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

A. 510(k) Number:

K163637

B. Purpose for Submission:

Addition of ceftazidime/avibactam to the BD Phoenix Gram Negative ID/AST and AST only Phoenix panels

C. Measurand:

Ceftazidime/avibactam 0.25/4 – 32/4 µg/mL

D. Type of Test:

Antimicrobial Susceptibility Test (Quantitative) colorimetric, oxidation-reduction, growth based

E. Applicant:

Becton, Dickinson and Company

F. Proprietary and Established Names:

BD Phoenix™ Automated Microbiology System- GN Ceftazidime/avibactam (0.25/4-32/4µg/mL)

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1645 – Short-Term Antimicrobial Susceptibility Test System

2. Classification:

   Class II

3. Product code:

   LON – System, Test, Automated, Antimicrobial Susceptibility, Short Incubation

4. Panel:

   83 Microbiology

H. Intended Use:

1. Intended use(s):

   The BD Phoenix Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of Gram Negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non-*Enterobacteriaceae*.

2. Indication(s) for use:

   The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram-negative aerobic and facultative anaerobic bacterial isolates from pure culture for *Enterobacteriaceae* and Non-*Enterobacteriaceae* and most Gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus*, *Enterococcus* and *Streptococcus*.

   Ceftazidime/avibactam has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA-approved package inserts for this antimicrobial agent.

   Active i*n vitro* and in Clinical Infections Against:
   Citrobacter freundii complex
   Citrobacter koseri
   Escherichia coli
   Enterobacter aerogenes
   Enterobacter cloacae
   Klebsiella pneumoniae
   Klebsiella oxytoca
   Proteus spp.
   Pseudomonas aeruginosa

   Active *in vitro* but clinical significance is unknown:
   Morganella morganii
   Providencia stuartii
   Serratia marcescens

3. Special conditions for use statement(s):

For prescription use only

Limitations:

- *The ability of the Phoenix System to detect resistance in the following combination(s) is unknown because a sufficient number of resistant strains were not encountered at the time of comparative clinical testing:*
  Ceftazidime/avibactam *Isolates other than Klebsiella pneumoniae and Pseudomonas aeruginosa*

- *Ceftazidime/avibactam: Providencia stuartii - Due to the lack of an intermediate breakpoint, three out of four major errors which occurred for P. stuartii were within essential agreement when compared to the reference method. The adjusted error rate was 3.4%. Testing should be repeated using an alternative testing/reference method prior to reporting results for the drug with Providencia stuartii when the Phoenix MIC is 16/4 μg/mL.*

- *Enzyme group characterization was not available at the time of comparative testing, and therefore the performance of the BD Phoenix ceftazidime/avibactam is unknown for Pseudomonas aeruginosa in the presence AmpC, or lacking outer membrane porin (OprD).*

4. Special instrument requirements:

BD Phoenix Instrument and software (V5.83A or higher)
BD PhoenixSpec Nephelometer
BD Phoenix AP instrument

I. Device Description:

This submission is for a single drug in the gram negative ID/AST or AST only panel. The ID System was not reviewed.

The Phoenix AST method is a broth based microdilution test. The Phoenix panel is a sealed and self-inoculating molded polystyrene tray, with 136 micro-wells containing dried reagents. The ID/AST combination panel includes an ID side (51 wells) with dried substrates for bacterial identification and an AST side (85 wells). The AST panel contains a wide range of two-fold doubling dilution concentrations of antimicrobial agents and growth and fluorescent controls at appropriate well locations. The AST panel does not include wells for isolate identification.

The Phoenix System utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. The organism to be tested must be a pure culture and be preliminarily identified as gram positive or gram negative. Colonies are then

suspended in ID broth, and equated to a 0.5 McFarland suspension using a nephelometer device. A further dilution is made into AST broth (a cation-adjusted formulation of Mueller-Hinton broth containing 0.010% Tween 80), to which the redox-buffered oxidation-reduction AST indicator solution is added producing a blue color in the wells. The concentration of organisms in the final AST broth suspension is approximately 5 X 10^5 CFU/mL.

