

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

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

k053097

**B. Purpose of Submission:**

For addition of Cefoxitin Screen to the VITEK®2 Antimicrobial Susceptibility Test System to predict *mecA* -mediated resistance in *Staphylococcus* spp

**C. Analyte**

Cefoxitin will be included in the VITEK®2 Cefoxitin Screen at a concentration of 6 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 Cefoxitin Screen

**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):

Cefoxitin at a concentration of 6 µg/mL on 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 *Staphylococcus* spp. to antimicrobial agents when used as instructed in the Online Product Information.

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK® 2 Compact Systems for the automated

quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.

2. Indication(s) for use:

This submission is for the addition of the VITEK® 2 Gram Positive Cefoxitin Screen to predict *mecA* -mediated resistance in staphylococci.

3. Special condition for use statement(s):

Prescription use only

Perform an alternative method of testing prior to reporting of results when a Positive (+) result is obtained with the Cefoxitin Screen and *Staphylococcus saprophyticus*

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 AST for High-Level Streptomycin

2. Predicate K number(s):

N50510/S113

3. Comparison with predicate

Similarities		
Item	Device	Predicate
Instrument	VITEK®2 System	Same
Test Card	VITEK®2 card, including the base broth	Same
Test organism	Colonies of Gram-Positive cocci	Same
	Provide qualitative, positive/negative test results	Same

Differences		
Item	Device	Predicate
Intended Use	Predict <i>mecA</i> -mediated resistance in staphylococci	Screen to determine if the enterococcal isolate will be affected synergistically by a combination of a penicillin or glycopeptide with an aminoglycoside
Antibiotic	Contains different antibiotic, Cefoxitin, and utilize different analysis algorithms	Contains different antibiotic, Streptomycin, and utilize different analysis algorithms

**K. 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-S15) “Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard”.

**L. Test Principle:**

The VITEK® 2 Cefoxitin Screen test is based on the CLSI Disk Diffusion Test for prediction of *mecA*-mediated resistance in *Staphylococci*. Each VITEK® 2 AST Card contains 64 wells. A control well containing only microbiological culture media is resident on all cards. The remaining wells contain premeasured portions of a specific antibiotic combined with culture media. The bacterial isolate to be tested is diluted to a standardized concentration with 0.45% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 automatically fills, seals and places the card into the incubator/reader. The VITEK® 2 Compact has a manual filling and sealing operation. Both VITEK® 2 systems monitor the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated. For the VITEK®2 Cefoxitin Screen, the report will list either a positive or negative result. The VITEK®2 Cefoxitin Screen and oxacillin work in combination to determine the final oxacillin interpretation based on the CLSI recommendations.

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

Ten strains of staphylococci were tested at three sites with >95% reproducibility. 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):*

The following table demonstrates the frequency of the quality control testing for both the reference method and the Vitek® 2.

<b>ORGANISM</b>	<b>Test Results</b>	<b>VITEK®2 AUTO-DIL</b>	<b>Reference AUTO-DIL</b>	<b>VITEK®2 MAN-DIL</b>	<b>Reference MAN-DIL</b>
<i>S. aureus</i> ATCC 29213 Expected Result: Neg	Negative	61	61	61	61
	Positive				
<i>S. aureus</i> ATCC BAA-1026 Expected Result: Pos	Negative				
	Positive	61	61	61	61

Quality Control was performed during the studies using both the auto-dilution and the manual method of diluting the organisms.

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 Cefoxitin test and the CLSI Cefoxitin Disk Diffusion test method prepared as recommended in CLSI M7 approved standard. Inoculum was prepared with direct colony suspension. Two methods of inoculation (manual and automated) were evaluated. Oxacillin is forced susceptible for coagulase negative staphylococci other than *S. lugdunensis* and *S. epidermidis* when the oxacillin MIC result is 0.5 – 2 µg/mL and the cefoxitin screen result is negative. This rule was used in the final analysis of the results. Clinical testing was performed using the automated method of inoculation and the challenge set was tested using both the manual and the automated method. Greater than 95% of the isolates grew in the VITEK®2 card in less than 16 hours.

The VITEK®2 system includes a limitation for not reporting results for *S. saprophyticus* when the oxacillin MIC and cefoxitin screen test together produce a resistant determination. The VITEK®2 over calls this group of organisms and a recommendation to use an alternate method is included in the labeling. With the removal of all *S. saprophyticus* that fall into that category the performance based on all other Staphylococcus is provided in

the following table when the testing was performed using the automated testing format in conjunction with the oxacillin result from the card.

	Total	Number Neg (S)	Number Pos (R)	CA	%CA	maj	vmj
<b>Clinical</b>	388	168	220	381	98.2	6	1
<b>Challenge</b>	74	49	25	74	100	0	0
<b>Combined</b>	462	217	245	455	98.5	6	1

**CA**-Category Agreement

**maj**-major discrepancies

**vmj**-very major discrepancies

CA is when the interpretation of the reference method agrees exactly with the interpretation of the VITEK®2 results.

The challenge set of organisms was also tested at one site using the manual method of inoculation demonstrating that there was no difference between the two inoculation methods.

*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:

Negative

Positive

Quality Control is the same as recommended in the CLSI standard and will be included in the package insert.

**N. Conclusion:**

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