510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k103456

B. Purpose for Submission:

To obtain substantial equivalence for the Autoinoculator 2, AIM™ inoculation system compared to the existing Autoinoculator I.

C. Measurand:

Antimicrobial susceptibility testing of Gram positive organisms, Streptococci, *H. influenzae*, and *C. albicans* on the Sensititre panels inoculated with AIM.

D. Type of Test:

Quantitative Antimicrobial Susceptibility Test (AST), growth based fluorescence. The minimum inhibitory concentration (MIC) is determined manually based on visual detection of growth or by the aid of a manual mirror viewer, an AutoReader or on the VIZION.

E. Applicant:

Trek Diagnostic Systems.

F. Proprietary and Established Names:

Sensititre 18 – 24 hour Susceptibility MIC Plates

Sensititre AIM™ inoculation system

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1640 Antimicrobial Susceptibility Test Powder

2. Classification:

   Class II

3. Product code:

LIE-Reagents/Device, Inoculum Calibration
JWY-Manual readings of AST testing of >16 hour incubation
LRG-Automated readings of AST of >16 hrs incubation

4. Panel:

83, Microbiology

H. Intended Use:

1. Intended use(s):

The Sensititre® AIM ™ is intended for use with the Sensititre® MIC or BP Susceptibility Test System. The Sensititre® AIM™ is an instrument used to inoculate Sensititre® MIC or BP Susceptibility plates.

The Sensititre MIC and Breakpoint Susceptibility system is an *in vitro* diagnostic product for clinical susceptibility testing of Gram positive organisms, Streptococci, *H. influenzae*, and *C. albicans*.

1. Indication(s) for use:

The Sensititre® AIM™ is intended for use with the Sensititre® MIC or BP Susceptibility Test System. The Sensititre® AIM™ is an instrument used to inoculate Sensititre MIC or BP Susceptibility plates.

The Sensititre MIC or Breakpoint Susceptibility System is an in vitro diagnostic product for clinical susceptibility testing of Gram positive organisms, *Streptococcus pneumoniae*, other *Streptococcus* spp., *H. influenzae*, and *Candida* spp.

This 510(k) is for the addition of: "AIM™"

The Sensititre AIM™ is a microprocessor controlled instrument that delivers inoculum in 50µl multiples to the Sensititre 96 well micro-titre plate. The user prepares the inoculum suspension in accordance with the package inert. A Sensititre disposable dosehead is affixed to the glass tube containing the final inoculum density which is placed into the AIM's pump assembly. The inoculum is then dispensed into the microtitre plates.

3. Special conditions for use statement(s):

Prescription use only.

4. Special instrument requirements:

   The Sensititre AutoReader

   The Sensititre viewer, VIZION

   The Sensititre Autoinoculator 2, AIM™ instrument

I. Device Description:

The Sensititre Autoinoculator 2, AIM™ instrument is an automated pipette system for the delivery of user prepared inoculated media in multiples of 50 and 100 µl into the Sensititre 96 well antimicrobial susceptibility plate.

The AIM™ is a bench-top instrument which dispenses bacterial suspension (inoculum) into a 96-well plate (MIC panel). The instrument has a display which presents options to the user graphically. The user may then select the well dose volume (a multiple of 50 µl) specific to each panel section. Different panel sections may be dosed differently. After selection of these parameters, the user loads the inoculum tube, a suitable panel and then starts the dosing cycle.

The AIM™ is a stand-alone device and requires no connections to other equipment in normal use. It currently provides no support for sample tracking.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Autoinoculator I

2. Predicate K number(s):

   k081063

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Delivery of prepared inoculum media in multiples of 50 µl into 96 microplate wells	Same
Inoculation and test organism	Isolated colonies from culture are used to prepare the inoculum	Same

Similarities		
Item	Device	Predicate
Dosing system /Technology	Automated pipette system using TREK dosehead consumables	Same
Well indexing method	Microplate wells are indexed beneath the dose head	Same
Calibration method	System is calibrated by weighing dosed plates	Same
Type of test	Automated or manual	Same

Differences		
Item	Device	Predicate
Size	250 mm wide/350 mm deep	413 mm wide/464 mm deep
Cycle speed	Between 27 and 35 seconds	35 seconds
Dose head drive system	Single stepper motor articulating mechanically slaved rotation and thrusting movements of dose head drive spigot	Two stepper motors. First stepper motor articulating rotation movement of dose head drive spigot. Second stepper motor articulating thrusting movements of dose head drive spigot
User interface	Single line LED display with keypad	Touch screen display with icon driven menu system

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

1. Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071462.pdf

2. Clinical and Laboratory Standards Institute (CLSI). Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically, Approved Standard -8th Edition, Document M7-A8.

3. CLSI. Performance Standards for Antimicrobial Susceptibility Testing – 19th Informational Supplement, Document M100-S19.

L. Test Principle:

Sensititre susceptibility plates are multi-well plastic microtiter plates that contain doubling dilutions of antibacterial agents. Each plate is dosed with antimicrobial agents at appropriate dilutions. Results can be read manually by visual reading of growth or automatically on an AutoReader using fluorescence. The Sensititre AutoReader system utilizes fluorescence technology which involves the detection of bacterial growth by monitoring the activity of specific surface enzymes produced by the test organism. Growth is determined by generating a fluorescent product from a non-fluorescent (f1uorogenic) substrate. The substrate can be added to the inoculum broth and dispensed into the test plates at the same time as the test organism or the plates can be prepared with the substrate already added to the plate. The non-fluorescent substrate is prepared by conjugating a fluorescent compound to the specific enzyme substrates with a bond, which prevents fluorescence (i.e. the f1uorophore is quenched in this state). Enzymatic action of the bacterial surface enzymes on the specific substrates cleaves this bond releasing the fluorophore which is now capable of fluorescence. The amount of fluorescence detected is directly related to the activity of the bacterial surface enzymes and, therefore, to bacterial growth.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

A reproducibility study was conducted at three study sites. For each group of organisms, twenty five isolates were inoculated using the AIM and tested at each site. The panels used included the antimicrobial agents as representatives of the various classes. These panels were tested one time at each of the three sites and results were read by both the AutoReader and the VIZION. The reproducibility of MIC tests was performed using Sensititre plates read on the VIZION, AutoReader, and/or mirror as follows

Gram positive - Read on AutoReader and VIZION
Streptococcus spp. - Read on AutoReader and VIZION
Haemophilus spp. - Read on the VIZION
Candida spp. - Read on manual mirror

Reproducibility was calculated as the percent of combined results were within +/- one doubling dilution of the mode MIC value for all sites.
The original AIM reproducibility studies included several drug/organism combinations that did not have sufficient number of on-scale MIC results. Another reproducibility study was conducted and included 10 isolates with on-scale MIC values for the antimicrobials that were not on-scale. Cumulative

reproducibility data is shown below.

