Poster #C-1568
ASM 2011

# An Evaluation of the New Sensititre AIM Performance Compared to the Existing Sensititre Autoinoculator for MIC Determination

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## Abstract

**Background:** The Sensititre® AIM™ is a microprocessor controlled instrument that delivers inoculum in 50µl multiples to the 96 wells of a Sensititre susceptibility plate comparable to the existing autoinoculator. An evaluation was undertaken to determine the substantial equivalence of the Sensititre AIM with the existing Sensititre Autoinoculator. **Methods:** Studies for performance comparison on the Sensititre AIM and the existing Autoinoculator were conducted at three trial sites using the Sensititre® 18-24 hour susceptibility system for non-fastidious, fastidious and yeast isolates. The study consisted of the following clinical non-fastidious, fastidious and yeast isolates at each of the three sites: 147 Gram negative, 145 Gram positive, 240 *Streptococcus* spp. isolates, 145 *Haemophilus* spp. isolates, 228 *Candida* spp. isolates, and a common set of 125 reproducibility isolates. CDC Challenge isolates were only tested at one site and consisted of: 75 Gram negative, 75 Gram positive, 75 *Streptococcus* spp., 50 *Haemophilus* spp., and 75 *Candida* spp. isolates. Isolates were tested on plates containing cleared FDA antimicrobics for the Sensititre 18-24 hour dried susceptibility system. The plates were inoculated and read as per manufacturers' instructions. Recommended quality control (QC) organisms were tested daily and all MIC results were within the expected QC ranges. **Results:** The results for the data sets representing the non-fastidious, fastidious, and yeast isolates for the overall essential agreement rate (+/- 1 $\log_2$ dilution of the AIM compared to the existing autoinoculator) were 99.6% and 99.8% for isolates read on the AutoReader, 99.9% and 99.6% for the Vizion, and 99.2% for yeast isolates read on the manual mirror. The overall categorical agreement according to the FDA MIC interpretive categories comparing the AIM to the existing autoinoculator, was 98.9% and 98.9% for the AutoReader, 99.2% and 99.9% for the Vizion, and 98.8% for manual mirror reads. Reproducibility results were calculated for the combined sites plus or minus one dilution of the modal value and resulted in 99.4% for the AutoReader, 98.7% for the Vizion, and 99.6% for manual mirror reads. **Conclusions:** The new Sensititre AIM demonstrated excellent MIC correlation compared to the existing Sensititre Autoinoculator.

## Introduction

The Sensititre® AIM™ System is an automated device recently developed for inoculum delivery into the 96 well Sensititre plates. The AIM was designed to dose single and multi-isolate plates with either 50µl or 100µl per well. It has a smaller foot print to fit in any lab and is operated by means of an icon driven touch screen.

## Objective

A multi-site study was undertaken to validate the AIM's performance versus the existing Sensititre Autoinoculator. The study compared the performance of non-fastidious gram positive and gram negative organisms, *Streptococcus* spp., *Haemophilus* spp. and *Candida* spp. read on both the Sensititre AutoReader and Vizion.

## Methods and Materials

**Susceptibility Testing Methods**:

- 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® 18-24 hour MIC or breakpoint susceptibility system is an *in vitro* diagnostic product for clinical susceptibility testing of fastidious and non-fastidious organisms.
- Sensititre 18 – 24 susceptibility plates containing cleared FDA antimicrobics, were tested according to the manufacturers' instructions.
- Each isolate was tested on 2 plates using the AIM™ and existing Autoinoculator and was read on both the Sensititre AutoReader and Vizion.
- Testing consisted of 1239 fresh clinical isolates; 145 gram positive isolates, 147 gram negative isolates, 240 *Streptococcus* spp., 195 *Haemophilus influenzae* isolates and 303 yeast isolates supplied by all sites, and 350 challenge isolates supplied to a single testing site. (Table 1).
- The reproducibility study was performed at 3 trial sites was measured against: 25 Gram negative isolates, 25 Gram positive isolates, 25 *Streptococcus* spp., 25 *Haemophilus* spp., 25 *Candida* spp. on the Sensititre 18-24 hour susceptibility plate. (Table 5.)
- Quality control was assured by testing 20 replicates of each ATCC strain. All MIC results were within expected QC ranges. (Table 2).
- Colony counts were performed on the inoculum of the QC strains on each day of testing.

**Table 1. Organisms Tested**

| | |
|---|---|
| *Staphylococcus aureus* | 89 |
| *Staphylococcus* spp. | 61 |
| *Enterococcus* spp. | 56 |
| Beta hemolytic *Streptococcus* spp. | 157 |
| *Streptococcus pneumoniae* | 84 |
| Viridans *Streptococcus* spp. | 72 |
| *Haemophilus influenzae* | 195 |
| *Candida* spp. | 303 |
| *Escherichia coli* | 40 |
| *Morganella morganii* | 8 |
| *Providencia* spp. | 10 |
| *Klebsiella* spp. | 30 |
| *Proteus* spp. | 17 |
| *Citrobacter* spp. - | 10 |
| *Enterobacter* spp. | 24 |
| *Serratia* spp. | 20 |
| *Burkholderia cepacia* | 1 |
| *Pseudomonas aeruginosa* | 27 |
| *Acinetobacter* spp. | 19 |
| *Pseudomonas* spp. | 13 |
| *Stenotrophomonas maltophilia* | 1 |
| *Aeromonas hydrophila* | 2 |
| TOTAL | 1239 |

