510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K193572

B Applicant

bioMérieux, Inc.

C Proprietary and Established Names

VITEK 2 AST-Gram Negative Imipenem/Relebactam (≤0.25/4 - ≥16/4 µg/mL)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	MI - Microbiology
LTW	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology
LTT	Class II	21 CFR 866.1640 - Antimicrobial susceptibility test powder	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for imipenem/relebactam for testing of Gram-negative bacilli on the VITEK 2 and VITEK 2 Compact Antimicrobial Susceptibility Test (AST) Systems

B Measurand:

Imipenem/Relebactam ≤0.25/4 – ≥16/4 µg/mL

C Type of Test:

Automated quantitative or qualitative antimicrobial susceptibility test

III Intended Use/Indications for Use:

A Intended Use(s):

The VITEK 2 Gram-Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

B Indication(s) for Use:

VITEK 2 AST-Gram Negative Imipenem/Relebactam is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. VITEK 2 AST-Gram Negative Imipenem/Relebactam is a quantitative test. Imipenem/Relebactam has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections:

Klebsiella (Enterobacter) aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Pseudomonas aeruginosa
Citrobacter freundii
Klebsiella oxytoca

In vitro data are available, but clinical significance is unknown:

Citrobacter koseri
Enterobacter asburiae

The VITEK 2 Gram-Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

The ability of the AST card to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were available at the time of comparative testing: Imipenem/Relebactam: C. freundii, C. koseri, and E. asburiae

D Special Instrument Requirements:

VITEK 2 and VITEK 2 Compact Systems using VITEK 2 Systems 9.03 software

IV Device/System Characteristics:

A Device Description:

The VITEK 2 AST card is a miniaturized, abbreviated and automated version of the doubling dilution technique for determining the minimum inhibitory concentration (MIC). Each VITEK 2 AST card contains 64 wells. A control well(s) which contain only nutrient medium is resident on all cards. The remaining wells contain premeasured portions of antimicrobials combined with the nutrient media. The isolate to be tested is diluted to a standardized concentration with 0.45% to 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System will automatically (or allow operator to manually) dilute the bacterial suspension to prepare an inoculum for susceptibility cards. Then, the VITEK 2 will fill, seal and place the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing, and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time. The analysis program determines when a well demonstrates growth based on attenuation of light measured by an optical scanner. This data is used to determine the minimum inhibitory concentration or "MIC" values for the antimicrobial agent. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK 2 AST-Gram Negative Imipenem/relebactam has the following concentrations in the card: 0.25/4, 1/4, 4/4, and 16/4 μg/mL (equivalent standard method concentration by efficacy in μg/mL). The imipenem/relebactam MIC result range for the VITEK 2 is ≤0.25/4 to ≥16/4 μg/mL. For *P. aeruginosa* and all *Enterobacteriaceae* species, the VITEK 2 system is capable of reporting the following MIC results: ≤0.25/4, 0.5/4, 1/4, 2/4, 4/4, 8/4 and ≥16/4 μg/mL for the AST-Gram Negative Imipenem/relebactam test.

B Principle of Operation:

The VITEK 2 and VITEK 2 Compact Systems utilize automated growth-based detection using attenuation of light measured by an optical scanner. The optics in the systems use visible light to directly measure organism growth within each of the 64 micro-wells. Transmittance optics is based on an initial light reading of a well before significant growth has begun. Every 15 minutes throughout the incubation cycle (defined period of time based on the VITEK 2 card), light transmittance readings of each well determine organism growth by the amount of light that is prevented from passing through the well. At the completion of the incubation period, the MIC values and their associated interpretive category results for each antimicrobial on the test card are displayed in an automatically generated report.

V Substantial Equivalence Information:

A Predicate Device Name(s):

VITEK 2 AST-Gram Negative Imipenem (<=0.25->= 16 ug/mL)

B Predicate 510(k) Number(s):

K183415

C Comparison with Predicate(s):

Table 1. Comparison with the Predicate

Device & Predicate Device(s):	**Device: K193572**	**Predicate: K183415**
Device Trade Name	VITEK 2 AST-Gram Negative Imipenem/relebactam	VITEK 2 AST-Gram Negative Imipenem
General Device Characteristic Similarities		
Intended Use	The VITEK 2 Gram-Negative Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	Same
Test Method	Automated quantitative antimicrobial susceptibility test for use with the VITEK 2 and VITEK 2 Compact Systems to determine the *in vitro* susceptibility of Gram-negative organisms	Same
Inoculum	Standardized saline suspension of test organism	Same
Test Card	VITEK 2 Gram Negative Susceptibility Test Card	Same
Instrument	VITEK 2 and VITEK 2 Compact Systems	Same
Analysis Algorithm	Growth pattern analysis	Same
General Device Characteristic Differences		

