

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

A. 510(k) Number:

K041776

B. Purpose of Submission:

To add telithromycin to the Pasco MIC Supplemental III panel

C. Analyte:

Telithromycin (0.015-4 ug/mL) AST

D. Type of Test:

Quantitative Antimicrobial Susceptibility Test (AST) growth based fluorescence

E. Applicant:

Pasco Laboratories-BD Diagnostic Systems

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 readings of AST testing of >16 hour incubation
4. Panel:
83 Microbiology

H. Intended Use:

5. 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 *Streptococcus 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 procedures.

6. Indication(s) for use:

The indication is for the addition of the antimicrobial telithromycin at concentrations of 0.015-4 ug/mL to the Pasco Panels for use in testing *Streptococcus pneumoniae* and *Streptococcus spp.* other than *Streptococcus pneumoniae*.

7. Special condition for use statement(s):

The ability of the MIC Supplemental III panel to detect resistance to telithromycin among *Streptococcus spp.* is unknown because sufficient numbers of resistant strains were not available at the time of testing and should be retested. If the non-susceptible result is confirmed, the strain should be sent to a reference laboratory for further testing.

For Prescription Use Only

8. Special instrument Requirements:

Not applicable

I. Device Description:

Pasco MIC panels are multi-well plastic microtitre plates. Various concentrations of antimicrobics are dispensed into the Pasco microdilution panels and the panels are then frozen. Inoculum is prepared in saline and equated to a 0.5 McFarland standard. A final dilution is prepared in lysed horse blood to yield a final concentration in the wells of the test panel of approximately 2.5%. Panels are thawed prior to use, and inoculated with the test organisms. Plates are incubated for 16-24 hours at 35° in a non-CO² incubator and 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, with recommendations to use a spectrophotometer to adjust the final inoculum concentration equal to the 0.5 McFarland standard.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Pasco MIC Panels with Daptomycin

2. Predicate K number(s):

K041214

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	an <i>in vitro</i> diagnostic product for clinical susceptibility testing of clinical organisms.	same
Inoculum	Prepared from colonies using the direct inoculation method	same
Panel type	Frozen panels	same
Inoculation method	Direct equated to a 0.5 McFarland	same
Incubation	16-24 hours	same
Reading method	Visual growth	same
Difference		
Item	Device	Predicate
Antibiotic	Serial dilutions of telithromycin	Serial dilutions of daptomycin

K. 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-S14)

“Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard”

L. Test Principle:

The test panels are dependent on the growth of the organisms in the presence of the antibiotics. The minimum inhibitory concentration (MIC) is determined by observing the lowest dilution of antimicrobial agent that inhibits growth of the organism.

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

Reproducibility testing was performed on 9 isolates of *Streptococcus pneumoniae* and 3 isolates of *Streptococcus spp.* other than *Streptococcus pneumoniae* appropriate for testing with telithromycin. The organisms were tested in triplicate at three sites on three separate days with a different inoculum prepared for each test. The testing demonstrated an intra- and inter- site reproducibility of 100% for the routine turbidity inoculum method.

b. *Linearity/assay reportable range:*

Not applicable

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

The recommended QC isolate was tested daily with acceptable results with the reference method. Quality control was also performed at all sites on each day of testing. The Pasco results demonstrate that the system can produce QC results in the recommended range.

ORGANISM	Conc ug/mL	Reference	Routine
<i>S. pneumoniae</i> ATCC 49619 Range 0.004-0.03 ug/ml	≤0.015	73	73
	0.03	1	1
	0.06		
<i>S. pneumoniae</i> ATCC 4223 Range 0.03-0.12 ug/ml	0.015		
	0.03	2	3
	0.06	35	33
	0.012	4	5

The Nephelometer was used at each site to standardize the inoculum and it was calibrated each time prior to setup. Colony counts were performed periodically with a mean range of 1×10^6 - 5×10^5 cfu/ml.

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 dilutions were made using Mueller-Hinton broth supplemented with lysed horse blood 2.5% v/v. Broth reference panels prepared according to the recommendations of the NCCLS M-7 document (Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically) were used to compare to the Pasco panel results. Testing was performed at 3 sites and included fresh and stock clinical isolates and a set of challenge organisms. The comparison resulted in the following performance evaluations for the MIC Supplemental III panel.

The following are the comparative results of test accuracy of the Pasco system as compared to the reference method.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	470	470	100	157	157	100	470	100	2	0	0	0
Challenge	200	199	99.5	79	78	98.7	200	100	6	0	0	0
Combined	670	669	99.9	236	235	99.6	670	100	8	0	0	0

EA-Essential agreement

maj-major discrepancies

CA-Category agreement

min-minor discrepancies

R- Resistant isolates

vmj-very major discrepancies

EA is when there is agreement between the reference method and the MIC Supplemental III panel within plus or minus one serial two-fold dilution of antibiotic. CA is when the interpretation of the reference method agrees exactly with the interpretation of the Pasco result. 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".

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 is not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range: (Interpretive Criteria)

Streptococcus pneumoniae and *Streptococcus spp. other than Streptococcus pneumoniae* ≤ 1 (S), 2 (I), ≥ 4 (R)

The Interpretative criteria, QC isolates and the expected ranges are the same as recommended by the NCCLS and the FDA.

N. Conclusion:

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