</b>	<b>Control 1</b>	<b>Control 2</b>
CTX-M	Not Detected	Detected
IMP	Not Detected	Detected
KPC	Detected	Not Detected
MCR	Not Detected	Detected
NDM	Detected	Not Detected
OXA	Not Detected	Detected
SME	Not Reviewed	Detected
VIM	Detected	Not Detected

**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.