The Phoenix AST Broth is poured into the inoculation port of the AST panel and the inoculum flows into the panel, filling panel wells. Polyethylene caps are applied to seal the inoculation ports. An air admittance port is located in the panel lid to ensure adequate oxygen tension in the panel for the duration of the test. Inoculated panels are barcode scanned and loaded into the BD Phoenix Automated Microbiology System instrument where panels are continuously incubated at 35˚C ± 1˚C.

Continuous measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. The instrument takes readings every 20 minutes. Organisms growing in the presence of a given antimicrobial agent reduce the indicator (changing it to a pink color). This signals organism growth and resistance to that antimicrobial agent. Organisms killed or inhibited by the antimicrobial agent do not cause reduction of the indicator and therefore do not produce a color change. The Phoenix instrument reads and records the results of the antimicrobial tests contained in the panel and interprets the reactions (based on the organism identification) to give a minimal inhibitory concentration (MIC) value and category interpretations (susceptible, intermediate, resistant or not susceptible). AST results are available within 4 to 16 hours. This is an autoread result; no manual readings are possible with this system.

Additional comments concerning specific organism/antimicrobial combinations is provided from the software-driven "EXPERT" system, using rules derived from CLSI documentation.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VITEK 2 Gram Negative Doxycycline

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

   K121546

3. Comparison with predicate:

Table 1: Similarities and Differences of the BD Phoenix Ceftazidime/avibactam and the Predicate

Similarities		
Item	**Device** **BD Phoenix Automated Microbiology System (Ceftazidime/avibactam)**	**Predicate** **VITEK 2 Gram Negative Doxycycline (K121546)**
Intended Use	Determination of *in vitro* antimicrobial susceptibility testing of aerobic and facultative anaerobic Gram-negative and Gram-positive bacteria	Same
Source of Microorganisms for Testing	Bacterial colonies isolated from culture	Same
Incubation Time	Short-term (<16 hours)	Same
Results	MIC and interpretive criteria (i.e., susceptible, intermediate, resistant and non-susceptible)	Same
Technology	Automated growth-based detection	Same
Differences		
MIC Results Achieved	Antimicrobials in serial doubling dilutions	Computer assisted extrapolation of doubling dilutions
Technology	Automated growth detection enhanced by use of a redox indicator (colorimetric oxidation-reduction)	Automated growth detection using an attenuation of light measured by an optical scanner
Antimicrobial	Ceftazidime/avibactam	Doxycycline

K. Standard/Guidance Document Referenced (if applicable):

- CLSI M7-A10 "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically"
- CLSI M100-S26 "Performance Standards for Antimicrobial Susceptibility Testing"
- Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA

L. Test Principle:

The BD Phoenix Automated Microbiology System is a broth based microdilution method that utilizes a redox indicator (colorimetric oxidation-reduction) to enhance detection of organism growth. The MIC is determined by comparing growth in wells containing serial two-fold dilutions of an antibiotic to the growth in "growth control wells" that contain no antibiotic.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility testing was conducted at three clinical trial sites. Testing was performed using inocula prepared manually using the PhoenixSpec nephelometer and the automated BD Phoenix AP instrument. The mode MIC value was determined and the reproducibility was calculated based on MIC values falling within ± 1 dilution of the mode MIC value.

Fourteen organisms with on-scale ceftazidime/avibactam modal MIC values were provided to the testing sites by BD with isolate identification and expected MIC result blinded to the testers. Isolates were tested in triplicate on three separate days.

14 isolates x 3 replicates x 3 sites x 3 days= 378 data points

Results of the inter-site and intra-site reproducibility studies were acceptable and demonstrated best case and worst case results of greater than 95%. There were no off-scale MIC results. A summary of the reproducibility study performance is shown in Table 2 below.

