Abstract

Background: The Sensititre® 18 – 24 hour susceptibility system is an automated instrument for determining minimum inhibitory concentrations (MICs) for clinical isolates, including testing for resistance to minocycline. To determine the accuracy and reproducibility of the system in a multi-site setting, a blinded evaluation was performed to determine the accuracy and reproducibility of the CLSI reference broth microdilution method (M07) using the Sensititre® 18 – 24 hour susceptibility system (Trek Diagnostic Systems, Cleveland, OH) compared to the CLSI reference broth microdilution method (M07). The study was conducted in three locations: Trek Diagnostic Systems, Cleveland, OH; JMI Lab., North Liberty, IA; Summa Health Systems, Akron, OH.

Materials & Methods

• Indications for use: The Sensititre® 18 – 24 hour MIC or breakpoint susceptibility system is an automated instrument for determining minimum inhibitory concentrations (MICs) for clinical isolates, including testing for resistance to minocycline.

• Clinical Microbiology Considerations: The Sensititre® 18 – 24 hour susceptibility system is an automated instrument for determining minimum inhibitory concentrations (MICs) for clinical isolates, including testing for resistance to minocycline.

• Quality Control Strains CLSI MIC Ranges (µg/ml): ATCC 25922, minocycline 0.25-1; ATCC 29212, minocycline 1-4; ATCC 29213, minocycline 0.06-0.5; Enterococcus faecalis strain 1009, minocycline 0.06-0.5.

• Indications for use: The Sensititre® 18 – 24 hour susceptibility system is an automated instrument for determining minimum inhibitory concentrations (MICs) for clinical isolates, including testing for resistance to minocycline.

Materials and Methods

The study was conducted in three locations: Trek Diagnostic Systems, Cleveland, OH; JMI Lab., North Liberty, IA; Summa Health Systems, Akron, OH. All isolates were tested according to the Clinical Laboratory Standards Institute (CLSI) M07. CLSI MIC ranges for Minocycline were 0.25-1 µg/ml for Enterobacteriaceae and 1-4 µg/ml for non-Enterobacteriaceae. The isolates were at least 99% essential agreement (+/- one log2 dilution of the modal MIC) for automated and manual reading methodologies were performed.

Results

• Reproducibility testing consisted of 25 gram positive and 25 gram negative challenge isolates consisted of: 60 gram positive and 75 gram negative isolates from each site. All isolates were inoculated as recommended by the manufacturer.

• The samples consisted of: 177 total gram positive and 176 total gram negative isolates. The isolates consisted of: 99.8% essential agreement (+/- one log2 dilution of the modal MIC) for automated and manual reading methodologies were performed.

• The study was conducted in three locations: Trek Diagnostic Systems, Cleveland, OH; JMI Lab., North Liberty, IA; Summa Health Systems, Akron, OH. All isolates were tested according to the Clinical Laboratory Standards Institute (CLSI) M07.

Conclusions

• The study validates that Sensititre® 18 – 24 hour susceptibility system compared to the CLSI reference broth microdilution method (M07) is reproducible, accurate, and effective. The high level of agreement observed in the study supports the acceptability of the sensitivity and specificity of the system for use in clinical laboratories.

References
