国際委員会　2025 Jun CLSI 報告

CLSI　1 - 3 Jun 2025 AST meeting 報告
（2025 年 6 月 1 日～3 日：米国テキサス州ダラス）
柳原 克紀（長崎大学），大楠 清文（東京医科大学）

2025 年 6 月 1 日～3 日に開催された Clinical Laboratory Standards Institute （CLSI）の Antimicrobial Susceptibility Testing（AST）ミーティングに，日本臨床微生物学会から柳原克紀 副委員長（長崎大学）と大楠清文 委員長（東京医科大学）が参加した。3 日間にわたるプレゼンテーションおよびディスカッションが行われたので，**決議事項を中心としてその概要**をワーキンググループ別に報告する。なお，今回の会議で決定された事項については 2026 年 1 月の AST ミーティングまでは最終ではなく，最終決定版はパブリックコメントを受けた上で 2026 年の 1 月に公表される予定である。

会議前日の5月31日（17時～19時までの2時間）に恒例となっているCLSI Education Sessionが開催された。今回のトピックスは「From Reads to Resistance: The Cutting Edge of Whole Genome Sequencing in Epidemiological and Antimicrobial Resistance Investigations」と題して，3名の演者；Amy Mathers, MD, D(ABMM); David Hess, PhD; and Trish Simner, PhD, D(ABMM)がプレゼンテーションを行った。各々，臨床現場における菌種同定と抗菌薬耐性予測への全ゲノム解析の活用，公衆衛生機関がアウトブレイク調査中に抗真菌薬耐性を特定するために全ゲノム解析をどのように活用しているか，患者診療において抗菌薬耐性を予測するために臨床微生物検査室で全ゲノム解析をどのように活用できるかの主旨で講演された。演者3名の講演スライドをリンクするので，参考にしていただきたい（PDF-1）。

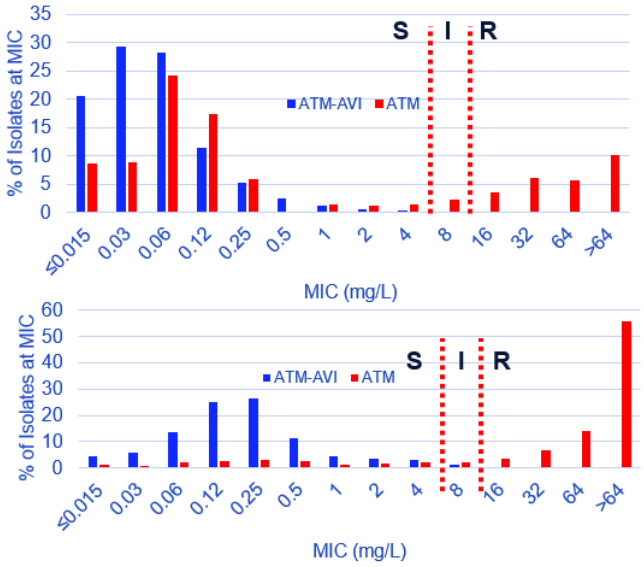
会議冒頭の Opening Remarks で Chairholder の Dr. Mathers が，CLSI 会議への参加者を歓迎して会議の開会を宣言した。その後，CLSI の Chief Executive Officer Dr. Jones から CLSI へのご尽力と献身的なご協力に感謝申し上げるとの挨拶と 2026 年 1 月から，すべての委員会週間の会議は対面形式のみとなり，オンライン配信は行われないことが報告された。

ブレイクポイントワーキンググループ（BPWG）
AZTREONAM-AVIBACTAM (ATM-AVI) MIC BREAKPOINTS FOR ENTEROBACTERALES

Enterobacterales に対する aztreonam-avibactam の MIC ブレイクポイントを S ≤4/4，I 8/4，R ≥16/4 μg/mL にすることが承認された（投票：賛成 11，反対 2，棄権 0，欠席 1）。

Organization	Minimum Inhibitory Concentration (µg/mL)		
	Susceptible	Intermediate	Resistant
Sponsor proposed	≤4/4	8/4	≥16/4
FDA	≤4/4	8/4	≥16/4
EUCAST	≤4/4	--	>4/4

Enzyme	n	MIC ≤4 µg/mL	MIC_{90} µg/mL
NDM	1421	98%	0.5
VIM	242	100%	1
IMP	49	100%	1
All MBL	1707	98%	1



All Enterobacterales (n=100228)

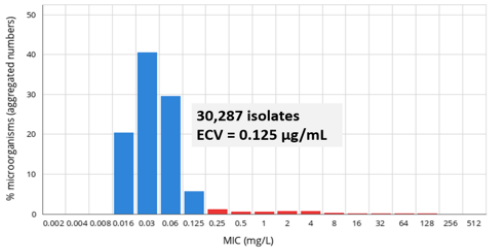
MBL-containing Enterobacterales (n=2449)

	0.002	0.004	0.008	0.016	0.03	0.06	0.125	0.25	0.5	1	2	4	8	16	32	64	128	256	512	Distributions	Observations	(T)ECOFF	Confidence interval
Escherichia coli	0	0	0	6153	12,260	8,951	1,719	348	150	167	201	195	83	36	10	8	6	0	0	5	30,287	0.125	0.06 - 0.25
Klebsiella pneumoniae	0	0	0	2,051	7,615	7,938	4,514	2,651	938	285	127	54	4	6	3	7	6	0	0	5	26,199	0.5	0.25 - 1
Klebsiella oxytoca	0	0	0	717	1,668	1,161	348	100	26	9	8	12	1	0	0	0	0	0	0	5	4,050	0.125	0.125 - 0.25
Klebsiella aerogenes	0	0	0	122	610	1,215	479	371	211	64	26	5	1	1	2	1	0	0	0	5	3,108	0.25	0.06 - 1
Enterobacter cloacae	0	0	0	254	1,565	2,495	970	629	627	354	129	38	2	3	0	2	1	0	0	5	7,069	0.25	0.125 - 0.25
Citrobacter freundii	0	0	0	244	783	712	505	264	102	22	23	8	0	0	1	1	0	0	0	5	2,665	0.25	0.25 - 1
Citrobacter koseri	0	0	0	166	692	281	58	17	8	0	3	3	0	0	0	1	0	0	0	3	1,229	0.125	0.03 - 0.125
Serratia marcescens	0	0	0	46	284	2,028	1,331	365	116	38	22	13	1	0	1	1	0	0	0	4	4,246	0.25	0.125 - 0.5

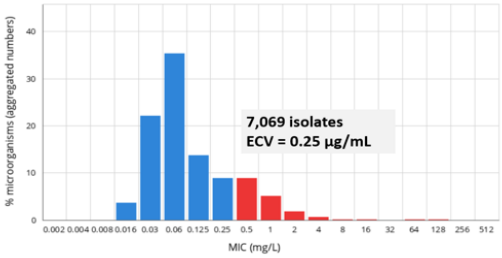
Epidemiologic cutoff values were calculated using the epidemiologic cutoff values finder statistical tool. Available at https://www.eucast.org/mic_distributions_and_ecoffs/

Turnidge J, et al. Statistical characterisation of bacterial wild-type MIC value distributions and the determination of epidemiological cut-off values. Clin Microbiol Infect. 2006;12(5):418-25

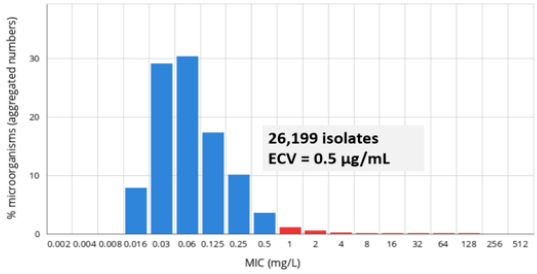
ATM-AVI & *Escherichia coli*



ATM-AVI & *Enterobacter cloacae*



ATM-AVI & *Klebsiella pneumoniae*



Drug (Target)	Hollow Fiber Target (to achieve 1-log reduction)	Murine Target (to achieve 80% max killing[a])	Target Used for Monte Carlo Simulations
Aztreonam (*f*T>MIC)	50-55%	Not tested	60%
			Joint Target
Avibactam (*f*T>C_T of 2.5 mg/L)	41-58%	14-43%	50%

[a]80% max killing correspond to different log reductions depending on the *species* and *model*
-*E. coli:* ~1.5-log (thigh) or ~2-log (pneumonia)
-*K. pneumoniae:* ~0.5-log (thigh) or ~2-log (pneumonia) reductions

Favorable Microbiological Response at Test of Cure Visit

Organism	ATM-AVI Group (n, %)	Meropenem Group (n, %)
Enterobacterales	130 (75%)	71 (72%)
E. coli	91 (72%)	44 (76%)
K. pneumoniae	14 (52%)	15 (65%)

Clinical cure at Test of Cure Visit

Organism*	ATM-AVI Group (n, %)	Meropenem Group (n, %)
E. coli	89 (78%)	43 (74%)
K. pneumoniae	15 (56%)	16 (70%)

*Data missing for other Enterobacterales species

		MIC (µg/mL)										
		0.008	0.016	0.03	0.06	0.12	0.25	0.5	1	2	4	8
Enterobacterales	**Number of isolates**	7	4	39	69	30	12	9	0	2	0	2
	Clinical cure	86%	100%	72%	81%	77%	58%	33%	NA	50%	NA	0%
	Microbiological cure	86%	100%	74%	83%	77%	58%	33%	NA	50%	NA	0%
E. coli	**Number of isolates**	3	1	31	59	15	3	0	0	0	0	2
	Clinical cure	100%	100%	71%	83%	73%	100%	NA	NA	NA	NA	0%
	Microbiological cure	100%	100%	74%	85%	73%	100%	NA	NA	NA	NA	0%
K. pneumoniae	**Number of isolates**	0	0	4	4	5	6	7	0	1	--	--
	Clinical cure	NA	NA	75%	50%	100%	33%	43%	NA	0%	--	--
	Microbiological cure	NA	NA	75%	50%	100%	33%	29%	NA	0%	--	--

Organism	ATM-AVI MIC range	Clinical cure percent
E. coli (3)	0.5-1 µg/mL	0%
K. pneumoniae (8)	0.12-0.5 µg/mL	63%

