510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K213236

B Applicant

GenMark Diagnostics, Incorporated

C Proprietary and Established Names

ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel

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

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to modify the ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel for use on the GenMark ePlex Instrument to include the detection of nucleic acids from additional strains of *E. coli, Citrobacter, Enterococcus,* and *P. aeruginosa*.

B Measurand:

Nucleic acid sequences from the following gram negative bacteria, gram positive bacteria, fungi and antibiotic resistance markers: *Acinetobacter baumannii*, *Bacteroides fragilis*, *Citrobacter*, *Cronobacter sakazakii*, *Enterobacter cloacae* complex, *Enterobacter* (non-*cloacae* complex), *Escherichia coli*, *Fusobacterium necrophorum*, *Fusobacterium nucleatum*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae* group, *Morganella morganii*, *Neisseria meningitidis*, *Proteus*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Salmonella*, *Serratia*,

Serratia marcescens, *Stenotrophomonas maltophilia*, CTX-M, IMP, KPC, NDM, OXA, and VIM, Pan Gram-Positive, Pan *Candida*

C Type of Test:

A multiplexed nucleic acid test intended for use with the GenMark ePlex instrument for the simultaneous qualitative in vitro detection and identification of multiple bacterial nucleic acids from positive blood culture specimens.

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) for Use:
The GenMark ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel is a qualitative nucleic acid multiplex *in vitro* diagnostic test intended for use on GenMark's ePlex Instrument for simultaneous qualitative detection and identification of multiple potentially pathogenic gram-negative bacterial organisms and, select determinants associated with antimicrobial resistance in positive blood culture. In addition, the ePlex BCID-GN Panel is capable of detecting, several gram-positive bacteria (Pan Gram-Positive assay) and several *Candida* species (Pan *Candida* assay) in positive blood culture. The ePlex BCID-GN test is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system and which contain gram-negative organism.

The following bacterial organisms and genes associated with antibiotic resistance are identified using the ePlex BCID-GN Panel: *Acinetobacter baumannii, Bacteroides fragilis, Citrobacter, Cronobacter sakazakii, Enterobacter cloacae complex, Enterobacter (non-cloacae complex), Escherichia coli, Fusobacterium necrophorum, Fusobacterium nucleatum, Haemophilus influenzae, Klebsiella oxytoca, Klebsiella pneumoniae group, Morganella morganii, Neisseria meningitidis, Proteus, Proteus mirabilis, Pseudomonas aeruginosa, Salmonella, Serratia, Serratia marcescens, Stenotrophomonas maltophilia*, CTX-M (*bla*CTX-M), IMP (*bla*IMP) , KPC (*bla*KPC) , NDM (*bla*NDM), OXA (*bla*OXA) (OXA-23 and OXA-48 groups only), and VIM (*bla*VIM).

The ePlex BCID-GN panel contains assays for the detection of genetic determinants associated with resistance to antimicrobial agents including CTX-M(*bla*CTX-M), which is associated with resistance to extended spectrum beta-lactamase (ESBL)-mediated resistance to penicillins, cephalosporins and monobactams, as well as OXA (*bla*OXA) (OXA-23 and OXA-48 groups only), KPC (*bla*KPC), and metallo-beta-lactamases IMP (*bla*IMP), VIM (*bla*VIM), and NDM (*bla*NDM), which is associated with carbapenemase-mediated resistance. The antimicrobial resistance gene detected may or may not be associated with the agent responsible for disease. Negative results for these select antimicrobial resistance assays do not indicate susceptibility, as there are multiple mechanisms of resistance in gram-negative bacteria.

The ePlex BCID-GN Panel also contains targets designed to detect a broad range of organisms with a potentially misleading Gram stain result or organisms that may be missed by Gram staining altogether, for example in the case of co-infections. These include a broad Pan Gram-Positive assay (which is designed to detect *Bacillus cereus* group, *Bacillus subtilis* group,

Enterococcus, *Staphylococcus*, and *Streptococcus*), as well as a Pan Candida assay, which is designed to detect four *Candida* species: *Candida albicans*, *Candida glabrata*, *Candida krusei*, and *Candida parapsilosis*.

