# Initial Quality Control (QC) Ranges for Fusidic Acid (FA) Using the CLSI Multi-Laboratory M23-A3 Study Design.

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## Background:

The increasing prevalence of resistances in staphylococci, especially CA-MRSA, has brought renewed interest in FA. A promising feature of FA is the lack of cross resistance with other antimicrobial classes, as a result of the unique mode of action that works by inhibiting bacterial protein synthesis at the translation stage. This study was performed to establish QC ranges for broth microdilution (BMD) and disk diffusion (DD) and follows the CLSI M23-A3 (2006) guideline document. The results are presented as proposed QC ranges for two ATCC strains (*S. aureus* ATCC 29213 [SA] and *S. pneumoniae* ATCC 49619 [SPN]).

## Methods:

CLSI BMD and DD methods were utilized in an eight laboratory study design compliant with M23-A3 specifications. For BMD, four media lots (three manufacturers) of cation-adjusted Mueller-Hinton (MH) broth (with 2-5% lysed horse blood for testing SPN) were evaluated and three agar lots for the DD method. Ten replicate tests were performed for each QC organism generating 320 BMD values per strain (640 total) and 480 DD zones (two lots of FA disks were tested; 960 total zones). Levofloxacin and linezolid and were used as controls.

## Results:

The table lists the recommended QC MIC and DD ranges for FA. Modal MIC values (% of total) observed were: SA at 0.12 µg/ml (77.5) and SPN at 8 µg/ml (60.6). No significant differences were noted among media lots or testing site performance for FA using BMD. Using DD, one laboratory reported zones that were significantly smaller than other participants and therefore excluded from analysis.

| | FA MIC/Disk zone diameters (% in range): | |
|---|---|---|
| QC organism (ATCC no.) | Proposed range for BMD (µg/ml) | Proposed range for DD (mm) |
| *S. aureus* ATCC 29213 | 0.06 – 0.25 (97.8) | 24 – 32 (99.8) |
| *S. pneumoniae* ATCC 49619 | 4 – 32 (100.0) | 8 – 16 (97.1) |

## Conclusions:

Proposed MIC and DD QC ranges for FA will guide clinical or reference laboratories involved in the testing of clinical trial isolates and facilitate the regulatory review process.