

Subcommittee (SC) on Veterinary Antimicrobial Susceptibility Testing (VAST)
The Westin Galleria Dallas
Dallas, Texas, USA

Meeting Title:	VAST SC and Working Group Meetings	Contact:	lmoon@clsi.org
Meeting Date:	14-15 June 2019	Secretary:	robert.bowden@tufts.edu
Meeting Purpose:	To review and discuss VAST WG and subcommittee business.		
Requested Attendee(s):	Subcommittee Chairholder, Vice-chairholder, Members, Advisors, Reviewers		
Actual Attendee(s):	See Attachment 1		
Brian V. Lubbers, DVM, PhD, DACVCP Chairholder	Kansas State Veterinary Diagnostic Laboratory		
Mark G. Papich, DVM, MS Vice-chairholder	College of Veterinary Medicine, North Carolina State University		
Robert Bowden, BS Secretary	Tufts University Sackler School of Graduate Biomedical Sciences - Student		
Members Present			
Dubraska V. Diaz-Campos, DVM, PhD	College of Veterinary Medicine, Veterinary Medical Center, The Ohio State University		
Cory Langston, DVM, PhD	Mississippi State University		
Sakurako Marchand,	BioMerieux, Inc.		
Marilyn N. Martinez, PhD	FDA Center for Veterinary Medicine		
Ian Morrissey, PhD (15 June 2019)	IHMA Europe Sarl		
Thomas R. Shryock, PhD	Antimicrobial Consultants, LLC		
Virginia Sinnott-Stutzman, DVM, DACVECC	Angell Animal Medical Center (MSPCA)		
Michael T. Sweeney, MS	Zoetis		
Members Excused			
Mark Fielder, PhD	School of Life Science, Kingston University London		
Xian-Zhi Li, PhD	Health Canada Veterinary Drugs Directorate		
Ian Morrissey, PhD (14 June 2019)	IHMA Europe Sarl		
Shabbir Simjee, MSc, PhD	Elanco Animal Health		
Darren Trott, PhD	School of Animal and Veterinary Sciences, The University of Adelaide		
Staff			
Lori T. Moon, MS, MT(ASCP)	CLSI		
Glen Fine, MS, MBA, CAE	CLSI		

14 June 2019			
#	Time	Presenter	Description
	7:00 AM	N/A	Continental breakfast
	7:30-9:30 AM	N/A	VAST SC Working Group (WG) meetings
1.	10:00 AM	B. Lubbers	Opening remarks
5.	10:05 AM	G. Fine	CLSI update
2.	10:10 AM	B. Lubbers	Updates to disclosure of interest (DOI) summary
3.	10:13 AM	B. Lubbers	Agenda approval
4.	10:15 AM	B. Lubbers	Summary minutes approval
5.	10:20 AM	B. Lubbers, V. Fajt	CLSI updates
6.	10:35 AM	D. Diaz-Campos, S. Yan, M. Papich	Liaison reports
7.	10:45 AM	R. Miller	WG on Aquatic Animals report

8.	11:15 AM	M. Papich	Generic Drug WG BP Presentation: Levofloxacin for Dogs
	12:00 PM	N/A	Luncheon
9.	1:00 PM	M. Papich	Generic Drug WG BP Presentation: Levofloxacin for Dogs
10.	1:30 PM	D. Diaz-Campos	VET08 Table 2C <i>Staphylococcus</i> spp. breakpoint issues
11.	2:00 PM	M. Martinez, R. Miller	VET08 Table 1 and FDA Center for Veterinary Medicine approvals
	3:00 PM	N/A	Break
11. (cont'd)	3:15 PM	M. Martinez, R. Miller	VET08 Table 1 and FDA Center for Veterinary Medicine approvals
12.	3:45 PM	D. Diaz-Campos	WG on Education report
13.	4:00 PM	R. Miller	WG on Editorial/VAST Breakpoint Tables (VET08) discussion
14.	4:30 PM	M. Papich	Generic Drug WG report
	5:30 PM	B. Lubbers	Adjournment

15 June 2019			
#	Time	Presenter	Description
	7:00 AM	N/A	Continental breakfast
15.	8:00 AM	M. Sweeney	WG on Editorial/VAST Breakpoint Tables (VET08) discussion
16.	8:05 AM	D. Bade	WG on Veterinary Fastidious Medium (VFM) review and discussion of data from testing VFM replacement medium (MHF-Y)
	10:15 AM	N/A	Break
16. (cont'd)	10:30 AM	D. Bade	WG on Veterinary Fastidious Medium (VFM) review and discussion
17.	11:30 AM	B. Lubbers	Other business
18.	12:00 PM	B. Lubbers	Adjournment

14 June 2019	
SUMMARY MINUTES	
Item	Description
1.	<p>Call to order and opening remarks</p> <p>Dr. Brian Lubbers opened the plenary session of the Subcommittee on Veterinary Antimicrobial Susceptibility Testing (VAST) at 10:00 AM US Central Daylight Time (CDT) by welcoming new and returning attendees and allowing time for each attendee to briefly introduce themselves. Dr. Lubbers offered a reminder that the primary purpose for these meetings is to allow sponsors to present breakpoint proposals for consideration, noting that no sponsor-generated breakpoints would be presented at this meeting, but that two proposals from the Generic Drugs Working Group (GWG) would be presented.</p> <p>There is also a full agenda through 12:00 pm on Saturday, 15 June 2019 with presentations from the working groups. During this time, the subcommittee will make motions and vote on the agenda topics, including discussion of VET08S Consensus Comments that need resolutions for the path forward to the projected June 2020 date for publication of the VET08, 5th edition. Meeting participants should have reviewed the background materials prior to the meeting for a productive discussion on Friday and Saturday.</p> <p>In addition to the procedural information in this year's meeting materials (refer to Folder #2), also included are the subcommittee approach to disclosures and voting, and the voting rules for this meeting (shown below).</p>

	<p align="center">2019 Roster - 12 voting members (excludes Chairholder and Vice-chairholder)</p> <table border="0"> <thead> <tr> <th align="left"><u>Committee Status</u></th><th align="left"><u>"Pass" Vote</u></th></tr> </thead> <tbody> <tr> <td>All members present and voting</td><td>12-0, 11-1, 10-2, 9-3, 8-4, 7-5</td></tr> <tr> <td>One member not present or abstaining</td><td>11-0, 10-1, 9-2, 8-3</td></tr> <tr> <td>Two members not present or abstaining</td><td>10-0, 9-1, 8-2, 7-3</td></tr> <tr> <td>Three members not present or abstaining</td><td>9-0, 8-1, 7-2</td></tr> </tbody> </table> <p>If more than three members not present: Chairholder's discretion to conduct vote or table until sufficient members are present or electronic vote taken.</p> <p>Since 5 members were unable to attend this meeting on Friday, 14 June 2019, and 4 members unavailable on Saturday, 15 June 2019, Dr. Lubbers announced that votes taken during this meeting will also be sent out following the meeting for a 5-day electronic vote by Dr. Ian Morrissey (Friday votes only), Dr. Mark Fielder, Dr. Xian-Zhi Li, Dr. Shabbir Simjee, and Dr. Darren Trott. Dr. Lubbers also announced that Ms. Lacie Johansen, Committee Secretary, was unable to attend and that Mr. Robert Bowden would be serving as secretary for this meeting.</p> <p>Dr. Lubbers also asked if there were any new volunteers or guests attending the meetings, and if so, to please see Ms. Lori Moon at the break or after adjournment or contact me after the meeting at lmoon@clsi.org for information on joining the VAST Subcommittee.</p>	<u>Committee Status</u>	<u>"Pass" Vote</u>	All members present and voting	12-0, 11-1, 10-2, 9-3, 8-4, 7-5	One member not present or abstaining	11-0, 10-1, 9-2, 8-3	Two members not present or abstaining	10-0, 9-1, 8-2, 7-3	Three members not present or abstaining	9-0, 8-1, 7-2
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Three members not present or abstaining	9-0, 8-1, 7-2										
2.	<p>Disclosures of interest (DOI)</p> <p>Dr. Lubbers asked for members and advisors to review and make any necessary changes or up-dates to their disclosures of interest listed in the updated DOI Summary provided in the meeting materials, and send any corrections or additional updates to Ms. Lori Moon at lmoon@clsi.org.</p>										
3.	<p>Approval of agenda</p> <p>Dr. Lubbers asked for approval of the meeting agenda as displayed in the updated version of meeting materials sent out prior to the start of the meeting, when it was noted that the agenda was revised for Mr. Glen Fine to report on CLSI updates (agenda item #5) immediately after the opening remarks. A motion was made by Dr. Thomas Shryock (1ST) and Dr. Cory Langston (2nd). With no objections or comments, the motion was passed (see Attachment 2 for voting details).</p>										
4.	<p>Approval of January 2019 meeting summary</p> <p>Dr. Lubbers asked if there were any additions, subtractions, or corrections needed to the January 2019 meeting summary minutes. Hearing none, a motion was made by Mr. Michael Sweeney and seconded by Dr. Virginia Sinnott-Stutzman, and the summary minutes were approved as written (see Attachment 2 for voting details).</p>										
5.	<p>CLSI Updates</p> <p>Mr. Fine provided an update on CLSI activities after welcoming and thanking attendees for their participation. He noted that the Subcommittee on VAST was the only antimicrobial susceptibility testing (AST) group establishing veterinary breakpoints for 30 years and highlighted its importance with the growing global emphasis on antimicrobial resistance and One Health. He announced that, as of 13 June 2019, the CLSI guideline M23 is available in its entirety for free on the CLSI website. Additionally, a call for committee members will soon go out in order to fill roles on several committees, including the Consensus Council.</p> <p>An update was given detailing that online usage of VET08 has doubled each year since it was first made</p>										

