510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K162740

B. Purpose for Submission:

To obtain a substantial equivalence determination for the addition of the reformulated imipenem to the MicroScan Dried Gram-Negative MIC/Combo Panels with Imipenem (0.25 – 8 µg/mL) for testing *Acinetobacter* spp. *Citrobacter* spp., *Enterobacter* spp., *Escherichia coli, Klebsiella spp., Morganella morganii, Proteus vulgaris, Providencia rettgeri* and *Pseudomonas aeruginosa***.**

C. Measurand:

Imipenem in the dilution range of 0.25 – 8 µg/mL

D. Type of Test:

Quantitative Antimicrobial Susceptibility Test (AST).

E. Applicant:

Beckman Coulter

F. Proprietary and Established Names:

MicroScan Dried Gram-Negative MIC/Combo Panels with Imipenem (0.25 -8 µg/ml)

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1640 Antimicrobial Susceptibility Test Powder

2. Classification:

   Class II

3. Product codes:

   LTT – Panels, Test, Susceptibility, Antimicrobial

JWY – Manual Antimicrobial Susceptibility Test Systems

LRG – Instrument for Auto Reader and Interpretation of Overnight Susceptibility Systems

LTW – Susceptibility Test Cards, Antimicrobial

4. Panel:

83 - Microbiology

H. Intended Use:

1. Intended use(s):

For use with MicroScan Dried Gram Negative MIC/Combo Panels and Dried Gram Negative Breakpoint Combo panels. MicroScan panels are designed for use in determining antimicrobial agent susceptibility and/or identification to the species level of aerobic and facultatively anaerobic gram-negative bacilli.

2. Indication(s) for use:

The MicroScan Dried Gram-Negative MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing and facultative anaerobic gram-negative bacilli. After inoculation, panels are incubated for 16 – 20 hours at 35°C ± 1°C in a non-CO_2 incubator and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the reformulated antimicrobial imipenem at concentrations of 0.25 to 8 µg/mL to the test panel.

The gram-negative organisms which may be used for imipenem susceptibility testing in this panel are:

Acinetobacter spp. *Citrobacter* spp., *Enterobacter* spp., *Escherichia coli, Klebsiella spp., Morganella morganii, Proteus vulgaris, Providencia rettgeri* and *Pseudomonas aeruginosa***.**

3. Special conditions for use statement(s):

For prescription use only.

Limitations:

Imipenem results obtained with P. aeruginosa and Acinetobacter sp. using the Prompt Inoculation system have shown potential major errors. If critical to

patient care, isolates of those species that provide a resistant interpretation should be retested using the turbidity inoculation method.

Results obtained with Proteus mirabilis, Providencia stuartii and Serratia species and imipenem have shown discrepant MICs when compared with the reference method. If the antimicrobial agent is critical to patient care, an alternative procedure should be used.

4. Special instrument requirements:

   MicroScan panels can be read either manually or automatically on the WalkAway or autoScan-4 instrument systems.

I. Device Description:

The MicroScan Dried Gram-Negative MIC/Combo panel with imipenem is used to determine the quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-negative bacilli. After inoculation panels are incubated for 16-20 hours at 35°C ± 1°C in a non-CO2 incubator and read either visually or with MicroScan instrumentation according to the package insert.

Inoculation methods: Turbidity, Prompt Inoculation System

Read methods: Manual, MicroScan WalkAway System and MicroScan-4 autoSCAN-4

J. Substantial Equivalence Information:

1. Predicate device name(s):

   MicroScan Dried Gram-Negative MIC/Combo Panels – Tigecycline

2. Predicate 510(k) number(s):

   K083262

3. Comparison with predicate:

Table 1. Comparison with the Predicate

Similarities		
Item	Device	Predicate
Product Name	MicroScan Dried Gram-Negative MIC/Combo Panels - Imipenem	MicroScan Dried Gram-Negative MIC/Combo Panels - Tigecycline
Technology	Overnight microdilution MIC susceptibility	Same
Result Reported	Report results as minimum inhibitory concentration (MIC) and categorical interpretation (SIR)	Same
Read Methods	Manual and automated	Same
Inoculation Methods	Turbidity and Prompt™	Same
Instrumentation	WalkAway or autoSCAN-4 Instrument systems	Same