AZTREONAM-AVIBACTAM (ATM-AVI) DISK DIFFUSION BREAKPOINTS FOR ENTEROBACTERALES

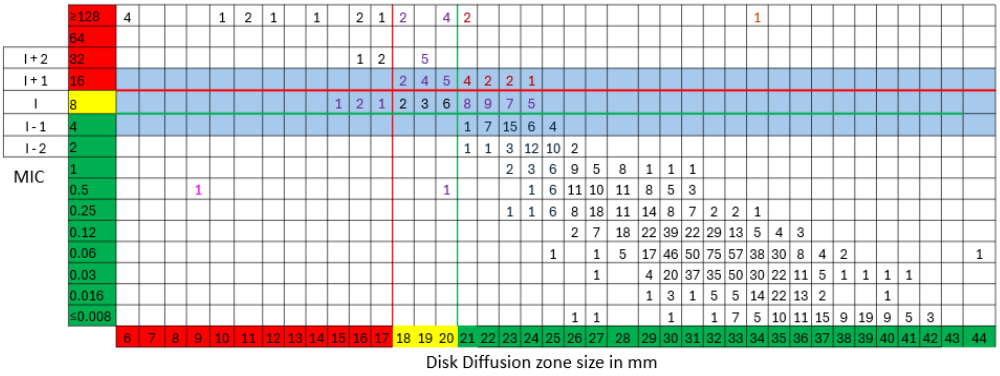
Enterobacterales に対する aztreonam-avibactam のディスク拡散法ブレイクポイントを S ≥ 25 mm, I 22-24 mm, R ≤ 21 mm にすること，「ディスク拡散法は S を I と過大評価する可能性がある。ディスク拡散法で I と判定された分離株については MIC 法による確認試験が示唆される」のような注釈を付けること，注釈文言を ceftazidime-tazobactam と同様に調整する修正案が提出され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。

Organization	Disk Diffusion Zone Diameters (mm)		
	Susceptible	Intermediate	Resistant
Sponsor proposed	≥25	22-24	≤21
FDA	≥21	18-20	≤17
EUCAST	≥25	--*	<25

FDA breakpoints

	S	I	R	ATU
FDA	≥ 21	18-20	≤ 17	-
EUCAST	≥ 25	-	< 25	22-24

Very major error and Minor error rate too high



MIC range	Number	Very Major Errors		Major Errors		Minor Errors	
		n	%	n	%	n	%
≥ I +2	29	3	10.3%	N/A	N/A	11	38%
I +1 to I - 1	97	9	9.3%	0	0%	44	45%
≤ I -2	1083	N/A	N/A	1	0.1%	1	0.1%
Total	1209	12	1.0%	1	0.1%	56	5%

AZTREONAM-AVIBACTAM TABLE 1 PLACEMENT

Table 1 における aztreonam-avibactam の配置について議論され，他の新規β-ラクタマーゼ/β-ラクタマーゼ阻害剤と共に Tier 3 に配置することが承認された（投票：賛成 12，反対 0，棄権 0，欠席 2）。

Table 1A-1. Enterobacterales (excluding *Salmonella* and *Shigella* spp.)[a]

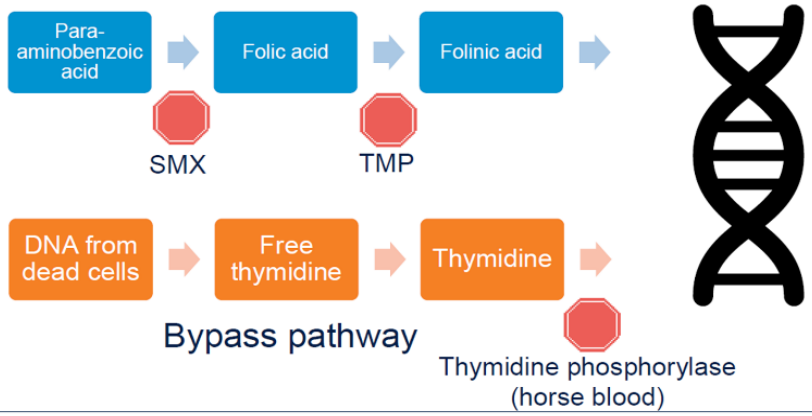
Tier 1: Antimicrobial agents that are appropriate for routine, primary testing and reporting	Tier 2: Antimicrobial agents that are appropriate for routine, primary testing but may be reported following cascade reporting rules established at each institution	Tier 3: Antimicrobial agents that are appropriate for routine, primary testing in institutions that serve patients at high risk for MDROs but should only be reported following cascade reporting rules established at each institution	Tier 4: Antimicrobial agents that may warrant testing and reporting by clinician request if antimicrobial agents in other tiers are not optimal because of various factors
Ampicillin			
Cefazolin	Cefuroxime		
Cefotaxime or ceftriaxone[b]	Cefepime[c]		
	Ertapenem Imipenem Meropenem	Cefiderocol	
		Aztreonam-avibactam	
		Ceftazidime-avibactam	
		Imipenem-relebactam	
		Meropenem-vaborbactam	
Amoxicillin-clavulanate Ampicillin-sulbactam			
Piperacillin-tazobactam			
Gentamicin	Tobramycin	Plazomicin	
	Amikacin		
Ciprofloxacin Levofloxacin			
Trimethoprim-sulfamethoxazole			
	Cefotetan Cefoxitin		
	Tetracycline		
			Aztreonam[d]
			Ceftaroline[b]
			Ceftazidime[b]
			Ceftolozane-tazobactam
Urine Only			
Cefazolin (surrogate for uncomplicated UTI)[e]			
Nitrofurantoin			
		Fosfomycin[f] (*Escherichia coli*)	

TRIMETHOPRIM-SULFAMETHOXAZOLE (SXT) MIC BREAKPOINTS FOR β-HEMOLYTIC STREPTOCOCCI

β-溶血性連鎖球菌に対する trimethoprim-sulfamethoxazole の MIC ブレイクポイントを S ≤ 0.5，I 1，R ≥ 2 μg/mL として，以下のコメントを付与することが提案され，承認された（投票：賛成 12，反対 0，棄権 0，欠席 2）。「寒天をベースの 5%ヒツジ血液を含む MHA を用いた方法（例：ディスク拡散法，勾配拡散法，寒天希釈法）は，チミジン含有量の上昇により偽耐性が生じるため実施すべきでない。皮膚および皮膚関連感染症の検体から分離された菌株以外では通常報告されない」。また，Table 1 の Tier 4 への配置が提案され，承認された（投票：賛成 10，反対 3，棄権 0，欠席 1）。

Lancefield Antigen Group	Organisms
Group A	*S. pyogenes*
Group B	*S. agalactiae*
Group C	*S. dysgalactiae* subsp. *equisimilis* *S. dysgalactiae* subsp. *dysgalactiae* (alpha-hemolytic) *S. equi* subsp. *equi* *S. equi* subsp. *zooepidemicus*
Group G	*S. dysgalactiae* subsp. *equisimilis* *S. canis*

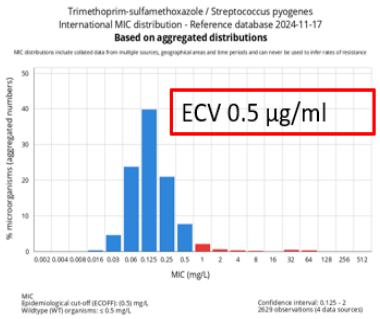
Resistance to TMP/SMX

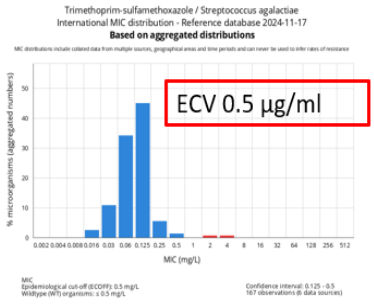


Goldstein EJC and Proctor RA. Clin Infect Dis 2008; 46(4): 584-593. https://doi.org/10.1086/525536

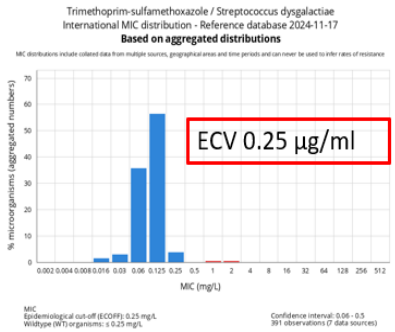
UCSF

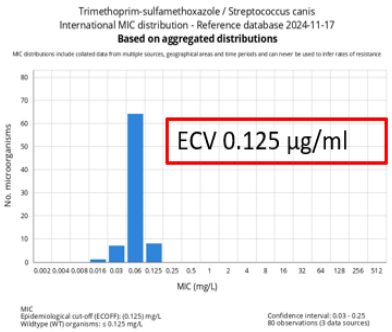
	Disk Diffusion	Broth Microdilution	Agar Dilution	SXT Breakpoints?
CLSI	MHA with **5% sheep blood** 35°C ± 2°C 5% CO_2; 20–24 hours	**CAMHB with lysed horse blood** (2.5% to 5% v/v) 35°C ± 2°C ambient air; 20–24 hours	**MHA with sheep blood** (5% v/v) 35°C ± 2°C ambient air; 20–24 hours (CO_2 if necessary, for growth with agar dilution)	**No**
EUCAST	Mueller-Hinton agar + **5% defibrinated horse blood** and 20 mg/L β-NAD (MH-F) Sealed panels, air, 35±1ºC, 18±2h (for glycopeptides 24h)	**Cation-adjusted Mueller-Hinton broth + 5% lysed horse blood** and 20 mg/L β-NAD (MH-F broth) 5% CO2, 35±1ºC, 18±2h	Guidance not available	**Yes**

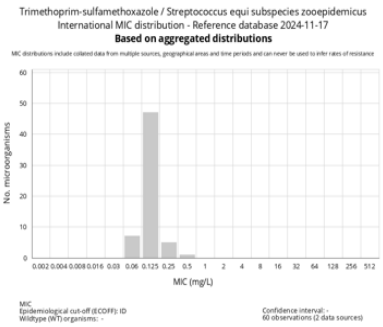




ECV of 0.125-0.5 µg/ml species dependent







CEFTRIAXONE AND CEFIXIME MIC BREAKPOINTS FOR *NEISSERIA GONORRHOEAE*

Neisseria gonorrhoeae **に対する ceftriaxone の MIC ブレイクポイント S ≤ 0.12，I 0.25，R ≥ 0.5 μg/mL を投与量 500 mg を基に採用し，ディスク拡散法のブレイクポイントを削除することが提案され，承認された。また，ディスク拡散法のブレイクポイントは見直しが進行中である旨のコメントが添えられた（投票：賛成 13，反対 0，棄権 0，欠席 1）。**