	<p>freely-available on the CLSI website. There were 5,500 unique users and 112,000 page-hits in 2018. Current statistics suggest that 2019 will see these numbers double again. As evidence to the global reach of the document, 7 out of 10 users online were from outside of the United States, with a very strong presence from China and western European countries. Mr. Fine will report on international breakdown statistics in January 2020.</p> <p>Dr. Lubbers mentioned there is a new opportunity for volunteers to help in developing breakpoint rationale documents (see Folder 8 for an example of human AST breakpoint rationale document format), and a need for a champion to work on a project proposal due in late August or early September 2019 (Action Item) to be approved by the Consensus Council in September 2019. Dr. Robert Hunter volunteered to serve as champion for the new Working Group (WG) on Veterinary Breakpoint Rationale being proposed and a Call for Volunteers will be posted for the VAST Subcommittee in July (Action Item). Dr. Mark Papich offered to test this template to create rationale documents using information from several of the antimicrobial agents with breakpoints established by the GWG for presentation to the subcommittee in January 2020 (Action Item).</p> <p>Dr. Virginia Fajt provided an update on the CLSI report VET09, which is scheduled for publication in late June 2019. She reminded attendees that the primary purpose of the document is to provide guidance to veterinarians on how to use AST reports, a demographic not previously targeted by CLSI documents. In an effort to provide better outreach to veterinarians, plans are underway for a CLSI webinar recording to introduce the document. Additionally, presentations highlighting VET09 will be given by VAST members at the American Academy of Veterinary Pharmacology and Therapeutics (AAVPT) meeting in August and at the AAVLD meeting in October. Dr. Papich added that there are current VAST attempts to identify an industry sponsor who might purchase and distribute VET09 to each veterinary teaching hospital's microbiology laboratory within the United States. Brief discussion occurred on perceptions that VET09 is largely US-centric. Dr. Fajt clarified that this was acknowledged during creation of the 1st edition but that the principles have global application and future editions will have a greater emphasis on other regions. The subcommittee gave input of marketing locations to target for VET09 sales, which should include Europe and Asian countries, and the American College of Veterinary Microbiology (ACVM).</p> <p>Dr. Lubbers gave an update on the progress of the CLSI standard M39, noting that VAST and AST are collaborating to include antibiogram examples specific to veterinary microbiology in the upcoming revised edition of the M39 document. Ms. Moon added that the CLSI AST June 2019 Newsletter just published and is available on the CLSI website under Microbiology Resources, AST Newsletter Archives (https://clsi.org/meetings/microbiology/newsletter-archives/). (NOTE: Volunteers may sign up to automatically receive CLSI AST News Updates from the CLSI AST Outreach Working Group [ORWG] at https://clsi.org/meetings/ast-news-update-download/)</p>
6.	<p>Liaison Reports</p> <p><u>AAVLD Planning</u> Dr. Dubraska Diaz-Campos gave an update on VAST Subcommittee activities in cooperation with American Association for Veterinary Laboratory Diagnosticians (AAVLD). Dr. Fajt and Dr. Lubbers are invited speakers at the upcoming October 2019 AAVLD meeting. Dr. Fajt will speak on the topic of VET09. Dr. Lubbers will speak on antibiograms and lead a brainstorming session on topics that attendees would like for the VAST Subcommittee Education WG to address.</p> <p><u>USCAST Update</u> Dr. Steve Yan attended the September 2018 meeting of The United States Committee on Antimicrobial Susceptibility Testing (USCAST). Many updates from The European Committee on Antimicrobial Susceptibility Testing (EUCAST) were presented, showing uptake of EUCAST methodology and breakpoints in Europe. Several human breakpoints' revision consultations were presented; and considerable time was devoted to discussing the new definition of the Intermediate category that has recently been adopted by EUCAST. Dr. Yan stated that Dr. Ronald Jones presented updates from USCAST, including a timeline and description of its status as a donor-driven, not-for-profit organization. Additionally, there was an update by the US Food and Drug Administration (FDA) at the USCAST</p>

	<p>meeting. There are several human breakpoint differences between the four organizations. In the United States, FDA breakpoints are used by automated, commercial AST devices. However, the 21st Century Cures Act requires frequent updates to labeling so that current breakpoints can be used to design panels. A procedure now exists to petition the FDA for breakpoint changes. Finally, breakpoints for meropenem-vaborbactam and plazomicin were presented at the USCAST meeting.</p> <p><u>VetCAST Update</u></p> <p>Drs. Thomas Fritsche and Stefan Schwarz are the VAST Subcommittee liaisons to the Veterinary Committee on Antimicrobial Susceptibility Testing (VetCAST) but were unable to attend the June VAST Subcommittee meeting. Slides describing VetCAST's activities were distributed in the meeting materials. Dr. Papich gave a brief update. VetCAST is an official subcommittee of EUCAST. Currently, they have set no breakpoints but are proposing florfenicol breakpoints. Additionally, they are now looking at developing canine breakpoints for cefazolin, equine breakpoints for marbofloxacin, and doxycycline. VetCAST is proposing creating their own document that instructs veterinarians and laboratories on how to report results in the absence of breakpoints.</p>
7.	<p>Working Group on Aquatic Animals (AWG)</p> <p>Dr. Ron Miller provided an update identifying the three published documents developed by the AWG: VET03-A for disk diffusion methods, VET04-A2 for broth microdilution methods, and VET03/VET04-S2 for breakpoints and epidemiological cutoff value (ECV) tables. Dr. Miller explained that the next edition scheduled for publication in 2020, the VET03, 2nd ed., will combine the two methods (disk diffusion [DD] and minimal inhibitory concentration [MIC]) documents into a single document. The VET03/VET04-S2 supplement is undergoing significant revisions and will be published concurrently with the revised code of VET04S, 3rd ed. Currently only <i>Aeromonas salmonicida</i> breakpoints exist, with ECVs listed for <i>A. salmonicida</i> and other aquatic animal pathogens. Previously, ECVs (also known as ECOFFs per EUCAST) were identified by the "eyeball method". Therefore, the goal of recent work by the AWG was to review current breakpoints by putting MIC distributions through ECOFFinder and normalized resistance interpretation (NRI) analysis in order to determine if revisions are necessary. Dr. Peter Smith recalculated zone diameters and MICs for <i>A. salmonicida</i>. 3 datasets were analyzed using the most recent version of NRI. The same was done for MIC analysis. It was noted by Dr. Miller that the study was done in only one lab, rather than three independent labs as EUCAST would require for setting ECOFFs. However, this was as comprehensive an effort as was possible, as there are only a few laboratories that perform testing for aquatic isolates and not all test all antimicrobial agents. The results of the study supported all breakpoints and ECVs as previously published. No changes are proposed by the AWG.</p> <p>Concerns were expressed regarding appropriate use standards for aquatics species, and whether the veterinarian or the client is responsible for following these standards. Members of the VAST Subcommittee agreed that language should be included in the upcoming documents which will differ from what is found in VET08, as the situation is different for aquaculture. Dr. Shryock suggested adding an example within a box that would describe the situation within the United States. This would convey the information while retaining sensitivity to the fact that regulatory situations may differ by region. In relation to revised wording, Ms. Moon added that comments and suggestions for rewording may be submitted during the upcoming 60-day Proposed Draft (PD) voting period by anyone and will be fully considered and addressed per CLSI policy. Ms. Moon requested that volunteers review the as VET03, 2nd ed. and VET04S, 3rd ed. early in the 60-day PD voting period, if possible, which is currently projected to begin in July. Lastly, Dr. Miller noted that VET04S, 3rd ed. will now include a table to indicate when breakpoints and ECV were established or were most recently revised, similar to the information found in the front matter of VET08 and VET08, Appendix E.</p>
8.	<p>GWG Breakpoint Presentation for Levofloxacin in Dogs</p> <p>The GWG proposed levofloxacin breakpoints for dogs, with the original presentation slides from the June 2019 VAST Meeting Materials updated by the GWG and presented by Dr. Papich. The updated slide presentation is posted in CLSI Exchange in the June 2019 VAST Meeting Updated Agenda and Presentations folder (available at https://www.clsiexchange.org/viewdocument/2019-jun-vast-sc-meeting-gwg-bp-p-1?CommunityKey=cdba2b98-8e43-499e-bf15-39d212841f04&tab=librarydocuments when logged in to your CLSI Exchange account) and a summary of the meeting discussion follows.</p>

(1) The following clinical breakpoints were proposed to be added for *Enterobacteriaceae* in Table 2A: S (≤ 0.5 µg/mL), I (1 µg/mL), R (≥ 2 µg/mL), and for *Pseudomonas aeruginosa* in Table 2B: S (≤ 1 µg/mL), I (2 µg/mL), R (≥ 4 µg/mL), as shown below:

Proposed action
VET 08, Table 2

Test/ Report Group	Body Site	Antimicrobial Agent	Organism	MIC Interpretive Criteria (µg/mL)			Comments
				S	I	R	
Fluoroquinolones							
Dogs							
B? or E?	Skin, soft tissue, Urine	Levofloxacin	Enterobacteriaceae	≤0.5	1	≥2	Levofloxacin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of levofloxacin, after administration at a dose of 25 mg/kg oral, every 24 hours.
B? or E?	Skin, soft tissue, Urine	Levofloxacin	<i>Pseudomonas aeruginosa</i>	≤1	2	≥4	Levofloxacin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of levofloxacin, after administration at a dose of 25 mg/kg oral, every 24 hours.

