

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

A. 510(k) Number:

k033119

B. Analyte:

Daptomycin – 0.06-8 ug/mL AST

C. Type of Test:

Quantitative – broth based growth detected by turbidity

D. Applicant:

Pasco Laboratories -BD Diagnostic Systems

E. Proprietary and Established Names:

Pasco™ MIC and MIC/ID Panels

F. 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

G. Intended Use:

1. Intended use(s):
Pasco™ 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.
2. Indication(s) for use:
The indication is for including the antibiotic daptomycin at concentrations of 0.06-8 ug/mL to Pasco™ Panels for testing *Staphylococcus spp.* and *Enterococcus spp.* on the gram positive panels.
3. Special condition for use statement(s):
The ability to detect resistance is unknown since there is no category but susceptible. Any result other than susceptible should be submitted to a reference laboratory.
4. Special instrument Requirements:
Manual reading only

H. 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.

Inoculation procedures include the Direct Turbidity Standard method and Stationary Phase methods which use a spectrophotometer to equate the suspension to a 0.5 McFarland and the Director™ Inoculation System which does not use a spectrophotometer.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Pasco MIC Panels
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 or Director™ Inoculator	Direct equated to a 0.5 McFarland or Director™ Inoculator
Incubation	16-24 hours	16-24 hours
Reading method	Visual growth	Visual growth
Differences		
Item	Device	Predicate
Antibiotic	Daptomycin	Gatifloxacin

J. 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*.

K. Test Principle:

The test panels are dependent on the growth of the organisms in the presence of the antibiotics. The lowest concentration of each antimicrobial agent with no apparent

visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC).

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Ten isolates with on-scale results were tested at three sites. These were evaluated for site to site reproducibility and inter site reproducibility using the ten isolate study described in the guidance document (10 organisms tested 3 times on 3 days at 3 sites).

This study was performed on both the turbidity standard method and the Director™ Inoculation System method. Both were reproducible at >95% for intra site and inter site testing.

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 demonstrate that the system can produce QC results in the recommended range for both the Direct and the Director methods of inoculation. The reference and the Director method of inoculation had the same mode while the turbidity method of inoculation has a mode that was one well more susceptible.

ORGANISM	conc	Reference	Pasco™ turbidity	Pasco™ Director
S. aureus ATCC 29213 Range 0.25-1 ug/mL	0.12			
	0.25	24	117	4
	0.5	113	21	102
	1	1		4
	2			
E. faecalis ATCC 29212 Range 1-8 ug/mL	0.5			
	1	5	15	4
	2	103	109	85
	4	30	14	11
	8			
	>8			

Inoculum Density Check- An internal study was performed to verify the colony counts (CC) that would be obtained with each method of inoculation. CC demonstrated that the Pasco™ direct turbidity inoculation method results in a slightly less concentration of organisms than the reference method. The Director appeared to have a slightly

wider range of results. Clinical site inoculum density checks were also performed on QC isolates with the Director Inoculation method and the Turbidity method demonstrating acceptable performance.

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 prepared according to the recommendations of the NCCLS were used to compare to the Pasco results. The concentration of calcium on the Mueller Hinton Broth was adjusted to 50 ug/mL as recommended by the NCCLS and FDA. Testing was performed at 3 sites and included fresh (78%) and stock (22%) clinical isolates and a set of challenge organisms. The comparison resulted in the following performance evaluations for the gram positive panel. Category agreement is not determined since there is only a susceptible interpretative category.

The following are the comparative results for the *Staphylococcus spp.*

	total	EA	%EA	Total evaluable	EA of evaluable	%EA
Clinical	349	348	99.7	346	345	99.7
Challenge	64	63	98.4	64	63	98.4
Combined	413	411	99.5	410	408	99.5

The following are the comparative results for the *Enterococcus spp.*

	total	EA	%EA	Total evaluable	EA of evaluable	%EA
Clinical	318	316	99.4	311	309	99.4
Challenge	47	47	100	47	47	100
Combined	365	363	99.4	358	356	99.4

EA-Essential Agreement

There is a trend for the direct turbidity method of inoculation with the Pasco™ panel to produce results that are more susceptible than the reference method result.

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 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”.

Testing of the challenge set was also performed using the Director™ Inoculation System method of inoculation demonstrating little difference between the two methods of inoculation. Summary table of the Director™ Inoculation System from two sites follows:

Staphylococcus spp.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA
Challenge	128	128	100	128	128	100

Enterococcus spp.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA
Challenge	94	94	100	93	93	100

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:

Staphylococcus spp. ≤ 1 (S)

Enterococcus spp. ≤ 4 (S)

The Interpretative criteria, QC isolates and the expected ranges are the same as recommended by the NCCLS and the FDA. All values will be included in the package insert

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 Pasco™ Panel with daptomycin is substantially equivalent to the Pasco™ Panels with other antibiotics for the testing of appropriate organisms.