Neisseria gonorrhoeae **に対する cefixime の MIC ブレイクポイント S ≤ 0.06，I 0.12，R ≥ 0.25 μg/mL を投与量 800 mg を基に採用し，ディスク拡散法のブレイクポイントを削除することが提案され，承認された。また，ディスク拡散法のブレイクポイントは見直しが進行中である旨のコメントが添えられた（投票：賛成 13，反対 0，棄権 0，欠席 1）。**

Drug	MIC (μg/mL)			Disk Diffusion (mm)			Comment
	S	I	R	S	R	I	
Ceftriaxone (500 mg IM)	≤0.125	0.25	≥0.5	No breakpoints are proposed today because testing of ceph-R isolates is needed. The AHWG recommends publishing revised MIC breakpoints without disk diffusion breakpoints now. In the following year, recommendations for disk diffusion breakpoints are expected.			The ceftriaxone breakpoints are based upon the clinical response of uncomplicated genital infections. Data describing drug exposure and outcome for infections at other body sites is limited.
Cefixime (800 mg oral)	≤0.06	0.125	≥0.25				No Comment

ECOFF 97.5%	Ceftriaxone	Cefixime
NML + WHO	0.125	0.063
US-CDC	0.032	0.063
NML+WHO+CDC	0.032	0.063

*CEFTRIAXONE

Data Type	Ceftriaxone MIC cutoff point (mg/L)	Considerations
ECOFF	0.03 (97.5%)	The ECOFF value is the minimum possible cutoff value. CLSI uses a 97.5% ECOFF and EUCAST uses 99.9%
Genomic Data	0.12	This value represents the lowest MIC at which *penA* A311V, associated with CRO-R has been detected
PK-PD	0.06 (500 mg dose)	- In vitro hollow fiber PK-PD model (500 mg dose) - PTA 89% at MIC 0.06 - PTA 81% at MIC 0.12
Therapeutic (Clinical)	Susceptible breakpoint at least as high as 0.25	-100% clinical cure with 1 g ceftriaxone IV at MICs of 0.25 -2 clinical failures at MICs of 0.25

Option	S	I	R	Comment
1	≤0.25	None	≥0.50	Intermediate not included because
2	≤0.25	0.5	≥1.0	This proposal includes an intermediate dilution, however clinical data and PK/PD data suggest an increased rate of therapeutic failure and the need for a higher dose.
3	≤0.125	0.25	≥0.5	Breakpoints include an intermediate range and is suitable for the 500mg ceftriaxone dose.
4	≤0.125	None	≥0.25	This breakpoint agrees with both the genomic and the therapeutic data and is one dilution higher than the breakpoint suggested by the PK-PD data

The breakpoints recommended by the AHWG

- The susceptible breakpoint is supported by mutational analysis and clinical outcome data.
- An intermediate breakpoint is included to account for technical variability. The MIC of 0.25 ug/mL is acceptable because of low rate of clinical failure and the option of a higher dose.
- The AHWG recommends a comment like this: The ceftriaxone breakpoints are based upon the clinical response of uncomplicated genital infections. Data describing drug exposure and outcome for infections at other body sites is limited.

***CEFIXIME**

Data Type	MIC cutoff point (mg/L)	Considerations
ECOFF	0.06 (97.5%)	The ECOFF value is the minimum possible cutoff value. CLSI uses a 97.5% ECOFF and EUCAST uses 99.9%
Genomic Data	No clear breakpoint	
PK-PD Breakpoint	0.06 (dose of 400 mg)	Limited data, but cefixime 400 mg effectively treated *N. gonorrhoeae* with cefixime MIC of 0.06 mg/L. Cefixime 800 mg was not modeled.
Therapeutic (Clinical)	0.125	Limited data, but treatment was successful at this MIC for uncomplicated urethral infections. For 3 infections at other sites (2 rectal and 1 pharynx specimens) the TOC culture was positive after treatment. Slide 53

Option	S	I	R	Comment
1	≤0.125	0.25	≥0.5	There is less data for cefixime than ceftriaxone because the drug is used less frequently. TOC recommendations in treatment guidelines can help to convey actions needed to minimize therapy risks if the drug is used as monotherapy. This would require a comment that the breakpoint applies to uncomplicated urethritis only.
2	≤0.06	0.12	≥0.25	This breakpoint applies to all infections.

The breakpoints recommended by the AHWG
- The susceptible breakpoint is supported by mutational analysis and clinical outcome data.
- An intermediate breakpoint is included to account for technical variability and variability in clinical outcome data by body site.
- No comment is needed because this is a breakpoint that is meant to support all infection types

TETRACYCLINE URINE BREAKPOINT FOR *ACINETOBACTER* SPP.

***Acinetobacter* spp.に対する tetracycline の尿のブレイクポイントを削除することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**

この提案が *Acinetobacter* AHWG で議論にあがった背景には，１）尿路感染症治療に関する臨床データがなく，尿中濃度は一般的に低い。２）臨床では使用されていない。３）現行の尿のブレイクポイント承認に使用されたデータが不明確である。４）ECV（8 mg/L）は現行のブレイクポイントを上回っており，更新を支持するデータがない。議論で提示された参考資料を以下に示す。

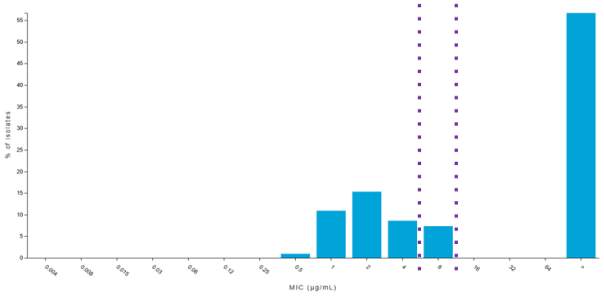
	Previous/old breakpoints (2024 M100-ED34)			Updated breakpoints		
	S	**I**	**R**	**S**	**I**	**R**
Minocycline (Revised June 2024)	≤ 4	8	≥ 16	≤ 1	2	≥ 4
Doxycycline	≤ 4	8	≥ 16	Removed (Jan 2025 meeting)		
Tetracycline *Urine only	≤ 4	8	≥ 16	Archived; under review		

Agent	Max dose per PI	Peak concentration (C_{max}; mg/L)	Time to peak concentration (t_{max})	Half-life ($t_{1/2}$)	AUC (mg/L·h)	*f*AUC (mg/L·h)	Protein binding (%)
Minocycline	200 mg q12 h	~3	2-3 h	~20	69.8 (0-8h)	**16.8**	76
Doxycycline	100 mg q12h	1.7-5.7 mg/L	2-3.5 h	~18-22 h	61	**7.3**	82-93 (mean, 88)
Tetracycline							55-64

Tetracycline MIC distribution: *A. baumannii* complex

(CLSI M100 Ed34)

S I R



JMI SENTRY Public
***A. baumannii* complex**
Tetracycline MIC distribution

9,434 *A. baumannii* complex isolates

Tetracycline MIC, µg/mL	0.5	1	2	4	8	≥ 16
Isolates (cumulative %)	89 (0.9)	1032 (11.9)	1444 (27.2)	815 (35.8)	702 (43.3)	5352

Data from sentry-mvp.jmilabs.com (accessed 3/7/2025)

A. baumannii complex/tetracycline ECOFF Finder summary (using a single JMI distribution at a time)

Data source(s) included	n	ECV 95.0%	ECV 97.5%	ECV 99.0%	ECV 99.5%	ECV 99.9%
JMI MVP SENTRY Public	9,434	8	8	16	16	32
JMI (2007-2011) worldwide surveillance	5,477	4	8	8	8	8
JMI (~2018) 34 countries	457	16	16	16	32	32
JMI data courtesy of M. Castanheira (for evaluation of tetra vs. mino MICs)	5,980	8	8	16	16	16

ECV (97.5%) = 8 µg/mL (?)

MINOCYCLINE BREAKPOINT COMMENT FOR *ACINETOBACTER* SPP.

***Acinetobacter* spp.に対する minocycline のブレイクポイントに以下のコメントを追加することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。「Minocycline が利用可能な場合，直接試験することが推奨される。Minocycline の試験が実施できない場合，doxycycline MIC 値が ≤ 1 µg/mL または tetracycline の MIC 値が ≤ 4 µg/mL の分離菌株は，minocycline に感性があるとみなされる。Doxycycline の MIC 値が ≥ 2 µg/mL または tetracycline の MIC 値が ≥ 8 µg/mL の分離菌株は，治療に必要な場合，minocycline の試験を実施すべきである」**

Activity of antimicrobial agents tested against 1,110 Acinetobacter isolates in the SENTRY program (excluding Acinetobacter baumannii-calcoaceticus species complexes) with a MIC less than or equal to 1.0 µg/mL tested against doxycycline

Organisms include *Acinetobacter beijerinckii* (8), *A. bereziniae* (96), *A. courvalinii* (22), *A. dispersus* (4), *A. gerneri* (2), *A. guillouiae* (15), *A. gyllenbergii* (2), *A. haemolyticus* (25), *A. indicus* (1), *A. johnsonii* (60), *A. junii* (96), *A. lwoffii* (176), *A. modestus* (3), *A. parvus* (1), *A. proteolyticus* (15), *A. radioresistens* (152), *A. schindleri* (10), *A. soli* (30), *A. towneri* (1), *A. ursingii* (263), *A. variabilis* (27), *A. venetianus* (1), *A. vivianii* (11), and unspeciated *Acinetobacter* (89).

