

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

A. 510(k) Number:

k031865

B. Analyte:

Moxifloxacin at equivalency concentrations of 0.25 - 2 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 Positive Moxifloxacin for *Streptococcus pneumoniae*

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 susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.
2. Indication(s) for use:
VITEK®2 Gram Positive Moxifloxacin for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of *Streptococcus pneumoniae*. It is intended for use with the VITEK®2 System as a laboratory aid in the determination of *in vitro* susceptibility antimicrobial agents.
3. Special condition for use statement(s):
The testing of moxifloxacin at equivalency concentration of 0.25, 1 and 2 ug/ml will provide MIC results in the range of 0.25-4 ug/ml.
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. (275 microliter/2.5ml for manual inoculations and 235 microliter/2.5 ml saline for gram positive cocci.). 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 pre-diluted inoculum method that may be used instead of the instrument auto-dilution method.

I. Substantial Equivalence Information:

1. Predicate device name(s):
VITEK®2 *Streptococcus pneumoniae* Susceptibility Test for Ceftriaxone.
2. Predicate K number(s):
N50510/S135
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	same	same
Test organism	Colonies of <i>Streptococcus pneumoniae</i>	Colonies of <i>Streptococcus pneumoniae</i>
Test Card	VITEK® 2 card format with base broth	same
Instrument	VITEK® 2 System	VITEK® 2 System
Differences		
Item	Device	Predicate
Indications	Concentrations of Moxifloxacin	Concentrations of Ceftriaxone
Reading algorithm	Unique for moxifloxacin	Unique for Ceftriaxone

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 with the majority of the *S. pneumoniae* between 5 and nine hours. The VITEK® 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 an MIC.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Twelve *S. pneumoniae* with on-scale results were tested at four different sites for an overall reproducibility of >95% for between site reproducibility. An additional site tested the same set three times for a within site 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):*

ORGANISM	conc	Reference	Auto-dilution	Manual dilution
<i>S. pneumoniae</i>	≤ 0.06	65		
ATCC 49619	0.125	93	80(≤ 0.25)	78(≤ 0.25)
Range	0.25			
0.06-0.25 ug/ml	0.5			

Quality Control was performed during the studies using both the auto-dilution and the manual method of diluting the organisms. The results were out of range for the panel for all results as would be expected with the range that is expected for this quality control organism.

Inoculum density control: The DensiChek instrument was calibrated weekly during the study with acceptable results at all times. Internal testing to verify the performance of the DensiChek was also provided.

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 reference method used for comparison was the broth dilution using 5% lysed horse blood. Studies were performed at three sites on clinical isolates of *S.*

pneumoniae using the auto-dilution feature of the VITEK® 2® instrument. A set of challenge isolates was also tested using the auto-dilution method of inoculation. There was a 1% “no growth” rate on the VITEK® 2® test panel for the challenge and the clinical isolates combined. The performance of these isolates is presented in the following table.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	464	462	99.6	35	34	97.1	438	94.4	25	26	0	0
Challenge	53	53	100	1	1	100	53	100	0	0	0	0
Combined	517	515	99.6	36	35	97.2	491	95	25	26	0	0

EA-Essential Agreement

maj-major discrepancies

CA-Category Agreement

vmj-very major discrepancies

R-resistant isolates

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.

Challenge set using manual dilution

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
challenge	53	53	100	0	0		53	100	0	0	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:

≤ 1 (S), 2 (I), ≥ 4 (R)

The expected value range, interpretative criteria and QC are the same as recommended in NCCLS. All values 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.