Differences		
Item	Device	Predicate
Intended Use	Determination of susceptibility to imipenem with gram-negative bacteria	Determination of susceptibility to tigecycline with gram-negative bacteria
Antimicrobial agent	Imipenem 0.25 – 8 µg/mL	Tigecycline 0.015 – 32 µg/mL

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

1. Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA
2. CLSI M7-A10. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, January, 2015.
3. CLSI M100-S26. Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Fourth Informational Supplement.

L. Test Principle:

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test which have been dehydrated. Various antimicrobial agents are diluted in Mueller Hinton broth supplemented with calcium and magnesium to concentrations bridging the range of clinical interest. Breakpoint Combo panels use concentrations equivalent to the categorical breakpoints of FDA and/or CLSI. After inoculation and rehydration with a standardized

suspension of organism and incubation of 35°C for a minimum of 16 hours, the minimum inhibitory concentration (MIC) for the test organism is determined by observing the lowest antimicrobial concentration showing inhibition of growth.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A reproducibility study was conducted at three sites using ten isolates of gram negative bacilli that were consistent with the intended use. Isolates were tested in triplicate over three days for a total of 270 data points. The isolates tested in the reproducibility study included *Acinetobacter baumannii*/*haemolyticus* (two isolates), *Citrobacter freundii* complex (one isolate), *Enterobacter aerogenes* (two isolates), *Escherichia coli* (two isolates) and *Pseudomonas aeruginosa* (three isolates). Inocula were prepared using both the turbidity and Prompt™ method and results were read manually and with the WalkAway and autoSCAN-4 instrument systems. The vast majority of data points were on-scale and only two to four data points were off-scale by the different read methods. The reproducibility is therefore calculated for "best case" and "worst case" as defined in the AST Special Controls Guidance taking into consideration the on-scale and off-scale data points.

Table 2. Reproducibility Results with all inoculation and read methods.

Read Method		Prompt Inoculation	Turbidity Inoculation
WalkAway	Best Case	267/270 (98.8%)	267/270 (98.9%)
	Worst Case	267/270 (98.8%)	267/270 (98.9%)
autoSCAN-4	Best Case	269/270 (99.6%)	266/270 (98.5%)
	Worst Case	269/270 (99.6%)	266/270 (98.5%)
Manual	Best Case	268/270 (99.3%)	270/270 (100%)
	Worst Case	268/270 (99.3%)	270/270 (100%)

The reproducibility results were acceptable.

b. Linearity/assay reportable range:

N/A

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Inoculum Density Check. A spectrophotometric device, the MicroScan Turbidity Meter) was used to ensure quality control of the turbidity inoculum method. The

turbidity inocula were prepared using the MicroScan Turbidity Meter with a reading of 0.08 ± 0.02 (equivalent to a 0.5 McFarland barium sulfate turbidity standard). The digital reading was recorded each day of use.

Data was also collected during the Reproducibility phase using the Prompt inoculum preparation method. Colony counts were performed weekly on the quality control strain *E. coli* ATCC 25922. Colony counts were also done once at each site for each reproducibility isolate.

Purity Check. Purity check plates were performed on all isolates from each inoculum preparation.

Growth Failure Rate. During the course of the study there were no growth failures with the MicroScan panel with imipenem.

Quality Control Testing. The CLSI and FDA recommended QC organisms (*E. coli* ATCC 25922 and *P. aeruginosa* ATCC 27853) were tested using all inoculation and read methods. The results are shown in Tables 3 and 4.