Antimicrobial Agent	Dilution (µg/mL)															
	0.004	0.008	0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	16	32	64	>
Minocycline					48.3 535	77.8 326	94.4 184	99.1 52	99.7 7	99.8 1	100.0 2					

Activity of antimicrobial agents tested against 1,087 Acinetobacter isolates in the SENTRY program (excluding Acinetobacter baumannii-calcoaceticus species complexes) with a MIC less than or equal to 4.0 µg/mL tested against tetracycline

Organisms include *Acinetobacter beijerinckii* (8), *A. bereziniae* (87), *A. courvalinii* (21), *A. dispersus* (4), *A. gerneri* (2), *A. guillouiae* (15), *A. gyllenbergii* (2), *A. haemolyticus* (27), *A. indicus* (1), *A. johnsonii* (56), *A. junii* (96), *A. lwoffii* (174), *A. modestus* (3), *A. parvus* (1), *A. proteolyticus* (13), *A. radioresistens* (151), *A. schindleri* (10), *A. soli* (31), *A. towneri* (1), *A. ursingii* (256), *A. variabilis* (27), *A. venetianus* (1), *A. vivianii* (10), and unspeciated *Acinetobacter* (90).

Antimicrobial Agent	Dilution (µg/mL)															
	0.004	0.008	0.015	0.03	0.06	0.12	0.25	0.5	1	2	4	8	16	32	64	>
Minocycline					49.4 536	78.7 317	95.1 178	99.3 45	99.8 6	99.8 0	100.0 2					

AMIKACIN MIC BREAKPOINTS FOR *ACINETOBACTER* SPP.

Acinetobacter spp.に対する amikacin の MIC ブレイクポイント S ≤ 8, I 16, R ≥ 32 µg/mL を投与量 20 mg/kg/day を基に採用することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。

FDA Package insert: 15 mg/kg

Intravenous Administration: The recommended daily dose for VPI-AMIKACIN is 15 mg/kg to be administered at 7.5 mg/kg every 12 hours (500 mg twice a day). The solution for intravenous use is prepared by adding the contents of a 500 mg/2 mL vial to 250 mL of sterile diluent and administered over a 30-60 minute period. Solutions for intravenous administration should be used within 24 hours after preparation.

EUCAST v15.0: 25-30 mg/kg

Aminoglycosides	Standard dosage	High dosage
Amikacin	25-30 mg/kg x 1 iv	None
Gentamicin	6-7 mg/kg x 1 iv	None
Netilmicin	6-7 mg/kg x 1 iv	None
Tobramycin	6-7 mg/kg x 1 iv	None

- amikacin dosage is most often 15 – 20 mg/kg/day, not the 25 – 30 mg/kg/day suggested by the pharmacokinetic/pharmacokinetic modelling and by the fact that amikacin is 4 times less active that gentamicin and tobramycin.

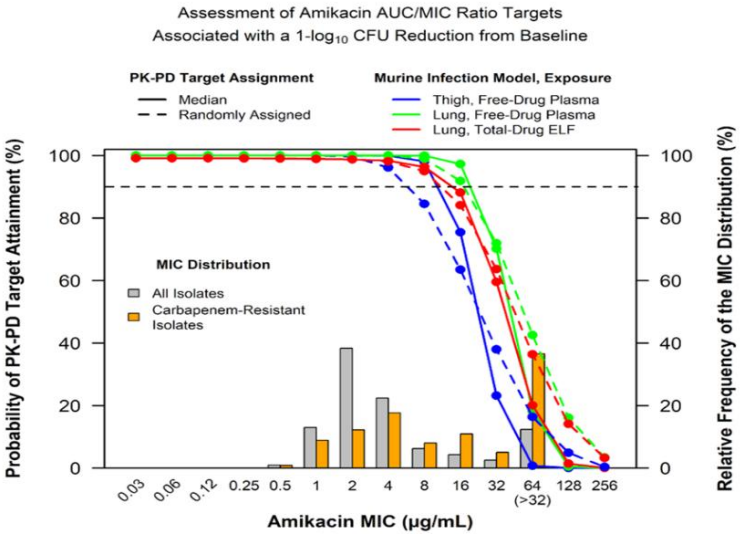
EUCAST is concerned that doses lower than those listed with the EUCAST breakpoints Dosages tab fail to deliver adequate exposure for the wild-type populations of target species, especially in serious systemic infections. This is particularly problematic foramikacin where dosing traditions are lower than in any European or FDA guideline [4 - 8] and acceptance of higher doses is lower than for other aminoglycosides [9]. EUCAST encourages the use of therapeutic drug monitoring for this drug class, which has a narrow window between efficacy and toxicity [9,10].

IDSA HAP/VAP guidelines: 15-20 mg/kg

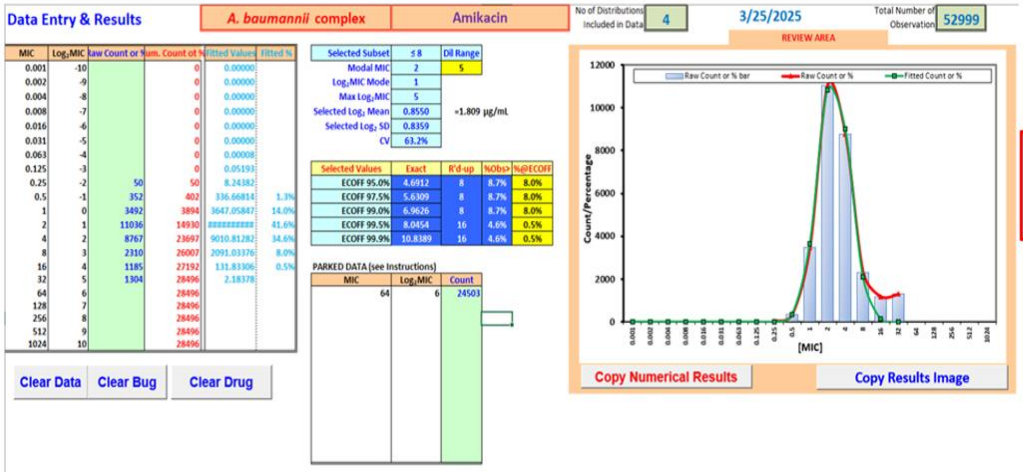
Table 3. Suggested Empiric Treatment Options for Clinically Suspected Ventilator-Associated Pneumonia in Units Where Empiric Methicillin-Resistant *Staphylococcus aureus* Coverage and Double Antipseudomonal/Gram-Negative Coverage Are Appropriate

A. Gram-Positive Antibiotics With MRSA Activity	B. Gram-Negative Antibiotics With Antipseudomonal Activity: β-Lactam–Based Agents	C. Gram-Negative Antibiotics With Antipseudomonal Activity: Non-β-Lactam–Based Agents
Glycopeptides[a] Vancomycin 15 mg/kg IV q8–12h (consider a loading dose of 25–30 mg/kg × 1 for severe illness)	Antipseudomonal penicillins[b] Piperacillin-tazobactam 4.5 g IV q6h[b]	Fluoroquinolones Ciprofloxacin 400 mg IV q8h Levofloxacin 750 mg IV q24h
OR	OR	OR
Oxazolidinones Linezolid 600 mg IV q12h	Cephalosporins[b] Cefepime 2 g IV q8h Ceftazidime 2 g IV q8h	Aminoglycosides[b,c] Amikacin 15–20 mg/kg IV q24h Gentamicin 5–7 mg/kg IV q24h Tobramycin 5–7 mg/kg IV q24h

Percent Probabilities of PK-PD Target Attainment for Amikacin by MIC Overlaid Over MIC Distributions for *A. baumannii* Isolates from the USA



Drug	USCAST-recommended STIC (µg/mL) based on analysis results[a]		
	S	I	R
Amikacin	≤ 8	-	≥ 16

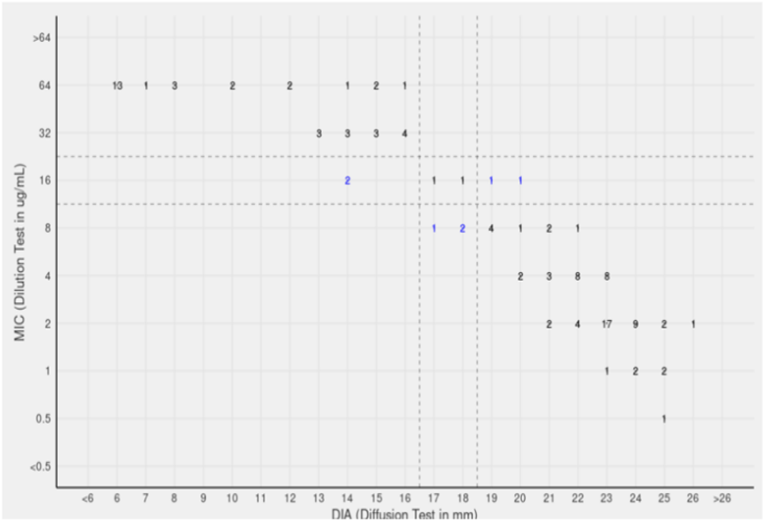


ECV (97.5%) = 8 µg/mL

Agrees with EUCAST

AMIKACIN DISK DIFFUSION BREAKPOINTS FOR *ACINETOBACTER* SPP.

