Comparative evaluation of Eravacycline MIC determination with the new ETEST® ERV* and CLSI broth microdilution method

* For Research Use Only. The performance characteristics of this product have not been established yet.

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BACKGROUND

Eravacycline (KRAVAIN®) is a novel, FDA and EMA approved fully-synthetic fluorocycline antibiotic developed by Tetraphase Pharmaceuticals Inc. for the treatment of complicated intra-abdominal infections (cIAI) including those caused by multidrug-resistant (MDR) pathogens that have been highlighted as urgent public health threats by the US CDC and the WHO. cIAI are an important cause of morbidity and are the second most common cause of infectious mortality in the intensive care unit.

The new ETEST® ERV strip (MIC range 0.002 – 32 µg/mL) has been developed and calibrated versus the broth microdilution reference method (BMD) as described by the Clinical and Laboratory Standards Institute (CLSI) to determine the minimal inhibitory concentration (MIC) of eravacycline against Enterobacteriales and Enterococci.

OBJECTIVE

The aim of the study was to compare ETEST ERV to the CLSI BMD method on a panel of 89 strains comprising 69 Enterobacteriales and 20 Enterococci.

METHODS

• The panel includes 89 strains (among them 69 Enterobacteriales and 20 Enterococci) and 3 CLSI QC strains.
• The details of QC strains and panel are presented in Tables 1 and 2.
• The strains were provided by bioMérieux internal collection and Tetraphase pharmaceuticals collection.
• The selected panel consisted of 21% of resistant strains and 18% of strains with MIC at the breakpoint. Enterobacteriales include strains with various beta-lactam resistance mechanisms including ESBL (13), AmpC high level (8), Carbapenemase (8) and various Tetracycline and Tigecycline resistance phenotypes as well as wild type strains. Enterococci strains include both Vancomycin Susceptible and Resistant Enterococci.

QC Strains ATCC® number CLSI 2019 MIC ranges (µg/mL)
E.coli ATCC 25922 0.03–0.12
E. faecalis ATCC 29212 0.03–0.06
P. aeruginosa ATCC 27853 2 – 16

Table 1 – CLSI QC strains and associated MIC ranges (µg/mL)

The strains were provided by bioMérieux internal collection and Tetraphase pharmaceuticals collection.

The MICs for QC strains are within the expected CLSI ranges with reproducible results. Ellipses are easy to read, clear, without trailing.

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RESULT

The essential MIC agreement [±1 dilution] is 99% without overestimation or underestimation trend between ETEST ERV and BMD (see Table 3).

CONCLUSION

In this study, the new ETEST ERV strip has been found to be substantially equivalent to the CLSI reference method. MIC end-points are easier to read in comparison to the reference method. With a 15-dilution MIC range and simplicity of use, ETEST ERV could represent a valuable tool for MIC determination and an alternative to the BMD reference method. ETEST will undergo clinical studies to seek IVD FDA clearance and CE marking.

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