Multicenter Quality Control Evaluation Results for Dalbavancin (BI397), An Investigational Glycopeptide With Potent Gram-Positive Activity

TR Anderegg, PR Rhomberg, RN Jones.
The JONES Group/JMI Laboratories, North Liberty, Iowa (www.jmilabs.com)

ABSTRACT
A quality control (QC) study following the guidelines of M23-A2 and broth microdilution test methods (ATCC) established by the National Committee for Clinical Laboratory Standards was performed to ensure quality control agent selection for Gram-positive pathogens. Phenotypic results and data from susceptibility testing results are based on the susceptibility test inoculum concentration: 3.5 x 10^5 CFU/ml. Table 1 shows an example of the dalbavancin MIC distribution for S. aureus ATCC 29213 between the eight laboratories. Over 95% of the combined results were at 0.06 µg/ml, which was also the modal value for all of the eight participating laboratories. The proposed range for S. aureus ATCC 29213 is 0.03 - 0.12 µg/ml, which would contain 100% of the reported results.

RESULTS

• Similar results were obtained for E. faecalis ATCC 29212 with over 85% of the total results at the modal value (0.06 µg/ml) and a range of 0.03 - 0.12 µg/ml (100% of the reported value).

• For S. pneumoniae ATCC 49619, over 78% of the total results were at the modal value (0.015 µg/ml) with a range of 0.008 - 0.03 µg/ml (97.6% of the reported values).

• Table 2 summarizes all of the proposed QC ranges for S. aureus ATCC 29213, E. faecalis ATCC 29212 and S. pneumoniae ATCC 49619 (0.06 µg/ml, 3.05 µg/ml, 0.015 µg/ml, respectively) were documented (data not shown).

• When the MICs occurrences by media lots were calculated, the same modal values were obtained for S. aureus ATCC 29213, 1 - 4 µg/ml for S. pneumoniae ATCC 49619, which was also the modal value for all of the eight participating laboratories.

• The proposed dalbavancin QC guidelines should be utilized during the initial clinical trials, especially since there will be a delay in the development of the disk agar diffusion method.

• These MIC ranges when applied, will promote the accuracy of dalbavancin susceptibility testing data for regulatory purposes worldwide.

MATERIALS & METHODS

A quality control (QC) study following the guidelines of M23-A2 and broth microdilution test methods (ATCC) established by the National Committee for Clinical Laboratory Standards was performed to ensure quality control agent selection for Gram-positive pathogens. Phenotypic results and data from susceptibility testing results are based on the susceptibility test inoculum concentration: 3.5 x 10^5 CFU/ml. Table 1 shows an example of the dalbavancin MIC distribution for S. aureus ATCC 29213 between the eight laboratories. Over 95% of the combined results were at 0.06 µg/ml, which was also the modal value for all of the eight participating laboratories. The proposed range for S. aureus ATCC 29213 is 0.03 - 0.12 µg/ml, which would contain 100% of the reported results.

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SELECTED REFERENCES


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