Table 3. Quality Control results for Imipenem with *E. coli*, ATCC 25922

Organism	Conc (µg/mL)	Ref	Prompt Inoculation Method			Turbidity Inoculation Method		
			Manual	WalkAway	AS4	Manual	WalkAway	AS4
E. coli ATCC 25922 Expected Range 0.06 – 0.25	≤ 0.25	187	193	190	193	183	182	182
	0.5	1	4	8	5	3	5	3
	1	-	-	-	-	1	1	1
	2	-	1	1	1	1	1	2
	4	1	1	-	-	1	1	-
	8	-	-	-	-	-	-	-
	16	-	-	-	-	-	-	-
	32	-	-	1	1	-	-	-
	>32	-	1	-	-	-	-	-

The expected range for *E. coli* ATCC 25922 with imipenem is 0.06 – 0.25 µg/mL and the whole range is below the dilutions included in the MicroScan panel with imipenem (0.25 – 8 µg/mL). Greater than 95% of the results obtained with the MicroScan panel were ≤0.25 µg/mL. Since the expected range is off-scale for the dilutions present on the MicroScan panel, the sponsor included the following footnote to the QC table in labeling:

> **"***Panels do not include the full CLSI/FDA recommended dilution range for QC testing with this organism."*

Because the expected range for *E. coli* ATCC 25922 with imipenem falls below the lowest concentration on the MicroScan panel, the sponsor conducted additional QC with *P. aeruginosa* ATCC 27853.

Table 4. Quality Control Results for Imipenem with *P. aeruginosa*, ATCC 27853

Organism	Conc (µg/mL)	Ref	Prompt Inoculation Method			Turbidity Inoculation Method		
			Manual	WalkAway	AS4	Manual	WalkAway	AS4
P. aeruginosa ATCC 27853 Expected Range 1 – 4 µg/mL	≤ 0.25	-	-	-	-	-	-	-
	0.5	-	-	-	-	-	-	-
	1	32	22	1	13	43	5	20
	2	149	175	185	181	142	177	164
	4	8	4	13	6	1	2	-
	8	-	-	3	-	1	2	1
	16	-	-	-	-	-	-	-
	32	-	-	-	-	-	-	-
	>32	-	-	-	-	-	-	-

Quality control results with *P. aeruginosa*, ATCC 27853 showed > 95% agreement with the expected value for all inoculation and read methods and demonstrated that the system could produce the expected quality control results.

The quality control results are acceptable.

d. Detection limit:

N/A

e. Analytical specificity:

N/A

f. Assay cut-off:

N/A

2. Comparison studies:

a. Method comparison with predicate device:

Results obtained with the MicroScan Dried Gram-Negative MIC/Combo Panel with reformulated imipenem were compared to results obtained with the CLSI frozen broth microdilution reference panel. The range of dilutions evaluated with the MicroScan panels was 0.25 – 8 µg/mL.

Two inoculation methods were used: the Prompt Inoculation System and the turbidity method. For the Prompt Inoculation System, inocula were prepared using the instructions of the manufacturer. For the turbidity method, inocula were standardized using the MicroScan Turbidity Meter to approximate a 0.5 McFarland turbidity standard. Reference panels were inoculated using the turbidity method.

Three read methods were evaluated: manual read, automated read using the WalkAway and automated read using the autoScan-4. Reference panels were manually read.

A total of 419 clinical isolates were evaluated including *Acinetobacter* spp. (39 isolates), *Citrobacter* spp. (21 isolates), *Enterobacter* spp. (60 isolates), *E. coli* (87 isolates), *Klebsiella* spp. (86 isolates), *M. morganii* (16 isolates), *P. aeruginosa* (85 isolates), *P. rettgeri* (11 isolates), and *Proteus* spp. (14 isolates including one isolate of *P. penneri* and 13 isolates of *P. vulgaris*). Of the 419 isolates 325 were fresh isolates and 94 were stock isolates; 59 isolates were resistant to imipenem by the reference method.

A total of 179 challenge isolates were evaluated including *Acinetobacter* spp. (42 isolates), *Citrobacter* spp. (6 isolates), *Enterobacter* spp. (18 isolates), *E. coli* (17 isolates), *Klebsiella* spp. (35 isolates), *M. morganii* (4 isolates), *P. aeruginosa* (43 isolates), *P. rettgeri* (8 isolates), and *Proteus* spp. (6 isolates of *P. vulgaris*). Isolates obtained from the FDA-CDC AR Isolate Bank were included as challenge strains. Of the 180 challenge isolates, 112 were resistant to imipenem by the reference method.