Overall Reproducibility of AIM vs. Autoinoculator I for Gram Positive organisms

	% Reproducibility (AIM vs. Autoinoculator I)		
	Best Case (assuming off scale result is within one well from the mode)	On scale (on scale values only)	Worst case* (assuming off scale result is greater than one well from the mode)
AutoReader	99.8	99.9	86.4
VIZION	99.7	99.7	85.8

* Off-scale isolates were used due to unavailability or insufficient number of isolates with on-scale MIC values for some drug/organism combinations

Overall Reproducibility of AIM vs. Autoinoculator I for *Streptococcus* spp.

	% Reproducibility (AIM vs. Autoinoculator I)		
	Best Case (assuming off scale result is within one well from the mode)	On scale (on scale values only)	Worst case* (assuming off scale result is greater than one well from the mode)
AutoReader	99.8	99.7	81.2
VIZION	99.6	99.6	80.2

* Off-scale isolates were used due to unavailability or insufficient number of isolates with on-scale MIC values for some drug/organism combinations

Overall Reproducibility of AIM vs. Autoinoculator I for *Haemophilus influenzae*.

	% Reproducibility (AIM vs. Autoinoculator I)		
	Best Case (assuming off scale result is within one well from the mode)	On scale (on scale values only)	Worst case* (assuming off scale result is greater than one well from the mode)
VIZION	99.7	99.8	99.4

* Off-scale isolates were used due to unavailability or insufficient number of isolates with on-scale MIC values for some drug/organism combinations

Overall Reproducibility of AIM vs. Autoinoculator I for *C. albicans*

	% Reproducibility (AIM vs. Autoinoculator I)		
	Best Case (assuming off scale result is within one well from the mode)	On scale (on scale values only)	Worst case* (assuming off scale result is greater than one well from the mode)
Manual Mirror	99.7	99.8	99.4

* Off-scale isolates were used due to unavailability or insufficient number of isolates with on-scale MIC values for some drug/organism combinations

Even though the MIC values were off-scale for a large number of isolates (varied by drug-organism combinations), which has resulted in low performance based on "worst-case" calculation, the overall reproducibility was considered acceptable, since best-case and on-scale reproducibility were greater than 95%.

b. Linearity/assay reportable range:

Not applicable

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

The FDA and CLSI recommended QC isolates were tested on every test occasion at each clinical site. The QC results obtained using Autoinoculator I and AIM were in range for every day tested.

Quality Control was performed at all sites during the studies using the existing Autoinoculator I and the new Autoinoculator, AIM. Results were read either on a manual mirror, the AutoReader, or the VIZION as appropriate for the organism.

S. aureus	ATCC 29213
E. faecalis	ATCC 29212, ATCC 51299
S. pneumoniae	ATCC 49619
H. influenzae	ATCC 49247, ATCC 49766
C. parapsilosis	ATCC 22019
C. krusei	ATCC 6258
S. aureus	ATCC BAA-976 (Cefoxitin screen & Dtest),
S. aureus	ATCC BAA-977 (Dtest)

The QC MIC values obtained by the AIM/Autoinoculator I were comparable. For some drugs, the concentration range was not sufficiently broad to provide definite MIC value for both QC organisms. However, the concentration range was sufficient to evaluate at least one QC organism per drug.

Percentage of results within the acceptable QC range

		AutoReader		VIZION	
QC Organism(s)	Antimicrobial Agent	Autoinoculator I	AIM	Autoinoculator I	AIM
S. aureus ATCC 29213 *E. faecalis* ATCC 29212	Chloramphenicol Ciprofloxacin Clindamycin Daptomycin Erythromycin Gentamicin Linezolid Oxacillin Penicillin Quinapristin/Dalfapristin Rifampin Tetracycline Trimethoprim/Sulfamethoxazole Vancomycin	100%	100%	100%	100%
S. aureus ATCC BAA-977, & ATCC BAA-976	Inducible Clindamycin (Dtest)	100%	100%	100%	100%
S. aureus ATCC BAA-976, & *S. aureus* ATCC 29213	Cefoxitin screen	100%	100%	100%	100%
E. faecalis ATCC 29212, ATCC 51299, & *S. aureus* ATCC 29213	Gentamicin 500 Streptomycin 1000	100%	100%	100%	100%
S. pneumoniae ATCC 49619	Amoxicillin/Clavulanic Acid Cefepime Cefotaxime Chloramphenicol Clindamycin				

		AutoReader		VIZION	
QC Organism(s)	Antimicrobial Agent	Autoinoculator I	AIM	Autoinoculator I	AIM
	Daptomycin Erythromycin Levofloxacin Linezolid Meropenem Penicillin Trimethoprim/Sulfamethoxazole Tetracycline Vancomycin	100%	100%	100%	100%
H. influenzae ATCC 49247	Amoxicillin/Clavulanic Acid Ampicillin Ampicillin/Sulbactam Cefepime Cefixime Ceftriaxone Chloramphenicol Clarithromycin Tetracycline Trimethoprim/Sulfamethoxazole	100%	100%	100%	100%
H. influenzae ATCC 49766	Cefaclor Cefuroxime Imipenem Meropenem	100%	100%	100%	100%
C. parapsilosis ATCC 22019 *C. krusei* ATCC 6258	5-Flucytosine Fluconazole Itraconazole Voriconazole	100%	100%	100%	100%

MIC results were in range for each drug for at least one Quality Control organism tested. Quality Control results for the Sensititre Susceptibility System using AIM as the inoculator or the existing Autoinoculator I demonstrated that the system could produce the expected quality control results whether results are read on the AutoReader or on the VIZION.

The Sensititre Nephelometer was used at each site to standardize the inoculum and it was calibrated every time it was switched on. Colony counts from QC and in-house source was performed using direct inoculum method and the mean result was within the minimum and maximum ranges" All results were within the expected range.

