Multicenter Evaluation of Erythromycin MIC Results for Enterobacteriaceae Using MicroScan Dried Gram Negative MIC Panels


1Clinical Microbiology Institute, Wilsonville, OR, 2Loyola University Medical Center, Maywood, IL, 3UCLA David Geffen School of Medicine, Los Angeles, CA, and 4Beckman Coulter, West Sacramento, CA

ABSTRACT

Background: A multicenter study was performed to evaluate the accuracy of erythromycin on a MicroScan Dried Gram Negative (MSDGN) MIC Panel compared to a manual broth microdilution reference panel. Methods: A total of 414 Enterobacteriaceae clinical isolates were tested using the turbidity and MicroScan PROMPT inoculation* (PROMPT method) and visually. For challenge, 79 Enterobacteriaceae isolates were tested on MSDGN panels at one site. For reproducibility, a subset of 11 organisms was tested on MSDGN panels at each site. MSDGN panels were incubated at ±1°C and read on the WalkAway Plus (WalkAway), the MicroScan autoSCAN-4 instrument (autoSCAN-4) or manually. Read times for the MSDGN panels were at 18 hours. Frozen reference panels, prepared according to CLSI/ISO methodology, were inoculated using the turbidity inoculation method. All frozen reference panels were incubated at ±2°C and read visually. Frozen reference panels were read at 16–20 hours. FDA breakpoints (μg/mL) were used for interpretation of MIC results were Enterobacteriaceae ≤ 0.5 μg/mL. Potential major and very major errors were calculated using the Potential Major Error (PME) method.

Results: When compared to frozen reference panel results, essential and categorical results for isolates tested in the Efficacy and Challenge are as follows:

<table>
<thead>
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<th>Read Method</th>
<th>Essential Agreement (%)</th>
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Reproducibility: Repeatability agreements were greater than 95% for all read methods for both the turbidity and Prompt inoculation methods.

Conclusion: This multicenter study showed that erythromycin MIC results for Enterobacteriaceae obtained with the MSDGN panel correlates well with MICs obtained using frozen reference panels using FDA interpretive criteria.

INTRODUCTION

A multicenter study was performed to evaluate the performance of a MicroScan Dried Gram Negative MIC panel with erythromycin using Enterobacteriaceae isolates with FDA interpretive breakpoints.

METHODS

Study Design: MicroScan Dried Gram Negative MIC panels were tested concurrently with a CLSI frozen broth microdilution reference panel at three sites using both the turbidity and Prompt Inoculation methods. A total of 430 Enterobacteriaceae clinical isolates were tested among the three sites.

Quality Control Expected Results. https://www.fda.gov/STIC

Erythromycin MIC results for Enterobacteriaceae obtained with the MSDGN panel correlate well with MICs obtained using frozen reference panels using FDA interpretive criteria. This study was supported by Tetraphase Pharmaceuticals Inc.

REFERENCES


RESULTS

Panels: Frozen reference and MicroScan Dried Gram Negative MIC panels contained a double dilution of erythromycin 0.016–32 μg/mL in cation-adjusted Mueller-Hinton broth. Reference panels were prepared and frozen following CLSI/ISO recommendations.

Quality Control: Essential Agreement (EA) testing was performed daily using ATCC 25922 E. coli and ATCC 27853 P. aeruginosa (see https://www.fda.gov/STIC).

Potential Inoculation, Inoculation and Reading: All isolates were subcultured onto trypticase soy agar (TSA) with 5% sheep blood and inoculated for 16–24 hours at 34–37°C prior to testing. Inoculum for MicroScan autoSCAN-4 panels was prepared visually. Read times for the MSDGN panels were at 18 hours. Frozen reference panels, prepared according to CLSI/ISO methodology, were inoculated using the turbidity inoculation method. All frozen reference panels were incubated at ±2°C and read visually. Frozen reference panels were read at 16–20 hours. FDA breakpoints (μg/mL) were used for interpretation of MIC results for Enterobacteriaceae ≤ 0.5 μg/mL. Potential major and very major errors were calculated using the Potential Major Error (PME) method.

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