Cefiderocol Interpretative Criteria

FDA Identified Breakpoints[1]	Minimum Inhibitory Concentrations (µg/mL)			Disk Diffusion (zone diameter in mm)		
	Susceptible	Intermediate	Resistant	Susceptible	Intermediate	Resistant
Enterobacterales[a,b]	≤4	8[c]	≥16	≥16	9-15[c]	≤8
Pseudomonas aeruginosa	≤1	2	≥4	≥22	13-21	≤12
Acinetobacter baumanii complex	≤1	2	≥4	≥19	12-18	≤11
Stenotrophomonas maltophilia	≤1[f]	-	-	≥17	-	-
CLSI Identified Breakpoints[2,d]	**Minimum Inhibitory Concentrations (µg/mL)**			**Disk Diffusion (zone diameter in mm)**		
	Susceptible	Intermediate	Resistant	Susceptible	Intermediate	Resistant
Enterobacterales	≤4	8[c]	≥16	≥16	9-15[c]	≤8
Pseudomonas aeruginosa	≤4	8[c]	≥16	≥18	13-17[c]	≤12
Acinetobacter baumanii complex	≤4	8	≥16	≥15[e]	-	-
Stenotrophomonas maltophilia[f]	≤1	-	-	≥15	-	-

Breakpoints are based on a dosage regimen of 2g every 8 hours administered over 3 hours. Disk content is 30 µg of cefiderocol.

[a]Clinical efficacy was shown for *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae* complex in patients with complicated urinary tract infections (cUTI). [b]Clinical efficacy was shown for *Escherichia coli*, *Klebsiella pneumoniae*, *Enterobacter cloacae* complex, and *Serratia marcescens* in patients with hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP). [c]Designation for agents that have the potential to concentrate in the urine. [d]The accuracy and reproducibility of cefiderocol testing results by disk diffusion and broth microdilution are markedly affected by iron concentration and inoculum preparation, and may vary by disk and media manufacturer. Depending on the type of variance observed, false-resistant or false-susceptible results may occur. Testing subsequent isolates is encouraged. Discussion with prescribers and antimicrobial stewardship members regarding the potential for inaccuracies is recommended. [e]Disk diffusion zone diameters ≤ 14 mm should not be interpreted or reported because zone diameters ≤ 14 mm occur with resistant, intermediate, and susceptible isolates. For isolates with zone diameters ≤ 14 mm, do not report cefiderocol without performing an MIC test. [f]Breakpoints are based on PK/PD properties, MIC distributions, and limited clinical data.

1. US FDA. Antibacterial Susceptibility Test Interpretive Criteria. 2024. https://www.fda.gov/drugs/development-resources/cefiderocol-injection. Accessed November 13, 2024. 2. CLSI. Performance Standards for Antimicrobial Susceptibility Testing, 35th Edition. M100. 2025. Accessed February 3rd, 2025.