Antimicrobial Agent	Imipenem/relebactam	Imipenem
Antimicrobial Concentration	0.25/4, 1/4, 4/4, and 16/4 µg/mL	0.5, 2, 8, 16 µg/mL
Reporting Range	≤0.25/4 to ≥16/4 µg/mL for *P. aeruginosa* and *Enterobacteriaceae*	≤ 0.25 - ≥ 16 µg/mL for *Enterobacteriaceae*, ≤ 0.5 - ≥ 16 µg/mL for *Acinetobacter* spp. and *P. aeruginosa*
Indicated Organisms	*E. coli, K. aerogenes, K. pneumoniae, K. oxytoca, E. cloacae, C. freundii, P. aeruginosa*	*Acinetobacter spp., Citrobacter spp., Enterobacter cloacae/E. cloacae complex, Escherichia coli, Klebsiella spp., Pseudomonas aeruginosa*

VI Standards/Guidance Documents Referenced:

1. Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. August 2009
2. CLSI M07-A10. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. 10th ed. (January 2015)
3. CLSI M100. Performance Standards for Antimicrobial Susceptibility Testing. 29th ed. (January 2019)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Reproducibility testing for the VITEK 2 AST-Gram Negative Imipenem/relebactam was conducted at three external clinical sites using a panel composed of five *Klebsiella pneumoniae* and five *P. aeruginosa* isolates as representative Gram-negative bacilli consistent with the indications for use. Each isolate was tested in triplicate over three days for a total of 270 data points. Inocula were prepared using both the auto-dilution and manual dilution methods for testing in the VITEK 2 System. In addition, inocula were prepared by the manual dilution method for use with the VITEK 2 Compact. The mode of MIC values was determined for each isolate and the reproducibility was calculated based on the number of MIC values that fell within ±1 doubling dilution of the mode.

There were two off-scale results noted for the auto-dilution method, one off-scale result for the manual dilution method for the VITEK 2 system and two off-scale results for the VITEK Compact system. The testing resulted in overall best and worst-case reproducibility of 99.3% (268/270) for auto-dilution and 99.6% (269/270) for manual dilution in the VITEK 2 System and 99.3%% (268/270) for the VITEK 2 Compact System (manual dilution only). The reproducibility data was acceptable.

2. Linearity:

   Not Applicable

3. Analytical Specificity/Interference:

   Not Applicable

4. Assay Reportable Range:

   Not Applicable

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

   Quality Control (QC) Testing:
   The CLSI recommended QC strains, namely *K. pneumoniae* ATCC BAA-1705 and *K. pneumoniae* ATCC BAA-2814 were tested a sufficient number of times (i.e., at least 20/site) at each testing site using both the VITEK 2 card and broth microdilution (BMD) reference methods. Both the automatic dilution and manual dilution methods were used for the VITEK 2 and the manual dilution method was used for the VITEK 2 Compact.

   Both the auto-dilution and the manual dilution methods for VITEK 2 and the manual dilution for VITEK 2 Compact QC results are summarized in **Table 2** below. Obtaining a VITEK result of ≤ 0.25 μg/mL (lowest dilution on the card) for *K. pneumoniae* ATCC BAA-1705 and *K. pneumoniae* ATCC BAA-2814 was considered as an indicator that the quality control test results were acceptable. The sponsor included the following footnote in the labeling for both CLSI QC isolates to indicate that the device does not include the full CLSI/FDA-recommended dilution range for QC testing:

   > *Does not include the full CLSI/FDA-recommended dilution range for QC testing with this organism.*

   Furthermore, the sponsor tested *K. pneumoniae* ATCC BAA-1705 with imipenem alone to ensure that the plasmid encoding the β-lactamase gene was not lost during testing with the reference only. Testing of this strain was performed only with VITEK 2 (Auto-dilution) method. All results were acceptable (**Table 3**).

   Because the VITEK card reporting range (≤0.25/4 - ≥ 16/4 μg/mL) does not include the full CLSI/FDA-recommended dilution range for QC testing, the sponsor conducted a study to validate a novel *P. aeruginosa* (bioMérieux strain 105617 strain which is not included in CLSI M100 standard) for recommended use as a QC strain for their device.