The following comments were made by meeting attendees:

Mr. Sweeney asked how frequently levofloxacin is being administered to dogs. Dr. Papich indicated that there is frequent and growing usage owing to decreased cost and easy administration due to availability of larger tablets than are offered for veterinary fluoroquinolones. He noted that in his experience it is well-tolerated in dogs. Dr. Langston agreed with these statements. Ms. Sakurako Marchand stressed the need for careful communication about antimicrobial stewardship and avoiding promotion of the use of levofloxacin when other approved antibiotics are available. Dr. Papich noted that some had wanted to include an investigation into levofloxacin breakpoints for *Staphylococcus* spp. but it was excluded due to evidence that it drives resistance in staphylococci and due to a lack of MIC distribution data for *Staphylococcus pseudintermedius*. Dr. Miller expressed concern about bone marrow suppression, as it's known to occur for pradofloxacin (another 3rd-generation quinolone). Dr. Hunter cited data suggesting wide safety margins.

Mr. Bowden suggested adopting the zone diameter breakpoints and interpretive categories from M100 if the proposed MIC breakpoints are to be accepted as they are identical to those found in M100-S29. However, he was concerned that, due to the very low cost of levofloxacin, setting veterinary-specific breakpoints will increase overall usage of fluoroquinolones in veterinary species, leading to an increased selection for multidrug-resistant isolates. The voting members agreed to add zone diameters and interpretive categories and generally felt that the agent is already being used and that veterinary breakpoints would be helpful.

Dr. Marilyn Martinez noted that it's important to develop a *Pseudomonas* fluoroquinolone breakpoint for dogs as there currently are none, adding that she was opposed to inclusion of ciprofloxacin several years ago due to poor bioavailability. However, she felt that the levofloxacin data strongly supported setting breakpoints and was favorable for its inclusion in Test/Report Group B. Dr. Lubbers gave an alternative suggestion to include it to the proposed Test/Report Group E (human breakpoints). Dr. Fajt indicated that she would prefer to set breakpoints for *P. aeruginosa* but not *Enterobacteriaceae*. Mr. Sweeney agreed, as it would seem like CLSI is promoting levofloxacin use in dogs when approved veterinary fluoroquinolones with efficacy against *Enterobacteriaceae* already exist. He stated that he

would also prefer the human breakpoints be listed in a grey-shaded box. Dr. Martinez, Dr. Sinnott-Stutzman, and Dr. Shryock felt that it would be disingenuous to list it as a grey-shaded breakpoint as this would indicate a human breakpoint for an agent that has not been examined by VAST Subcommittee. Discussion ensued as to whether a grey-shaded box would be possible so long as a comment were added with the dosage regimen that was examined for dogs, which would be similar to the grey-shaded (human) breakpoints for chloramphenicol. Dr. Papich noted that the situations are different as there were no pharmacokinetics-pharmacodynamic (PK-PD) targets identified for chloramphenicol. Dr. Diaz-Campos asked whether a footnote could be added to remind users to refer to the new definition for Group B. Dr. Miller agreed that this would be helpful.

(2) As a result of discussion, the proposed Table 2A and 2B entries were amended to the following:

Proposed action

VET 08, Table 2 for canine, tentatively for Test/Report Group B (TBD)

Test/Report Group	Body Site	Antimicrobial Agent	Organism	Disk Content	Interpretive Categories and Zone Diameter Breakpoints, nearest whole mm			Interpretive Categories and MIC Breakpoints, µg/mL			Comments
					S	I	R	S	I	R	
TBD	Skin and soft tissue	Levofloxacin	<i>Enterobacteriaceae</i>	5 µg	≥ 21	17–20	≤ 16	≤ 0.5	1	≥ 2	(XX) Levofloxacin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of levofloxacin, after administration at a dose of 25 mg/kg oral, every 24 hours.
TBD	Skin and soft tissue	Levofloxacin	<i>Pseudomonas aeruginosa</i>	5 µg	≥ 22	15–21	≤ 14	≤ 1	2	≥ 4	(XX) Levofloxacin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of levofloxacin, after administration at a dose of 25 mg/kg oral, every 24 hours.

A motion was made by Dr. Martinez (1st) and Dr. Langston (2nd) to accept the breakpoints proposed for *Enterobacteriaceae* to be added to Table 2A (as amended) and breakpoints proposed for *Pseudomonas aeruginosa* to be added to Table 2B (as amended):

In favor: 6; abstained: 0; against: 1; absent: 4 - **MOTION TABLED***

Against: Mr. Michael Sweeney (reason: preferred listing the human BPs in grey-shading)

The decision was tabled pending 5-day post-meeting electronic vote by 5 members absent from the 14 June 2019 meeting) and the five absent voting members were asked to review and provide their vote electronically between 17-21 June 2019. The motion passed (see Attachment 2 for final voting details).

9. GWG Breakpoint Presentation for Ampicillin in Horses

The GWG proposed ampicillin breakpoints for horses, with the original presentation slides in the June 2019 VAST Meeting Materials updated by the GWG and presented by Dr. Papich. The updated slide presentation is posted in CLSI Exchange in the June 2019 VAST Meeting Updated Agenda and Presentations folder (available at <https://www.clsiexchange.org/viewdocument/2019-jun-vast-sc-meeting-gwg-bp-p?CommunityKey=cdba2b98-8e43-499e-bf15-39d212841f04&tab=librarydocuments>) when logged in to your CLSI Exchange account) and a summary of the meeting discussion follows.

(1) The following clinical breakpoints were proposed to be added for ampicillin in horses for *Enterobacteriaceae* in Table 2A: S (≤ 0.25 µg/mL), I (0.5 µg/mL), R (≥ 1 µg/mL) and for *Staphylococcus aureus* in Table 2C: S (≤ 0.25 µg/mL), I (0.5 µg/mL), R (≥ 1 µg/mL).

Proposed action: VET 08, Table 2

Test/ Report Group	Body Site	Antimicrobial Agent	Organism	MIC Breakpoints and Interpretive Categories (µg/mL)			Comments
				S	I	R	
Penicillins							
Horses							
A	Respiratory Skin, Soft Tissue	Ampicillin	Enterobacteriaceae	≤ 0.25	0.5	≥ 1	(x) E. coli and other Enterobacteriaceae will test resistant to ampicillin.
A	Respiratory Skin, Soft Tissue	Ampicillin	Staphylococcus aureus	≤ 0.25	0.5	≥ 1	Ampicillin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of ampicillin in horses after administration at a dose of 22 mg/kg IM or IV every 12 hours

Similar comment as dog and cat:

- (2) Additionally, a Susceptible breakpoint is currently listed for *Streptococcus equi* subsp. *equi* and subsp. *zooepidemicus* in Table 2D: S (≤ 0.25 µg/mL) (no I or R breakpoints), and a dosage regimen comment is proposed, as shown below:

Proposed action: VET 08, Table 2

Test/ Report Group	Body Site	Antimicrobial Agent	Organism	MIC Breakpoints and Interpretive Categories (µg/mL)			Comments
				S	I	R	
Penicillins							
Horses							
A	Respiratory	Ampicillin	<i>S. equi</i> subsp. <i>equi</i> and subsp. <i>zooepidemicus</i>	≤0.25	—	—	(13) For strains yielding results suggestive of a “ <u>nonsusceptible</u> ” category, organism identification and antimicrobial susceptibility test results should be confirmed. (X) Ampicillin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of ampicillin in horses after administration at a dose of 22 mg/kg IM or IV every 12 hours.

During Dr. Papich’s presentation, he discussed that the GWG revisited ampicillin breakpoints as it had been recognized that no dosage regimen was listed for the equine respiratory breakpoints for *Streptococcus equi* subsp. *equi* and subsp. *zooepidemicus*. Upon review, the dosage regimen used for setting the breakpoints was found to be higher (22 mg/kg intramuscularly [IM] or intravenously [IV] every 12 hours) than the labeled dose (6.6 mg/kg IM or IV every 12 hours). Therefore, the GWG reanalyzed the PK-PD data using both dosage regimens and %T>MIC of 40% and 60%. Based on this analysis, it was decided by the GWG that the labeled dosage was not sufficient to support the existing breakpoint if %T>MIC=60 were applied. As this would split the wild-type and render many isolates not treatable with ampicillin, the GWG recommended to support inclusion of the dosage of 22 mg/kg IM or IV every 12 hours as originally examined. Additionally, it was noted by Dr. Papich that this is the standard clinical dosage regimen currently in use, most often administered IV.