Table 2: Summary of Reproducibility Studies

BD Phoenix Instrument Platform	Inoculation Method	Reproducibility
BD Phoenix	Phoenix AP Instrument	97.9% (370/378)
	Manual PhoenixSpec Nephelometer	99.2% (375/378)

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Testing of the FDA and CLSI recommended quality control (QC) strains, *E. coli*

ATCC 25922, *E. coli* ATCC 35218, *K. pneumoniae* ATCC 700603, and *P. aeruginosa* ATCC 27853 were performed each day of the challenge and clinical study testing with the reference method and with the BD Phoenix Systems. The inocula were standardized using both the Phoenix AP instrument and PhoenixSpec Nephelometer (manual). A sufficient number of tests were performed and all quality control results for the BD Phoenix fell within the acceptable ranges as per the FDA drug label, demonstrating that the BD Phoenix System can consistently produce quality control results in the recommended range for ceftazidime/avibactam. Results demonstrate that acceptable results were achieved >95% of the time by both Phoenix AP and manual inoculum preparation methods as shown in Table 3 below.

Table 3: Summary of Quality Control Results

ORGANISM	conc.[a] (µg/mL)	Reference	Inoculum Preparation	
			Manual (PhoenixSpec)	Phoenix AP
P. aeruginosa ATCC 27853 Expected Range: 0.5/4 – 4/4µg/mL	≤0.25			
	0.5			
	1	75		
	2	55	134	82
	4	1	2	
	8			
	16			
	32			
	>32			
E. coli ATCC 25922 Expected Range: 0.06/4 - 0.5/4µg/mL (Phoenix: ≤0.25/4- 0.5/4µg/mL)	≤0.25[c]	130	127	74
	0.5		7	11
	1			
	2			
	4			
	8			
	16			
	32			
	>32		1	
E. coli ATCC 35218 Expected Range: 0.03/4 – 0.12/4 µg/mL (Phoenix: ≤0.25/4µg/mL)	≤0.25[c]	130	133	81
	0.5		1	
	1	1		
	2			
	4			
	8			
	16			
	32			
	>32			

Table 3: Summary of Quality Control Results (continued)

ORGANISM	conc.[a] (µg/mL)	Reference	Inoculum Preparation	
			Manual (PhoenixSpec)	Phoenix AP
[redacted]				
K. pneumoniae ATCC 700603[b] Expected Range: 0.25/4 – 2/4 µg/mL (Phoenix: ≤0.25/4- 2/4µg/mL)	≤0.25[c]	3	1	
	0.5	118	56	23
	1	8	75	29
	2	1		
	4			
	8			
	16		1	
	32			
	>32			

[a] MIC for ceftazidime in the presence of a fixed concentration of 4 µg/mL of avibactam.
[b] *K. pneumoniae* ATCC 700603 should be tested against ceftazidime and avibactam and ceftazidime alone to confirm the activity of avibactam in the combination and to ensure that the plasmid encoding the beta-lactamase has not been lost in this strain. The acceptable range for ceftazidime alone is greater than16 µg/mL.
[c] The lowest dilution of the BD Phoenix Automated Microbiology System ceftazidime/avibactam MIC range is ≤0.25 µg/mL. Obtaining this value was considered as an indicator that the quality control test results were acceptable.

The expected range of *Pseudomonas aeruginosa* ATCC 27853 is 0.5/4 – 4/4µg/mL. All *P. aeruginosa* results were on-scale and within the MIC reporting range of Phoenix ceftazidime/avibactam. However, the Phoenix MIC reporting range is 0.25/4 to 32/4 µg/mL and does not provide results lower than 0.25/4 µg/mL to cover the expected range of *E. coli* ATCC 35218 (0.03/4 – 0.12/4), the lower end of the expected ranges for *E. coli* ATCC 25922 (0.06/4), and *K. pneumoniae* ATCC 700603 (0.25/4). A MIC value of ≤0.25/4 µg/mL indicated that the results for these three QC organisms were acceptable.

The footnote below is included in *Table 1*, *Quality Control Organisms and Expected Results* of the BD Phoenix ceftazidime/avibactam package insert.