***Acinetobacter* spp.に対する amikacin のディスク拡散法のブレイクポイント S ≥ 20, I 17-19, R ≤ 16 mm にすることが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**



	S	I	R
MIC	≤ 8	16	≥ 32
Disk	≥ 19	17-18	≤ 16

	n	VME	ME	mE
≥ I+2	25	0 (0%)	NA	0 (0%)
I+1 to I-1	30	0 (0%)	0 (0%)	7 (23.3%)
≤ I-2	62	NA	0 (0%)	0 (0%)

2 mm intermediate range

Minimizes error rates

	n	VME	ME	mE
≥ I+2	25	0 (0%)	NA	0 (0%)
I+1 to I-1	30	0 (0%)	0 (0%)	7 (23.3%)
≤ I-2	62	NA	0 (0%)	0 (0%)

Approved by breakpoint WG

3 mm intermediate range

Acceptable error rates

	n	VME	ME	mE
≥ I+2	25	0 (0%)	NA	0 (0%)
I+1 to I-1	30	0 (0%)	0 (0%)	10 (33.3%)
≤ I-2	62	NA	0 (0%)	0 (0%)

Option to expand to a 3 mm range to allow for additional interlaboratory variation; still meets M23 criteria

4 mm intermediate range

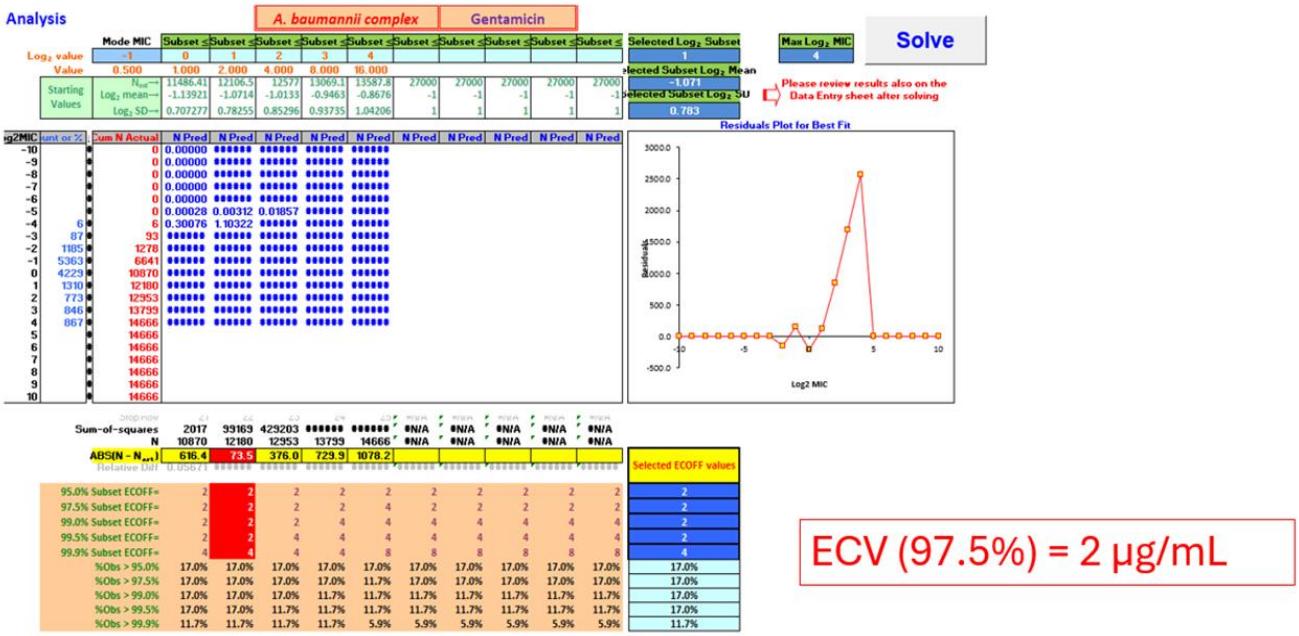
Acceptable error rates

	n	VME	ME	mE
≥ I+2	25	0 (0%)	NA	0 (0%)
I+1 to I-1	30	0 (0%)	0 (0%)	12 (40%)
≤ I-2	62	NA	0 (0%)	2 (3.2%)

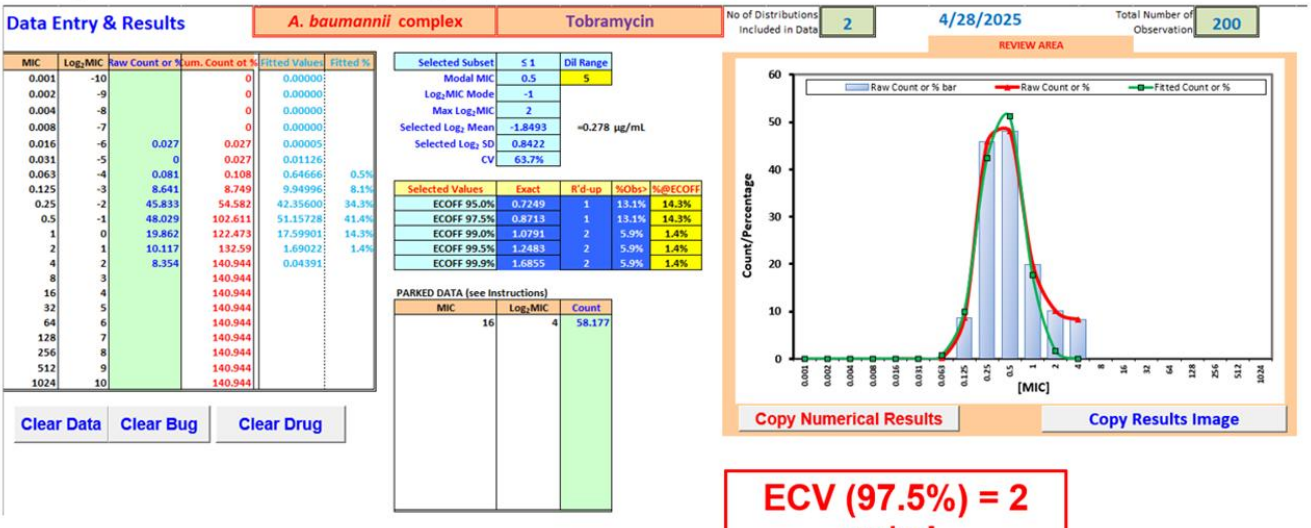
← Borderline, since guideline criterion is <40%

GENTAMICIN AND TOBRAMYCIN MIC BREAKPOINTS FOR *ACINETOBACTER* SPP.

***Acinetobacter* spp.に対する gentamicin と tobramycin の MIC ブレイクポイント S ≤ 2, I 4, R ≥ 8 µg/mL を投与量 7 mg/kg/day を基に採用することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**



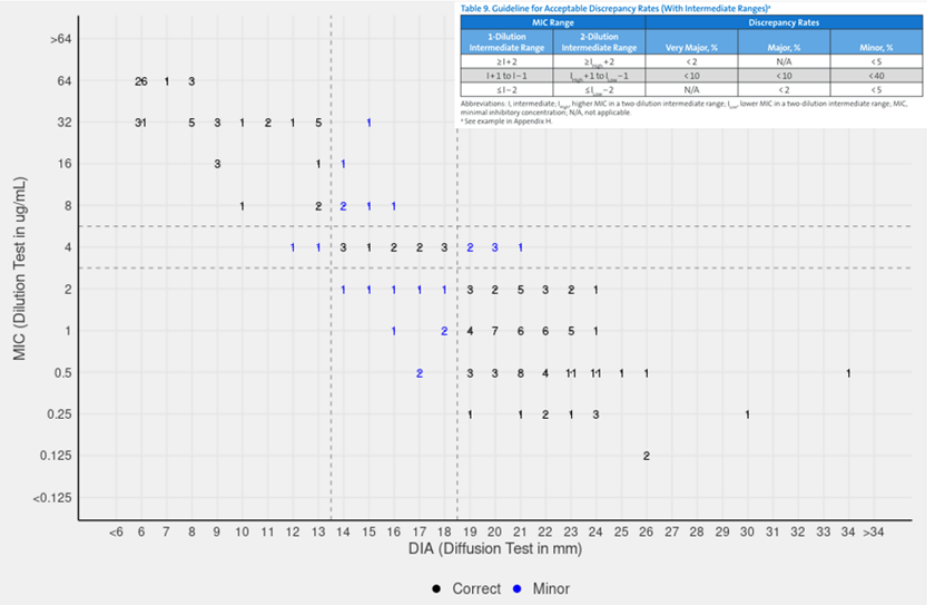
Weighted dataset because 1 lab (JMI) >50% of total



EUCAST: tobramycin ECV 4 µg/mL

GENTAMICIN DISK DIFFUSION BREAKPOINTS FOR *ACINETOBACTER* SPP.

***Acinetobacter* spp.に対する gentamicin のディスク拡散法のブレイクポイントを S ≥ 19, I 14-18, R ≤ 13 mm にすることが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**



≤13 R; 14-18 I; ≥19 S

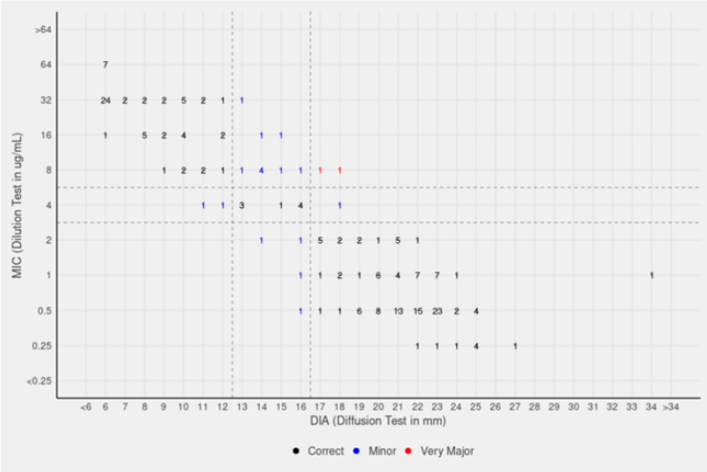
	VME	ME	mE
I + 2	0	0	2.4
I +/-1	0	0	36.2
I -2	0	0	4.5

≤13 R; 14-17 I; ≥18 S

	VME	ME	mE
I + 2	0	0	2.4
I +/-1	0	0	46.3
I -2	0	0	0

TOBRAMYCIN DISK DIFFUSION BREAKPOINTS FOR *ACINETOBACTER* SPP.

***Acinetobacter* spp.に対する tobramycin のディスク拡散法のブレイクポイントを S ≥ 17, I 13-16, R ≤ 12 mm にすることが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**



	S	I	R
MIC	≤ 2	4	≥ 8
Disk	≥ 17	13-16	≤ 12

	n	VME	ME	mE
≥ I+2	62	0 (0%)	NA	3 (4.8%)
I+1 to I-1	44	2 (4.5%)	0 (0%)	12 (27.3%)
≤ I-2	113	NA	0 (0%)	2 (1.8%)

Methods Application and Interpretation ワーキンググループ

INTRINSIC RESISTANCE DEFINITION AD HOC WORKING GROUP REPORT

内因性耐性（本質的耐性）；intrinsic resistance (IR)の定義を見直すことが提案され，“予測される耐性”“expected resistance” (ER)を採用することが承認された（投票：賛成 10，反対 3，棄権 0，欠席 1）。

提案された定義の原文と仮訳を以下に記載する。

（原文）

The concept of “expected resistance” (ER) includes both intrinsic resistance (IR), which is a property inherent to an organism, and expected clinical failure (ie, treatment failure or insufficient antimicrobial exposure in a host species). Antimicrobial agent-organism combinations qualify for ER if they display either IR or expected clinical failure.