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:

Performance was established through a clinical study which was conducted at three sites. The studies were designed to evaluate performance of the updated version of the Autoinoculator, AIM to the existing Autoinoculator I using the Sensititre 18-24 hour susceptibility plates. Specially prepared MIC susceptibility panels containing serial dilutions of selected antimicrobial agents representing various classes of antimicrobial agents were inoculated by either the AIM or the Autoinoculator I. Duplicate plates were inoculated. One was inoculated using the Autoinoculator I and the other using the AIM. Plates were read after 18-24 hours of incubation at 35^{o}C. The plate readings were made either on a manual mirror, the AutoReader, or the VIZION as appropriate for the organism. The MIC results obtained for plates inoculated with Autoinoculator I were compared to those obtained for plates inoculated with the AIM. The criteria outlined in the AST Special Controls Guidance Document were used in evaluation of performance of AIM as follows:

AutoReader results comparing AIM versus Autoinoculator I

VIZION results comparing AIM versus Autoinoculator I

Mirror read results comparing AIM versus Autoinoculator I

Clinical testing was performed on Gram positive isolates (89 *S. aureus*, 61 *Staphylococcus* spp., 56 *Enterococcus* spp., 157 beta hemolytic *Streptococcus* spp, 84 *Streptococcus pneumoniae*, and 72 viridans streptococci), 195 isolates of *H. influenzae* and 303 *Candida spp.* The growth rate for the clinical and challenge isolates was 100%. The performance evaluations are shown in the tables below.

Summary Table (**AutoReader)**

Clinical and challenge isolate results summary for the AIM vs. Existing Autoinoculator (AutoReader)

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Oxacillin + 2% NaCl	Coagulase Negative Staph	42	19	61	30	98.4	96.7	100	23	0	38	0	0	0
Oxacillin + 2% NaCl	*Staphylococcus aureus*	62	27	89	55	100	100	100	47	0	42	0	0	0
Penicillin	Coagulase Negative Staph	42	19	61	39	100	100	100	12	0	12	0	0	0
Penicillin	*Enterococcus* sp.	40	16	56	41	100	100	100	41	0	41	0	0	0
Penicillin	*Staphylococcus aureus*	62	27	89	30	100	100	100	12	0	12	0	0	0
Penicillin	*Streptococcus agalactiae*	0	5	5	0	100	N/A	100	5	0	5	0	0	0
Penicillin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	6	0	0	0
Linezolid	Coagulase Negative Staph	42	19	61	34	100	100	100	60	0	1	0	0	0
Linezolid	*Enterococcus* sp.	40	16	56	48	100	100	100	51	0	5	0	0	0
Linezolid	*Staphylococcus aureus*	62	27	89	88	100	100	100	89	0	0	0	0	0
Linezolid	*Streptococcus agalactiae*	0	5	5	5	100	100	100	5	0	0	0	0	0
Linezolid	*Streptococcus pyogenes*	0	6	6	6	100	100	100	6	0	0	0	0	0
Rifampin	Coagulase Negative Staph	42	19	61	1	100	100	100	59	0	2	0	0	0
Rifampin	*Enterococcus* sp.	40	16	56	29	100	100	85.7	23	17	16	0	0	8
Rifampin	*Staphylococcus aureus*	62	27	89	1	100	100	100	87	0	2	0	0	0
Chloramphenicol	Coagulase Negative Staph	42	19	61	57	98.4	100	100	58	0	3	0	0	0
Chloramphenicol	*Enterococcus* sp.	40	16	56	46	100	100	94.6	43	4	9	0	0	3
Chloramphenicol	*Staphylococcus aureus*	62	27	89	84	100	100	94.4	69	15	5	0	0	5
Chloramphenicol	*Streptococcus agalactiae*	0	5	5	5	100	100	100	5	0	0	0	0	0
Chloramphenicol	*Streptococcus pyogenes*	0	6	6	6	100	100	100	6	0	0	0	0	0
Clindamycin	Coagulase Negative Staph	42	19	61	7	100	100	100	37	2	22	0	0	0
Clindamycin	*Staphylococcus aureus*	62	27	89	3	100	100	100	72	0	17	0	0	0
Clindamycin	*Streptococcus agalactiae*	0	5	5	0	100	N/A	100	5	0	0	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Clindamycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Tetracycline	Coagulase Negative Staph	42	19	61	43	98.4	97.7	100	43	0	18	0	0	0
Tetracycline	*Enterococcus* sp.	40	16	56	20	100	100	100	10	0	46	0	0	0
Tetracycline	*Staphylococcus aureus*	62	27	89	78	100	100	100	77	0	12	0	0	0
Tetracycline	*Streptococcus agalactiae*	0	5	5	4	100	100	100	1	0	4	0	0	0
Tetracycline	*Streptococcus pyogenes*	0	6	6	5	100	100	100	5	0	1	0	0	0
Erythromycin	Coagulase Negative Staph	42	19	61	7	98.4	85.7	98.4	24	1	36	0	0	1
Erythromycin	*Enterococcus* sp.	40	16	56	18	100	100	100	9	13	34	0	0	0
Erythromycin	*Staphylococcus aureus*	62	27	89	31	98.9	96.8	97.8	25	6	58	0	0	2
Erythromycin	*Streptococcus agalactiae*	0	5	5	1	100	100	100	4	0	1	0	0	0
Erythromycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Ciprofloxacin	Coagulase Negative Staph	42	19	61	32	100	100	100	31	0	30	0	0	0
Ciprofloxacin	*Staphylococcus aureus*	62	27	89	61	100	100	100	55	4	30	0	0	0
Quinapristin/Dalfapristin	Coagulase Negative Staph	42	19	61	0	100	N/A	100	61	0	0	0	0	0
Quinapristin/Dalfapristin	*Enterococcus* sp.	40	16	56	32	100	100	100	17	3	36	0	0	0
Quinapristin/Dalfapristin	*Staphylococcus aureus*	62	27	89	0	100	N/A	100	89	0	0	0	0	0
Quinapristin/Dalfapristin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Daptomycin	Coagulase Negative Staph	42	19	61	56	100	100	100	61	0	0	0	0	0
Daptomycin	*Enterococcus* sp.	40	16	56	52	100	100	100	54	0	2	0	0	0
Daptomycin	*Staphylococcus aureus*	62	27	89	86	100	100	100	89	0	0	0	0	0
Daptomycin	*Streptococcus agalactiae*	0	5	5	5	100	100	100	5	0	0	0	0	0
Daptomycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Vancomycin	Coagulase Negative Staph	42	19	61	54	100	100	100	61	0	0	0	0	0
Vancomycin	*Enterococcus* sp.	40	16	56	27	100	100	100	28	3	25	0	0	0
Vancomycin	*Staphylococcus aureus*	62	27	89	83	100	100	100	89	0	0	0	0	0
Vancomycin	*Streptococcus agalactiae*	0	5	5	0	100	N/A	100	5	0	0	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Vancomycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Trimethoprim/Sulfamethoxazole	Coagulase Negative Staph	42	19	61	2	100	100	100	36	0	25	0	0	0
Trimethoprim/Sulfamethoxazole	*Staphylococcus aureus*	62	27	89	2	100	100	100	87	0	2	0	0	0
Gentamicin	Coagulase Negative Staph	42	19	61	23	98.4	95.7	95.1	43	3	15	0	0	3
Gentamicin	*Staphylococcus aureus*	62	27	89	80	98.9	98.8	100	85	0	4	0	0	0
Streptomycin-1000 ug/mL	*Enterococcus* sp.	40	16	56	0	100	N/A	100	36	0	20	0	0	0
Clindamycin	*Streptococcus pneumoniae*	60	24	84	48	98.8	97.9	98.8	48	0	36	0	0	1
Penicillin	Beta hemolytic strep	27	0	27	7	100	100	100	27	0	0	0	0	0
Penicillin	Strep viridans	46	25	71	49	100	100	97.2	46	17	8	0	0	2
Penicillin	*Streptococcus agalactiae*	52	11	63	50	98.4	100	100	63	0	0	0	0	0
Penicillin	*Streptococcus pneumoniae*	60	24	84	68	98.8	98.5	98.8	11	22	51	0	0	1
Penicillin	*Streptococcus pyogenes*	53	14	67	0	100	N/A	100	67	0	0	0	0	0
Amoxicillin/Clavulanate	*Streptococcus pneumoniae*	60	24	84	69	98.8	98.6	95.2	64	11	9	0	0	4
Linezolid	Beta hemolytic strep	26	0	26	26	100	100	100	26	0	0	0	0	0
Linezolid	*Streptococcus agalactiae*	53	11	64	64	100	100	100	64	0	0	0	0	0
Linezolid	*Streptococcus pneumoniae*	60	24	84	84	100	100	100	84	0	0	0	0	0
Linezolid	*Streptococcus pyogenes*	53	14	67	67	100	100	100	67	0	0	0	0	0
Linezolid	*Streptococcus* sp.	47	25	72	72	100	100	100	72	0	0	0	0	0
Chloramphenicol	Beta hemolytic strep	26	0	26	26	100	100	100	26	0	0	0	0	0
Chloramphenicol	*Streptococcus agalactiae*	53	11	64	64	100	100	98.4	63	1	0	0	0	1
Chloramphenicol	*Streptococcus pneumoniae*	60	24	84	55	100	100	100	55	0	29	0	0	0
Chloramphenicol	*Streptococcus pyogenes*	53	14	67	67	100	100	100	67	0	0	0	0	0
Chloramphenicol	*Streptococcus* sp.	47	25	72	67	100	100	100	72	0	0	0	0	0
Cefepime	Beta hemolytic strep	27	0	27	27	100	100	100	27	0	0	0	0	0
Cefepime	*Streptococcus agalactiae*	52	11	63	62	100	100	100	63	0	0	0	0	0
Cefepime	*Streptococcus pneumoniae*	60	24	84	84	98.8	98.8	92.9	54	27	3	0	0	6