The detection and identification of specific bacterial and fungal nucleic acids from individuals exhibiting signs and/or symptoms of bloodstream infection aids in the diagnosis of bloodstream infection when used in conjunction with other clinical information. The results from the ePlex BCID-GN Panel are intended to be interpreted in conjunction with Gram stain results and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

Negative results in the setting of a suspected bloodstream infection may be due to infection with pathogens that are not detected by this test. Positive results do not rule out co-infection with other organisms; the organism(s) detected by the ePlex BCID-GN Panel may not be the definite cause of disease. Additional laboratory testing (e.g. sub-culturing of positive blood cultures for identification of organisms not detected by ePlex BCID-GN Panel and for susceptibility testing, differentiation of mixed growth, and association of antimicrobial resistance marker genes to a specific organism) and clinical presentation must be taken into consideration in the final diagnosis of bloodstream infection.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

See K182619.

D Special Instrument Requirements:

GenMark ePlex Instrument and Software

IV Device/System Characteristics:

A Device Description:
See K182619 for additional details. The ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel is designed for use with the GenMark ePlex Instrument. The original BCID-GN Panel was cleared for identification of microorganisms and resistance markers from positive blood cultures in K182619. The modified BCID-GN panel adds primers and/or probes to improve inclusivity of four assays in the original panel: *E.coli*, *Pseudomonas aeruginosa*, *Citrobacter* and *Enterococcus*. The Panel is contained on a consumable cartridge which consists of a printed circuit board (PCB) surface electrodes. This single use cartridge incorporates digital microfluidics and eSensor technology to automate all assay steps. The cartridge chamber contains immiscible fluid to facilitate sample transport and contains reagent droplets for sample processing.

Nucleic acid extraction from whole blood samples occurs within the cartridge via cell lysis, nucleic acid capture onto magnetic beads, and release for amplification. The nucleic acid extraction is processed through microfluidic liquid handling. Once the nucleic acid targets are captured and inhibitors are washed away, the magnetic particles are delivered to the electrowetting environment on the PCB and the targets are eluted from the particles and amplified by RT-PCR.

After amplification, the double-stranded PCR amplicons are digested with exonuclease to generate single-stranded DNA suitable for hybridization. During hybridization, the single-stranded target DNA binds to a complementary, single-stranded capture probe immobilized on the working gold electrode surface. Single-stranded signal probes (labeled with electrochemically active ferrocenes) bind to specific target sequence / region adjacent to the capture probe. Simultaneous hybridization of target to signal probes and capture probe is detected by alternating current voltammetry (ACV). Each working electrode on the array contains specific capture probes, and sequential analysis of each electrode allows detection of multiple analyte targets.

A summary of microorganisms and resistance markers detected by the ePlex BCID-GN Panel are presented in Table 1:

Table 1: ePlex BCID-GN Panel, organism and resistance marker targets

Bacterial Targets	
Acinetobacter baumanii	*Klebsiella pneumonia group*
Bacteroides fragilis	*Morganella morganii*
Citrobacter	*Neisseria meningitidis*
Cronobacter sakazakii	*Proteus*
Enterobacter cloacae complex	*Proteus mirabilis*
Enterobacter (non-cloacae complex)	*Pseudomonas aeruginosa*
Escherichia coli	*Salmonella*
Fusobacterium necrophorum	*Serratia*
Fusobacterium nucleatum	*Serratia marcescens*
Haemophilus influenzae	*Stenotrophomonas maltophilia*
Klebsiella oxytoca	
Antimicrobial Resistance Markers	
CTX-M (*bla*CTX-M)	NDM (*bla*NDM)
IMP (*bla*IMP)	OXA (*bla*OXA)
KPC (*bla*KPC)	VIM (*bla*VIM)
Pan Targets	
Pan Gram-Positive	*Pan Candida*

Materials provided
ePlex Blood Culture Identification Gram-Negative Panel kit containing 12 individual test cartridges. Storage is at 2-8°C.

