

QC Working Group Voting Members

Name	Affiliation	Category
Sharon Cullen (co-chair)	Siemens (MicroScan)	Dx Industry
Steven Brown, Ph.D (co-chair)	Retired	QC/Research
Bob Rennie, Ph.D.	U. of Alberta	Clinical Lab/Broth QC
Janet Hindler	UCLA	Clinical Lab
Susan Munro	Retired	Clinical Lab
Michael Huband	AstraZeneca	Industry
Patricia Conville	FDA/CDRH	Government
Ross Mulder	bioMerieux-Vitek	Dx Industry
Mary York	MKY Consulting	Industry
Stephen Hawser, Ph.D.	IHMA	Clinical Lab & Industry Support
Frank Wegerhoff	Covance	Dx Industry
Erica Matuschek, Ph.D.	EUCAST	Clinical Lab
Denise Holliday	BDMS	Industry
Bob Flamm	JMI	QC/Research

AGENDA

- ▶ **Propose QC ranges based on M23 Tier 2 Studies:**
 - ▶ **AZD0914 – agar dilution QC for**
N. gonorrhoeae ATCC 0.06-0.5 µg/ml 7/1/0
 - ▶ **TD-1607 – broth microdilution QC for**
S. aureus ATCC® 29213 = 0.002-0.008 µg/ml 7/0/0
E. faecalis ATCC 29212 = 0.002-0.008 µg/ml 7/0/0
S. pneumoniae ATCC 49619 0.001-0.004 µg/ml 7/0/0
 - ▶ **Pefloxacin – disk diffusion QC for**
 - ▶ *E. coli* ATCC 25922 = 22-33 mm 5/2/1

Update *K. pneumoniae* ATCC 700603 QC Table

Page 156, M100-S24, supplement to Table 5A.

There is no proposal at this time to try to replace *E. coli* ATCC 35218 with *K. pneumoniae* ATCC 700603.

MIC (µg/ml) Quality Control Ranges for *Klebsiella pneumoniae* ATCC® 700603* as supplemental-QC.

Antimicrobial Agent	<i>Klebsiella pneumoniae</i> ATCC 700603 (µg/ml)
Amoxicillin	>128
Amoxicillin-clavulanic acid	4/2-16/8
Ampicillin	>128
Ampicillin-sulbactam	8/4-32/16
Aztreonam	8–64
Aztreonam-avibactam*	0.06/4–0.5/4
Biapenem	0.03–0.12
Ceftaroline	2-8
Ceftaroline-avibactam*	0.25/4–1/4
Ceftazidime	16-64
Ceftazidime-avibactam*	0.25/4–2/4
Ceftolozane-tazobactam	0.5/4–2/4
Piperacillin	--**
Piperacillin-tazobactam	8/4-32/4
Ticarcillin	>256
Ticarcillin-clavulanic acid	32/2-128/2

****K. pneumoniae* ATCC 700603 must be used for routine QC of ceftazidime-avibactam, ceftaroline-avibactam and Aztreonam-avibactam. Either *K. pneumoniae* ATCC 700603 or *E. coli* ATCC 35218 can be used for routine QC of other β -lactam/ β -lactamase inhibitor combination agents.**

***K. pneumoniae* ATCC® 700603 should be tested against ceftazidime-avibactam and ceftazidime alone, ceftaroline-avibactam and ceftaroline alone or aztreonam-avibactam and aztreonam alone to confirm the activity of avibactam in the combination and to ensure that the plasmid encoding the β -lactamase has not been lost in this strain. ~~The acceptable range for ceftazidime alone is >16 μ g/ml.~~ Any of the above β -lactams can be used to test the strain for loss of plasmid. It is not necessary to test each one.**

****No range recommended due to off-scale results on the low end.**

Add as a supplement to Table 4A, page 143, M100-S24 (similar to the supplemental table at the bottom of Table 5A, page 156).

Disk Diffusion Quality Control Ranges (mm) for *Klebsiella pneumoniae* ATCC® 700603

Antimicrobial Agent	<i>Klebsiella pneumoniae</i> ATCC 700603 (mm)
Ceftaroline-Avibactam*	21-27
Ceftazidime-avibactam*	21-27
Ceftolozane-tazobactam	17-25

****K. pneumoniae* ATCC 700603 must be used for routine QC of ceftaroline-avibactam and ceftazidime-avibactam. Either *K. pneumoniae* ATCC 700603 or *E. coli* ATCC 35218 can be used for routine QC of ceftolozane-tazobactam.**

Eliminate footnotes (d) and (e) to Table 4A, page 143 of M100-S24.

Quality Control Tier 3 Monitoring

Request for MIC data for
meropenem and/or
clarithromycin vs.
S. pneumoniae 49619

Please submit data directly to
Sharon Cullen.

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