A Multi-Site Study Comparing an 18-24h Sensititre® Susceptibility System to the CLSI Broth Microdilution Method for Iclaprim Using Fastidious and Non-Fastidious Gram-Positive Organisms

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Introduction

Iclaprim is a novel macrolide antibiotic which has shown extended-spectrum activity against aerobic bacteria, including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-intermediate Staphylococcus aureus (VISA), methicillin-resistant Staphylococcus epidermidis (MRSE), and Enterococcus faecalis and faecium. Results from a multi-site study, performing a series of evaluations in laboratories across several countries, demonstrated the accuracy and reproducibility of the Sensititre® 18 – 24 hour MIC susceptibility system when compared to the CLSI reference broth microdilution method (CLSI M07). Results

Materials & Methods

- Indicator for use: The Sensititre® 18 – 24 hour MIC or breakpoint susceptibility system is an in vitro diagnostic product for clinical susceptibility testing of both fastidious and non-fastidious organisms.
- Each isolate was tested using the Sensititre® 18 – 24 hour susceptibility plate containing Iclaprim (0.002-32µg/mL) (Arpida Ltd., Reinach, Switzerland). The disks were set up and tested according to the manufacturer’s instructions.
- The CLSI reference broth microdilution plate was prepared and tested on each isolate according to the Clinical Laboratory Standards Institute (CLSI M07).
- Testing consisted of 960 fresh clinical isolates (combined 3 sites). Approximate 330 gram-positive isolates, and 351 fastidious isolates from each site. 150 Centers for Disease Control and Prevention (CDC) challenge isolates consisted of 78 gram-positive and 72 fastidious supplied to a single testing site (Table 1 and 2).
- Reproducibility testing consisted of 30 gram-positive and 28 challenge isolates. Isolates tested at 3 were on the Sensititre® 18 – 24 hour susceptibility plates (Table 1). The test result was compared with those of the CLSI reference broth microdilution plate.
- Quality control (QC) was assured by testing 20 replicates of each ATCC strain including S. aureus 29213, E. faecalis 29212, and S. pneumoniae 49615, at each site (Table 1 and 3).
- Colony counts were performed on the inoculum of the QC strains on each day of testing.

Results

- Between-site reproducibility ratio 73/75 73/75 75/75 75/75 between the Sensititre® 18 – 24 hour susceptibility system and CLSI reference BMD was both acceptable for the fastidious and non-fastidious organisms.
- The essential agreement obtained by the Sensititre® 18 – 24 hour susceptibility system and CLSI reference BMD was both acceptable for the fastidious and non-fastidious organisms.
- Clinical isolates and CDC challenge isolates tested separately. Both acceptable for the fastidious and non-fastidious organisms.
- Overall agreement for the respiratory test strains were: 95.3% for the manual read method and 95.2% for the automated method (Tables 3 and 4).
- Modal MIC for Iclaprim was tested against 860 fresh clinical isolates, 150 challenge isolates and 50 reproducibility isolates. These isolates consisted of: 117 coagulase-negative Staphylococcus spp., 172 Streptococcus spp. isolates tested at all 3 sites on the Sensititre® 18 – 24 hour susceptibility plate (Table 1). The test result compared with those of the CLSI reference broth microdilution plate.

Conclusions

This study validates that the Sensititre® 18 – 24 hour susceptibility system (both manual and automated) demonstrated an equivalent level of performance compared to the CLSI reference broth microdilution plate when testing Iclaprim against gram positive and Streptococcus spp. clinical and challenge isolates. The high level of essential agreement obtained by the Sensititre® 18 – 24 hour susceptibility system and the CLSI reference method suggests that this is an acceptable method for susceptibility testing of Iclaprim.

References


Acknowledgement

The research and publication process was supported by Arpida Ltd., Reinach, Switzerland.