Materials needed but not provided
Equipment

- GenMark ePlex instrument and software
- Pipettes calibrated to deliver 50 µL
- Printer (optional)

B Principle of Operation:
See K182619 for additional details. The test is performed directly on blood culture samples identified as positive by continuous monitoring blood culture system that demonstrates the presence of organisms as confirmed by Gram stain. After the sample is loaded onto the single

use ePlex cartridge, no further operator intervention is necessary, and the following automated procedures occur inside the cartridge. Nucleic acids are extracted and purified via magnetic solid phase extraction. For each of the BCID-GN Panel analytes, there are one or more forward or reverse primer pairs. PCR amplification of DNA targets occurs in eight reaction mixes or drops. After amplification double stranded DNA is digested with lambda exonuclease to generate single stranded DNA, to which ferrocene-labeled signal probes and gold electrode-bound capture probes hybridize. The presence of each target is determined by voltammetry which generates specific electrical signals from ferrocene-labeled signal probe which is measured by gold electrodes. Sequential analysis of each electrode allows detection of multiple analyte targets. The ePlex Instrument measures and interprets this electrical output to determine the results for each target on the BCID-GN Panel (Detected or Not Detected).

V Substantial Equivalence Information:

A Predicate Device Name(s):
ePlex Blood Culture Identification Gram Negative (BCID-GN) Panel

B Predicate 510(k) Number(s):
K182619

C Comparison with Predicate(s):

Item:	**Predicate Device** K182619	**Device** K213236
Device Trade Name	ePlex BCID-GN Panel	Same
Manufacturer	GenMark Diagnostics, Inc.	Same
General Device Characteristic Similarities		
Intended Use	The ePlex Blood Culture Identification Gram-Negative (BCID-GN) Panel is a qualitative nucleic acid multiplex in vitro diagnostic test intended for use on GenMark's ePlex instrument for simultaneous detection and identification of multiple potentially pathogenic gram negative bacterial organisms and select determinants of antimicrobial resistance in positive blood culture. In addition, the ePlex Panel is capable of detecting several gram-positive bacteria (Pan Gram-Positive assay), and several Candida species (Pan Candida assay). The ePlex BCID-GN Panel is performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as confirmed by Gram stain.	Same

Item:	Predicate Device K182619	Device K213236
Resistance Genes Detected	CTX-M, IMP, KPC, NDM, OXA and VIM	Same
Specimen Type	Blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms (Gram-positive, Gram-negative, yeasts) as confirmed by Gram stain	Same
Chemistry	Reagents on cartridge include: sample lysis and nucleic acid extraction, PCR amplification and hybridization-based electrochemical detection	Same
Hardware	GenMark ePlex Instrument & Single Use Cartridge	Same
Software	GenMark ePlex System Software GenMark ePlex BCID-GN Panel Software	Same
General Device Characteristic Differences		
Organisms Detected	*Acinetobacter baumannii, Bacteroides fragilis, Citrobacter, Cronobacter sakazakii, Enterobacter cloacae* complex*, Enterobacter (*non-cloacae complex)*, Escherichia coli, Fusobacterium necrophorum, Fusobacterium nucleatum, Haemophilus influenzae, Klebsiella pneumoniae, Klebsiella oxytoca, Morganella morganii, Neisseria meningitidis, Proteus, Proteus mirabilis, Pseudomonas aeruginosa, Salmonella, Serratia, Serratia marcescens, Stenotrophomonas maltophilia,* Pan Gram-Positive (selected organisms), Pan Candida (selected species)	Additional strains detected: *H. influenzae* (ATCC33930) *N. meningitidis* (NCTC10026) *E. coli* (JHU01-D80401147) *P. aeruginosa* (SDx071)

VI Standards/Guidance Documents Referenced:

- Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures
- CLSI MM17-A, Vol. 9, Verification and Validation of Multiplex Nucleic Acid Assays
- CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline-Second Edition
- CLSI EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition

- CLSP EP-25A Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Linearity:
   Not applicable.

