

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

A. 510(k) Number:

k031679

B. Analyte:

Gentamicin Synergy (500 ug/ml) and Streptomycin Synergy (1000 ug/ml)-AST

C. Type of Test:

Qualitative, colorimetric oxidation-reduction, growth-based

D. Applicant:

BD Diagnostic Systems

E. Proprietary and Established Names:

BD Phoenix™ Automated Microbiology System

F. Regulatory Information:

1. Regulation section:
CFR 866.1645
2. Classification:
II
3. Product Code:
LON
4. Panel:
83

G. Intended Use:

1. Intended use(s):

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 most glucose nonfermenting gram-negative rods and gram-positive bacteria belonging to the genera *Staphylococcus* and *Enterococcus*.

2. Indication(s) for use:

This is for the addition of the antimicrobial agents gentamicin synergy at a concentration of 500 ug/ml and streptomycin synergy at a concentration of 1000 ug/ml to Gram Positive ID/AST or AST only Phoenix panels.

Gentamicin synergy and streptomycin synergy are used to predict synergy between ampicillin, penicillin or vancomycin and an aminoglycoside with enterococci.

3. Special condition for use statement(s):

4. Special instrument Requirements:

H. Device Description:

The PHOENIX 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 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 a 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 auto-read 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
specimen	Isolated colonies from culture used	Isolated colonies from culture used
Inoculum	Inoculum density to 0.5 McFarland standard	Inoculum density to 0.5 McFarland standard
Incubation	<16 hours	< 16 hours
panels	Dried antibiotics at different concentrations	Dried antibiotics at different concentrations
Differences		
Item	Device	Predicate
results	Qualitative based on a single concentration	Qualitative based on extrapolation of a single concentration.

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

NCCLS M7 for the method

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 PHOENIX™ 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:*

Inter-site and intra-site reproducibility was >95 % for both antimicrobial agents when testing 10 *Enterococcus* isolates 3 times at each of the three sites

b. *Linearity/assay reportable range:*

Not applicable

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

NCCLS recommended Quality Control strains *E. faecalis* ATCC 29212 (susceptible) and *E. faecalis* ATCC 51299 (resistant) were tested over 200 times each with expected results 99.6% of the time.

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.

d. Detection limit:

e. Analytical specificity:

f. Assay cut-off:

2. Comparison studies:

a. Method comparison with predicate device:

The NCCLS recommended broth reference panel prepared according to the NCCLS recommendation was used to compare the Phoenix™ results. Clinical testing was performed at four sites. The testing included both fresh clinical isolates and stock isolates along with a challenge set with known results. Average time to final result on the BD Phoenix™ was determined in 5 hours. All reference Gentamicin results were read at 24 hours and all negative streptomycin were read at 48 hours. There was a 0.9% no growth rate in the study. A comparison was provided to the reference method with the following agreement.

Performance of high level Gentamicin

	total	CA	%CA	#R	maj	vmj
Clinical	718	709	98.7	246	3	6
Challenge	45	43	95.6	21	1	1
Combined	763	752	98.6	267	4	7

Performance for high level streptomycin

	total	CA	%CA	#R	maj	vmj
Clinical	711	696	97.9	258	4	11
Challenge	45	43	95.6	17	2	0
Combined	756	739	97.8	275	6	11

CA = category agreement where the Phoenix® result is exactly the same as the reference method result.

R = Resistant number of isolates tested

Maj= major error where the reference method is susceptible and the Phoenix® is resistant

Vmj = very major error when the reference method is resistant and the Phoenix® is susceptible

b. Matrix comparison:

3. Clinical studies:

a. Clinical sensitivity:

b. Clinical specificity:

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
5. Expected values/Reference range:
Gentamicin; ≤ 500 ug/ml (S), ≥ 500 ug/ml (R)
Streptomycin; ≤ 1000 ug/ml (S), ≥ 1000 ug/ml (R)

M. Conclusion:

Data analysis when analyzed as recommended in the “Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA” demonstrates that the Phoenix® System is substantially equivalent to the Vitek® System for the detection of high level gentamicin and streptomycin synergy.