For *Enterobacteriaceae* overall essential and category agreement was acceptable at >89.9%. There was an increased occurrence of minor errors for *P. rettgeri* and *Proteus* spp. with all read and inoculation methods and with *M. morganii* for all read methods with turbidity inoculation. However, because the EA of evaluable MIC results was acceptable for all inoculation and read methods (≥97.3%), the performance was considered to be acceptable.

For *Acinetobacter* species essential agreement for both inoculation methods and all read methods was acceptable at >89.9%. For *Acinetobacter* isolates inoculated using the Prompt system, category agreement was 88.9%, 87.7% and 88.9% for the WalkAway, autoSCAN-4 and manual read methods, respectively. This low category agreement is attributed to the occurrence of minor errors and a single major error. Category agreement for *Acinetobacter* species inoculated using the turbidity method is acceptable at >89.9% for MICs read using the WalkAway and autoSCAN-4. Category agreement for the turbidity inoculation method with the manual read was low at 88.9% due to a minor errors; however the essential agreement of evaluable results was 100%. The category agreement obtained with the turbidity inoculation method was determined to be acceptable.

For *P. aeruginosa*, essential and categorical agreement for all inoculation and read methods was acceptable at >89.9%. However, for *P. aeruginosa* inoculated with using the Prompt system, there was an increased occurrence of major errors with all read methods.

For isolates inoculated using the Prompt Inoculation system and read using the WalkAway instrument, overall EA and CA were acceptable at 95.5% and 90.6%, respectively.

To address major errors with the Prompt Inocuation system with isolates of *Acinetobacter* spp. and *P. aeruginosa* the sponsor included the following limitation in the device labeling:

> *Imipenem results obtained with P. aeruginosa and Acinetobacter sp. using the Prompt Inoculation system have shown potential major errors. If critical to patient care, isolates of those species that provide a resistant interpretation should be retested using the turbidity inoculation method.*

Tables 5-10 below summarize the performance with imipenem for clinical and challenge isolates of each organism group: *Enterobacteriaceae*, *Acinetobacter* species and *P. aeruginosa*. Data is shown for each inoculum preparation method (Prompt and turbidity) and for each read method (WalkAway, autoSCAN-4 and manual read).

Table 5. Performance of MicroScan Dried Gram-Negative Panels with Imipenem with *Enterobacteriaceae*, Prompt Inoculation Method, All Read Methods

	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
WalkAway													
Clinical	295	285	96.6	98	97	99.0	272	92.2	31	245	23	0	0
Challenge	94	88	93.6	48	45	93.8	80	85.1	62	23	14	0	0
Combined	389	373	95.9	146	142	97.3	352	90.5	93	268	37	0	0
autoSCAN-4													
Clinical	295	284	96.3	98	97	99.0	275	93.2	31	245	19	0	1
Challenge	94	88	93.6	48	45	93.8	82	87.2	62	23	12	0	0
Combined	389	372	95.6	146	142	97.3	357	91.8	93	268	31	0	1
Manual													
Clinical	295	286	96.9	97	97	100.0	274	92.9	31	245	21	0	0
Challenge	94	89	94.7	48	45	93.8	81	86.2	62	23	13	0	0
Combined	389	375	96.4	145	142	97.9	355	91.3	93	268	34	0	0

Table 6. Performance of MicroScan Dried Gram-Negative Panels with Imipenem with *Acinetobacter* spp., Prompt Inoculation Method, All Read Methods

	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
WalkAway													
Clinical	39	37	94.9	6	6	100	35	89.7	17	19	3	1	0
Challenge	42	40	95.2	13	11	84.6	37	88.1	34	4	5	0	0
Combined	81	77	95.1	19	17	89.5	72	88.9	51	23	8	1	0
AutoSCAN-4													
Clinical	39	38	97.4	6	6	100	35	89.7	17	19	3	1	0
Challenge	42	41	97.6	14	13	92.9	36	85.7	34	4	6	0	0
Combined	81	79	97.5	20	19	95.0	71	87.7	51	23	9	1	0