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Cefepime	*Streptococcus pyogenes*	53	14	67	26	98.5	100	100	67	0	0	0	0	0
Cefotaxime	Beta hemolytic strep	27	0	27	18	96.3	94.4	100	27	0	0	0	0	0
Cefotaxime	Strep viridans	46	25	71	62	98.6	98.4	97.2	63	4	4	0	0	2
Cefotaxime	*Streptococcus agalactiae*	52	11	63	61	100	100	100	63	0	0	0	0	0
Cefotaxime	*Streptococcus pneumoniae*	60	24	84	73	100	100	97.6	64	14	6	0	0	2
Cefotaxime	*Streptococcus pyogenes*	53	14	67	2	100	100	100	67	0	0	0	0	0
Tetracycline	Beta hemolytic strep	27	0	27	18	100	100	100	15	3	9	0	0	0
Tetracycline	*Streptococcus agalactiae*	52	11	63	10	100	100	100	10	0	53	0	0	0
Tetracycline	*Streptococcus pneumoniae*	60	24	84	35	100	100	98.8	35	0	49	0	0	1
Tetracycline	*Streptococcus pyogenes*	53	14	67	57	98.5	98.2	100	56	1	10	0	0	0
Tetracycline	*Streptococcus* sp.	47	25	72	51	100	100	97.2	49	2	21	0	0	2
Erythromycin	Beta hemolytic strep	26	0	26	15	100	100	100	16	0	10	0	0	0
Erythromycin	*Streptococcus agalactiae*	53	11	64	38	100	100	100	38	0	26	0	0	0
Erythromycin	*Streptococcus pneumoniae*	60	24	84	40	100	100	98.8	39	1	44	0	0	1
Erythromycin	*Streptococcus pyogenes*	53	14	67	58	100	100	100	58	0	9	0	0	0
Erythromycin	*Streptococcus* sp.	47	25	72	33	100	100	100	29	0	43	0	0	0
Levofloxacin	Beta hemolytic strep	26	0	26	24	100	100	100	26	0	0	0	0	0
Levofloxacin	*Streptococcus agalactiae*	53	11	64	64	100	100	100	64	0	0	0	0	0
Levofloxacin	*Streptococcus pneumoniae*	60	24	84	83	100	100	100	84	0	0	0	0	0
Levofloxacin	*Streptococcus pyogenes*	53	14	67	66	100	100	100	66	1	0	0	0	0
Levofloxacin	*Streptococcus* sp.	47	25	72	69	100	100	100	68	0	4	0	0	0
Meropenem	Beta hemolytic strep	26	0	26	6	100	100	100	26	0	0	0	0	0
Meropenem	*Streptococcus agalactiae*	53	11	64	49	100	100	100	64	0	0	0	0	0
Meropenem	*Streptococcus pneumoniae*	60	24	84	64	100	100	97.6	35	26	23	0	0	2
Meropenem	*Streptococcus pyogenes*	53	14	67	0	100	N/A	100	67	0	0	0	0	0
Meropenem	*Streptococcus* sp.	47	25	72	34	100	100	100	65	0	7	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Daptomycin	Beta hemolytic strep	27	0	27	27	100	100	100	27	0	0	0	0	0
Daptomycin	*Streptococcus agalactiae*	53	11	64	63	100	100	98.4	64	0	0	0	1	0
Daptomycin	*Streptococcus pyogenes*	53	14	67	64	98.5	98.4	100	67	0	0	0	0	0
Daptomycin	*Streptococcus* sp.	47	25	72	64	100	100	100	64	0	8	0	0	0
Vancomycin	Beta hemolytic strep	26	0	26	26	96.2	96.2	100	26	0	0	0	0	0
Vancomycin	*Streptococcus agalactiae*	53	11	64	64	100	100	100	64	0	0	0	0	0
Vancomycin	*Streptococcus pneumoniae*	60	24	84	84	100	100	100	84	0	0	0	0	0
Vancomycin	*Streptococcus pyogenes*	53	14	67	67	100	100	100	67	0	0	0	0	0
Vancomycin	*Streptococcus* sp.	47	25	72	71	100	100	100	71	0	1	0	0	0
Trimethoprim/Sulfamethoxazole	*Streptococcus pneumoniae*	60	24	84	35	100	100	96.4	20	17	47	0	0	3