IR is defined as inherent or innate (not acquired) antimicrobial resistance, evidenced by high MICs or reduced zone diameter values for specific antimicrobial agent-organism combinations for all or nearly all isolates (≥ 90%) of a microbial species or organism group

(e.g. species complex). The MIC distribution for an antimicrobial agent-organism combination exhibiting IR generally displays a high modal MIC.

Expected clinical failure includes antimicrobial agent-organism combinations for which available PK/PD data show insufficient antimicrobial exposure at clinically achievable concentrations, or when available microbiologic or clinical data demonstrate lack of efficacy against a species in vivo.

Antimicrobial susceptibility testing (AST) is unnecessary for organisms considered to have ER to an antimicrobial agent. However, if testing is performed, the AST result should be suppressed or reported as resistant. MIC and zone diameter values should not be reported, as some isolates may exhibit low MICs or large zone diameters despite lack of in vivo utility of the antimicrobial agent.

（仮訳）

「予想される耐性」（ER）の概念には，微生物に固有の性質である内在性耐性（IR）と予測される臨床的失敗（すなわち治療失敗または宿主における抗菌薬曝露不足）の両方が含まれる。抗菌薬と微生物の組み合わせは，IR または予測される臨床的失敗のいずれかを示す場合に ER に該当する。

IR は，特定の抗菌薬-微生物組合せにおいて，菌種または菌群（例：種複合体）の全分離菌株またはほぼ全分離菌株（≥90%）で高い MIC 値またはディスク径値の低下が認められる，獲得性ではない固有の（または生来の）抗菌薬耐性として定義される。IR を示す抗菌薬ー微生物組合せの MIC 分布は，一般的に高い MIC 値モード（最頻値）を示す。

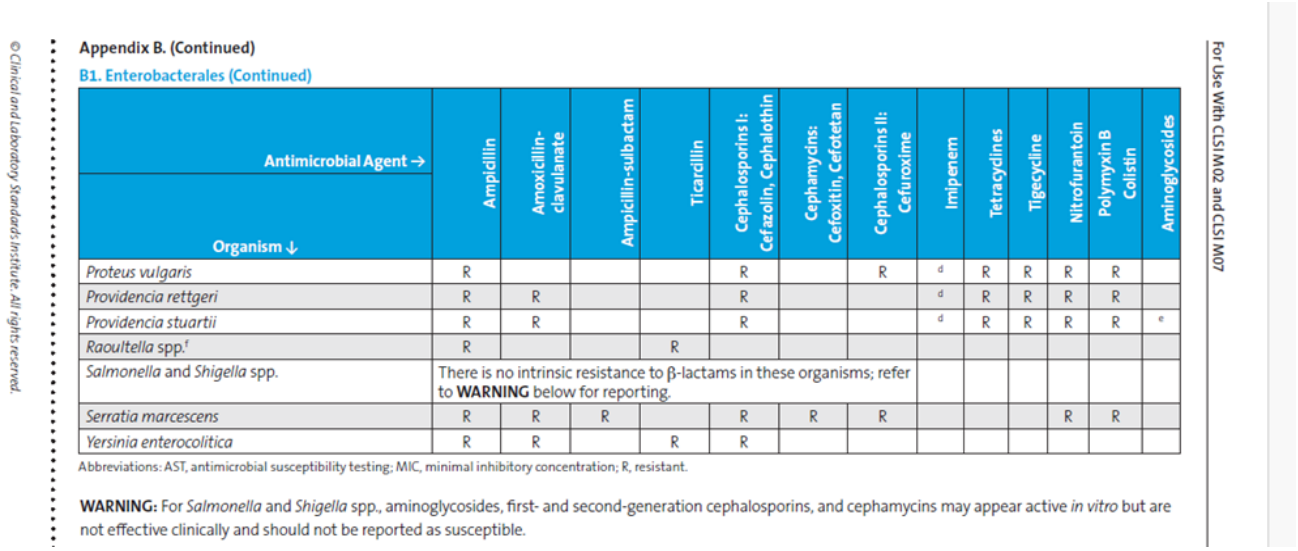
予測される臨床的失敗には，利用可能な PK/PD データが臨床的に達成可能な濃度での抗菌薬曝露不足を示す場合，または利用可能な微生物学的・臨床的データが当該菌種に対する in vivo での有効性欠如を実証する場合の抗菌薬ー微生物組合せが含まれる。

抗菌薬に対して ER（耐性）が認められる微生物については，その抗菌薬の感受性試験（AST）は不要である。ただし，試験が実施された場合，AST の結果は非公表とするか，耐性として報告すべきである。一部の分離菌株は，生体内での有用性が欠如しているにもかかわらず，低い MIC 値やディスク径値の拡大を示す可能性があるため，MIC 値およびディスク径値は報告すべきではない。

M100 Intrinsic Resistance Definition (Currently Published)	Proposed Revision of Expected Resistance
Only intrinsic resistance addressed	Includes intrinsic resistance and expected clinical failure
Does not address PK/PD or clinical failure; restricted definition	Addresses PK/PD and clinical failure for more comprehensive assessment of clinically applicable failure of an antimicrobial agent
Includes wording “susceptible” and “resistant” despite lack of breakpoints	Descriptive use of values or MICs without using terms associated with breakpoints (e.g., “displays a high modal MIC”)
Cutoff of 97%	Cutoff of 90%
States that IR is seen in “almost all representatives of a species”	Further clarifies by stating “all or nearly all isolates of a species or organism group (eg, species complex”
Addresses only MICs	Includes MICs and zone diameter values
Report as “resistant”	Report as “resistant”

INTRINSIC RESISTANCE AD HOC WORKING GROUP REPORT

***Salmonella* and *Shigella* spp.に対する cephalosporins, cephamycin, aminoglycosides における耐性（R）を内在性耐性の表および表 1A に脚注警告付きで追加することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**



Appendix B. (Continued)

B1. Enterobacterales (Continued)

Organism ↓ / Antimicrobial Agent →	Ampicillin	Amoxicillin-clavulanate	Ampicillin-sulbactam	Ticarcillin	Cephalosporins I: Cefazolin, Cephalothin	Cephamycins: Cefoxitin, Cefotetan	Cephalosporins II: Cefuroxime	Imipenem	Tetracyclines	Tigecycline	Nitrofurantoin	Polymyxin B Colistin	Aminoglycosides
Proteus vulgaris	R				R		R	[d]	R	R	R	R	
Providencia rettgeri	R	R			R			[d]	R	R	R	R	
Providencia stuartii	R	R			R			[d]	R	R	R	R	[e]
Raoultella spp.[f]	R			R									
Salmonella and *Shigella* spp.	There is no intrinsic resistance to β-lactams in these organisms; refer to **WARNING** below for reporting.												
Serratia marcescens	R	R	R		R	R	R				R	R	
Yersinia enterocolitica	R	R		R	R								

Abbreviations: AST, antimicrobial susceptibility testing; MIC, minimal inhibitory concentration; R, resistant.

WARNING: For *Salmonella* and *Shigella* spp., aminoglycosides, first- and second-generation cephalosporins, and cephamycins may appear active *in vitro* but are not effective clinically and should not be reported as susceptible.

Organism	Ampiciillin	Amoxicillin-clavulanate	Ampicillin-Sulbactam	Cephalosporin I	Cephamycins	Cephalosporin II		Aminoglycosides (AK, GM, TO)
Salmonella and Shigella spp.	There is no intrinsic resistance to β-lactams in this organism.			R*	R*	R*		R*

DIRECT DISK DIFFUSION SUSCEPTIBILITY TESTING AD HOC WORKING GROUP REPORT

Piperacillin-tazobactam 直接血液培養ディスク拡散法（16-18 時間）のブレイクポイント（R ≤ 17 mm）を *Proteus* spp.を含む Enterobacterales において採用することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。

BURKHOLDERIA CEPACIA COMPLEX AD HOC WORKING GROUP REPORT

***Burkholderia cepacia* complex の ECVs を削除することが提案され，承認された（投票：賛成 13，反対 0，棄権 0，欠席 1）。**

Table F1. ECVs for *Burkholderia cepacia* Complex[a]

Antimicrobial Agent	Interpretive Category and MIC, µg/mL	
	WT[b,c]	NWT
Ceftazidime	≤ 16	≥ 32
Levofloxacin	≤ 8	≥ 16
Meropenem	≤ 16	≥ 32
Minocycline	≤ 8	≥ 16
Trimethoprim-sulfamethoxazole	≤ 2	≥ 4

Abbreviations: ECV, epidemiological cutoff value; MIC, minimal inhibitory concentration; NWT, non-wild