2. Analytical Specificity/Interference:

   Analytical Specificity/Cross-reactivity:
   Analytical specificity of all oligonucleotides in the original ePlex BCID-GN Panel was evaluated previously (refer to K182619). An *in silico* analysis was conducted to evaluate off-panel and on-panel targets for potential cross-reactivity with the newly added primers/probes.

   A BLASTN search for the amplicon sequence matching newly added primers and/or probes while filtering out the correctly identified species (*P. aeruginosa*, *E. coli*, *Citrobacter* or *Enterococcus)* was performed. Results for organisms that are predicted to generate false positive results with the ePlex BCID-GN Panel are presented in Table 2.

Table 2: Cross-reactivity with new oligonucleotides, *in silico* analysis

ePlex BCID-GN target	Organism	No. of Sequences	Predicted Cross-reactive Sequences (%)
P. aeruginosa	None	0	0%
E.coli	*Shigella flexneri*	63	100%
	Shigella sonnei	44	100%
	Shigella boydii	26	100%
	Shigella dysenteriae	29	100%
	unclassified Shigella	1	100%
	unclassified Escherichia	3	100%
	Salmonella sp. HNK130	1	100%
	Salmonella sp. S13	1	100%
	Enterobacter hormaechei strain RHBSTW-00218	1	100%
Citrobacter	*E. coli* strain Colony214	1	100%
Enterococcus	*Tetragenococcus halophilus*	6	0%
	Lactococcus lactis	1	100%
	Lactobacilus sp. Koumiss	1	100%

3. Assay Reportable Range:

   Not Applicable

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

See K182619.

5. Detection Limit:

The limit of detection (LoD) for each target on the ePlex BCID-GN Panel was determined previously (refer to K182619).

For the new target strains that were not tested with the original panel (*E.coli* JHU01-D80401147, *P. aeruginosa* SDx071, *H. influenzae* ATCC33930, and *N. meningitidis* NCTC10026), LoD was determined using samples prepared in negative blood culture matrix and tested with the ePlex BCID-GN Panel. Organisms were pooled together and serially diluted to create 11 organism mixes containing two organisms in negative blood culture matrix. At least ten replicates were tested at four dilutions and the lowest concentration that resulted in ≥95% detection was selected as the estimated LoD. A minimum of 20 replicates per organism mix were tested to confirm the final LoD for each assay target. The limit of detection was defined as the lowest concentration at which each target is detected at least 95% of the time. Results from the study demonstrated that all targets were detected in ≥ 95% of tested replicates at ≤1 x 10^8 CFU/mL (see Table 3).

Table 3: LoD results summary for additional strains

Organism	LoD Concentration (CFU/ml)
H. influenzae ATCC33930	1 x 10^4
N. meningitidis NCTC10026	1 x 10^4
E. coli JHU01-D80401147	1 x 10^7
P. aeruginosa SDx071	1 x 10^5

Additional wet testing was conducted to assess the impact of the newly incorporated primers and probes on the LoD for the organism targets on the BCID-GN Panel. LoD verification testing was conducted to evaluate the original organism targets of the modified PCR mixes: *Citrobacter sp., E. coli, P. mirabilis, A. baumannii, Serratia sp., Enterococcus sp., P. aeruginosa, H. influenzae, N. meningitidis, M. morganii, K. pneumoniae, E. faecalis.* Panel targets were tested in twenty replicates each of at least two different strains per target organisms at the LoD concentration (CFU/mL) previously determined for the BCID-GN panel (refer to K182619). Two strains from the original study were not available for verification of LoD and were replaced with new strains: *H. influenzae* ATCC33930 (replacing ATCC19418 evaluated with the original BCID-GN panel), *N. meningitidis* NCTC10026 (replacing ATCC13102 evaluated with the original BCID-GN panel). All organisms were detected in ≥ 95% of tested replicates at ≤1 x 10^8 CFU/mL with the modified panel. The results are shown in Table 4.

