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

A. 510(k) Number:
k063492

B. Purpose of Submission:

Addition of Erythromycin to the VITEK®2 and VITEK®2 Compact Systems Antimicrobial Susceptibility Test (AST) System

C. Measurand
Erythromycin ≤0.25 - ≥ 1 μg/mL

D. Type of Test:
Qualitative growth based detection algorithm using predetermined growth thresholds

E. Applicant:
bioMerieux, Inc.

F. Proprietary and Established Names:
VITEK®2 Gram Positive Erythromycin

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):

   The VITEK®2 Antimicrobial Susceptibility Test 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 Positive Susceptibility Card is intended for use with the VITEK®2 system 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 submission is for the addition of the VITEK® 2 Gram Positive Erythromycin for *Streptococcus pneumoniae* at a concentration of 0.06, 0.125, and 0.25 µg/mL and a calling range of range of ≤0.25, and ≥ 1 µg/mL.

3. Special condition for use statement(s):
   Prescription use only

   VITEK®2 does not report intermediate results for *Streptococcus pneumoniae*/Erythromycin. At this time, intermediate strains for *Streptococcus pneumoniae*/Erythromycin are very rare.

4. Special instrument Requirements:
   Not applicable

I. Device Description:

The VITEK® 2 AST card containing the test is inoculated with a standardized organism suspension. The card is incubated within the instrument and optically monitored throughout the incubation cycle. Results are automatically calculated once a predetermined growth threshold is reached and a report is generated that contains the final result.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   VITEK® 2 Gram Positive Telithromycin for *Streptococcus pneumoniae*
2. Predicate K number(s):
   k053186
3. Comparison with predicate

Similarities		
Item	**Device**	**Predicate**
Intended Use	Determine antimicrobial susceptibility to antimicrobial agents	Same
Instrument	VITEK®2 System	Same
Test Card	VITEK®2 card, including the base broth	Same
Test organism	Colonies of Gram-Positive cocci	Same
Differences		
Item	**Device**	**Predicate**
Antibiotic	Erythromycin at specific concentrations	Telithromycin at specific concentrations
Reading algorithm	Unique for erythromycin	Unique for telithromycin

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

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) 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:

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 a "rapid" read but may be extended to 18 hours in some instances. 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 organism identification in order to determine a category interpretation. A category interpretation (SIR) will be reported along with a MIC.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:
   Ten strains of *Streptococcus pneumoniae* were tested at three sites. This testing was performed using both the manual dilution of the inoculum and also the automatic dilution method. Acceptable reproducibility was demonstrated with only category agreement (S, R) since that is all that is detected.

   b. Linearity/assay reportable range:
   Not applicable

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

   The recommended QC isolate was tested on every test occasion with the reference method and the VITEK®2. The reference method QC results were in range for every day tested. The VITEK®2 was tested a sufficient number of times to demonstrate that the system can produce QC results in the recommended range.

   Quality Control was performed during the studies using both the auto-dilution and the manual method of diluting the organisms. Results demonstrated that methods were comparable with the same mode.

ORGANISM	**Test Results**	***VITEK®2*** ***AUTO-DIL***	***VITEK®2*** ***MAN-DIL***	***Reference Conc. (ug/mL)***	***Reference***
S. pneumoniae	≤0.25	79	79	≤0.03125	41
ATCC 49619				0.0625	19
Expected Range:				0.125	19
0.03125 – 0.125 µg/mL					

Inoculum density control was monitored using the DensiChek instrument. This was standardized weekly with all results recorded and in the expected range. Verification was performed during internal 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:

A clinical study was conducted at three sites using the VITEK®2 gram positive cards with erythromycin and the broth microdilution method using Mueller Hinton (MH) broth with lysed horse blood prepared as recommended by CLSI. Inoculum was prepared with direct colony suspension. The testing included both fresh clinical isolates and stock isolates along with a challenge set with known results. Two methods of inoculation (manual and automated) were evaluated. Clinical testing was performed using the automated method of inoculation and the challenge set was tested using both the manual and the automated method. The test device had a growth rate of >90%. All isolates grew in the VITEK®2 cards in less than 16 hours. Essential agreement was not calculated because the VITEK®2 card contained <5 dilutions of erythromycin. A comparison was provided to the reference method with the following agreement.

Summary Table for *S. pneumoniae*

	CA Tot	**CA N**	**CA %**	**#R**	**Min**	**maj**	**vmj**
Clinical	**379**	**375**	**98.9**	**99**	**1**	**2**	**1**
Challenge	**58**	**57**	**98.3**	**16**	**1**	**0**	**0**
Combined	**437**	**432**	**98.9**	**115**	**2**	**2**	**1**

CA-Category Agreement
R-resistant isolates
min-min discrepancies
maj-major discrepancies
vmj-very major discrepancies

Category Agreement is when the interpretation (SIR) of the reference method agrees exactly with the interpretation (SIR) of the VITEK®2 results.

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 no difference between the two inoculation methods.

Summary Table for *S. pneumoniae*

	CA Tot	CA N	CA %	#R	Min	maj	vmj
Challenge	**58**	**57**	**98.3**	**16**	**1**	**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:
S. pneumoniae $\leq$0.25 (S), 1 (I), $\geq$2 (R)

N. Labeling

The expected value range, interpretive criteria and QC for gram negative panels 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**.**