Manual Read													
Clinical	39	39	100	6	6	100	36	92.3	17	19	3	0	0
Challenge	42	41	97.6	14	13	92.9	36	85.7	34	4	6	0	0
Combined	81	80	98.8	20	19	95.0	72	88.9	51	23	9	0	0

Table 7. Performance of MicroScan Dried Gram-Negative Panels with Imipenem with *P. aeruginosa*, Prompt Inoculation Method, All Read Methods

	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
WalkAway													
Clinical	85	82	96.5	65	64	98.5	80	94.1	13	68	4	1	0
Challenge	43	39	90.7	20	16	80.0	38	88.4	24	18	3	2	0
Combined	128	121	94.5	85	80	94.1	118	92.2	37	86	7	3	0
AutoSCAN-4													
Clinical	85	83	97.6	63	61	96.8	82	96.5	13	68	2	1	0
Challenge	43	41	95.3	20	18	90.0	41	95.3	24	18	1	1	0
Combined	128	124	96.9	83	79	95.2	123	96.1	37	86	3	2	0
Manual Read													
Clinical	85	83	97.6	64	63	98.4	82	96.5	13	68	2	1	0
Challenge	43	41	95.3	20	18	90.0	41	95.3	24	18	1	1	0
Combined	128	124	96.9	84	81	96.4	123	96.1	37	86	3	2	0

Table 8. Performance of MicroScan Dried Gram-Negative Panels with Imipenem with *Enterobacteriaceae*, Turbidity Inoculation Method, All Read Methods

	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
WalkAway													
Clinical	295	290	98.3	99	98	99.0	269	91.2	31	245	24	2	0
Challenge	94	92	97.9	49	48	98.0	87	92.6	62	23	7	0	0
Combined	389	382	98.2	148	146	98.6	356	91.5	93	268	31	2	0
AutoSCAN-4													
Clinical	295	290	98.3	100	99	99.0	272	92.2	31	245	21	2	0
Challenge	94	93	98.9	50	49	98.0	86	91.5	62	23	8	0	0
Combined	389	383	98.5	150	148	98.7	358	92.0	93	268	29	2	0
Manual Read													
Clinical	295	290	98.3	100	99	99.0	269	91.2	31	245	24	2	0
Challenge	94	93	98.9	49	48	98.0	88	93.6	62	23	6	0	0
Combined	389	383	98.5	149	147	98.7	357	91.8	93	268	30	2	0

Table 9. Performance of MicroScan Dried Gram-Negative Panels with Imipenem with *Acinetobacter* spp., Turbidity Inoculation Method, All Read Methods

	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
WalkAway													
Clinical	39	39	100.0	6	6	100.0	36	92.3	17	19	3	0	0
Challenge	42	42	100.0	15	15	100.0	38	90.5	34	4	4	0	0
Combined	81	81	100.0	21	21	100.0	74	91.4	51	23	7	0	0
AutoSCAN-4													
Clinical	39	39	100.0	6	6	100.0	36	92.3	17	19	3	0	0
Challenge	42	42	100.0	15	15	100.0	38	90.5	34	4	4	0	0
Combined	81	81	100.0	21	21	100.0	74	91.4	51	23	7	0	0
Manual Read													
Clinical	39	39	100.0	6	6	100.0	36	92.3	17	19	3	0	0
Challenge	42	42	100.0	15	15	100.0	36	85.7	34	4	6	0	0
Combined	81	81	100.0	21	21	100.0	72	88.9	51	23	9	0	0

Table 10. Performance of MicroScan Dried Gram-Negative Panels with Imipenem with *P. aeruginosa*, Turbidity Inoculation Method, All Read Methods