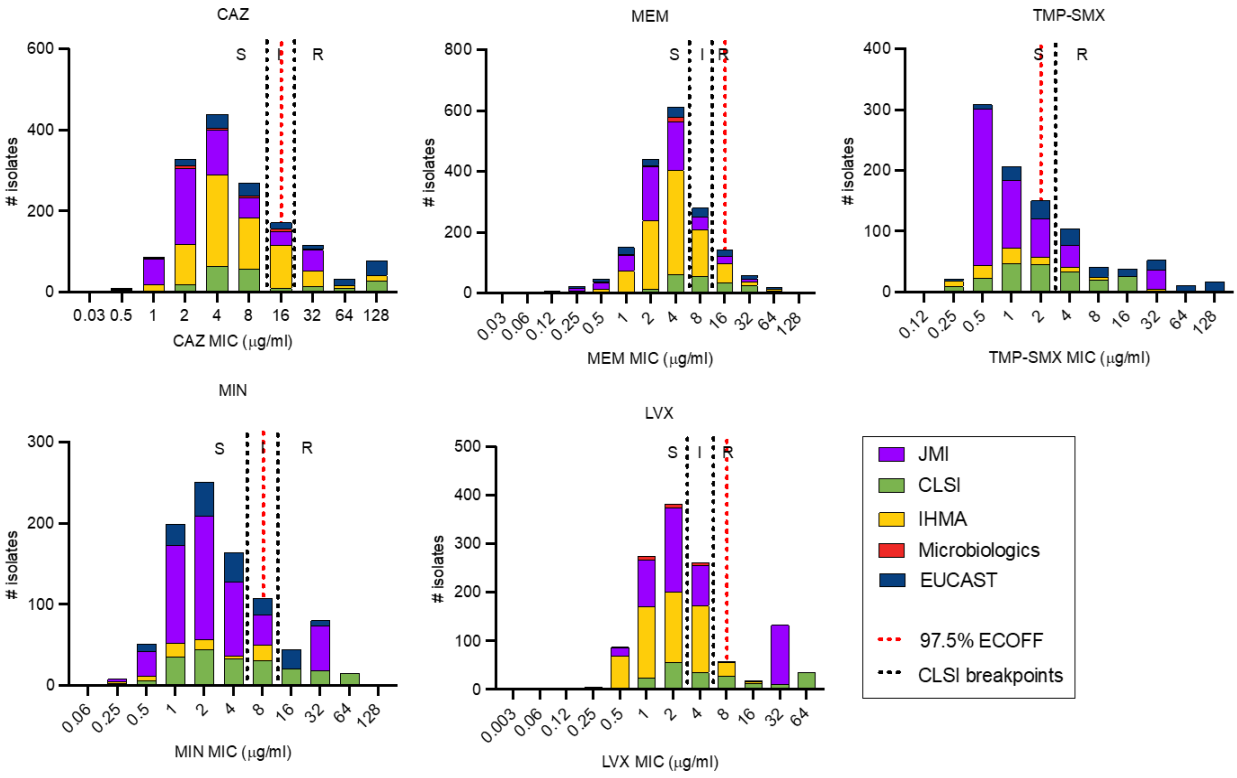
Footnotes

a. Insufficient data were available to establish ECVs for individual species within the *B. cepacia* complex. Although more than 50% of the data were contributed by a single laboratory for minocycline and trimethoprim-sulfamethoxazole, the data were not weighted before pooling and analysis. The ECVs are under review and will be updated if appropriate.

b. The ECV is the highest MIC that defines the WT population of isolates (eg, the ECV for ceftazidime is 16 µg/mL and the WT population is ≤ 16 µg/mL).

c. The ECVs for ceftazidime, levofloxacin, meropenem, and minocycline are above MICs typically achievable by routine antimicrobial dosing for similar organisms and are higher than the archived susceptible breakpoints (8, 2, 4, and 4 µg/mL, respectively).

ECVs listed in Table F2 are applicable only to the species indicated. Currently, there are insufficient data to support their use with other species.



Quality Control ワーキンググループ

TIER 2 QC

1) GDC-0829 QC レンジ

***E. coli* ATCC 25922 (0.12-0.5 µg/mL) の GDC-0829 MIC QC レンジを承認した（投票：賛成 13，反対 0，棄権 0，欠席 1）**

***P. aeruginosa* ATCC 27853 (0.25-2 µg/mL) の GDC-0829 MIC QC レンジを，以下のコメントを付きで承認した「*P. aeruginosa* ATCC 28753 の範囲は 0.25-2 µg/mL で，最頻値は 0.5-1 µg/mL である。0.25 µg/mL および 2 µg/mL での結果は，Tier 2 では頻度が低く，日常的な検査で頻繁に観察される場合はトラブルシューティングを検討する」（投票：賛成 13，反対 0，棄権 0，欠席 1）**

Drug Name:	GDC-0829					**Votes:**	12/0/0/2 for *E. coli* ATCC 25922 for 0.12-0.5 µg/mL) 10/2/0/2 for *P. aeruginosa* ATCC 27853 for 0.25-2 µg /mL			
QC Strain	**Range**	**% In**	**Mode**	**Dil**	**Shoulder**	**Media Mode**	**Lab Mode**	**M23 Range**	**Range Finder**	**Comments**
Escherichia coli ATCC 25922	0.125-0.5	100%	0.25	3	45% @ 0.125	0.13 (1), 0.25 (2)	0.13 (2), 0.25 (7)	0.125-0.5, 3, 100%	0.125-0.5, 3, 100%	Some media variability.
P. aeruginosa ATCC 27853	~~0.25-1~~ ~~0.5-2~~ 0.25-2	~~100%~~ ~~99.6%~~ 100%	0.5	3	54% @ 1	0.5 (2), 1 (1)	0.5 (8), 1 (1)	0.25-1, 3, 100%	0.25-1, 3, 100%	Media variability (Lot 1 commonly used, mode at top of proposed range). No significant impact with parameters evaluated in Tier 1 study. Option 5 approved. Include 0.5-2 with footnote to address early Tier 3 data

P. aeruginosa ATCC 27853: Mode in additional studies (early Tier 3) was 1 µg/mL with some results at 2 µg/mL. See next slide.
EDL proposes to include 2 µg/mL within the QC range. EDL does not support a four-dilution range 0.25-2 µg/mL (potentially allowing too much deviations) but would accept a three-dilution range 0.5-2 µg/mL based on

1) infrequent occurrences at 0.25 µg/mL.
2) high likelihood of Lot 1 medium use in future laboratories and the non-negligible frequency of the occurrence at 2 µg/mL with this medium
3) bimodal distribution; significant shoulder at 1 µg/mL in the Tier 2 study and in the global distribution.

Options

1) *P. aeruginosa* ATCC 27853 range 0.25-2 (4 dil): not acceptable to EUCAST, not ideal to have different EUCAST & CLSI ranges.
2) *P. aeruginosa* ATCC 27853 range 0.5-2 (3 dil) 99.6% in range: 0.25 rare – only 1 occurrence, acceptable to EUCAST
3) Only use *E. coli* ATCC 25922 range 0.125-0.5: acceptable to EUCAST, requires additional dilution for on-scale QC
4) *E. coli* ATCC 0.125-0.5 and *P. aeruginosa* ATCC 27853 0.25-1 (monitor QC): risk 10% of QC could be invalid
5) P. aeruginosa ATCC 28753 range is 0.25-2 µg/ml with mode 0.5-1 µg/m . Results at 0.25 and 2 were seen less frequently in Tier 2 studies and if observed frequently in routine testing, consider troubleshooting.

2) AZTREONAM-NACUBACTAM QC レンジ

~~*P. aeruginosa* ATCC 27853 (17-23 mm), *K. pneumoniae* ATCC 700603 (20-26 mm),~~
~~*K. pneumoniae* BAA-2814 (18-26 mm) の aztreonam-nacubactam ディスク(10/20 µg)~~ 拡散法 QC レンジを承認した（投票：賛成 13，反対 0，棄権 0，欠席 1）

Drug Name:	Aztreonam/nacubatam (1:1, 10/20 µg) ANC	Votes:	12/0/0/2

QC Strain	Range	% In	Median	Mm	Media	Disk	Labs	Gavan	Range Finder	Comments
~~*E.coli* ATCC 25922 (page 28)~~	~~27-37~~	~~99.3%~~	~~32~~	~~11~~	~~32 (2), 33 (1)~~	~~32 (1), 33 (1)~~	~~28 (1), 30 (1), 32 (3), 34 (2)~~	~~29-35, 7mm, 86.9%~~	~~27-37, 8mm, 99.3%~~	~~Aztreonam CLSI range 28-36 Variability: media 1mm, disk 1mm, labs 7mm.~~ Range not needed.
P. aeruginosa ATCC 27853 (page 33)	17-23	95.6%	20	7	19 (1), 20 (2)	19 (1), 20 (1)	18 (1), 19 (3), 20 (4), 21 (1)	17-23, 7 mm, 95.6%	16-23, 8 mm, 97.8%	Aztreonam CLSI range 23-29 Variability: media 1mm, disk 1mm, labs 4mm
K. pneumoniae ATCC 700603 (page 38)	20-26	99.6%	23	7	23 (3)	22 (1), 24 (1)	22 (1), 23 (5), 24 (2), 25 (1)	20-26, 7mm, 99.6%	20-26, 7mm, 99.6%	Aztreonam CLSI range 10-16 Variability: media none, disk 2mm, labs 4mm Routine QC (shade green)
K. pneumoniae ATCC BAA-2814 (page 41)	18-26	95.8%	22	9	22 (2), 23 (1)	21 (1), 23 (1)	21 (2), 22 (2), 23 (2), 24 (1), 25 (1)	18-26, 9mm, 95.8%	18-27, 10mm, 98.1%	No CLSI range, study results ≤6 Routine QC (shade green) Variability: media 1mm, disk 2mm, labs 5mm. Excluded lab 9 (expired)

- Breakthrough colonies seen with QC strains except *K. pneumoniae* ATCC 700603. No footnote needed since ranges based on reading inner zone per normal instructions. Used Gavan range since it was same for inner and outer zones and included ≥95% of results. Range finder range only differed by 1mm for some bug/drugs.
- Refer to Tables 3, 6, 10 in report for proposed ranges and performance when including and excluding breakthrough colonies
- A fifth lot of MH agar tested with *P. aeruginosa* ATCC 27853 for repeat test due to expiry of medium 4 plates.
- Breakthrough colonies were also observed with *P. aeruginosa* ATCC 27853 with MEV disk. 96.4% were in range using inner zones but 100% if using outer zones. Excluding out of range MEV data had no impact of proposed ranges. Added to Tier 3 monitoring.