   The validation study included testing of at least 80 replicates on at least two different lots over two days according to FDA recommendations. Testing was performed with all inoculation methods used on the VITEK 2 System. Colony counts of the inoculum suspension verified the organism concentration. Results were within the established range for

≥ 95% of the replicates. The results for this strain are summarized in **Table 4** below. The sponsor established the QC range for this strain at 2-8 µg/mL and recommends that users obtain this strain from ATCC (strain reference number is currently undetermined) and routinely test with the imipenem/relebactam test.

Table 2: Quality Control Summary Results for VITEK 2 (Auto-Dilution and Manual Dilution Methods) and VITEK 2 Compact (Manual Dilution Method)

Imipenem/ relebactam		VITEK 2				VITEK 2 Compact Manual Dilution	
		Auto-Dilution		Manual Dilution			
Organism	Conc. (µg/mL)**	Reference	Test	Reference	Test	Reference	Test
K. pneumoniae ATCC BAA-1705 Expected Range* 0.03/4 – 0.25/4 µg/mL (VITEK 2: ≤0.25/4 µg/mL)	≤0.008						
	0.016						
	0.03						
	0.06	6		4		4	
	0.12	92		70		70	
	0.25	18		14		14	
	≤0.25***		115		86		89
	0.5	2	4	1	3	1	
	1	1					
	≥2						
K. pneumoniae ATCC BAA-2814 Expected Range* 0.06/4 – 0.25/4 µg/mL (VITEK 2: ≤0.25/4 µg/mL)	≤0.008						
	0.016						
	0.03						
	0.06						
	0.12	31		24		22	
	0.25	83		62		62	
	≤0.25***		120		88		89
	0.5	5		4	1	4	
	1	1		1		1	
	≥2						

* Expected range per CLSI M100.

** The relebactam concentration is fixed at 4 µg/mL

*** The lowest dilution of the VITEK 2 Imipenem/relebactam MIC range is ≤0.25/4 µg/mL. Obtaining this value was considered an indicator that the quality control test results were acceptable.

Table 3: Quality Control Summary Results for the VITEK2 and Imipenem Alone

Organism	Conc. (µg/mL)	VITEK 2 (Auto-Dilution)
K. pneumoniae ATCC BAA-1705 Expected Range* 4 – 16 µg/mL	2	
	4	
	8	26
	16	92
	32	1

* Expected range per CLSI M100.

Table 4: Quality Control Summary Results for *P. aeruginosa* bioMérieux Strain 105617

Imipenem/ relebactam		
Organism	**Conc. (µg/mL)**	**VITEK 2 Systems**
P. aeruginosa bioMérieux Strain 105617, Proposed QC Range 2/4 – 8/4 µg/mL	1/4	
	2/4	7
	4/4	100
	8/4	
	16/4	

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

Testing of imipenem/relebactam on the VITEK 2 AST-Gram Negative card was performed at three external sites and one internal site. There were 379 clinical isolates and 118 challenge isolates tested for a total of 497 isolates. Results obtained with the VITEK 2 AST-Gram Negative card with imipenem/relebactam were compared to results obtained with the CLSI broth microdilution reference panel. The MIC result range for the VITEK 2 AST-Gram Negative Imipenem/relebactam is ≤0.25/4 – ≥16/4 µg/mL for all species. The reference panel contained two-fold serial dilutions with a range of ≤0.015 to ≥64 µg/mL. The testing conditions for the reference method consisted of the following:

- Medium – Cation Adjusted Mueller Hinton broth
- Inoculum – Direct colony suspension
- Incubation – 35°C; 16-24 hours

The VITEK 2 AST cards were inoculated with test organisms using the auto-dilution method (VITEK 2) and using the manual dilution method (VITEK 2 and VITEK 2 Compact). All test inocula used for the VITEK 2 AST cards and the reference method were standardized using the DensiCHEK Plus instrument.

A total of 379 clinical *Enterobacteriaceae* isolates were evaluated: 62% were considered contemporary isolates and 38% were stock isolates. One isolate did not grow in the VITEK 2 AST-Gram Negative Imipenem/relebactam test card so complete test results are available for 378 clinical isolates: 349 isolates from indicated species (17 *C. freundii*, 15 *C. koseri*, 39 *K. aerogenes*, 15 *E. asburiae*, 10 *E. cloacae*, 97 *E. coli*, 23 *K. oxytoca*, 4 *K. pneumoniae pneumoniae*, 52 *K. pneumoniae*, and 77 *P. aeruginosa*) and 29 isolates from non-indicated species (1 *C. braakii*, 22 *E. cloacae* complex, 2 *E. vulneris*, 1 *L. amnigena* 2, 2 *P. dispersa* and 1 *R. ornithinolytica*). The clinical isolates were tested with the auto-dilution option of the VITEK 2.