	<p>The following comments were made by meeting attendees:</p> <p>Much of the conversation centered on differing target attainment rates when the two dosage regimens and various PK-PD targets were applied. However, it was acknowledged that any concerns about target attainment were minimized by retaining the higher dosage regimen used in the initial GWG analysis. Mr. Robert Bowden suggested that an alternate way for indicating clinical resistance should be pursued for <i>E. coli</i> rather than setting breakpoints, as application of veterinary ampicillin breakpoints for <i>E. coli</i> will give the impression that veterinary <i>E. coli</i> isolates are more resistant than human isolates.</p> <p>Ms. Marchand questioned why ampicillin would be tested for staphylococci rather than penicillin. This topic was to be addressed later during the plenary session in the presentation on Table 2C, and for that reason, it was not discussed further during this presentation. Additional discussion amongst the group addressed the rationale for including only a Susceptible breakpoint for <i>S. equi</i> subsp. <i>equi</i> and subsp. <i>zooepidemicus</i>. It was agreed upon by the group that this was done because, at the initial time the breakpoints were set, no resistant isolates had been identified.</p> <p>A motion was made by Dr. Langston (1st) and Dr. Martinez (2nd) to accept the breakpoints proposed for <i>Enterobacteriaceae</i> be added to Table 2A, the breakpoints proposed for <i>S. aureus</i> to be added to Table 2C, and the proposed comment be added for the horse ampicillin breakpoint for <i>S. equi</i> subsp. <i>equi</i> and subsp. <i>zooepidemicus</i> in Table 2D.</p> <p style="color: blue;">In favor: 6; abstained: 1; against: 0; absent: 5 - MOTION TABLED* Abstained: Mr. Sweeney (reason: conflict of interest)</p> <p>The decision was tabled pending 5-day post-meeting electronic vote by 5 members absent from the 14 June 2019 meeting) and the five absent voting members were asked to review and provide their vote electronically between 17-21 June 2019. The motion passed (see Attachment 2 for final voting details).</p>
10.	<p>VET08 Table 2C <i>Staphylococcus</i> spp. Presentation on <i>Staphylococcus</i> spp. Breakpoint Issues</p> <p>Dr. Diaz-Campos presented material compiled by Mr. Bowden which proposed changes to be made for equine penicillin breakpoints and canine and feline ampicillin breakpoints. The primary proposed change was to harmonize with the M100 document's penicillin breakpoints for staphylococci (≤ 0.12 $\mu\text{g/ml}$ S, ≥ 0.25 $\mu\text{g/ml}$ R). Evidence from the June 2011 AST meeting was presented which demonstrated that isolates with MICs > 0.12 $\mu\text{g/ml}$ are beta-lactamase producers. PK-PD supports a CO_{pd} higher than 0.12 in both humans and horses but this breakpoint chosen to avoid categorizing beta-lactamase-positive as Susceptible. Current horse penicillin breakpoints (≤ 0.5 $\mu\text{g/ml}$ S, 1 $\mu\text{g/ml}$ I, ≥ 2 $\mu\text{g/ml}$ R) will categorize beta-lactamase-positive isolates as Susceptible. Additionally, it was noted that VET08 lists the testing procedure for performing beta-lactamase testing but does not specify that this test needs to be performed if veterinary breakpoints are applied. Meeting materials provided in the agenda book demonstrated that penicillin-susceptible isolates will be ampicillin-susceptible, so long as the isolate is confirmed as penicillin-susceptible by performing beta-lactamase testing. The proposal was to change equine MIC breakpoints for penicillin from those currently in VET08 to those that are in M100, adopt the zone diameters and interpretive criteria from M100, and adopt the comments from M100 on use of penicillin to predict results for other beta-lactams and the need for performing beta-lactamase testing before reporting isolates as Susceptible.</p> <p>Furthermore, she noted that VET08 staphylococcal ampicillin breakpoints for dogs and cats do not mention a need for beta-lactamase testing and showed data suggesting ampicillin breakpoints will categorize a greater percentage of beta-lactamase-positive isolates as Susceptible than would occur if the M100 penicillin breakpoints used as a surrogate to predict results for ampicillin and amoxicillin. The proposal was to delete dog and cat ampicillin breakpoints for staphylococci and adopt the penicillin MIC and disk diffusion breakpoints and zone diameters from M100 to be applicable for all <i>Staphylococcus</i> spp. and applied to the body sites of skin, soft tissue, and the urinary tract, along with the comments from M100 on use of penicillin to predict results for other beta-lactams and the need for</p>

	<p>performing beta-lactamase testing before reporting isolates as Susceptible.</p> <p>Dr. Fajt reminded the subcommittee of previous work demonstrating that differing urine concentrations are attainable in cats and dogs. Dr. Papich added that cats are being reevaluated, as concentrations may be higher than previously thought. Dr. Hunter expressed concern that the proposal would be replacing a veterinary breakpoint with a human breakpoint. Mr. Bowden responded that it should not be considered a human breakpoint but use of penicillin as a surrogate agent due to improved performance. Dr. Lubbers added that this would be a new direction for VAST to move in the process of setting breakpoints and Dr. Martinez suggested that it may require revisions to VET02. Dr. Martinez additionally questioned whether, from a PK-PD perspective, if the agent might work, assuming sufficient concentrations are present to overwhelm the amount of enzyme present. Members were not certain. Drs. Hunter and Martinez expressed concern about the change creating an apparent increase in resistance with Dr. Hunter suggesting another route is needed rather than designating it as a clinical breakpoint. Dr. Joshua Hayes offered the possibility of a comment directing users to the beta-lactamase screening tests. It was decided that the topic would not be voted upon now and will be revisited during the January 2020 meeting (Action Item).</p>
11.	<p>VET08 Table 1 and FDA Center for Veterinary Medicine (CVM) Approvals</p> <p>Dr. Martinez led a presentation of observations made by a WG of the FDA CVM consisting of Dr. Martinez and Dr. Miller as co-chairs, along with Dr. Eden Birmingham, Dr. Michele Sharkey, and Dr. Yan. (Note: this is a WG within the FDA CVM, not a CLSI VAST Subcommittee WG). The presentation's purpose was to explain the rationale for the working group's formation and to present their findings to the Subcommittee on VAST for consideration, with the proposal that a VAST WG form to address the issues discovered by FDA CVM. The FDA CVM WG developed as a result of Dr. Papich's suggestion that FDA CVM place a reference on their website explaining the FDA's lack of clinical breakpoints for veterinary species and directing readers to CLSI VAST. The FDA CVM spoke with Mr. Fine from CLSI and developed a proposal to include a statement on the CVM website noting that CVM doesn't develop veterinary clinical breakpoints but listing the CVM-approved agents for which there are CLSI VAST veterinary breakpoints. Through this process, several issues relating to extralabel dosages and inconsistencies were identified within VET08 and VET09 which caused the FDA CVM WG to perform an in-depth review.</p> <p>Dr. Shryock sought clarification about what was missing from the CLSI documents and Dr. Martinez specified that the lack of a dosage regimen for all breakpoints was the primary concern of the FDA CVM WG. Dr. Papich clarified that VAST has always subscribed to the format that when dosages are not listed, the lowest labeled dose was used for analysis in setting the Susceptible breakpoint. Dr. Martinez further described the issues as whether CLSI lists a dose, if that dose is consistent with the FDA labeled dose, if breakpoints are applied to only the labeled species, and if breakpoints are consistent with the approved indication. She noted that the use of "extralabel" in the context of this discussion was not intended to be synonymous with "inappropriate use" but was simply to indicate that a higher than the labeled dose was used or that there was an application to bacteria not included on the label. To catalog all of the information, the FDA CVM WG created a CVM table containing all current VET08 breakpoints along with the different salts and dosing regimens, CVM dose and indications, and CLSI VET08 or VET09 dose. The table was presented as providing VAST with a derivative tool that may serve as a living document and resource to compare current approvals with VAST breakpoints and allow for continual updates.</p> <p>Specific issues raised by the CVM WG for VAST consideration included: 1. Body site - examples in which nothing related to urinary tract infection (UTI) is on the label but CLSI breakpoints include UTI as a body site. 2. Pathogen - examples in which a pathogen is not listed on a label but CLSI includes a breakpoint for that bug-drug combination. 3. Dose - examples in which extralabel (higher) doses are used as the basis of the CLSI breakpoint.</p> <p>Dr. Lubbers asked if it was still a goal to place something on the CVM website directing users to CLSI. This idea was of concern to Dr. Hunter as he noted that nothing off-label can be used and sponsors might attempt to market around it. No clear consensus was drawn.</p>