Clinical and challenge isolate results summary for the AIM vs. Existing Autoinoculator (VIZION)

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Oxacillin + 2% NaCl	Coagulase Negative Staph	42	19	61	30	98.4	96.7	100	23	0	38	0	0	0
Oxacillin + 2% NaCl	*Staphylococcus aureus*	62	27	89	55	100	100	100	47	0	42	0	0	0
Penicillin	Coagulase Negative Staph	42	19	61	39	100	100	100	12	0	12	0	0	0
Penicillin	*Enterococcus* sp.	40	16	56	41	100	100	100	41	0	41	0	0	0
Penicillin	*Staphylococcus aureus*	62	27	89	30	100	100	100	12	0	12	0	0	0
Penicillin	*Streptococcus agalactiae*	0	5	5	0	100	N/A	100	5	0	5	0	0	0
Penicillin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	6	0	0	0
Linezolid	Coagulase Negative Staph	42	19	61	34	100	100	100	60	0	1	0	0	0
Linezolid	*Enterococcus* sp.	40	16	56	48	100	100	100	51	0	5	0	0	0
Linezolid	*Staphylococcus aureus*	62	27	89	88	100	100	100	89	0	0	0	0	0
Linezolid	*Streptococcus agalactiae*	0	5	5	5	100	100	100	5	0	0	0	0	0
Linezolid	*Streptococcus pyogenes*	0	6	6	6	100	100	100	6	0	0	0	0	0
Rifampin	Coagulase Negative Staph	42	19	61	1	100	100	100	59	0	2	0	0	0
Rifampin	*Enterococcus* sp.	40	16	56	29	100	100	85.7	23	17	16	0	0	8
Rifampin	*Staphylococcus aureus*	62	27	89	1	100	100	100	87	0	2	0	0	0
Chloramphenicol	Coagulase Negative Staph	42	19	61	57	98.4	100	100	58	0	3	0	0	0
Chloramphenicol	*Enterococcus* sp.	40	16	56	46	100	100	94.6	43	4	9	0	0	3
Chloramphenicol	*Staphylococcus aureus*	62	27	89	84	100	100	94.4	69	15	5	0	0	5
Chloramphenicol	*Streptococcus agalactiae*	0	5	5	5	100	100	100	5	0	0	0	0	0
Chloramphenicol	*Streptococcus pyogenes*	0	6	6	6	100	100	100	6	0	0	0	0	0
Clindamycin	Coagulase Negative Staph	42	19	61	7	100	100	100	37	2	22	0	0	0
Clindamycin	*Staphylococcus aureus*	62	27	89	3	100	100	100	72	0	17	0	0	0
Clindamycin	*Streptococcus agalactiae*	0	5	5	0	100	N/A	100	5	0	0	0	0	0
Clindamycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Tetracycline	Coagulase Negative Staph	42	19	61	43	98.4	97.7	100	43	0	18	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Tetracycline	*Enterococcus* sp.	40	16	56	20	100	100	100	10	0	46	0	0	0
Tetracycline	*Staphylococcus aureus*	62	27	89	78	100	100	100	77	0	12	0	0	0
Tetracycline	*Streptococcus agalactiae*	0	5	5	4	100	100	100	1	0	4	0	0	0
Tetracycline	*Streptococcus pyogenes*	0	6	6	5	100	100	100	5	0	1	0	0	0
Erythromycin	Coagulase Negative Staph	42	19	61	7	98.4	85.7	98.4	24	1	36	0	0	1
Erythromycin	*Enterococcus* sp.	40	16	56	18	100	100	100	9	13	34	0	0	0
Erythromycin	*Staphylococcus aureus*	62	27	89	31	98.9	96.8	97.8	25	6	58	0	0	2
Erythromycin	*Streptococcus agalactiae*	0	5	5	1	100	100	100	4	0	1	0	0	0
Erythromycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Ciprofloxacin	Coagulase Negative Staph	42	19	61	32	100	100	100	31	0	30	0	0	0
Ciprofloxacin	*Staphylococcus aureus*	62	27	89	61	100	100	100	55	4	30	0	0	0
Quinapristin/Dalfapristin	Coagulase Negative Staph	42	19	61	0	100	N/A	100	61	0	0	0	0	0
Quinapristin/Dalfapristin	*Enterococcus* sp.	40	16	56	32	100	100	100	17	3	36	0	0	0
Quinapristin/Dalfapristin	*Staphylococcus aureus*	62	27	89	0	100	N/A	100	89	0	0	0	0	0
Quinapristin/Dalfapristin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Daptomycin	Coagulase Negative Staph	42	19	61	56	100	100	100	61	0	0	0	0	0
Daptomycin	*Enterococcus* sp.	40	16	56	52	100	100	100	54	0	2	0	0	0
Daptomycin	*Staphylococcus aureus*	62	27	89	86	100	100	100	89	0	0	0	0	0
Daptomycin	*Streptococcus agalactiae*	0	5	5	5	100	100	100	5	0	0	0	0	0
Daptomycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Vancomycin	Coagulase Negative Staph	42	19	61	54	100	100	100	61	0	0	0	0	0
Vancomycin	*Enterococcus* sp.	40	16	56	27	100	100	100	28	3	25	0	0	0
Vancomycin	*Staphylococcus aureus*	62	27	89	83	100	100	100	89	0	0	0	0	0
Vancomycin	*Streptococcus agalactiae*	0	5	5	0	100	N/A	100	5	0	0	0	0	0
Vancomycin	*Streptococcus pyogenes*	0	6	6	0	100	N/A	100	6	0	0	0	0	0
Trimethoprim/Sulfamethoxazole	Coagulase Negative Staph	42	19	61	2	100	100	100	36	0	25	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Trimethoprim/Sulfamethoxazole	*Staphylococcus aureus*	62	27	89	2	100	100	100	87	0	2	0	0	0