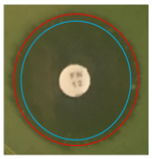
3) CEFEPIME-NACUBACTAM QC レンジ

***P. aeruginosa* ATCC 27853 (21-29 mm), *K. pneumoniae* ATCC 700603 (24-29 mm),**
***K. pneumoniae* BAA-2814 (20-27 mm) の cefepime-nacubactam ディスク(10/20 µg)**
拡散法 QC レンジを承認した（投票：賛成 13，反対 0，棄権 0，欠席 1）

Drug Name:	cefepime/nacubactam (10/20 µg) FNC	Votes:	12/0/0/2

QC Strain	Range	% In	Median	Mm	Media	Disk	Labs	Gavan	Range Finder	Comments
E.coli ATCC 25922 (page 45)	~~30-37~~	~~99.6~~	~~34~~	~~8~~	~~33 (1), 34 (2)~~	~~33 (2)~~	~~29 (1), 31 (1), 32 (1), 33 (1), 34 (3), 35 (2)~~	~~31-37 7mm, 97.5%~~	~~30-37, 8mm, 99.6%~~	~~Cefepime CLSI range 31-37 Variability: media 1mm, disk none, labs 6mm~~
P. aeruginosa ATCC 27853 *(page 50)*	21-29	97.6%	25	9	25 (2), 26 (1)	25 (2)	22 (2), 24 (1), 25 (3), 26 (2), 27 (1),	22-28, 7mm, 94.3%	21-29, 9mm, 97.6%	Cefepime CLSI range 25-31 Variability: media 1mm, disk none, labs 6mm
K. pneumoniae ATCC 700603 (page 55)	24-29	100%	27	6	27 (3)	27 (2)	26 (4), 27 (4), 28 (1)	25-29, 5mm, 98.1%	24-29, 6mm, 100%	Cefepime CLSI range 23-29 Variability: media none, disk none, labs 3mm
K. pneumoniae ATCC BAA-2814 (page 57)	20-27	97.9%	23	8	23 (2), 24 (1)	23 (1), 24 (1)	22 (1), 23 (3), 24 (2), 25 (2)	20-26, 7mm, 93.8%	20-27, 8mm, 97.9%	No CLSI range, results from this study 6-10 Routine QC (shade green) Variability: media 1mm, disk 1mm, labs 4mm

Breakthrough colonies seen with QC strains except *K. pneumoniae* ATCC 700603.
No footnote needed since ranges based on reading inner zone per normal instructions. Only slight difference between range using inner or outer zone. Range finder used to include ≥95% in range.
A fifth lot of MH agar tested with *P. aeruginosa* ATCC 27853 for repeat test due to expiry of medium 4 plates
Refer to Tables 13, 16, 20 in report for proposed ranges and performance when including and excluding breakthrough colonies. See page 62 in report.



Blue line: inner colony diameter
Red line: outer zone diameter

TIER 3 DISK DIFFUSION QC

1) SPECTINOMYCIN

***Neisseria gonorrhoeae* ATCC 49226 の spectinomycin ディスク（100 µg）拡散法 QC レンジを 24-30 mm に変更することを承認した（投票：賛成 12，反対 0，棄権 0，欠席 2）**

QC Strain (ATCC)	Antimicrobic	Current Range	Action Recmd	Concern	Update	Date Reported
N. gonorrhoeae ATCC 49226	Spectinomycin 100 µg	23-29	Continue to monitor until June 2025. Request additional data. Approved range change to 24-30 11/0/2/1)	QC study out high	June 2025: No additional data. June 2022: Observations in gentamicin QC study, especially with one lab and media	June-22
E. coli NCTC 13353	Ceftibuten 30 µg		Continue to monitor until January 2027. Request additional data.	Zone diameters in the lower part of range and out of range	June 2025: No additional data.	Jan-24

Spectinomycin *N. gonorrhoeae* ATCC 49226
Additional Analysis

Compare Media Lots (Excluding Lab 8)

Media Lot	Lot 1	Lot 2	Lot 3
ZOI (mm)			
22			
23			
24	1	4	
25	12	10	1
26	24	20	12
27	14	33	4
28	13	11	17
29	13	4	20
30	3	5	18
31	3	2	8
32		1	2
33	2		7
34	5		1
35			
36			
Mean	27.62	26.94	29.09
SD	2.38	1.59	2.01
+2 SD	32.4	30.1	33.1
-2 SD	22.9	23.8	25.1

RangeFinder

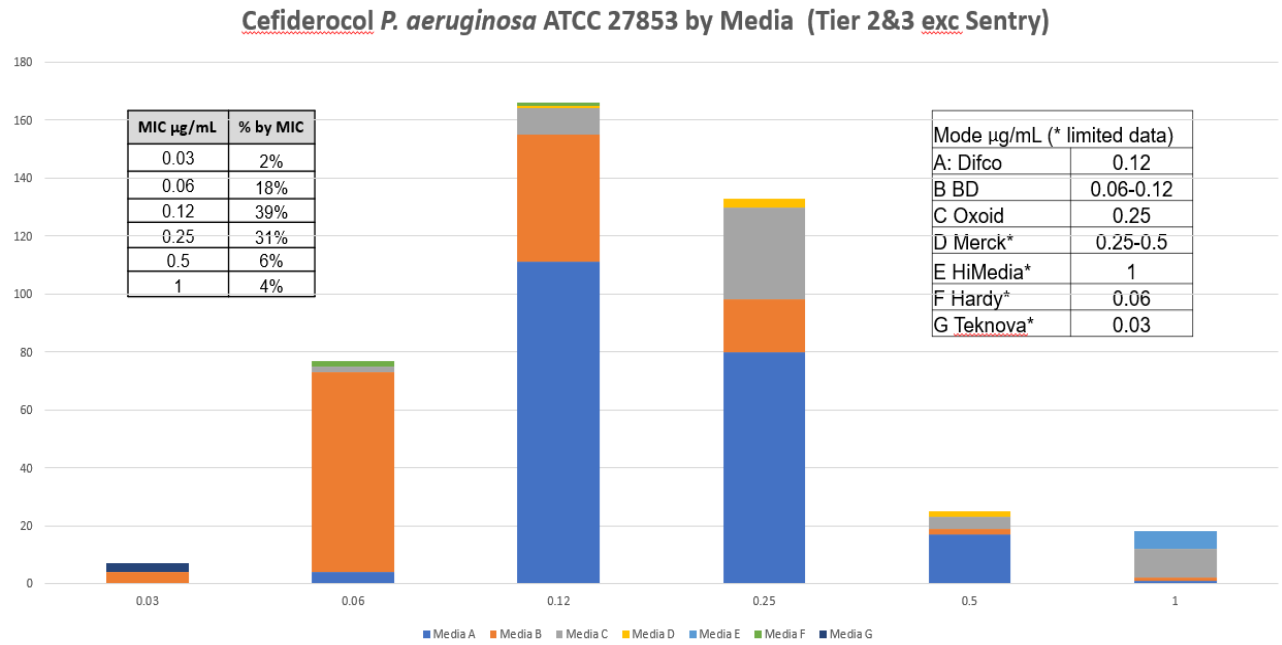
All Labs		
Calculated QC Range	Gavan QC Range	Mean
23 to 33	24 to 31	27.9
Range	Range	StDev
11	7	2.2
% Obs. Captured	% Captured	+2 SD
97.8%	93.3%	32.3
Prob'ty Outside Range		-2 SD
0.023		23.5

Exclude Lab 8		
Calculated QC Range	Gavan QC Range	Mean
24 to 31	25 to 29	27.4
Range	Range	StDev
8	4	1.7
% Obs. Captured	% Captured	+2 SD
99.2%	85.4%	30.8
Prob'ty Outside Range		-2 SD
0.041		24.0

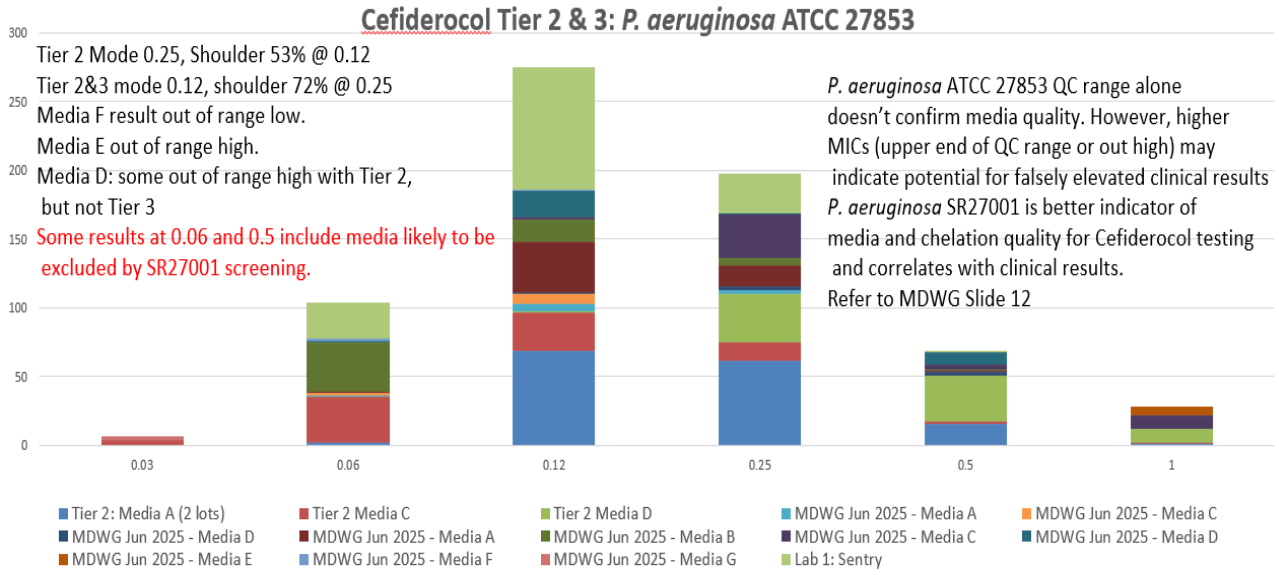
TIER 3 MIC QC

1) CEFIDEROCOL

表 5A-1 の cefiderocol QC 脚注を「*P. aeruginosa* ATCC 27853 はルーチン QC に推奨される（0.06-0.5 µg/mL，最頻値 0.12-0.5 µg/mL）。最も頻度の高い MIC 値は 0.5 µg/mL であり，一部の培地メーカーではこの結果が観察される可能性があるため，臨床分離株において MIC 値の上昇（偽耐性）が生じる可能性がある」に変更することを承認した（投票：賛成 13，反対 0，棄権 0，欠席 1）



Significant difference in media manufacturers with *P. aeruginosa* ATCC 27853
Overall mode 0.12 with 80% shoulder at 0.25 µg/mL



次回の AST ミーティング

次回の CLSI（Clinical and Laboratory Standards Institute）AST（Antimicrobial Susceptibility Test）ミーティングは，2026 年 1 月 25 日～1 月 27 日に，米国アリゾナ州テンピで開催されることが報告された。

（文責：大楠清文）