	<p>Dr. Martinez returned to the earlier discussion and explained that the salt form and formulation are known to have great effects on the characteristics of agents which affect PK-PD, but that this is not reflected by current breakpoints. She provided several examples, one being that ampicillin is approved in swine for PO and IM administration, but breakpoints are based only on the IM route. Dr. Miller added that these differences are acknowledged in VET09 but not VET08. Some discussion followed between several members on the potential for rationale documents to solve most of these issues and it was generally agreed by all that this would provide a solution. Additionally, discussion occurred on extrapolation of breakpoints to other body sites and whether the information should be routinely conveyed to clinicians when breakpoints are dependent upon specific formulations or body sites. Dr. Lubbers indicated that requests to produce a document that simply listed all CLSI VAST breakpoints was denied by CLSI on the grounds that it duplicates content from existing documents. Mr. Bowden suggested producing a product that is only a list of the CLSI-evaluated dosages for each antibiotic and host organism, like the table to be included in VET09, so that clinicians could refer to this when looking at AST reports. He noted as precedent that CLSI has published a standalone intrinsic resistance tables product which is copied out of M100. Dr. Papich stated that veterinarians will choose their dosage from a textbook or formulary and that CLSI does not want to publish a formulary.</p> <p>Further discussions occurred on the topics of the discrepancy between VET08 breakpoints being applied to all <i>Enterobacteriaceae</i> while others are applied only to <i>E. coli</i>, the extent to which jurisdictional differences should be addressed within the documents, and discrepancies in VET09 recommendations vs. VET08 standards.</p> <p>The CVM WG had the following recommendations:</p> <ul style="list-style-type: none"> • Short-term - improve footnote accuracy in VET08 Table 1, and add dosage regimens to all veterinary breakpoints in Table 2 • Long-term - identification by the VAST Subcommittee of ways by which to address all issues brought forward by the FDA CVM WG, and for the VAST Subcommittee to encourage laboratories to provide comments on AST reports that will aid practitioners <p>Additionally, CVM encouraged CLSI to consider allowing countries to contribute to a continually updated table on the CLSI website describing what constitutes on-label and off-label use in different regions. Dr. Martinez showed a mock-up of this table with boxes that may be checked to designate whether breakpoints refer to an: extralabel dose, extralabel indication, or are prohibited from use. Dr. Shryock thought this would not be possible as it expects international users to precisely follow CLSI methods, which they often do not. Dr. Papich asked if there is the opportunity for FDA CVM to review several 40-50-year-old labels and assess the possibility for changes. Dr. Martinez acknowledged that there are many outdated labels but suggested that there often is insufficient new data to enable updating of labels.</p> <p>Dr. Lubbers proposed that a VAST WG be formed to look into what the FDA CVM WG has done and what can be addressed through rationale documents, VET08 and VET09 updates, and whether any remaining gaps are a priority for CLSI to address (Action Item). Dr. Hunter was identified to be the chair of this as-of-yet unnamed WG and a call for volunteers will be sent out (previous Action Item). No vote was necessary but there was strong support for this effort from the voting members, with no objections. The subcommittee thanked the FDA CVM for their efforts and for bringing the issues to the subcommittee for further consideration.</p>
12.	<p>Education WG Report</p> <p>Dr. Diaz-Campos provided an update on recent activities. A review paper offering advice to researchers and reviewers is currently in review for publication as a peer-reviewed journal article. The idea behind this is to orient researchers in how to follow CLSI methods when designing studies, and to help reviewers in the assessment of whether submitted papers adhere to CLSI methods.</p> <p>Additionally, the Education WG is investigating ways in which to perform more outreach through promotion of VAST when attending international conferences and collaboration with other</p>

	<p>organizations. She highlighted Dr. Fajt's and Dr. Lubber's roles as invited speakers at the upcoming AAVLD conference. As an additional method for outreach, Dr. Diaz-Campos announced a plan to develop a VAST Newsletter like the AST Newsletter as a tool to reach out to laboratories (Action Item). Identified topics include case scenarios, use of surrogate or confirmatory tests, frequently asked questions, QC issues, and promotion of other VAST documents. Guidance on therapy will not be a purpose of the newsletter. Dr. Lubbers commented that a slide deck is available on CLSI Exchange which may be used for outreach presentations by members representing VAST. Dr. Martinez suggested short videos posted to YouTube could be another form of outreach that would enable self-study.</p>
13.	<p>WG on Editorial/VAST Breakpoint Tables (VET08)</p> <p>Dr. Miller gave an update to suggest that an effort be made to include dosages for all breakpoints in VET08. He acknowledged that the need for this was already largely addressed by the proposals of the CVM WG that had immediately preceded his update. Additionally, he pointed out that if all doses from VET09 were applied to VET08, only three gaps would remain. Discussion on these 3 identified gaps led to the conclusion that all 3 issues may have already been resolved or were misinterpretations. The subcommittee was in agreement with Dr. Miller's suggestions and supported the idea of including dosage regimens for all veterinary breakpoints. No vote was necessary.</p>
14.	<p>GWG Report</p> <p>Dr. Papich updated the subcommittee on the progress made by the GWG. There are now 182 VAST-approved veterinary species-specific drug-bug combinations, 37 of which have been added since 2015, with 30 of that subset having been developed by the GWG. The VET08 now includes a list of the dates when breakpoints were added to the tables and by which group they were developed (GWG or sponsor's name), both new to the current issues (in VET08, front matter) and all veterinary specific breakpoints (in VET08, Appendix E).</p> <p>Dr. Papich listed several antibiotics for consideration as future agents for which the GWG might attempt to develop breakpoints. Chloramphenicol, trimethoprim-sulfamethoxazole, rifampin, cefotaxime (noted that it's no longer available), tylosin for cattle and swine, and amoxicillin and amoxicillin-clavulanate urine breakpoints for cats were identified as possible agents to examine. He noted that a presentation on carbapenems is planned for the January 2020 meeting. Other suggestions from attendees included azithromycin, ceftriaxone breakpoints for dogs, levofloxacin breakpoints for cats, and rifampin breakpoints to be applied to isolates of <i>Rhodococcus equi</i>.</p> <p>A discussion occurred based upon Action Item #8 from the January 2019 meeting regarding whether <i>E. coli</i> breakpoints should all be changed to <i>Enterobacteriaceae</i> breakpoints. Dr. Papich showed EUCAST amikacin ECOFFs for <i>E. coli</i>, <i>Klebsiella pneumoniae</i>, and <i>Proteus mirabilis</i> which demonstrate identical COwt of 8 µg/ml. Much discussion followed regarding whether to leave breakpoints as <i>E. coli</i> only, change to <i>Enterobacteriaceae</i>, change to <i>E. coli</i> + <i>K. pneumoniae</i> + <i>P. mirabilis</i>, or change to <i>Enterobacteriaceae</i> with a comment designating which limited number of species are intended when the term <i>Enterobacteriaceae</i> is used. Mr. Bowden commented that when veterinary breakpoints are listed only for <i>E. coli</i> in VET08, commercial AST devices default to using human breakpoints for species of <i>Enterobacteriaceae</i> other than <i>E. coli</i>. In light of this, Dr. Martinez moved to change all veterinary <i>E. coli</i> breakpoints to be <i>Enterobacteriaceae</i> breakpoints, which was seconded by Dr. Langston. Dr. Sinnott-Stutzman made an amendment that, rather than changing all to <i>Enterobacteriaceae</i>, a General Comment be added to the beginning of Table 2A that it is preferable to extrapolate a veterinary-specific <i>E. coli</i> breakpoint to other species of <i>Enterobacteriaceae</i> rather than use a human <i>Enterobacteriaceae</i> breakpoint. Dr. Diaz-Campos seconded the amended motion. After more discussion, a straw vote of members was taken with results 4 (approve) and 3 (reject) on the amended motion. Drs. Langston and Martinez objected because they believed it did not do enough to protect patients from human breakpoints being applied. Dr. Sinnott-Stutzman objected because she wished to make a new revised motion, after this motion having failed to pass.</p> <p>Dr. Sinnott-Stutzman made a motion to change all GWG <i>E. coli</i> breakpoints to <i>Enterobacteriaceae</i> breakpoints and add a General Comment at the beginning of Table 2A to indicate that for most <i>Enterobacteriaceae</i> breakpoints, the breakpoints were established using <i>E. coli</i> MIC data, but ECOFFs support application of the breakpoints to other species of <i>Enterobacteriaceae</i>. Dr. Langston seconded</p>