Gentamicin	Coagulase Negative Staph	42	19	61	23	98.4	95.7	95.1	43	3	15	0	0	3
Gentamicin	*Staphylococcus aureus*	62	27	89	80	98.9	98.8	100	85	0	4	0	0	0
Streptomycin-1000 ug/mL	*Enterococcus* sp.	40	16	56	0	100	N/A	100	36	0	20	0	0	0
Clindamycin	*Streptococcus pneumoniae*	60	24	84	48	98.8	97.9	98.8	48	0	36	0	0	1
Penicillin	Beta hemolytic strep	27	0	27	7	100	100	100	27	0	0	0	0	0
Penicillin	Strep viridans	46	25	71	49	100	100	97.2	46	17	8	0	0	2
Penicillin	*Streptococcus agalactiae*	52	11	63	50	98.4	100	100	63	0	0	0	0	0
Penicillin	*Streptococcus pneumoniae*	60	24	84	68	98.8	98.5	98.8	11	22	51	0	0	1
Penicillin	*Streptococcus pyogenes*	53	14	67	0	100	N/A	100	67	0	0	0	0	0
Amoxicillin/Clavulanate	*Streptococcus pneumoniae*	60	24	84	69	98.8	98.6	95.2	64	11	9	0	0	4
Linezolid	Beta hemolytic strep	26	0	26	26	100	100	100	26	0	0	0	0	0
Linezolid	*Streptococcus agalactiae*	53	11	64	64	100	100	100	64	0	0	0	0	0
Linezolid	*Streptococcus pneumoniae*	60	24	84	84	100	100	100	84	0	0	0	0	0
Linezolid	*Streptococcus pyogenes*	53	14	67	67	100	100	100	67	0	0	0	0	0
Linezolid	*Streptococcus* sp.	47	25	72	72	100	100	100	72	0	0	0	0	0
Chloramphenicol	Beta hemolytic strep	26	0	26	26	100	100	100	26	0	0	0	0	0
Chloramphenicol	*Streptococcus agalactiae*	53	11	64	64	100	100	98.4	63	1	0	0	0	1
Chloramphenicol	*Streptococcus pneumoniae*	60	24	84	55	100	100	100	55	0	29	0	0	0
Chloramphenicol	*Streptococcus pyogenes*	53	14	67	67	100	100	100	67	0	0	0	0	0
Chloramphenicol	*Streptococcus* sp.	47	25	72	67	100	100	100	72	0	0	0	0	0
Cefepime	Beta hemolytic strep	27	0	27	27	100	100	100	27	0	0	0	0	0
Cefepime	*Streptococcus agalactiae*	52	11	63	62	100	100	100	63	0	0	0	0	0
Cefepime	*Streptococcus pneumoniae*	60	24	84	84	98.8	98.8	92.9	54	27	3	0	0	6
Cefepime	*Streptococcus pyogenes*	53	14	67	26	98.5	100	100	67	0	0	0	0	0
Cefotaxime	Beta hemolytic strep	27	0	27	18	96.3	94.4	100	27	0	0	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Cefotaxime	Strep viridans	46	25	71	62	98.6	98.4	97.2	63	4	4	0	0	2
Cefotaxime	*Streptococcus agalactiae*	52	11	63	61	100	100	100	63	0	0	0	0	0
Cefotaxime	*Streptococcus pneumoniae*	60	24	84	73	100	100	97.6	64	14	6	0	0	2
Cefotaxime	*Streptococcus pyogenes*	53	14	67	2	100	100	100	67	0	0	0	0	0
Tetracycline	Beta hemolytic strep	27	0	27	18	100	100	100	15	3	9	0	0	0
Tetracycline	*Streptococcus agalactiae*	52	11	63	10	100	100	100	10	0	53	0	0	0
Tetracycline	*Streptococcus pneumoniae*	60	24	84	35	100	100	98.8	35	0	49	0	0	1
Tetracycline	*Streptococcus pyogenes*	53	14	67	57	98.5	98.2	100	56	1	10	0	0	0
Tetracycline	*Streptococcus* sp.	47	25	72	51	100	100	97.2	49	2	21	0	0	2
Erythromycin	Beta hemolytic strep	26	0	26	15	100	100	100	16	0	10	0	0	0
Erythromycin	*Streptococcus agalactiae*	53	11	64	38	100	100	100	38	0	26	0	0	0
Erythromycin	*Streptococcus pneumoniae*	60	24	84	40	100	100	98.8	39	1	44	0	0	1
Erythromycin	*Streptococcus pyogenes*	53	14	67	58	100	100	100	58	0	9	0	0	0
Erythromycin	*Streptococcus* sp.	47	25	72	33	100	100	100	29	0	43	0	0	0
Levofloxacin	Beta hemolytic strep	26	0	26	24	100	100	100	26	0	0	0	0	0
Levofloxacin	*Streptococcus agalactiae*	53	11	64	64	100	100	100	64	0	0	0	0	0
Levofloxacin	*Streptococcus pneumoniae*	60	24	84	83	100	100	100	84	0	0	0	0	0
Levofloxacin	*Streptococcus pyogenes*	53	14	67	66	100	100	100	66	1	0	0	0	0
Levofloxacin	*Streptococcus* sp.	47	25	72	69	100	100	100	68	0	4	0	0	0
Meropenem	Beta hemolytic strep	26	0	26	6	100	100	100	26	0	0	0	0	0
Meropenem	*Streptococcus agalactiae*	53	11	64	49	100	100	100	64	0	0	0	0	0
Meropenem	*Streptococcus pneumoniae*	60	24	84	64	100	100	97.6	35	26	23	0	0	2
Meropenem	*Streptococcus pyogenes*	53	14	67	0	100	N/A	100	67	0	0	0	0	0
Meropenem	*Streptococcus* sp.	47	25	72	34	100	100	100	65	0	7	0	0	0
Daptomycin	Beta hemolytic strep	27	0	27	27	100	100	100	27	0	0	0	0	0
Daptomycin	*Streptococcus agalactiae*	53	11	64	63	100	100	98.4	64	0	0	0	1	0
Daptomycin	*Streptococcus pyogenes*	53	14	67	64	98.5	98.4	100	67	0	0	0	0	0