- "*The lowest dilution of the BD Phoenix Automated Microbiology System ceftazidime/avibactam MIC range is ≤0.25/4 µg/mL. Obtaining this value was considered as an indicator that the quality control test results were acceptable.*"

In addition, *K. pneumoniae* ATCC 700603 is recommended to test against ceftazidime alone to ensure the presence of the plasmid encoding beta-lactamase when testing this beta-lactam/beta-lactamase inhibitor combination, ceftazidime/avibactam. The acceptable result for ceftazidime alone is greater than 16µg/mL. The footnote below is included in *Table 1*, *Quality Control Organisms and Expected Results* of the BD Phoenix ceftazidime/avibactam package insert.

- *"K. pneumoniae ATCC 700603 should be tested against ceftazidime and avibactam and ceftazidime alone to confirm the activity of avibactam in the combination and to ensure that the plasmid encoding the beta-lactamase has not been lost in this strain. The acceptable range for ceftazidime alone is greater than16 µg/mL."*

Growth Rate: Seven isolates failed to grow during the clinical study. The overall growth rate during the clinical studies was 99.5%.

Purity Check Plates**:** Purity check plates were inoculated from the standardized organism suspensions for both the Phoenix and reference methods. Any isolate that showed mixed growth on the purity check plate was considered noncompliant and not included in result analysis.

Inoculum Density Control: The PhoenixSpec Nephelometer was used to prepare the inocula for testing of the clinical, challenge, reproducibility and QC isolates. The same inoculum suspension was used for both the Phoenix System and the reference method testing. The BD Phoenix AP instrument was used to standardize the inocula for challenge, QC, and reproducibility isolates. Validation data for both the PhoenixSpec and the Phoenix AP instrument was provided and found to be acceptable.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The accuracy of results obtained with the Phoenix System was determined by comparison to the CLSI-recommended broth dilution method (reference method). Reference panels were prepared according to CLSI M07-A10 guidelines. In addition, specific to ceftazidime/avibactam, reference panels need to be read within 18 hours of incubation because of degradation of ceftazidime activity by 24 hours. During the comparative studies, the reference results were read after 16 to 18 hours of incubation. Sites performed testing on Gram negative isolates using Phoenix and reference panel formats appropriate for gram negative organisms. Antimicrobial

agents in the test and reference panels had identical dilution ranges which were appropriate for the interpretive breakpoints of the drug. Testing was performed using at least two different production lots of Phoenix panels, AST broth and AST indicator at each study site. A minimum of three different lots of the Phoenix panel were used across all sites for the entire study. Phoenix and reference panels were inoculated using the same organism suspension.

Growth in the Phoenix panels was determined from data recorded by the instrument. Performance was analyzed using FDA breakpoints for ceftazidime/avibactam, and results were compared to results obtained by the broth microdilution reference method based on the guidelines provided in the *Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems.*

A total of 1216 clinical isolates were tested at the three study sites and included both fresh and stock isolates. Stock isolates comprised 9.0% of total isolates tested. Clinical isolates tested included representatives of species listed in the FDA pharmaceutical drug label and were tested using inocula prepared by the PhoenixSpec nephelometer (manual method).

A total of 132 unique challenge isolates with expected results (expected MIC value of each isolate was the mode after testing with the reference broth dilution multiple times) were also supplied to the testing sites by the sponsor. Challenge isolates were obtained from BD's internal collection and from external laboratories. The challenge isolates were randomized and divided equally among the testing sites. Results obtained for Challenge isolates using the Phoenix System were compared to expected MIC results. Identification and expected results were masked to the study sites. The inocula for the challenge isolates were prepared using both the PhoenixSpec Nephelometer (manual method) and the Phoenix AP (automated method).

The performance evaluation summary of essential and categorical agreement results for clinical and challenge isolates with inocula prepared using the PhoenixSpec nephelometer (manual method) is shown in Table 4 below.