A total of 118 challenge isolates (3 *K. aerogenes,* 5 *E. cloacae*, 10 *E. coli*, 1 *K. oxytoca,* 1 *K. pneumoniae ozaenae*, 1 *K. pneumoniae pneumoniae*, 42 *K. pneumoniae*, and 55 *P. aeruginosa*) were evaluated at one site. The challenge set was tested with the auto-dilution and manual dilution options of the VITEK 2 and with the manual dilution method on the VITEK 2 Compact.

At the time of comparative testing, resistant isolates were not available for *C. freundii, C. koseri,* and *E. asburiae*. Thus, the following statement is included in the Limitations section of the device labeling:

> *The ability of the AST card to detect resistance with the following combination(s) is unknown because an insufficient number of resistant strains were available at the time of comparative testing: Imipenem/Relebactam: C. freundii, C. koseri, and E. asburiae*

To address testing of non-indicated species, the following statement is included in the *Precautions* section of the device labeling:

> *Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.*

Clinical and Challenge Data –VITEK 2 Auto-Dilution

The results obtained using the auto-dilution method of the VITEK 2 from the 486 total isolates (378 clinical isolates and 118 challenge isolates) are summarized in **Table 5.**

Table 5. Performance of All *Enterobacteriaceae* and *P. aeruginosa* Isolates: VITEK 2 Auto-Dilution

Organism Type	EA Tot	EA N	EA %	Eval. EA Tot	Eval. EA N	Eval. EA%	CA N	CA%	#R	min	maj	vmj
***Enterobacteriaceae*, ≤1/4 (S), 2/4 (I), ≥4/4 (R)**												
Clinical	**301**	**286**	**95.0**	**43**	**28**	**65.1**	**297**	**98.7**	**6**	**3**	**1**	**0**
Challenge	**63**	**61**	**96.8**	**37**	**35**	**94.6**	**63**	**100.0**	**37**	**0**	**0**	**0**
Combined	**364**	**347**	**95.3**	**80**	**63**	**78.8**	**360**	**98.9**	**43**	**3**	**1**	**0**
***P. aeruginosa*, ≤2/4 (S), 4/4 (I), ≥8/4 (R)**												
Clinical	**77**	**55**	**97.4**	**73**	**71**	**97.3**	**72**	**93.5**	**4**	**5**	**0**	**0**
Challenge	**55**	**52**	**94.5**	**50**	**47**	**94.0**	**54**	**98.2**	**14**	**1**	**0**	**0**
Combined	**132**	**127**	**96.2**	**123**	**118**	**95.9**	**126**	**95.5**	**18**	**6**	**0**	**0**

EA – Essential Agreement
CA – Category Agreement
EVAL – Evaluable isolates
R – Resistant isolates
min – minor errors
maj – major errors
vmj – very major errors

When using the auto-dilution method of the VITEK 2, the overall performance with all *Enterobacteriaceae* is acceptable with an EA of 95.3% and a CA of 98.9%. As summarized in **Table 5**, there is one major error (1/319 = 0.3%) and no very major.

For *P. aeruginosa*, the overall performance was acceptable with an EA of 96.2% and CA of 95.5%. There were no major or very major errors.

Challenge Data –VITEK 2 and VITEK 2 Compact Manual Dilution
The 118 challenge isolates were also evaluated at one site with the manual dilution options of the VITEK 2 and VITEK 2 Compact systems (summarized in **Table 6**). The performance was acceptable using both VITEK 2 and VITEK 2 systems with an EA and CA of >90% for both *Enterobacteriaceae* and *P. aeruginosa* respectively. There was one major error and one very major error with the VITEK 2 Compact, however, they were considered acceptable.

Table 6: Performance of Challenge Isolates: VITEK 2 and VITEK 2 Compact Manual Dilution

Organism Type	EA Tot	EA N	EA %	Eval. EA Tot	Eval. EA N	Eval. EA%	CA N	CA%	#R	min	maj	vmj
VITEK 2												
Enterobacteriaceae	**63**	**60**	**95.2**	**36**	**33**	**91.7**	**61**	**96.8**	**37**	**1**	**0**	**1**
P. aeruginosa	**55**	**52**	**94.5**	**49**	**46**	**93.9**	**53**	**96.4**	**14**	**2**	**0**	**0**
VITEK 2 Compact												
Enterobacteriaceae	**63**	**60**	**95.2**	**38**	**35**	**92.1**	**62**	**98.4**	**37**	**0**	**0**	**1**
P. aeruginosa	**55**	**51**	**92.7**	**50**	**46**	**92.0**	**53**	**96.4**	**14**	**1**	**1**	**0**

Resistance Mechanism Characterization
Challenge isolates of *Enterobacteriaceae* and *P. aeruginosa* harboring various molecular mechanisms of resistance noted in the FDA drug label were evaluated with AST-Gram Negative Imipenem/Relebactam. The following drug label listed mechanisms were evaluated: KPC, CTX-M, TEM, SHV, PDC, GES, VEB, and PER.

