

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number:

k032788

B. Analyte:

Gatifloxacin (1-8 ug/mL) AST

C. Type of Test:

Quantitative growth based detection algorithm using optics light detection

D. Applicant:

bioMerieux, Inc.

E. Proprietary and Established Names:

VITEK®2 Gram Negative Gatifloxacin

F. Regulatory Information:

1. Regulation section:
866.1645 Short-Term Antimicrobial Susceptibility Test System
2. Classification:
II
3. Product Code:
LON System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
4. Panel:
83 Microbiology

G. Intended Use:

1. Intended use(s):
The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.

The VITEK®2 Gram Negative Susceptibility CARD is intended for use with the VITEL®2 System in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents.
2. Indication(s) for use:
The intent is to include Gatifloxacin at concentrations of 1, 4, and 8 ug/mL for a range of ≤ 0.25 to ≥ 8 ug/mL on the VITEK®2 gram negative AST panel for testing the appropriate *Enterobacteriaceae*.

3. Special condition for use statement(s):

Not applicable

4. Special instrument Requirements:

Not applicable

H. Device Description:

Each VITEK® 2 test card contains 64 microwells. A control well, that contains only microbiological culture medium is resident on all cards, with the remaining wells containing premeasured amounts of a specific antibiotic combined with culture medium. A suspension of organism is made in 0.45-0.5% sterile saline from a pure culture and standardized to a McFarland 0.5 standard using the DensiChek. The desired card (s) are placed in the cassette along with an empty tube for the susceptibility card. The cassette is placed into the VITEK® 2 instrument where a susceptibility test will be automatically diluted from the ID suspension by the VITEK® 2. The cards are then automatically vacuum filled; the tubes are cut and the cards sealed prior to proceeding to the Incubator Loading Station. Cards are then transferred from the cassette into the carousel for incubation (35.5° C) and optical scanning during testing. Readings are performed every 15 minutes.

There is also a manual dilution of the organism that is recommended in the package insert.

I. Substantial Equivalence Information:1. Predicate device name(s):

VITEK®2 Gram Negative AST Panel for cefpodoxime

2. Predicate K number(s):

N50510/S120

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Same
Test organism	Colonies of <i>Enterobacteriaceae</i>	Colonies of <i>Enterobacteriaceae</i>
Test Card	VITEK® 2 card format with base broth	same
Instrument	VITEK® 2 System	VITEK® 2 System
Differences		
Item	Device	Predicate
Antibiotic	Gatifloxacin	Cefpodoxime
Reading algorithm	Unique for gatifloxacin	Unique for cefpodoxime

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

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA”; NCCLS M7 (M100-S13)
 “Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard”.

K. Test Principle:

Optics systems use visible light to directly measure organism growth. These transmittance optics are based on an initial light reading of a well before significant growth has begun. Periodic light transmittance samplings of the same well measure organism growth by how much light is prevented from going through the well. An interpretive call is made between 4 and 16 hours for an early reading of results with an option to incubate up to 18 hours if necessary. The VITEK®2 Susceptibility Card test is based on the microdilution minimum inhibitory concentration technique with concentrations equivalent to standard method concentrations. Several parameters based on the growth characteristics observed are used to provide appropriate input for the MIC calculations. Discriminate analysis is used to develop the algorithm that determines the susceptibility result for all antimicrobials on the VITEK® 2 system. The MIC result must be linked to an organism identification in order to determine a category interpretation. A category interpretation will be reported along with a MIC.

L. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Twenty five on-scale gram negative organisms were tested one time at each of three sites for an overall reproducibility of >95%. Twenty five on-scale organisms were also tested at one site three times each to determine intra reproducibility of >95%. This testing was performed using both the manual dilution of the inoculum and also the automatic dilution method.

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability (controls, calibrators, or method):*

Quality Control was performed during the studies using both the auto-dilution and the manual method of diluting the organisms. This included the two recommended QC organisms with the following results.

ORGANISM	Reference conc.	Reference	VITEK® Conc.	Auto-dilution	Manual dilution
<i>E. coli</i> ATCC 25922 Range 0.008-0.03 ug/mL	≤ 0.125				
	0.25	151	≤ 0.5	80	71
	0.5				
	1				
<i>P. aeruginosa</i> ATCC 27853 Range 0.5-2 ug/mL	≤ 0.125				
	0.25				
	0.5	3	≤ 0.5	2	7
	1	129	1	78	64
	2	19	2		
	4				

The modes for the reference method, the autodilution and the manual dilution are the same.

Inoculum density control: Internal verification of the DensiChek was performed using 2 ATCC organisms and five instruments with 50 results available for each organism. The clinical sites also performed weekly standardization of the DensiChek used at that site.

- 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:*

A comparison of the clinical data was performed to the agar dilution reference method described in the NCCLS M7.

Enterobacteriaceae were tested at three sites that included both clinical and challenge isolates. The “no growth” rate was less than 1%. All of the test organisms that provided results did so in <16 hours. Testing was performed using the auto dilution feature. The overall performance is listed in the table below:

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	599	597	99.7	22	20	90.9	588	98.2	44	11	0	0
Challenge	83	83	100	24	24	100	77	92.8	58	6	0	0
Combined	682	680	99.7	46	44	95.7	665	97.5	58	17	0	0

EA-Essential Agreement

CA-Category Agreement

R-resistant isolates

maj-major discrepancies

vmj-very major discrepancies

min- minor discrepancies

Evaluable results are those that fall within the test range of the reference method and could also be on-scale with the new device if within the plus/minus one well variability. EA is when there is agreement between the reference method and the VITEK® 2 within plus or minus one serial two-fold dilution of antibiotic. CA is when the interpretation of the reference method agrees exactly with the interpretation of the VITEK ® 2 result.

Manual Dilution:

The challenge set of organisms was also tested at one site using the manual method of inoculation with the following performance that demonstrated that there was little or no difference between the two inoculation methods.

Manual testing

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Challenge	83	83	100	22	22	100	77	92.8	58	6	0	0

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:

≤ 2 (S), 4 (I), ≥ 8 (R)

The interpretative criteria and QC are the same as recommended in NCCLS and will be included in the package insert.

M. Conclusion:

The reproducibility, quality control results and overall performance is acceptable as described in the “Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA” which was used in the design and evaluation of the study. The appropriate control organisms are included in the labeling and are the same as those recommended in the NCCLS M7-(M100-S13) document. This performance as compared to a standard method demonstrates substantial equivalency to the predicate.