

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

A. 510(k) Number:
K060493

B. Purpose for Submission:
To remove a limitation for the detection of vancomycin resistant staphylococci (VRSA) on Gram Positive AST Phoenix™ panels.

C. Measurand:
Vancomycin at 0.5-32 µg/mL

D. Type of Test:
Antimicrobial Susceptibility Test (Quantitative and Qualitative) colorimetric oxidation-reduction, growth-based

E. Applicant:
Becton, Dickinson & Company

F. Proprietary and Established Names:
BD Phoenix™ Automated Microbiology System – vancomycin 0.5-32 µg/mL –
Detection of VRSA

G. Regulatory Information:

1. Regulation section:
21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle
Antimicrobial
2. Classification:
Class II
3. Product Code:
LON
4. Panel:
83 Microbiology

H. Intended Use:

1. Intended use(s):
Vancomycin at 0.5-32 µg/mL on the Phoenix™ Gram Positive AST panel is intended for use with the BD Phoenix™ Automated Microbiology System for the quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus* and *Enterococcus*.

2. Indication(s) for use:

This submission is for the detection of VRSA with the antibiotic Vancomycin at 0.5-32 µg/mL on the Phoenix™ Gram Positive AST panel.

3. Special condition for use statement(s):

The Phoenix™ Gram Positive AST panel detected vancomycin resistance in the VRSA *S. aureus* strains available at the time of comparative testing. The ability to detect resistance in other *S. aureus* strains is unknown due to the limited number of resistant strains available for comparative testing.

Prescription Use Only

4. Special instrument Requirements:

Not Applicable

I. Device Description:

The BD Phoenix™ Automated Microbiology System includes instrumentation and software, sealed and self-inoculating molded polystyrene trays with 136 micro-wells containing dried reagents, and specific inoculum broth formulations for AST Indicator. The organism to be tested must be a pure culture and be preliminarily identified as gram positive or gram negative. Colonies are then suspended in broth, and equated to a 0.5 McFarland with the recommendation to use the BD CrystalSpec™ Nephelometer. A further dilution is made into an AST broth, which contains an AST indicator, prior to inoculating the panel. The AST broth is a cation-adjusted broth containing Tween 80. After adding the indicator solution to the AST inoculum, the color is blue, and after inoculation, incubation and organism growth, it changes to pink then colorless as reduction in the panel well proceeds. Inoculated panels are barcode scanned and loaded into the BD Phoenix™ Automated Microbiology System instrument where the panels are continuously incubated at 35°C. The resulting AST has a final inoculum of 5×10^5 CFU/ml. The instrument incubates, reads and records the results of the biochemical substrates and antimicrobial agents and interprets the reactions to give an MIC value and category interpretation of the antimicrobial agents. Organisms growing in the presence of a given antimicrobial agent reduce the indicator, signaling organism growth and resistance to the antimicrobial agent. Organisms killed or inhibited by a given antimicrobial do not cause reduction of the indicator and therefore do not produce a color change. Additional interpretation is done using software driven “EXPERT” System using rules derived from the Clinical and Laboratory Standards Institute (CLSI). Readings are taken every 20 minutes with an AST result available between 4-16 hours. This is only an autoread result; there are no manual readings possible.

J. Substantial Equivalence Information:

1. Predicate device name(s):

VITEK® System

2. Predicate K number(s):
N50510

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Intended for the <i>in vitro</i> quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most bacteria.	Same
Isolates	Isolated colonies from culture used	Same
Results	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR)	Same
Incubation conditions	<16 hours	Same
Type of Test	Automated	Same

Differences		
Item	Device	Predicate
Reading algorithm	Results are determined from serial twofold dilutions of antimicrobial agents	Results are determined from extrapolation of doubling dilutions
Technology	Automated growth based enhanced by use of a redox indicator (colorimetric oxidation-reduction) to detect organism growth.	Automated growth based with detection using an attenuation of light measured by an optical scanner.

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:

The AST portion of the BD Phoenix™ Automated Microbiology System is a broth based microdilution method that utilizes a redox indicator (colorimetric oxidation-reduction) to enhance detection of organism growth. The MIC is determined by comparing growth in wells containing serial two-fold dilutions of an antibiotic to the growth in “growth control wells” which contain no antibiotic.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility

Intersite and Intrasite testing demonstrated >95% reproducibility using 12 strains. The ten isolate study described in the guidance document was used (10 organisms tested 3 times on 3 days at 3 sites).

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or method):

Ability to provide acceptable Quality Control with the recommended strains was established previously with additional testing during the study. Comparison was made to expected values as established for the well characterized strains.

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 well characterized challenge set of 53 staphylococci with MICs ranging from 2 -8 were tested on the Phoenix™ Gram Positive AST panel and compared to an expected value pre determined using the broth reference method. Additionally 3 known VRSA were also tested on the Phoenix™ Gram Positive AST Panel with results that were >16 for all three isolates. The combined EA was 96.2% with no major or very major errors. There is a slight trend for the Phoenix result to produce a more resistant result if only by one well.

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:

Interpretative criteria – ≤ 4 µg/ml (S) 8-16 µg/ml (I) and ≥ 32 µg/ml (R)

N. Labeling:

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

Vancomycin MIC of ≥ 4 µg/mL are recommended for follow up because this is considered an unusual result for staphylococcus

O. Conclusion:

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