

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

A. 510(k) Number:

k041214

B. Purpose of Submission:

Addition of daptomycin to the Pasco MIC and MIC/ID Panels

C. Analyte:

Daptomycin at 0.06 - 8 ug/ml

D. Type of Test:

Quantitative – broth based growth detected by turbidity

E. Applicant:

BD Diagnostic Systems – Pasco Laboratories

F. Proprietary and Established Names:

Pasco MIC and MIC/ID Panels

G. Regulatory Information:

1. Regulation section:
866.1640 - Antimicrobial Susceptibility Test Powder
2. Classification:
II
3. Product Code:
JWY - Manual Antimicrobial Test Systems
4. Panel:
83 - Microbiology

H. Intended Use:

1. Intended use(s):
Pasco MIC and MIC/ID panels are used for quantitatively measuring the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of these organisms.

The MIC Supplemental III panel contains antimicrobial agents fully diluted to concentrations appropriate for testing *S. pneumoniae* and other *Streptococcus spp.* which require the use of SP Blood Supplement for inoculation. This panel also contains antimicrobial agents at concentrations appropriate for testing various non-fastidious organisms which use routine inoculation procedure.

2. Indication(s) for use:
The indication is for the addition of the antimicrobial Daptomycin at concentrations of 0.06 – 8 ug/ml to Pasco Panels for use in testing *Streptococcus spp.* other than *S. pneumoniae*.
3. Special condition for use statement(s):
Routine turbidity method of inoculation.
Beta Hemolytic Streptococci only

Prescription use only
4. Special instrument Requirements:
Not Applicable

I. Device Description:

Various concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco microdilution panels and the panels are then frozen. Panels are thawed prior to use, inoculated with the test organisms, incubated the traditional 16-24 hours at 35° in a non-CO₂ incubator and panels are then observed for visible growth or color changes (ID portion). The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Only manual readings are performed using an indirect lighted background viewer.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Pasco MIC Panels- gatifloxacin
2. Predicate K number(s):
K032259
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Type panel	100 µl/well frozen	100 µl/well frozen
Inoculum	5 µl	5 µl
Inoculation method	Direct equated to a 0.5 McFarland	Direct equated to a 0.5 McFarland
Incubation	16-24 hours	16-24 hours
Reading method	Visual growth	Visual growth
Differences		
Item	Device	Predicate
Antibiotic	Daptomycin at predefined 2-fold dilutions	Gatifloxacin at predefined 2-fold dilutions

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

“Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA”, NCCLS Standard M7 *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard; M100 Performance Standards for Antimicrobial Susceptibility Testing*.

L. Test Principle:

The test panels are dependent on the growth of the organisms in the presence of antibiotics. These antibiotics are diluted to appropriate test concentrations in cation adjusted Mueller Hinton Broth adjusted to ionized physiologic levels with calcium and magnesium. The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC).

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

Thirteen on-scale *Streptococcus spp.* were tested at three sites on three separate days in triplicate. The reproducibility was acceptable at >95%.

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 Pasco results demonstrated that the system can produce QC results in the recommended range.

ORGANISM	Conc ug/ml	Reference	Pasco turbidity
<i>S. pneumoniae</i>	0.06		
ATCC 49619	0.12	53	46
Expected Range	0.25	21	28
0.06-0.5 ug/ml	0.5		

Inoculum Density Check- An internal study was performed to verify the colony counts (CC) that would be obtained with the routine turbidity method of inoculation. Clinical site inoculum density checks were also performed on QC isolates, reproducibility isolates

and a subset of the clinical isolates and demonstrated the appropriate inoculum was 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:*

Broth reference panels supplemented with 2-5% lysed horse blood prepared according to the recommendations of the NCCLS were used to compare with the Pasco results. The concentration of calcium on the Mueller Hinton Broth was also adjusted to 50 ug/mL as recommended by the NCCLS and FDA. Testing was performed at 3 sites and included fresh and stock clinical isolates and a set of challenge organisms. Although the number of challenge isolates tested was not that many, there were sufficient number tested in clinicals with a very good EA%. Category agreement is not determined since there is only a susceptible interpretative category. The comparison resulted in the following performance evaluations.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA of evaluable	#R	min	maj	vmj
Clinical	181	181	100.0	97	97	100.0	2	0	0	0
Challenge	25	25	100.0	9	9	100.0	0	0	0	0
Combined	206	206	100.0	106	106	100.0	2	0	0	0

EA-essential agreement

R-resistant isolates

maj-major discrepancies

vmj-very major discrepancies

min- minor discrepancies

EA is when there is agreement between the reference method and the Pasco panel within plus or minus one serial two-fold dilution of antibiotic. The %EA is acceptable with acceptable discrepancy rates when compared to the reference method as described in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA".

There are no vmj, maj or minor errors encountered in the overall submission. The %EA and %EA of evaluable are both very good.

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:

Streptococcus spp. ≤ 1 (S)

These interpretative criteria are the same as those in the FDA approved daptomycin pharmaceutical package insert. The recommended QC is also the same and appears in the package insert.

The current absence of data on resistant strains precludes defining any results other than “Susceptible”. Strains yielding MIC results suggestive of a “non-susceptible” category should be submitted to a reference laboratory for further testing.

N. Conclusion:

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