	<p>the motion. A vote taken of members present with results 6(approve)-1(reject) but before any further discussion, Dr. Hunter suggested it be tabled until the January 2020 meeting so that the VET08 WG could discuss it further and bring back a proposal in January (Action Item). Dr. Lubbers asked for the subcommittee to disregard the vote and to table discussion so that Dr. Hunter's suggestion could be carried out and the issue revisited in January.</p>
	<p>Adjournment</p> <p>The meeting was suspended at 5:30 PM.</p>
15 June 2019	
	<p>Call to order</p> <p>Dr. Lubbers called the meeting to order at 8:05 AM CDT.</p>
15.	<p>WG on Editorial/VAST Breakpoint Tables (VET08)</p> <p>Table 1</p> <p>Dr. Sinnott-Stutzman provided a summary of the proposals developed by the Subgroup on Table 1. She outlined current definitions for the 4 current Test/Report Groups listed in VET08 (Group A, B, C, D) and presented the working group's proposal to adjust definitions and add a 5th Test/Report Group. The proposal was for Group A to designate veterinary-specific breakpoints, Group B to contain veterinary-specific breakpoints for agents considered "drugs of last resort," Group C to designate "human and dog-only breakpoints," Group D to be used for agents having QC ranges but lacking clinical breakpoints, and Group E for agents with human breakpoints that may be tested and reported if an isolate is resistant to agents in Groups A, B, and C. This Group E description aligns with the description for Group D agents in VET08_Ed4. A mock-up of the proposal for a revised Table 1 was displayed, including changes resulting from the subgroup meeting on June 14th. After some discussion among members regarding confusion over application of "dog-only" in the proposed Group C definition, it was agreed to remove the "dog-only" breakpoints and description from Group C. Dr. Lubbers suggested Group C be used to denote "human or species non-specific breakpoints." Drs. Fajt and Martinez proposed that it would be best to split columns for dogs and cats, acknowledging that the list for cats in Group A is short. A straw vote showed 8-0 support for splitting dogs and cats into separate columns in Table 1 (Action Item).</p> <p>The following information was sent to the 4 members absent from the meeting on 15 June 2019 to review the spreadsheet showing the proposed plan for VET08 Table 1 Test/Report Groups posted in CLSI Exchange in the June 2019 VAST Meeting Updated Agenda and Presentations folder (available at the following link when you are logged in to your CLSI Exchange account: https://www.clsiexchange.org/viewdocument/2019-jun-vast-sc-meeting-vet08-wg?CommunityKey=cdba2b98-8e43-499e-bf15-39d212841f04&tab=librarydocuments), and review the motions made, notes on discussions, preliminary voting results, and submit their vote by 21 June 2019.</p> <p>Currently there are 4 Test/Report Groups listed in VET08 Table 1: A, B, C, and D. Dr. Sinnott-Stutzman, Chairholder of the VET08 WG Subgroup on Table 1 Revisions, presented the proposed changes to the definitions and applications of the Test/Report Group categories as follows:</p> <p>Group A - Veterinary specific breakpoints (BP)</p> <p>Group B - Veterinary-specific BPs that are considered drugs of last resort, which is proposed to include ceftazidime, piperacillin-tazobactam, and potentially levofloxacin</p> <p>Group C - Human and dog-only breakpoints (Note: "dog" later removed)</p> <p>Group D - Agents for which QC ranges exist but not clinical BPs</p> <p>Group E - Formerly Group D drugs, which are drugs that may be tested and reported if an isolate is resistant to drugs in A, B, C. BPs are human BPs.</p> <p>The following comments on proposed changes to VET08, Table 1 were made by meeting attendees:</p> <ul style="list-style-type: none"> • Dr. Martinez sought clarification for what would happen if an isolate IS from a dog. The Subcommittee agreed to remove the mention of dogs from the Group C description. Dr. Lubbers suggested that Group C be listed as "human or species-non-specific BPs".

- Dr. Fajt mentioned that VET09 specifies which BPs makes the most sense and which BPs shouldn't be used without consultation. Drs. Fajt and Martinez agreed that it would be best to split the columns for dogs and cats. The Subcommittee generally agreed. Dr. Martinez asked whether CLSI volunteers teach veterinary students at any point, and the consensus was no, that does not happen. Dr. Sinnott-Stutzman noted that very few drugs will be listed in column for cats. The Subcommittee agreed that this is acceptable and accurate.
- Dr. Lubbers asked for a straw vote to approve splitting antimicrobial agents with species-specific BPs for dogs and cats into separate columns, which the Subcommittee approved as shown below.

In favor: 8; abstained: 0; against: 0; absent: 4

The decision was passed, however, a 5-day post-meeting electronic vote was sent to the 4 members absent from the 15 June 2019 meeting), who were asked to review and provide their vote electronically between 17-21 June 2019 (see Attachment 2 for final straw vote details).

Tables 2A-2J

Following this, Mr. Sweeney led a discussion on the reformatting of VET08 Tables 2A-2J first proposed at the January 2019 meeting. At that time, it was agreed that the working group would investigate Table 2 reorganization to sort each table first by animal species, and then alphabetically by antimicrobial agent. Dr. Lubbers noted that this was an attempt to make the tables easier to use. Beta testing of this format by users in at least 5 laboratories showed strong support for the reformatting. Dr. Diaz-Campos commented that there is often a long delay before commercial AST device manufacturers update their software following CLSI breakpoint changes, and that the proposed reformatting will make it much easier for laboratories to locate breakpoints when making manual changes to reports. Discussion followed about retaining the Test/Report Group for antibiotics listed in grey-shaded boxes. Dr. Yan questioned whether the Groups are for use by clinicians or labs and Dr. Lubbers confirmed they are intended only for labs to use when determining what to test and report to clinicians. Dr. Lubbers asked for a straw vote to accept the proposed formatting changes, noting that VET08, including Tables 2A-2J are subject to future official vote but a straw vote was taken for preapproval to proceed with the revision, with the following results:

In favor: 8; abstained: 0; against: 0; absent: 4

The decision was passed, however, a 5-day post-meeting electronic vote was sent to the 4 members absent from the 15 June 2019 meeting), who were asked to review and provide their vote electronically between 17-21 June 2019 (see Attachment 2 for final straw vote details). The VET08 Tables 2A-2J will be reorganized first by animal species, and then by agent in alphabetical order without grouping by antimicrobial agent class (**Action Item**).

Dr. Langston asked if interactive tables could be developed to allow sorting by a variety of different criteria. Dr. Lubbers responded that it has been suggested to CLSI but that the proposals have thus far been rejected. Ms. Moon clarified that a searchable online format is available using CLSI Eclipse, but resources do not currently exist to allow for development of a sortable version of a particular document. Dr. Lubbers created an Action Item for VAST to raise the issue to CLSI for allowing development of an interactive sortable document (**Action Item**).

It was recognized that the formatting which had just been approved would create issues with inclusion of the grey-shaded (human) breakpoints in the tables as, in some cases, their comments rely on formatting by antimicrobial class or other unique groupings. Dr. Diaz-Campos (1st) and Dr. Sinnott-Stutzman (2nd) moved that an exception be made to retain the formatting as it appears in M100 Table 2C specifically for the testing of penicillin and cefoxitin or oxacillin to detect resistance in staphylococci, and that this portion of the table be placed at the very beginning of Table 2C in VET08. Dr. Hayes pointed out that high-level aminoglycoside resistance (HLAR) testing is listed 1st for *Enterococcus* but is referred to Table 7. He questioned whether it would be best to do the same for staphylococcal penicillin and cefoxitin/oxacillin testing. Dr. Diaz-Campos believed the situations differ

as the testing of penicillin and ceftiofur/oxacillin affect results for all other beta-lactam agents routinely reported for staphylococci, and therefore all staphylococcal AST reports, while HLAR results for enterococci only impact results for aminoglycosides, which are less frequently used for treatment. Discussion then followed on whether to split Table 2C into Tables 2C-1 and 2C-2 so that penicillin and oxacillin testing would exist in a different space from the rest of the agents with clinical breakpoints. Dr. Diaz-Campos withdrew her motion and will work to create mock-ups with several examples of how Table 2C might be revised, sending them out to the VET08 WG for further discussion.

Mr. Sweeney then led the subcommittee in addressing and providing resolutions to particular VET08 consensus comments which were included in the agenda book's meeting materials.

Comment 7

#	Commenter's Name and Affiliation	Comment Type (ie, general [ge], editorial [ed], technical [te])	Page Number	Chapter Number (eg, 3.1) Paragraph/ Figure/ Table/Note (eg, Table 1)	Comment (justification for change provided by the commenter)	Proposed Change (provided by the commenter)	Resolution (to be completed by committee and/or committee leadership)
7.					From Jan 2018 VET08 Outstanding Issue #23 resolution: Consider during next revision adding <i>Staphylococcus aureus</i> ATCC 29213 QC (in LHB) for antimicrobial agents with veterinary-specific BPs for organisms that require lysed horse blood (LHB) media (eg, <i>Streptococcus</i> spp.) for AST when using the reference method (comment to distinguish between reference method and commercial methods).		This would require laboratories to do QC testing to see if <i>S. aureus</i> 29213 QC tested the same in LHB as in MHB (Tier 2 QC study?) Action Item: Ask Robert for a list of antimicrobial agents that don't have QC ranges in lysed horse blood (LHB). 25 Jan 2019: The VAST SC discussed this issue and rather than proposing a full Tier 2 QC study, they suggested asking a few laboratories to do some preliminary testing and share the results with the VET08 WG before a VAST SC future discussion (VET08 WG Action Item).

Dr. Miller suggested that the next VET08 revision include a comment for those agents that have no QC ranges when testing is performed using CAMHB + LHB. The subcommittee opted to resolve the issue by noting that it was reviewed, but due to the Tier 2 QC study that would be required, no action will be taken.