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Daptomycin	*Streptococcus* sp.	47	25	72	64	100	100	100	64	0	8	0	0	0
Vancomycin	Beta hemolytic strep	26	0	26	26	96.2	96.2	100	26	0	0	0	0	0
Vancomycin	*Streptococcus agalactiae*	53	11	64	64	100	100	100	64	0	0	0	0	0
Vancomycin	*Streptococcus pneumoniae*	60	24	84	84	100	100	100	84	0	0	0	0	0
Vancomycin	*Streptococcus pyogenes*	53	14	67	67	100	100	100	67	0	0	0	0	0
Vancomycin	*Streptococcus* sp.	47	25	72	71	100	100	100	71	0	1	0	0	0
Trimethoprim/Sulfamethoxazole	*Streptococcus pneumoniae*	60	24	84	35	100	100	96.4	20	17	47	0	0	3

Clinical and challenge isolate results summary for the AIM vs. Existing Autoinoculator (VIZION-Site 3)

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Ampicillin	*H. influenzae*	46	0	46	11	69.6	90.9	71.7	26	0	20	7	5	1
Amoxacillin/Clavulanate		46	0	46	1	100	100	100	46	0	0	0	0	0
Ampicillin/Sulbactam		46	0	46	3	100	100	95.7	43	0	3	1	1	0
Chloramphenicol		46	0	46	7	97.8	100	97.8	46	0	0	0	1	0
Cefaclor		46	0	46	7	100	100	84.8	39	5	2	0	2	5
Cefepime		46	0	46	0	97.8	N/A	100	46	0	0	0	0	0
Cefexime		46	0	46	0	97.8	N/A	100	46	0	0	0	0	0
Ceftriaxone		46	0	46	0	89.1	N/A	93.5	39	0	7	2	1	0
Cefuroxime (sodium)		46	0	46	11	89.1	100	100	46	0	0	0	0	0
Tetracycline		46	0	46	32	87	96.9	91.3	44	0	2	2	0	2
Clarithromycin		46	0	46	25	87	80	69.6	21	8	17	3	1	10
Imipenem		46	0	46	1	97.8	100	97.8	45	0	1	1	0	0
Meropenem		46	0	46	1	93.5	100	95.7	44	0	2	2	0	0
Trimethoprim/Sulfamethoxazole		46	0	46	9	76.1	77.8	76.1	28	4	14	4	1	6

Clinical and challenge isolate results summary for the AIM vs. Existing Autoinoculator (VIZION-Sites 1, 2 and 4)*

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
Ampicillin	*H. influenzae*	150	49	199	89	100	100	98.9	127	9	63	0	0	2
Amoxacillin/Clavulanate		150	49	199	30	99.5	100	99.5	169	3	27	0	0	1
Ampicillin/Sulbactam		150	49	199	31	100	100	99.5	169	0	30	0	1	0
Chloramphenicol		150	49	199	46	100	100	99.5	188	2	9	0	0	1
Cefaclor		150	49	199	31	100	100	97.5	179	6	14	0	0	5
Cefepime		150	49	199	13	100	100	100	187	0	12	0	0	0
Cefexime		150	49	199	8	100	100	100	188	0	11	0	0	0
Ceftriaxone		150	49	199	7	100	100	100	190	0	9	0	0	0
Cefuroxime (sodium)		150	49	199	101	100	100	100	188	2	9	0	0	0
Tetracycline		150	49	199	186	99.5	100	100	196	0	3	0	0	0
Clarithromycin		150	49	199	185	100	100	96.9	124	63	12	0	0	6
Imipenem		150	49	199	30	100	100	100	190	0	9	0	0	0
Meropenem		150	49	199	24	100	100	100	186	0	13	0	0	0
Trimethoprim/Sulfamethoxazole		150	49	199	104	100	100	99.5	137	18	44	0	0	1

***** Studies with *H. influenzae* were conducted at 2 external and one internal site. Forty-six *H. influenzae* isolates, which were originally tested at one of the external sites (site 3), showed unacceptable major error rates (i.e. 3.6 to 19%) and very major error rates (i.e. 17.5 to 100%) with the use of the VIZION for the following drugs: Ampicillin, Chloramphenicol, Cefaclor, Ceftriaxone, Tetracycline, Clarithromycin, Imipenem, Meropenem, and TMP/SMX. This was attributed to site-specific issues of failure to follow on-site training along with failure to confirm the VIZION readings on a mirror viewer. These 46 isolates were later sent to another external laboratory (site 4) for retesting using the VIZION. Site 4 tested the same 46 clinical isolates as site 3 as per the TI**.** The results presented in this table (3C) reflect the overall results from sites 1, 2 and 4. Please refer to the limitations section.

The following limitation will be included in labeling: “Major and very major errors have occurred when reading *H. influenzae* results on the VIZION. When using the AIM to inoculate *H. influenzae*, results obtained by reading on the VIZION should be confirmed with the mirrored viewer."

