

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

**A. 510(k) Number:**

k063623

**B. Purpose for Submission:**

To add the antibiotic meropenem to the VITEK® 2 Gram Positive device for *Streptococcus pneumoniae*

**C. Measurand:**

Meropenem at 0.125-1 µg/mL

**D. Type of Test:**

Quantitative and Qualitative Antimicrobial Susceptibility Test (AST) growth based fluorescence

**E. Applicant:**

bioMerieux, Inc.

**F. Proprietary and Established Names:**

VITEK® 2 Gram Positive Meropenem for *Streptococcus pneumoniae*

**G. 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

**H. Intended Use:**

1. Intended use(s):

Meropenem at 0.125-1 µg/mL with the VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae* to antimicrobial agents when used as instructed in the Online Product Information.

2. Indication(s) for use:

This application is for the testing of *Streptococcus pneumoniae* with Meropenem at 0.125-1 µg/mL for use with VITEK® 2 GP panel Susceptibility Plates with a calling range of  $\leq 0.06$ -  $\geq 4$  µg/mL

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Not Applicable

**I. 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.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

VITEK® 2 Gram Positive Telithromycin for *Streptococcus pneumoniae*

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

K053186

3. Comparison with predicate:

<b>Similarities</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended use	an <i>in vitro</i> diagnostic device for clinical susceptibility testing of <i>Streptococcus species</i>	Same
Inoculum	Prepared from colonies using the direct inoculation method	Same
Type panel	VITEK® 2 test card format, including the base broth	Same
Inoculation method	Direct equated to a 0.5 McFarland	Same
Incubation	<16 hours	Same
Technology	Automated using analysis of growth patterns	Same
<b>Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
antibiotic	Specific concentrations of meropenem	Specific concentrations of telithromycin

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

“Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test Systems; Guidance for Industry and FDA”; CLSI M7 (M100-S16) “Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard.”

**L. Test Principle:**

The VITEK® 2 System evaluates each organism’s growth pattern in the presence and absence of antimicrobials to read 20 -24 hour *Streptococcus spp.* plates. The technology involves the detection of bacterial growth by monitoring the activity of specific surface enzymes produced by the test organism. Several parameters based on the growth characteristics observed are used to provide appropriate input for the MIC calculations. Discriminant analysis is used to develop the algorithm that determines the susceptibility result for all antimicrobials on VITEK®2 systems. The MIC is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism.

**M. Performance Characteristics (if/when applicable):**

**Performance established for the AST testing only. The Identification function of this panel was not evaluated.**

1. Analytical performance:

a. *Precision/Reproducibility:*

A reproducibility study was performed on 10 *Streptococcus pneumoniae*. These isolates were tested once for each antimicrobial at each of the three sites on the automated and manual inoculation methods demonstrating >95% reproducibility for both inoculation methods.

b. *Linearity/assay reportable range:*  
Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*  
The recommended QC isolate, *S. pneumoniae* ATCC 49619 was tested daily with acceptable results. Quality control was also performed at all sites using both manual and autoread methods. The test results demonstrated that the system can produce QC results in the recommended range for both manual and automated read methods. The Table below includes the frequency of each result in the range tested.

Antimicrobial	ORGANISM	Conc ug/mL Vitek tested	VITEK® 2 Autodilution	VITEK® 2 manual	Conc ug/mL Ref tested	Reference
Meropenem	<i>S. pneumoniae</i> ATCC 49619 Exp. Range: 0.06-0.25 ug/ml				≤ 0.015	1
					0.03	2
		≤ 0.06	79	79	0.06	70
		0.12			0.12	5
		0.25			0.25	1
		0.5			0.5	
		1			1	

The DensiChek instrument used for the inoculation preparation was standardized weekly. Verification of the use of the DensiChek was performed prior to the testing.

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:*

Comparison was performed to the broth dilution reference panel prepared according to the CLSI recommendation for the testing of *Streptococcus pneumoniae*. Clinical testing included both fresh and stock clinical isolates of *Streptococcus pneumoniae* and a set of challenge organisms. The broth

reference panel was set up using MH supplemented with 2% to 5% lysed horse blood as recommended by CLSI and incubated in a non CO<sub>2</sub> incubator for 20 – 24 hours. The comparison resulted in the performance evaluations as reflected below. The same challenge set was tested using the manual inoculation method. Both methods produced similar results so only one method is presented below.

Summary Table for *S. pneumoniae*

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
<b>Clinical</b>	379	369	97.4	58	48	82.8	354	93.4	14	24	1	0
<b>Challenge</b>	58	56	96.5	22	20	90.9	52	89.7	8	6	0	0
<b>Combined</b>	437	425	97.3	80	68	85	406	92.9	22	30	1	0

**EA**-Essential Agreement

**CA**-Category Agreement

**R**-resistant isolates

**maj**-major discrepancies

**vmj**-very major discrepancies

**min**- minor discrepancies

EA is when there is agreement between the reference method and the VITEK® 2 panel within plus or minus one serial two-fold dilution of antibiotic. Category agreement (CA) is when the VITEK® 2 panel result interpretation agrees exactly with the reference panel result interpretation. Evaluable is a result that is on scale for the reference method providing the opportunity to perform an EA analysis with the test. The EA% is acceptable when compared to the reference method as described in the FDA guidance document, “Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA”.

In this study the growth rate for *Streptococcus pneumoniae* was greater than 90%.

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:

<b>Antibiotic</b>	<b>Organism</b>	<b>Interpretative Criteria</b>
Meropenem	<i>Streptococcus pneumoniae</i>	$\leq 0.25$ (S) $0.5$ (I), $\geq 1$ (R)

**N. Proposed Labeling:**

The expected value range, interpretive criteria and QC are included in the package insert. The labeling is sufficient and 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.