Table 4: Performance of BD Phoenix with Clinical and Challenge Isolates- Manual Inoculum Preparation‡

Ceftazidime/ avibactam	EA Total	EA N	EA %	Eval EA Total	Eval EA N	Eval EA %	CA N	CA %	#R	Maj	Vmj
	***Enterobacteriaceae* ≤8/4 (Susceptible), ≥16/4 (Resistant)**										
Clinical	1083	1061	98.0	110	100	90.9	1077	99.4	1	6	0
Challenge	108	107	99.1	32	32	100	108	100	12	0	0
Combined	1191	1168	98.1	142	132	93.0	1185	99.5	13	6	0
	***P. aeruginosa* ≤8/4 (Susceptible), ≥16/4 (Resistant)**										
Clinical	133	126	94.7	130	125	96.2	129	97.0	1	4	0
Challenge	24	24	100	17	17	100	24	100	9	0	0
Combined	157	150	95.5	147	142	96.6	153	97.5	10	4	0
	Enterobacteriaceae* + *P. aeruginosa										
Clinical	1216	1187	97.6	240	225	93.8	1206	99.2	2	10	0
Challenge	132	131	99.2	49	49	100	132	100	21	0	0
Total	1348	1318	97.8	289	274	94.8	1338	99.3	23	10	0

‡**EA** – Essential Agreement (+/- 1 doubling dilution)
CA – Category Agreement
EVAL – Evaluable isolates
R – Resistant isolates
Maj – Major discrepancies
Vmj – Very major discrepancies
NOTE: There are no minor discrepancy calculations due to lack of intermediate category for ceftazidime/avibactam

Essential Agreement (EA) occurs when there is agreement between the result of the reference method and that of BD Phoenix within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the BD Phoenix panel and the reference method. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the BD Phoenix result.

The Phoenix ceftazidime/avibactam performance met the acceptance criteria for *Enterobacteriaceae* and *Pseudomonas aeruginosa* with overall EA and CA greater than or equal to 90%. Due to lack of intermediate category, there are no minor discrepancy calculations for ceftazidime/avibactam. There were no very major discrepancies. The major (maj) discrepancy rate was 0.5% (6/1178) and 2.7% (4/147) for *Enterobacteriaceae* and *Pseudomonas aeruginosa* respectively. When stratified by organisms, a high maj discrepancy rate was observed with *Providencia stuartii.*

Providencia stuartii: There were four maj discrepancies (13.8%, 4/29) observed. Of the four maj discrepancies, three were at the reference breakpoints of 8µg/mL but within EA (i.e., resistant Phoenix MIC at 16µg/mL). Taking into consideration the three values within essential agreement, the maj discrepancy rate became 3.4% (1/29) for *P. stuartii.* The concern for major discrepancies is addressed in the limitations section:

> *"Ceftazidime/avibactam: Providencia stuartii - Due to the lack of an intermediate breakpoint, three out of four major errors which occurred for P. stuartii were within essential agreement when compared to the reference method. The adjusted error rate was 3.4%. Testing should be repeated using an alternative testing/reference method prior to reporting results for the drug with Providencia stuartii when the Phoenix MIC is 16/4µg/mL."*

Resistant Isolates: There were a total of 23 resistant isolates in the evaluation of ceftazidime/avibactam. However, ten isolates each were from *K. pneumoniae* and *P. aeruginosa*. A limitation of insufficient resistant isolates was included:

"*The ability of the Phoenix System to detect resistance in the following combination(s) is unknown because a sufficient number of resistant strains were not encountered at the time of comparative clinical testing:*
Ceftazidime/avibactam *Isolates other than Klebsiella pneumoniae and Pseudomonas aeruginosa"*

The challenge organisms were also tested using suspensions prepared by the Phoenix AP instrument. The comparison between manual (PhoenixSpec) method and Phoenix AP is shown in Table 5 below. The overall % EA and % CA consistently met the acceptance criteria of greater than or equal to 90%. There were no very major or major discrepancies with either inoculation method.