Table 4: LoD verification results summary

Target	Strain	LoD Concentration (CFU/ml)
Acinetobacter baumannii	NCTC13421	1x10^6
	NCTC13304	1x10^6

Target	Strain	LoD Concentration (CFU/ml)
Citrobacter	NCTC9750	$1x10^6$
	ATCC27156	$1x10^6$
E. coli	NCTC13441	$1x10^6$
	CDC#0118	$1x10^7$
	JHU01-D80401147*	$1x10^7$
H. influenzae	ATCC9006	$1x10^7$
	ATCC33930*	$1x10^4$
Klebsiella pneumoniae	CDC#0106	$1x10^6$
	CDC#0107	$1x10^6$
Morganella morganii	ATCC25829	$1x10^7$
	CDC#0133	$1x10^7$
Neisseria meningitidis	ATCC13090	$1x10^5$
	NCTC10026*	$1x10^4$
Proteus mirabilis	CDC#0159	$1x10^6$
	ATCC43071	$1x10^6$
Pseudomonas aeruginosa	CDC#0103	$1x10^6$
	NCTC13437	$1x10^6$
	SDx071*	$1x10^5$
Serratia	ATCC27592	$1x10^6$
	ATCC53858	$1x10^7$
Pan Gram positive	ATCC51575 (*E. faecalis*)	$1x10^5$
	ATCC31282 (*E. faecium*)	$1x10^7$
CTX	CDC#0107 (*Klebsiella pneumoniae*)	$1x10^6$
	NCTC13441 (*E. coli*)	$1x10^6$
IMP	CDC#0103 (*P. aeruginosa*)	$1x10^6$
KPC	CDC#0133 (*M. morganii*)	$1x10^7$
NDM	CDC#0159 (*P. mirabilis*)	$1x10^6$
OXA-23	NCTC13421 (*A. baumannii*. OXA- 23)	$1x10^6$
	NCTC13304 (*A. baumannii,* OXA-27)	$1x10^7$
OXA-48	CDC#0160 (*K. pneumoniae*, OXA-48)	$1x10^6$

*LoD established for additional target strains using a range finding study and confirmation of detection ≥95% of the time.

Additional evaluations were performed to demonstrate that the incorporation of the oligonucleotides in two PCR reaction mixes do not adversely impact the performance of the assay targets in other PCR mixes on the BCID-GN. Specifically, performance was assessed for several targets using a multianalyte test mix that contained one representative target from each of the eight multiplex PCR mixes in the previously cleared BCID-GN panel. At least 20 replicates per target were tested at the following three concentrations: HIGH (target levels 10X above LoD), MED (target levels near the LoD) and LOW (target levels 10X below the LoD).

The study acceptance criteria were as follows: detection of ≥95% replicates at HIGH and MED concentrations and detection of ≤95% replicates at the LOW concentration. Results from the study are shown in Table 5.

Table 5: Detection rates of all targets at indicated concentrations

Organism	Test concentration CFU/mL (% detected)		
	HIGH	MED	LOW
E. coli	$1x10^7$ (100%)	$1x10^6$ (100%)	$1x10^5$ (70%)
CTX-M	$1x10^7$ (100%)	$1x10^6$ (100%)	$1x10^5$ (80%)
S. marcescens	$1x10^6$ (100%)	$1x10^5$ (100%)	1x104 (60%)
S. aureus	$2x10^6$ (100%)	$2x10^5$ (100%)	$2x10^4$ (20%)
H. influenzae	$6x10^6$ (100%)	$6x10^5$ (100%)	$6x10^4$ (80%)
K.a oxytoca	$1x10^7$ (100%)	$1x10^6$ (95%)	$1x10^5$ (25%)
KPC	$1x10^7$ (100%)	$1x10^6$ (100%)	$1x10^5$ (80%)
C. albicans[*]	$1x10^6$ * (100%)	$1x10^6$ (95%)	$1x10^5$ (80%)

* The maximum concentration possible for *C. albicans* is $1x10^6$ CFU/mL, and this concentration represents both the bottle positive concentration and LoD concentration. Therefore, the same concentration was used for the HIGH and MED levels for this organism.

