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

A. 510(k) Number:
k032299

B. Analyte:
Ampicillin 0.5 – 32 µg/mL Gram-Negative AST

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

D. Applicant:
Becton, Dickinson & Company

E. Proprietary and Established Names:
BD Phoenix™ Automated Microbiology System – Ampicillin Gram Negative

F. 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

G. Intended Use:

1. Intended use(s):
   BD Phoenix™ Automated Microbiology System:
   The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration of gram-negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non – *Enterobacteriaceae* and gram-positive bacteria belonging to the genera *Staphylococcus* and *Enterococcus*.

   The BD Phoenix™ GN Panel:
   The BD Phoenix™ Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of gram-negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non – *Enterobacteriaceae*.

2. Indication(s) for use:

This submission is for the addition of the antibiotic ampicillin at concentrations of 0.5 – 32 µg/mL to the gram negative susceptibility panel for testing *Enterobacteriaceae*.

3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   Not applicable

H. 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 ID and 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 formulation of Mueller-Hinton broth containing 0.01% Tween 80. After adding the indicator solution to the AST inoculum the color is blue and after inoculation and incubation goes to pink to 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 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 ID of the isolate and MIC value and category interpretation of the antimicrobial agents. Organisms growing in the presence of a given antimicrobic agent reduce the indicator, signaling organism growth and resistance to the antimicrobic agent. Organisms killed or inhibited by a given antimicrobic 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 NCCLS documentation.

Readings are taken every 20 minutes with an ID result available between 2-12 hours and an AST result available between 4-16 hours. This is only an autoread result; there are no manual readings possible.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   VITEK® System
2. Predicate K number(s):
   N50510
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
1.	Isolated colonies from culture used	Isolated colonies from culture used
2.	Inoculum density equated to 0.5 McFarland standard	Inoculum density equated to 0.5 McFarland standard
3.	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR)	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR)
4.	<16 hours	<16 hours
Differences		
Item	**Device**	**Predicate**
1.	Results are determined from serial twofold dilutions of antimicrobial agents	Results are determined from extrapolation of doubling dilutions
2.	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.

J. 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-S13) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard."

K. Test Principle:

The system employs conventional, colorimetric, fluorogenic and chromogenic substrates to identify the genus and species of the isolate. 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.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*
      Reproducibility within sites was determined using the QC isolates for >95% reproducibility. Between sites was performed at three sites for three days in triplicate for >95% reproducibility on 16 isolates.
    - *b. Linearity/assay reportable range:*
      Not applicable
    - *c. Traceability (controls, calibrators, or method):*

The recommended QC isolate was tested a sufficient number of times with acceptable results with the reference method. The Phoenix results demonstrate that the system can produce QC results in the recommended range.

ORGANISM	**conc.**	**Reference**	**Phoenix**
E. coli	2	3	383
ATCC 25922	4	318	1
Expected Range:	8	63	3
2 – 8 µg/mL	>32	1	

Inoculum density control: The organism suspension density of the ID broth was equivalent to a 0.5 McFarland standard using the BBL™ CrystalSpec™ Nephelometer which was verified each day of testing. Internal data was used to demonstrate that the use of the BBL™ CrystalSpec™ Nephelometer would produce reproducible results. Five different instruments were used.

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:
The NCCLS recommended broth dilution reference panel was prepared according to the NCCLS recommendation. Clinical testing was performed at six sites. The testing included both fresh clinical isolates and stock isolates along with a challenge set with known results. The test device had a growth rate of >99%. A comparison was provided to the reference method with the following agreement.

	EA Tot	**EA N**	**EA %**	**Eval EA Tot**	**Eval EA N**	**Eval EA %**	**CA N**	**CA %**	**#R**	**min**	**maj**	**vmj**
Clinical	**802**	**788**	**98.3**	**342**	**331**	**96.8**	**790**	**98.5**	**398**	**7**	**3**	**2**
Challenge	**36**	**34**	**94.4**	**5**	**5**	**100.0**	**34**	**94.4**	**29**	**1**	**0**	**1**
Combined	**838**	**822**	**98.1**	**347**	**336**	**96.8**	**824**	**98.3**	**427**	**8**	**3**	**3**

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

Essential agreement (EA) is when the BD Phoenix™ panels agree with the reference test panel results exactly or within one doubling

dilution of the reference method. Category agreement (CA) is when the BD Phoenix™ panel result interpretation agrees exactly with the reference panel result interpretation.

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:
   ≤8(S), 16(I), ≥32(R)
   The expected value range, interpretative criteria and QC are the same as recommended in NCCLS. All values will be included in the package insert.

M. Conclusion:

This demonstrates acceptable performance as described in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA" and therefore the testing of ampicillin on the BD Phoenix™ Automated Microbiology System is substantially equivalent to other commercial devices such as bioMerieux VITEK® AST panels.