

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

A. 510(k) Number:

k080201

B. Purpose of Submission:

Addition of Inducible Clindamycin Resistance (ICR) test to the VITEK®2 and VITEK®2 Compact Systems Antimicrobial Susceptibility Test (AST) System

C. Measurand

Clindamycin 0.5 µg/mL

Clindamycin/Erythromycin 0.25/0.5 µg/mL

Type of Test:

Quantitative growth based detection algorithm using predetermined growth thresholds

Applicant:

bioMerieux, Inc.

Proprietary and Established Names:

VITEK®2 Gram Positive Inducible Clindamycin Resistance

D. 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

Intended Use:

5. Intended use(s):
The VITEK®2 Antimicrobial Susceptibility Test is intended for use with the VITEK®2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus spp.*, *Enterococcus spp.*, and *Streptococcus agalactiae*, to antimicrobial agents when used as instructed in the Online Product Information.
6. Indication(s) for use:
This application is indicated for the addition of the VITEK® 2 Gram Positive Inducible Clindamycin Resistance for testing *Saphylococcus* species at a clindamycin concentration of 0.5 µg/mL, and clindamycin/erythromycin

concentration of 0.25/0.5 µg/mL respectively and a calling range of negative and positive on the VITEK®2 Gram Positive Susceptibility Cards for use with the VITEK®2 Systems.

7. Special condition for use statement(s):
Prescription use only
8. Special instrument Requirements:
Not applicable

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.

E. Substantial Equivalence Information:

1. Predicate device name(s):
VITEK® 2 Gram Positive Cefoxitin Screen
2. Predicate K number(s):
k053097
3. Comparison with predicate

Similarities		
Item	Device	Predicate
Intended Use	Determine antimicrobial susceptibility to antimicrobial agents	Same
Instrument	VITEK®2 and VITEK®2 Compact Systems	Same
Test Card	VITEK®2 card, including the base broth	Same
Test organism	Colonies of Gram-Positive cocci	Same
Differences		
Item	Device	Predicate
Antibiotic	Clindamycin and erythromycin at specific concentrations	Cefoxitin at specific concentrations
Reading algorithm	Unique for Inducible Clindamycin Resistance (clindamycin and erythromycin)	Unique for cefoxitin

Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA”; Clinical Laboratory Standards Institute (CLSI) M7-M100-S18, “Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard”.

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.

F. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Ten *S. aureus* isolates were tested at three sites using both the manual dilution and the automatic dilution method. These same organisms were tested at one site three times to determine within site reproducibility. Acceptable reproducibility was demonstrated with only category agreement since that is all that is detected.

b. *Linearity/assay reportable range:*

Not applicable

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

The CLSI recommended QC isolates, *S. aureus* ATCC BAA-976, and *S. aureus* ATCC BAA-977 were tested on every test occasion with the D-Test disk approximation test 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 auto-dilution and the manual dilution method.

Quality Control Summary

ORGANISM	Test Results	VITEK®2 AUTO-DIL	VITEK®2 MAN-DIL	Reference AUTO-DIL	Reference MAN-DIL
<i>S. aureus</i>	Neg	71	70	71	70
ATCC BAA-976	Pos	0	0	0	0
Expected Res: Neg					
<i>S. aureus</i>	Neg	0	0	0	0
ATCC BAA-977	Pos	70	70	70	70
Expected Res: Pos					

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 external sites using the VITEK®2 gram positive inducible clindamycin resistance and the inducible clindamycin resistance test (disk approximation test) as recommended by CLSI. Inoculum was prepared with direct colony suspension and incubated in ambient air at 35°C for 16 – 18 hours for *Staphylococcus* spp. 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. If the ICR test is positive when testing *Staphylococcus* species and the clindamycin result is susceptible or intermediate, then the clindamycin result will be forced resistant by the ICR test.

The test device had a growth rate of >90%. A comparison was provided to the reference method with the following agreement.

Summary Table

	Total	CA	%CA	Neg	Pos	maj	vmj
Clinical	463	459	99.1	400	63	2	2
Challenge	99	99	100	62	37	0	0
Combined	562	558	99.3	462	100	2	2

CA-Category Agreement

vmj-very major discrepancies

maj-major discrepancies

CA is when the interpretation of the reference method agrees exactly with the interpretation 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 is minimal difference between the two inoculation methods.

Summary Table

	Total	CA	%CA	Neg	Pos	maj	vmj
Challenge	99	100	100	62	37	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:

Staphylococcus species: Positive – Detection of inducible resistance to clindamycin

Negative – No inducible resistance to clindamycin

Labeling

The labeling is sufficient and satisfies the requirements of 21 CFR Part 809.10.

Conclusion:

The information submitted in this premarket notification is complete and supports a substantial equivalence decision.