MIC Trends:
A trending analysis was conducted using the combined data (clinical and challenge) obtained from the VITEK 2 auto-dilution method for each organism species and group. This trending calculation analyzes device MIC values that are determined to be one or more doubling dilutions lower or higher than the reference method. MIC values that are off-scale for both the reference and device are not considered in the trending analysis.

Trending results were stratified by species to determine if species-related trends were observed (**Table 7**). Species for which the difference between the percentage of isolates with higher or lower MIC values was ≥30% with a statistically significant confidence interval were considered to have evidence of trending.

A trend was not observed for the *Enterobacteriaceae* family combined; however, a trend towards lower MIC values was observed for *C. koseri* and *K. pneumoniae* while a trend towards higher MIC values was observed for *E. cloacae* when compared to reference testing. The following footnote to the performance table is included in the package insert to address the trending observed for VITEK 2 AST-Gram Negative Imipenem/relebactam:

> *A trending analysis was conducted using combined data (clinical and challenge) for Enterobacteriaceae and Pseudomonas aeruginosa. The trending analysis determined the VITEK 2 Imipenem/Relebactam, when compared to the reference broth microdilution,*

tended to be at least one doubling dilution lower for Citrobacter koseri and K. pneumoniae, and at least one doubling dilution higher for Enterobacter cloacae.

Table 7. Trending by Species (clinical and challenge isolates)

VITEK 2 Auto-Dilution (Challenge and Clinical isolates)						
Organism	**Total Evaluable for Trending**	**≥ 1 Dilution lower No. (%)**	**Exact No. (%)**	**≥ 1 Dilution Higher No. (%)**	**Percent Difference (CI)**	**Trending Noted**
C. braakii	1	1 (100)	0	0	-100	No
C. freundii	2	1 (50.0)	1 (50.0)	0	-50.0	No
C. koseri	2	2 (100)	0	0	-100	Yes
E. aerogenes	24	7 (29.2)	9 (37.5)	8 (33.3)	4.2	No
E. asburiae	4	2 (50.0)	2 (50.0)	0	-50.0	No
E. cloacae	8	2 (25.0)	0	6 (75.0)	50.0	Yes
E. cloacae complex	5	2 (40.0)	0	3 (60.0)	20.0	No
E. coli	13	6 (46.2)	0	7 (53.9)	7.7	No
E. vulneris	2	0	2 (100)	0	0	No
K. oxytoca	5	3 (60.0)	1 (20.0)	1 (20.0)	-40.0	No
K. pneum. ozaenae	1	0	1 (100)	0	0	No
K. pneum. pneumoniae	4	2 (50.0)	2 (50.0)	0	-50.0	No
K. pneumoniae	52	32 (61.5)	13 (25.0)	7 (13.5)	-48.1	Yes
L. amnigena 2	1	1 (100)	0	0	-100	No
P. dispersa	1	1 (100)	0	0	-100	No
R. ornithinolytica	1	1 (100)	0	0	-100	No
All *Enterobacteriaceae*	126	63 (50.0)	31 (24.6)	32 (25.4)	-24.6	No
P. aeruginosa	123	26 (21.1)	82 (66.7)	15 (12.2)	-8.9	No

2. Matrix Comparison:

   Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable

2. Clinical Specificity:

   Not applicable

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

   Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Table 8. FDA-Identified Interpretive Criteria for Imipenem/relebactam

Organism	Interpretive Criteria for Imipenem/relebactam (µg/mL)[a]		
	Susceptible	Intermediate	Resistant
Enterobacteriaceae	≤ 1/4	2/4	≥ 4/4
P. aeruginosa	≤ 2/4	4/4	≥ 8/4

[a]FDA STIC Webpage

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.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a breakpoint change protocol that was reviewed and accepted by FDA. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/drugs/development-resources/fda-recognized-antimicrobial-susceptibility-test-interpretive-criteria). The protocol outlined the specific procedures and acceptance criteria that bioMérieux intends to use to evaluate the VITEK 2 AST-GN Imipenem/relebactam when revised breakpoints for imipenem/relebactam are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, bioMérieux will update the imipenem/relebactam device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.