

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

A. 510(k) Number:

k032518

B. Analyte:

Gemifloxacin at 0.015-4 ug/ml

C. Type of Test:

Quantitative – broth based growth detected by turbidity

D. Applicant:

BD Diagnostic Systems – Pasco Laboratories

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 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 Gemifloxacin at concentrations of 0.015– 4 ug/ml to Pasco Panels for use in testing *Streptococcus pneumoniae* and *Streptococcus spp.* other than *S. pneumoniae*.
3. Special condition for use statement(s):
Direct turbidity method of inoculation.
4. Special instrument Requirements:
Not Applicable

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.

I. 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	Gemifloxacin at predefined 2-fold dilutions	Gatifloxacin at predefined 2-fold dilutions

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 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 Quality Control (QC) isolate was tested a sufficient number of times with acceptable results with the reference method. An additional isolate was selected that would provide on scale results all the time. The Pasco results demonstrate that the system can produce QC results in the recommended range.

ORGANISM	Conc ug/ml	Reference	Pasco turbidity
S. pneumoniae	≤ 0.015	71	74
ATCC 49619	0.03	3	
Expected Range	0.06		
0.008-0.03			
ug/ml			
S. pneumoniae	0.12		
Pasco 4223	0.25	3	
Expected Range	0.5	38	40
0.25-2 ug/ml	1		1
	2		

Inoculum Density Check- An internal study was performed to verify the colony counts (CC) that would be obtained with each 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 M7 were used to compare to the Pasco results. Testing was performed at 3 sites and included fresh and stock clinical isolates and a set of challenge organisms. The selection of *S. pneumoniae* included both penicillin resistant and penicillin susceptible. The comparison resulted in the following performance evaluations.

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	Min	maj	vmj
Clinical	470	468	99.6	194	192	99	464	98.7	8	6	0	0
Challenge	100	100	100	30	30	100	100	100	5	0	0	0
Combined	570	568	99.6	224	222	99	564	98.9	13	6	0	0

EA-Essential Agreement

CA-Category 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. CA is when the interpretation of the reference method agrees exactly with the interpretation of the Pasco result. The %EA and CA are 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".

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:

≤ 0.12 (S), 0.25 (I), ≥ 0.5 (R)

These interpretative criteria are the same as those in the FDA approved gemifloxacin pharmaceutical package insert and the NCCLS M100 Standard.

The recommended QC is also the same and appears 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 System is substantially equivalent to the predicate.