	Tot	No. EA	EA %	Eval EA Tot	No. Eval EA	Eval EA %	No. CA	CA %	No. R	No. S	min	maj	vmj
WalkAway													
Clinical	85	81	95.3	66	64	97.0	79	92.9	13	68	5	1	0
Challenge	44	44	100.0	20	20	100.0	43	97.7	25	18	1	0	0
Combined	129	125	96.9	86	84	97.7	122	94.6	38	86	6	1	0
AutoSCAN-4													
Clinical	85	83	97.6	65	63	96.9	82	96.5	13	68	2	1	0
Challenge	44	44	100.0	20	20	100.0	44	100.0	25	18	0	0	0
Combined	129	127	98.4	85	83	97.6	126	97.7	38	86	2	1	0
Manual Read													
Clinical	85	83	97.6	66	65	98.5	82	96.5	13	68	2	1	0
Challenge	44	44	100.0	20	20	100.0	44	100.0	25	18	0	0	0
Combined	129	127	98.4	86	85	98.8	126	97.7	38	86	2	1	0

EA – Essential Agreement (+/- 2 dilutions)
CA – Category Agreement
EVAL – Evaluable isolates
R or NS – Resistant or non-susceptible isolates

min – minor discrepancies
maj – major discrepancies
vmj – very major discrepancies

Essential Agreement (EA) occurs when there is agreement between the result of the reference method and that of the MicroScan panel within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the MicroScan panel and the reference method. Category Agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation of the MicroScan panel.

MIC Trend Analysis

Using the data provided by the sponsor in the diagonal table format recommended in the AST Special Controls guidance document, an analysis was conducted for trending in MIC values.

As summarized in Table 11 below, a higher trending was observed for members of the *Enterobacteriaceae* and *P. aeruginosa*. There was no trending observed for *Acinetobacter* species.

Table 11. Trending of Results by Prompt Inoculation Method and WalkAway Read Method with Clinical and Challenge isolates.

Organism	Total No. isolates	Total No. Evaluable MICs for Trending Analysis	Difference in MIC as compared to the CLSI Reference Method			
			≥ 1 dilution lower	Equal to Reference Method	≥ 1 dilution higher	Unevaluable for Trending Analysis
Enterobacteriaceae	389	335	20 (6.0%)	236 (70.4%)	79 (23.6%)	54 (13.9%)
P. aeruginosa	128	92	6 (6.5%)	62 (67.4%)	24 (26.1%)	36 (28.1%)
***Acinetobacter* spp**	81	38	4 (10.5%)	29 (76.9%)	5 (13.2%)	43 (53.1%)

Trending analysis indicated that MICs for *Enterobacteriaceae* and *P. aeruginosa* trended at least one dilution higher than the MICs obtained with the reference method. MIC results with *Acinetobacter* showed no trending. The trending calculation takes into account MIC values that are determined to be ≤ 1 doubling dilution or ≥ 1 doubling dilution compared to the reference method irrespective whether the device MIC values are on-scale or not. The sponsor added the following footnote to the performance table in the device labeling:

> *Imipenem MIC values tended to be one doubling dilution higher compared to the reference broth microdilution method for Enterobacteriaceae and P. aeruginosa.*

Prompt Hold Study

An additional study was performed to determine the agreement of results obtained with the Prompt inoculation method using hold times of 0 hours and 4 hours prior to inoculation of the panels. The following times and comparisons were made with each of the read methods (WalkAway, autoSCAN-4 and manual).

Results of 4-hour hold vs. results of 0-hour hold

Results of 4-hour hold vs. results obtained with the frozen reference method

Results of 0-hour hold vs. results obtained with the frozen reference method

All tests showed overall acceptable essential agreement; category agreement was <90.0% for some organism groups due to the presence of minor errors. One major error was obtained with one *Acinetobacter* isolate with the 0-hour vs. frozen reference with all read methods (2.0% major error rate).

Results were determined to be acceptable.

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

The FDA interpretive criteria shown below were used to evaluate all performance data.

Table 12. Interpretive Criteria for Imipenem (FDA Drug Label)

Organism	FDA Interpretive Criteria for Ertapenem MIC (µg/mL)		
	S	**I**	**R**
Enterobacteriaceae	≤1	2	≥4
Pseudomonas aeruginosa	≤2	4	≥8
Acinetobacter spp.	≤2	4	≥8

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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