Analytical Reactivity/Inclusivity:
Inclusivity of all oligonucleotides in the original BCID-GN Panel was evaluated previously (refer to K182619). The performance of the modified ePlex BCID-GN Panel for the detection of strains targeted by the modified PCR mixes was evaluated in a clinical agreement study to support inclusivity. The study included testing with multiple unique clinical specimens and contrived specimens prepared from unique isolates targeted by the PCR mixes that were modified by the addition of new oligonucleotides. A total of 122 clinical samples collected from multiple sites and 138 individually contrived blood culture bottles were used. A minimum of ten unique clinical patient samples or strains were tested per target, with the exception of *Neisseria* and *H. influenzae* for which six and eight samples were evaluated, respectively. The results showed acceptable positive percent agreement (PPA) and negative percent agreement (NPA) of 95% or more for all targets. These results support the inclusivity of the modified panel. See Table 7 below.

6. Assay Cut-Off:

   See K182619.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   Not applicable.

2. Matrix Comparison:
   Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

   Clinical validation of the BCID-GN Panel was established in a previous clinical study testing prospective, retrospective, and contrived specimens (refer to K182619). To evaluate the impact of new assay primers and probes, additional clinical and contrived specimens were tested as described below.

New oligonucleotides were added to PCR reaction mixes that include the following organism targets: *Acinetobacter baumannii*, *Citrobacter*, *Escherichia coli*, *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Morganella morganii*, *Neisseria meningitidis*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Serratia,* Pan-Gram positive *Enterococcus faecalis,* and Pan-Gram positive *Enterococcus.* The new oligonucleotides were added to detect additional strains of *E. coli* (JHU01-D80401147) and *Pseudomonas aeruginosa* (SDx071) and to increase detection of *Citrobacter* and *Enterococcus* strains.

Additional testing was conducted to demonstrate that the modified ePlex BCID-GN Panel detects the targeted strains not detected by the original ePlex BCID-GN Panel and to verify that the clinical performance of the modified ePlex BCID-GN Panel for other organism targets is not adversely impacted by the introduction of the additional oligonucleotides. The performance of the modified device was evaluated by testing a total of 20 samples for each organism target that included a combination of unique clinical specimens and contrived blood culture specimens as indicated in Table 6 and Table 7. The identity of strain *E. coli* JHU01-D80401147 was confirmed by PCR and sequencing. The other organism targets evaluated in the study were obtained from previously collected frozen samples. Equivalence between fresh and frozen specimens on the ePlex BCID-GN Panel was previously established in K182619.

Contrived specimens were prepared by independently inoculating low concentrations of organism into blood culture bottles and incubating on a continuously monitoring blood culture system until the bottle was identified as positive. The inoculated concentrations (CFU/mL) were at least four logs below the load observed at bottle positivity. The strains used to prepare contrived specimens are shown in Table 6.

Table 6: Contrived specimen study, organisms evaluated

Target	Strain	Independent Contrived Specimens Tested
Acinetobacter baumannii	ATCCBAA-747	3
	ATCCBAA-1605	3
	ATCCBAA-2093	1
	ATCC19606	1
	AR-0033	2
	NCTC13302	1
	NCTC13303	2
	NCTC13304	2
	NCTC13305	2
	NCTC13423	3
Citrobacter	ATCC8090	1
	ATCC27156	2
	ATCC29935	1
	ATCC43864	1
	ATCC51113	2
	ATCC51493	1
	CDC AR-0116	1
	JMI2047	2
	NCTC8581	1
	NCTC9750	1
Haemophilus influenzae	ATCC10211	3
	ATCC43065	3