Comment 9

9.	M. Sweeney, Zoetis	ed	Page #: 7, 20	VII. Warning and Table 2A	This section may need to be revised based on Brian's question on similar wording in VET01, esp for the aminoglycosides and Salmonella	Re-word or delete based on feedback (from VET08 SC Vote comment #62, change not made but saved in VET08 Consensus Comments)	Reviewed previous (email) discussion that there is no reference to the origin of this comment but it probably true because aminoglycosides don't reach intracellular pathogens. It comes from M100 and long institutional history. The potential issue is that this is a presumption in a standard. Keep this in mind for future editions (Action Item).
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It was agreed by members of the subcommittee to retain the comment as currently printed in VET08. Clinical evidence for the comment is lacking, but Dr. Langston recalled finding a report describing lower efficacy of aminoglycosides when compared to other classes of active antimicrobial agents in humans with Salmonella infections. Dr. Lubbers noted that he and several members made attempts to find source material for the comment but that much of it is historical and documentation is hard to come by. The subcommittee agreed to retain the comment as there is no evidence that it is incorrect.

Comment 13

13.	Robert Bowden, UF Veterinary Diagnostic Laboratories	te	Page #: 25	Table 2A	<p>"Laboratories should only<u>exercise caution in</u> reporting results for agents <u>not</u> listed in Table 2 specific to the organism being tested; it is <u>generally</u> not appropriate to apply disk diffusion or MIC breakpoints borrowed from a table where the organism is not listed."<u> For more information on extrapolating breakpoints, see CLSI document VET09.</u>"</p> <p>The wording seems too restrictive given that there are still many gaps in the tables of species-specific break-points. As this document is a standard, this statement would make laboratories out of compliance if they report, for example, Amikacin 8 Intermediate for an MDR <i>Klebsiella pneumoniae</i> from a dog, ampicillin results for <i>Staphylococcus schleiferi</i> from a dog, any fluoroquinolones for <i>Pseudomonas aeruginosa</i> from a dog, etc. This will create a direct conflict for VET09 which seeks to offer advice on how to approach some of these gaps.</p>	Needs consultation with other VET08 WG members. (from VET08 SC Vote comment #80, change not made but saved in VET08 Consensus Comments)	<p>25 Jan 2019: VET08 WG Action Item: VET08 WG will consider and propose revision of the comment to make the it less prescriptive and/or restrictive (see edited text).</p> <p>R. Bowden suggests removing this paragraph. V. Sinnott suggested adding a caution and cross-referencing to VET09 for more information. D. Diaz-Campos, B. Lubbers in favor of keeping the comment</p>
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Mr. Bowden clarified that he agreed with the comment as revised (edits shown in red).

Vote: 9-0 to accept the revised comment as listed in the agenda.

Comment 20

20.	CLSI staff	ed		Tables 2A through 2J	<p>Breakpoint comments have similar information but slightly different wording.</p> <p>(Editor's comment in Overview of Changes): For example Table 2A itself uses "dosage regimen." I noticed similar discrepancies in other bullets (eg, the bullet uses "dosing regimen" but the table itself uses "dose"). Should these discrepancies be addressed now, or just held until the next revision? You mentioned in a Table 2C comment response that a note has already been added to the consensus comments regarding consistent wording throughout breakpoint comments, so maybe this should just be addressed as part of that review. We haven't always been strict about "dose" vs "dosage," but we've recently started trying to enforce the AMA style definitions (ie, "dose" is used for a single dose, and "dosage" is used in the context of "dosage regimen").</p>	Review all breakpoint comments for consistency where the meaning is the same.	<p>7 May 2019: Action Item: Review comment text during "one voice editing" (M. Sweeney) and when reviewing Overview of Changes (M. Sweeney, M. Traczewski, L. Moon).</p>
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Mr. Sweeney volunteered to take this on as an action item (Action Item).

Comment 22

22.	CLSI staff	ed		Table 6	Some antimicrobial agents missing (eg, marbofloxacin), some solvents missing information (eg, concentration of NaOH not listed for Difloxacin, DMSO)	Review for completeness	<p>7 May 2019: Action Item: Review Table 6 for completeness compared to M100 Table (volunteer?)</p>
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Mr. Sweeney volunteered to compare Table 6 to M100 and also to compare Table 6 with Tables 2A-2J to ensure completeness (Action Item).

Comment 23

23.	CLSI staff	ed/te		Table 2D	Should breakpoints for " <i>Streptococcus</i> spp." have any additional clarification (eg, M100 Tables 2G, 2H-1, and 2H-2), such as which	Review and update as needed	7 May 2019: Action Item: Review Table 2D for additional comments and/or clarifications in M100 Tables 2G, 2H-1, and 2H-2 (volunteer?).
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Mr. Sweeney volunteered to take this on as an action item (**Action Item**).

Comment 24

24.	CLSI staff	ed		Table 4D	In the second-to-last and third-to-last rows, should the wording in the "Observation" column be revised to match similar wording in the last three rows of Table 5F? In Table 4D, the QC strain itself is identified as out of range. In Table 5F, it is the results from the strains that are out of range.	Review as to whether AST results noted for imipenem broth dilution QC also occur with imipenem disk diffusion QC. In Table 4D, revise wording to identify the QC strain results as out of range.	7 May 2019: Action Item: Review VET08 imipenem QC in Tables 4 and 5 compared with M100 QC Tables 4 and 5 (volunteer?).
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Mr. Sweeney volunteered to take this on as an action item (**Action Item**).

Final table comments 1, 2, 3:

Comment 1

#	Commenter's Name and Affiliation	Comment Type (ie, general [ge], editorial [ed], technical [te])	Page Number in VET08S, 4th ed.	Chapter Number (eg, 3.1) Paragraph/ Figure/Table/ Note (eg, Table 1)	Comment (justification for change provided by the commenter)	Proposed Change (provided by the commenter)	Resolution (to be completed by committee and/or committee leadership)
1.	M. Sweeney, Zoetis	ge	14	Table 1, Group A	Ampicillin is listed twice: one for "dogs only" and once for "cats only" in bold (new in previous version VET01-S3, 2015)	List "Ampicillin" without listing dogs or cats since it applies to both (and is no longer new for cats)	7 May 2019: Action Item: Forward to Table 1 Subgroup for consideration during revision of VET08, Table 1 (L. Moon).

This issue was found to have already been addressed by the Subgroup on Table 1.

Comment 2

2.	M. Sweeney, Zoetis	ge	144	Appendix B, Table B2	Remove "R" for ciprofloxacin from <i>Burkholderia cepacia</i> complex.	Remove "R" for ciprofloxacin from <i>Burkholderia cepacia</i> complex (and check all entries in M100, Appendix B)	7 May 2019: Action Item: Review VET08 imipenem QC in Tables 4 and 5 compared with M100 QC Tables 4 and 5 (volunteer?). (and M100 Ed30 in January 2020).
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Mr. Sweeney volunteered to take this on as an action item (**Action Item**).

Comment 3

3.	L. Moon	Ge	(several)	(several)	Make sure everyone received notification of VET08 corrections	VET08 corrections are posted on the CLSI website at https://clsi.org/media/2950/vet08ed4_correction_notice_20190110_web.pdf	Action Item: Send discussion post with link to VAST SC (L. Moon).
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This issue was found to have already been addressed.

Ms. Moon encouraged attendees to make sure messages from the CLSI domain are not directed to spam folders.

16. WG on Veterinary Fastidious Medium (VFM)

Mr. Donald Bade presented testing results, data analysis, and proposals resulting from the study examining use of Mueller-Hinton-Fastidious medium + yeast extract (MHF-Y) broth as a replacement for VFM broth. The goal of the presentation was to provide evidence that would support a vote to replace VFM with MHF-Y in the next editions of VET01 and VET08.

VFM was used as a QC comparator and 10 replicates each of *Actinobacillus pleuropneumoniae* ATCC 27090 and *Histophilus somni* ATCC 700025 were tested in CO₂ at 7 laboratories. One lot of VFM was tested. For MHF-Y, 10 replicates each of *A. pleuropneumoniae* ATCC 27090 and *H. somni* ATCC 700025 were incubated both aerobically and in CO₂ at the same 7 laboratories. Three lots of MHF-Y were used for testing. One-hundred clinical isolates each of *A. pleuropneumoniae* and *H. somni* were also tested,

with testing split among 3 laboratories. One lot of MHF-Y was used to test clinical isolates. Mr. Scott Killian clarified that all lots were produced by Thermo Fisher within a 2-month time period. Due to the start date of the study, some lots were as old as 3-4 months when testing was conducted, which was noted to be a good thing as it is more reflective of usage in clinical laboratories. Clinical isolates were not tested in VFM as this was outside the scope of the study. 19 antimicrobial agents having approved VAST breakpoints and/or QC ranges for VFM were tested (see below for table).

For data analysis, a random number was assigned to each laboratory in order to blind the study. Discrepant data was corrected or excluded if corrections were not possible. Isolates were excluded if they grew in only 1 of the 2 types of media. Initial impressions of MHF-Y prior to data analysis were highly favorable. Most of the laboratories observed light or no growth of *H. somni* ATCC 700025 when tested in VFM. The darker color of MHF-Y made reading difficult in some cases, mostly for *H. somni*, and it is suspected that autoreaders may not work. As autoreaders also perform poorly with VFM, a change to the use of MHF-Y is not anticipated to negatively impact laboratory workflow. An additional difficulty in interpretation of results was due to observation of two types of growth regardless of media used: typical "button" growth, and diffuse growth which folds over upon itself within the well. The consensus of testing laboratories was that results from MHF-Y are easier to read than VFM results. Isolates of *H. somni* grew much better with CO₂ than aerobically, and for that reason, only results from growth with CO₂ were proposed by the working group for inclusion in VET08.