Table 5: Comparison of Inoculation Methods with Challenge Isolates

Ceftazidime/ avibactam	**EA Total**	**EA N**	**EA %**	**Eval EA Total**	**Eval EA N**	**Eval EA %**	**CA N**	**CA %**	**#R**	**Maj**	**Vmj**
	***Enterobacteriaceae* ≤8/4 (Susceptible), ≥16/4 (Resistant)**										
Manual (PhoenixSpec)	108	107	99.1	32	32	100	108	100	12	0	0
Phoenix AP	108	107	99.1	32	32	100	108	100	12	0	0
	***P. aeruginosa* ≤8/4 (Susceptible), ≥16/4 (Resistant)**										
Manual (PhoenixSpec)	24	24	100	17	17	100	24	100	9	0	0
Phoenix AP	24	24	100	17	17	100	24	100	9	0	0

MIC Trends:
The claimed *Enterobacteriaceae* and *Pseudomonas aeruginosa* organisms were also evaluated for trending. This trending calculation takes into account MIC values that are determined to be ≤1 and ≥1 doubling dilutions compared to the reference method irrespective whether the device MIC values are on-scale or not. The trending analysis is shown in Table 6.

Table 6: Trending Analysis of Evaluable Clinical and Challenge Isolates

Ceftazidime/avibactam 0.25/4 – 32/4 µg/mL	Total [a]	Difference in MIC as Compared to the CLSI Reference Method				
		≤2 dil. lower	1 dil. lower	Exact	1 dil. higher	≥2 dil. higher
(Enterobacteriaceae + P. aeruginosa)	460	7	43	160 (34.78%)	227	23
		50 (10.87%)[b] 95% CI (8.34% to 14.04%)			250 (54.35%)[b] 95% CI (49.78% to 58.85%	

[a] Total number of evaluable results for trending analysis

[b] Difference between isolates trending lower and isolates trending higher: -43.48 ; 95% CI (-48.64% to -37.91%)

A trend towards higher MIC was observed with claimed *Enterobacteriaceae* isolates and *P. aeruginosa* when compared to the CLSI broth microdilution reference method. This trending and the potential for occurrence of major discrepancies for ceftazidime/avibactam when testing clinical and challenge isolate results with the Phoenix ceftazidime/avibactam was addressed by adding the following footnote:

> "*BD Phoenix ceftazidime/avibactam MIC values tended to be in exact agreement or at least one doubling dilution higher when testing Enterobacteriaceae or P. aeruginosa compared to the reference broth micro-dilution."*

Enzyme Group Characterization/Resistance Markers Information

Enterobacteriaceae with beta-lactamases were included in the ceftazidime/avibactam comparative studies. They were AmpC (6), KPC (16), OXA (9), CTX-M (8), TEM (14), and SHV (8). The *Enterobacteriaceae* included *Citrobacter freundii, Enterobacter aerogenes, Enterobacter cloacae, E. coli, Klebsiella oxytoca, Klebsiella pneumoniae* and *Proteus mirabilis.*

The study indicated that when beta-lactamases were known, eight *K. pneumoniae* demonstrated ceftazidime/avibactam resistance (>32/4µg/mL) in the presence of AmpC, KPC, OXA, CTX-M, TEM, and/or SHV. However, twelve *K. pneumoniae* showed susceptibility to ceftazidime/avibactam with MIC values range from ≤0.25/4 to 4/4µg/mL in the presence of KPC, OXA, CTX-M, TEM, and/or SHV.

In addition, seven metallo-beta-lactamase producing *Pseudomonas aeruginosa* were tested and demonstrated resistance (≥32/4µg/mL) to ceftazidime/avibactam. The following limitation was added to the ceftazidime/avibactam labeling regarding other resistance markers and enzyme characterization:

> "*Enzyme group characterization was not available at the time of comparative testing, and therefore the performance of the BD Phoenix ceftazidime/avibactam is unknown for Pseudomonas aeruginosa in the presence AmpC, or lacking outer membrane porin (OprD).*"

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The FDA interpretive categories for susceptible(S) and resistant (R) as listed below were used to evaluate all performance data.

Enterobacteriaceae	≤ 8/4 µg/mL (susceptible), ≥ 16/4 µg/mL (Resistant)
Pseudomonas aeruginosa	≤ 8/4 µg/mL (susceptible), ≥ 16/4 µg/mL (Resistant)

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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