**Table 2. Quality Control Strains**

| | |
|---|---|
| *Staphylococcus aureus* | ATCC 29213 |
| *Enterococcus faecalis* | ATCC 29212, ATCC 51299 |
| *Escherichia coli* | ATCC 25922, 35218 |
| *Pseudomonas aeruginosa* | ATCC 27853 |
| *Streptococcus pneumoniae* | ATCC 49619 |
| *Haemophilus influenzae* | ATCC 49247, ATCC 49766 |
| *Candida parapsilosis* | ATCC 22019 |
| *Candida krusei* | ATCC 6258 |
| *Staphylococcus aureus* | ATCC BAA-976, ATCC BAA-977 |

## Results

**Table 3: Clinical and Challenge isolate Autoread Results for the AIM vs. Existing Autoinoculator**

| Organism | Total Isolates Tested | % Essential agreement | % Categorical agreement |
|---|---|---|---|
| *Staphylococcus aureus* | 89 | 99.8 | 99.4 |
| *Staphylococcus* spp. (CNS) | 61 | 99.4 | 99.5 |
| *Enterococcus* spp. | 56 | 100 | 98.2 |
| Beta-hemolytic group *Streptococcus* spp. (MHB) | 11 | 100 | 100 |
| *Enterobacteriaceae* | 161 | 99.8 | 98.7 |
| *Non-Enterobacteriaceae* | 22 | 99.3 | 97.4 |
| *Pseudomonas aeruginosa* | 27 | 100 | 100 |
| *Acinetobacter baumannii* | 12 | 100 | 97.6 |
| *Streptococcus 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 |

**Table 4: Clinical and Challenge isolate VIZION /Mirror Results for the AIM vs. Existing Autoinoculator**

| Organism | Total Isolates Tested | % Essential agreement | % Categorical agreement |
|---|---|---|---|
| *Staphylococcus aureus* | 88 | 99.9 | 99.2 |
| *Staphylococcus* spp. (CNS) | 63 | 99.9 | 99.3 |
| *Enterococcus* spp. | 57 | 100 | 98.9 |
| Beta-hemolytic group *Streptococcus* spp. (MHB) | 12 | 100 | 100 |
| *Enterobacteriaceae* | 161 | 99.9 | 98.4 |
| *Non-Enterobacteriaceae* | 22 | 99.3 | 98.7 |
| *Pseudomonas aeruginosa* | 27 | 100 | 100 |
| *Acinetobacter baumannii* | 12 | 100 | 98.8 |
| *Streptococcus 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* spp. | 195 | 99.5 | 99.2 |
| ***Candida* spp. (Mirror) | 303 | 99.9 | 99.2 |

***Candida* spp. Is not FDA cleared to read on the VIZION

**Table 5: Interlaboratory Reproducibility % Essential Agreements +/- $\log_2$ Dilution of the Modal MIC**

| Instrument | Sensititre Vizion<br>% Overall<br>25N/25P/25S/25H | Sensititre Autoread<br>% Overall<br>25N/25P/25S | Sensititre Mirror<br>% Overall<br>25Y |
|---|---|---|---|
| AIM vs. Existing Autoinoculator | % Essential Agreement (off scale result is within one well from the mode)<br>99.2/99.3/99/99.3 | % Essential Agreement (off scale result is within one well from the mode)<br>99.4/99.3/99.4 | % Essential Agreement (off scale result is within one well from the mode)<br>99.6 |

25 Gram negative isolates, (N),25 Gram positive isolates, (P),25 Streptococcus spp., (S),25 Haemophilus spp., (H),25 Candida spp., (Y)

## Summary

**Performance Characteristics**
**(Clinical and Challenge data)**
The AIM was validated in the following manner:
A variety of clinical and challenge isolates, including isolates with current resistance patterns were tested on the AIM and the performance was compared to the existing Autoinoculator.
The results for the data sets representing the non-fastidious, fastidious, and yeast isolates for the overall essential agreement rate (+/- 1 $\log_2$ dilution of the AIM compared to the existing autoinoculator) were 99.7% for the AutoReader, 99.8% for the Vizion, and 99.2% for mirror reads. The overall categorical agreement (qualitative (S,I,R)), according to the FDA MIC interpretive categories comparing the AIM to the existing autoinoculator, was 99% for the AutoReader, 99% for the Vizion, and 98.8% for mirror reads. (Tables 3 and 4)

**Interlaboratory Reproducibility Data:**
Testing was performed on the AIM and existing autoinoculator using Sensititre plates read on the Vizion, AutoReader, and mirror. Reproducibility was calculated as occurrences of the difference in number of wells between the test result and test mode. Percentages of results were calculated for the combined sites plus or minus one dilution of the modal value (Please refer to Table 5 for results).

## Conclusions

This study validates that the new Sensititre AIM demonstrates excellent correlation when compared to the existing Sensititre Autoinoculator. The high level of essential and categorical agreements obtained with the Sensititre AIM suggests that this is an acceptable inoculation method for Sensititre MIC plates in the clinical, vet and pharmaceutical laboratory.

## References

Clinical and Laboratory Standards Institute. **2009**. *Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard-Eighth Edition*. Approved document M07-A8. Wayne, PA: CLSI.
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