Clinical and challenge isolate results summary for the AIM vs. existing Autoinoculator for Cefoxitin Screen Test and Dtest (AutoReader/VIZION)

Cefoxitin Screen-*S. aureus*	Total	# CA	% CA	#R	# VMJ	%VMJ	#S	#MAJ	%MAJ
AutoReader	89	86	96.6	41	1	2.4	48	2	4.2
VIZION	88	87	98.9	42	0	0.0	46	1	2.2
Dtest *S. aureus*	Total	# CA	% CA	#R	# VMJ	%VMJ	#S	#MAJ	%MAJ
AutoReader	89	87	97.8	42	1	2.4	47	1	2.1
VIZION	88	87	98.9	42	1	2.4	46	0	0.0
Dtest Coagulase Negative Staphylococci	Total	# CA	% CA	#R	# VMJ	%VMJ	#S	#MAJ	%MAJ
AutoReader	61	61	100.0	30	0	0.0	31	0	0.0
VIZION	61	61	100.0	30	0	0.0	31	0	0.0

The following limitation will be included in labeling: "One major and one very major error occurred when reading S. aureus results on the AutoReader and the VIZION. When using the AIM to inoculate *S. aureus* for Dtest, consider alternative inoculation methods if inducible clindamycin resistance is suspected."

Clinical and challenge isolate results summary for the AIM vs. existing Autoinoculator (Mirror Read)

Drug	Organism Group	Clinical	Challenge	Total	Total Evaluable	%EA Total	% EA of Evaluable	%CA	S	I	R or NS	VMJ	MAJ	Minor
5-Flucytocine	*C. albicans*	48	13	61	51	100	100	100	61	0	0	0	0	0
	C. glabrata	17	24	41	1	100	100	100	41	0	0	0	0	0
	C. krusei	57	7	64	64	100	100	96.9	12	52	0	0	0	2
	C. lusitinae	15	5	20	1	100	100	100	20	0	0	0	0	0
	C. parapsilosis	58	10	68	58	100	100	100	66	0	2	0	0	0
	C. tropicalis	33	16	49	32	100	100	100	39	0	10	0	0	0
Itraconazole	*C. albicans*	48	13	61	57	100	100	96.7	50	8	3	0	0	2
Fluconazole	*C. albicans*	48	13	61	59	100	100	100	59	1	1	0	0	0
	C. glabrata	17	24	41	41	100	100	95.1	16	15	10	0	0	2
	C. krusei	57	7	64	64	100	100	100	3	27	34	0	0	0
	C. lusitinae	15	5	20	17	100	100	100	20	0	0	0	0	0
	C. parapsilosis	58	10	68	67	100	100	100	66	2	0	0	0	0
	C. tropicalis	33	16	49	47	100	100	100	46	1	2	0	0	0
Voriconazole	*C. albicans*	48	13	61	12	100	100	100	60	1	0	0	0	0
	C. glabrata	17	24	41	40	97.6	100	100	37	2	2	0	0	0
	C. krusei	57	7	64	63	100	100	100	63	0	1	0	0	0
	C. lusitinae	15	5	20	5	100	100	100	20	0	0	0	0	0
	C. parapsilosis	58	10	68	55	100	100	100	68	0	0	0	0	0
	C. tropicalis	33	16	49	45	100	100	98	47	0	2	0	0	1

Essential agreement (EA) is when the Sensititre panels inoculated with the AIM produced MIC results that are within +/- one doubling dilution of the results obtained from the Sensititre panels inoculated with Autoinoculator I. Category agreement (CA) is when the Sensititre panel inoculated with the AIM produced interpretative results (SIR) that agreed exactly with those of the Autoinoculator I.

The percent 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".

Overall, results for all the drugs evaluated were comparable whether the inoculation method was with the existing Autoinoculator I or with the AIM. As shown in the table below, the EA and CA rates were greater than 90% for each group of organisms for all drugs combined.

Organism/Group	Number of isolates tested	EA (%)	CA (%)
	AutoReader		
S. aureus	**89**	**99.8**	**99.4**
Staphylococcus spp. (CNS)	**61**	**99.4**	**99.5**
Enterococcus spp.	**56**	**100**	**98.2**
Beta hemolytic Streptococcus spp.(MHB)	**11**	**100**	**100**
S. pneumoniae	**84**	**99.2**	**97.7**
Viridans *Streptococcus* spp.	**72**	**99.8**	**99.1**
Beta hemolytic group *Streptococcus* spp. (LHB)	**157**	**99.7**	**99.8**
	VIZION		
S. aureus	**88**	**99.9**	**99.2**
Staphylococcus spp. (CNS)	**63**	**99.9**	**99.3**
Enterococcus spp.	**57**	**100**	**98.9**
Beta hemolytic Streptococcus spp.(MHB)	**12**	**100**	**100**
S. pneumoniae	**89**	**99.6**	**97.5**
Viridans *Streptococcus* spp.	**72**	**99.3**	**98.4**
Beta hemolytic group *Streptococcus* spp. (LHB)	**156**	**99.8**	**100**
Haemophilus influenzae	**195**	**99.5**	**99.2**
	Manual Mirror		
Candida spp	303	99.9%	99.2%

*MHB= Mueller-Hinton Broth
*LHB = Lysed Horse Blood added to MHB

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:

   Not applicable.

N. Instrument Name:

Sensititre® AIM ™

O. System Descriptions:

1. Modes of Operation:

   The Autoinoculator 2/AIM is a bench-top instrument which dispenses bacterial suspension (inoculum) into the Sensititre 96-well plate. The instrument has a display which presents options to the End User graphically. After making a selection of the panel layout/configuration, the user may then select the well dose volume (a multiple of 50 µl) specific to each panel section (note that different panel sections may be dosed differently). Having selected these parameters, the user loads the sample, loads a suitable plate and then starts the dosing cycle.

   The Autoinoculator 2/AIM is a stand-alone device and requires no connections to other equipment in normal use. It currently provides no support for sample tracking.

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ___X_____ or No _____

3. Specimen Identification:

   The specimen is identified manually by the user. The AIM instrument provides no support for sample tracking.

4. Specimen Sampling and Handling:

   The bacterial suspension (inoculum) is prepared by the user. A Sensititre disposable dosehead is affixed to the glass tube containing the final inoculum density which is placed into the instrument's pump assembly. The AIM instrument then dispenses the inoculum into the Sensititre 96-well plate.

5. Calibration:

   The AIM instrument is calibrated by weighing inoculated plates. It is recommended that calibration should be carried out at intervals of no less than 1 year.

6. Quality Control:

   The AIM instrument uses a built-in routine allowing the adjustment and calibration of the plate dosing. The QC is performed by measuring the weight of a panel before and after dosing, to establish the weight and thus volume of the dosing droplets.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Not applicable. All instrument data is included above in section M.

Q. Proposed Labeling:

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

R. Conclusion:

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