Target	Strain	Independent Contrived Specimens Tested
	ATCC49144	4
	NCTC8468	3
	NCTC12699	4
Klebsiella pneumoniae	CDC AR-140	1
Morganella morganii	CDC AR-0057	2
	CDCAR-0133	2
	GM148-200	3
	GM148-204	3
	GM148-205	2
	GM148-206	2
	GM148-209	2
Neisseria meningitidis	ATCC13077	4
	ATCC13090	4
	ATCC13102	4
	ATCC13113	3
	ATCC35561	4
	NCTC10026	1
Proteus mirabilis	CDC AR-0155	4
	CDC AR-0159	5
Pseudomonas aeruginosa	CDC AR-0054	3
	CDC AR-0092	2
	CDC AR-100	1
	CDC AR-103	3
	CDC AR-108	1
	NCTC13437	2
Serratia	ATCC8100	1
	ATCC13880	1
	ATCC14460	1
	ATCC14756	1
	ATCC29025	1
	ATCC33105	1
	ATCC43861	1
	ATCC43862	1
	ATCC53858	1
	JMI10244	1
	LMC-DR23105	1
Pan-GP (*Enterococcus faecalis)*	ATCCBAA-236	1
	ATCC700802	1
Pan-GP (*Enterococcus*)	ATCCBAA-2316	1
	ATCCBAA-2318	1
	ATCCBAA-2319	1
	ATCCBAA-2320	1
	ATCC10541	1
	ATCC49996	1
	ATCC51559	1
	ATCC51858	1
	ATCC700221	2
	ATCC700425	1
	LMC002867	1
	LMC003921	1
	LMC032261	1
	LMC055971	1
	LMC103676	1
	LMC104266	1

Overall, two hundred forty negative clinical samples were tested for NPA determination. These samples were collected previously as part of the clinical agreement study for the original device (refer to K182619 for details).

A summary of the modified ePlex BCID-GN Panel performance for each organism target for clinical and contrived specimens is shown in Table 7. Performance is based on comparison of ePlex BCID-GN Panel results to results from comparator methods for clinical specimens and based on comparison of ePlex BCID-GN Panel results to the expected result for contrived specimens.

Table 7: Clinical performance summary

Target	Specimen Type	Sensitivity/PPA	Specificity/NPA
		TP/TP+FN (%)	TN/TN+FP (%)
A. baumanii	Contrived	20/20 (100)	---
	Clinical	---	239/240 (99.6)*
Citrobacter	Contrived	13/13(100)	---
	Clinical	7/7 (100)	240/240 (100)
E. coli	Contrived	---	---
	Clinical	40/40 (100)	240/240 (100)
H. influenzae	Contrived	17/17 (100)	---
	Clinical	3/3 (100)	240/240 (100)
K. pneumoniae	Contrived	1/1 (100)	---
	Clinical	19/19 (100)	240/240 (100)
M. morganii	Contrived	16/16(100)	---
	Clinical	4/4 (100)	240/240 (100)
N. meningitidis	Contrived	20/20 (100)	---
	Clinical	---	240/240 (100)
P. mirabilis	Contrived	9/9 (100)	---
	Clinical	11/11 (100)	239/240 (99.6)*
P. aeruginosa	Contrived	12/12(100)	---
	Clinical	8/8 (100)	240/240 (100)
Serratia	Contrived	11/11(100)	---
	Clinical	9/9 (100)	240/240 (100)
Pan-GP (*Enterococcus faecalis*)	Contrived	2/2(100)	---
	Clinical	18/18 (100)	240/240 (100)
Pan-GP (*Enterococcus*)	Contrived	17/17(100)	---
	Clinical	3/3 (100)	240/240 (100)

* Root cause analysis of the false positive results indicate workflow contamination during preparation/loading of the samples.

2. Clinical Specificity:

See Clinical Sensitivity section above.

D Clinical Cut-Off:

Not Applicable.

E Expected Values/Reference Range:

For the expected values from a prospectively enrolled clinical study population, refer to K182619.

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.