Results and analyses were shown for all 19 antimicrobial agents, requiring no changes or only minor changes from current VFM QC ranges. A target agreement of 95% was sought between VFM and MHF-Y, requiring several organisms to have small adjustments made to their QC Ranges. In general, MHF-Y yielded MICs that were slightly higher than with VFM, which generated some discussion. Dr. Miller asked whether increased MICs with MHF-Y as compared to VFM will falsely suggest MIC creep. The voting members were in general agreement that the slight increase was within acceptable limits of MIC variability and will not cause a problem. Furthermore, Dr. Shryock stated that, in recent years, Supplement C used for VFM has not been properly supporting growth, such that VFM MIC results in the present study may be lower than historical MICs, and MHF-Y MICs may be more representative of historical VFM MICs for *H. somni*. Mr. Bade pointed to the cefquinome slide to show that the VFM QC results in the study were now left-shifted within the VFM QC range, adding evidence to Dr. Shryock's suggestion (see below). This same trend was demonstrated for multiple agents.

Individual agents which generated more extensive discussion are detailed as follows:

- Cefquinome - for *A. pleuropneumoniae*, discussion took place regarding use of a 3-dilution or 4-dilution QC range. Dr. Ian Morrissey (1st) and Dr. Martinez (2nd) proposed keeping the 4-dilution range as proposed by the VFM WG. Vote: 8-0 to retain a 4-dilution range.
- Tetracycline - for *A. pleuropneumoniae*, a 4-dilution range was previously recommended for VFM QC but a 3-dilution range was recommended by the working group for use with MHF-Y. For *H. somni*, discussion was focused on the QC range's nearly bimodal distribution. Dr. Morrissey (1st) and Mr. Sweeney (2nd) moved to change the tetracycline QC range for *H. somni* from 0.5-2 ug/ml to 0.25-2 ug/ml, with the members voting 8(accept)-0(reject) to accept this 4-dilution range.
- Trimethoprim/Sulfamethoxazole - for *A. pleuropneumoniae*, one lab was consistently out of range. RangeFinder identified their values as outliers and this laboratory's results were excluded from analysis of trimethoprim/sulfamethoxazole. Dr. Miller asked that consideration be given to including a note that will provide clarification about the difficulty in reading wells for this bug-drug combination. Mr. Bade responded that the cause for the outlier results was not apparent as trailing endpoints, a frequently encountered problem when testing this agent, did not seem to be an issue for this bug-drug combination. He also questioned whether the agent is used clinically to treat *A. pleuropneumoniae* infections.

No changes to interpretive criteria were recommended as only minor QC range adjustments were required. The VFM WG proposed to the Subcommittee on VAST: that MHF-Y QC ranges be adopted as proposed and revised during the meeting (see below, version with finalized QC ranges needs to replace

the version currently shown), that all references to VFM in future VET documents be changed to MHF-Y, that the VFM recipe in VET01 Appendix A3.5 be removed and replaced with the recipe for MHF-Y, and that a step action table for making MHF-Y be added (see below).

Table 6. Acceptable Quality Control Ranges for *Histophilus somni* and *Actinobacillus pleuropneumoniae*¹

Antimicrobial Agent	Disk Content	Zone Diameter (mm)		MIC (µg/mL)	
		<i>Histophilus somni</i> ATCC® 700025	<i>Actinobacillus pleuropneumoniae</i> ATCC® 27090	<i>Histophilus somni</i> ATCC® 700025	<i>Actinobacillus pleuropneumoniae</i> ATCC® 27090
Ampicillin	—	—	—	—	0.06–0.25
Cefovecin	30 µg	—	34–43 ^b	0.004–0.016	0.008–0.06
Cefquinome	30 µg	33–44	31–41	0.002–0.008	0.004–0.03
Ceftiofur	30 µg	36–46	34–42	0.001–0.004	0.004–0.03
Danofloxacin	5 µg	26–36	27–36	0.03–0.25	0.03–0.12
Enrofloxacin	5 µg	32–38	31–38	0.016–0.12	0.016–0.06
Florfenicol	30 µg	34–44	31–40	0.12–0.5	0.25–1
Gamithromycin	15 µg	18–29	14–19	0.5–2	2–8
Gentamicin	10 µg	14–22	15–19	4–16	8–32
Marbofloxacin	5 µg	30–41	30–40	0.016–0.12	0.016–0.06
Penicillin	10 units	35–44	29–36	0.016–0.06	0.12–1
Pradofloxacin	5 µg	—	32–41	0.004–0.016	0.008–0.03
Spectinomycin	—	—	—	16–64	32–128
Tetracycline	30 µg	27–33	23–30	0.5–2	0.5–2
Tiamulin	30 µg	—	12–19	—	8–32
Tildipirosin	60 µg	15–24	15–23	2–16	2–16
Tilmicosin	15 µg	8–16	8–15	4–16	8–32
Trimethoprim-sulfamethoxazole (1/19)	1.25/23.75 µg	26–32	28–32	0.06/1.14–0.25/4.75	0.06/1.14–0.25/4.75
Tulathromycin	30 µg	16–26	8–18 ^c	4–32	16–128

The steps for preparing 1 L MHF-Y for broth microdilution testing of *H. somni* and *A. pleuropneumoniae* are listed below.

Step	Action	Comments
1.	Prepare the MHB according to the manufacturer's instructions (see Appendix A3.1).	MHB (22.0 g) per L: <ul style="list-style-type: none"> 3.0 g beef extract (from 300 g beef infusion) 17.5 g acid hydrolysis of casein 1.5 g starch Unless the MHB has the correct concentrations of divalent cations (Ca ⁺⁺ and Mg ⁺⁺), add appropriate salts to provide 20 to 25 mg/L calcium and 10 to 12.5 mg/L magnesium (see A2.1).
2.	Mix the MHB and yeast extract (water-soluble portion of autolyzed yeast containing vitamin B complex) with 95.5% of total water volume and steam sterilize.	20.0 g yeast extract
3.	Cool to 8°C and add the LHB Add β-NAD (filter sterilized 10 mg/mL in purified water)	100mL or 50mL LHB (see A2.2 for preparation of 50% water lysed horse blood, or use 50mL if use horse blood lysed by freeze/thaw without water dilution in water) 2.0mL β-NAD

Abbreviations: LHB, lysed horse blood; MHB, Mueller-Hinton broth; pH, negative logarithm of hydrogen ion concentration; β-NAD, beta-nicotinamide adenine dinucleotide

The original VFM WG presentation slides in the June 2019 VAST Meeting Materials were updated and posted in CLSI Exchange in the June 2019 VAST Meeting Updated Agenda and Presentations folder (available at <https://www.clsiexchange.org/viewdocument/2019-jun-vast-sc-meeting-gwg-bp-p?CommunityKey=cdba2b98-8e43-499e-bf15-39d212841f04&tab=librarydocuments>) when logged in to your CLSI Exchange account). The following changes to specific QC ranges were voted on and although the motions all passed, were also sent to the 4 members who were unable to attend the meeting on 15 June 2019 to submit their vote by 21 June 2019 (see Attachment 2 for the final voting results):

- Mr. Bade's presentation included cefquinome QC ranges for *Actinobacillus pleuropneumoniae* ATCC® 27090 in MHF-Y in 98.6% agreement with VFM (see updated presentation slides #20-21), which is a 4-dilution range. Ms. Maria Traczewski suggested that the proposed 4-dilution range for *A. pleuropneumoniae* ATCC® 27090 should be a 3-dilution range since it isn't bimodal. RangeFinder showed a 4-dilution range but doesn't always agree with Gavin and a 3-dilution range is normal if

unimodal, 4-dilution range if bimodal. However, this would drop agreement with VFM from 98.6% to 94%.

A motion was made by Dr. Morrissey (1st) and Dr. Martinez (2nd) to stay with the proposed 4-dilution QC range for *A. pleuropneumoniae* ATCC® 27090 for cefquinome. There was no further discussion and the Subcommittee approved the motion as shown below.

In favor: 8; abstained: 0; against: 0; absent: 4 (see Attachment 2 for final voting results)

- During Mr. Bade's presentation of tetracycline QC ranges for *Histophilus somni* ATCC® 700025 (see updated presentation slides #77-79), it was noted that the *H. somni* ATCC® 700025 range narrowed but shifted higher. There was discussion about the minimal inhibitory concentration (MIC) distribution being close to bimodal and that it may be better to have a 4-dilution range.

A motion was made by Dr. Morrissey (1st) and Mr. Michael Sweeney (2nd) to change the QC range for *H. somni* ATCC® 700025 for tetracycline from 0.5-2 µg/mL to 0.25-2 µg/mL. There was no further discussion and the Subcommittee approved the motion as shown below.

In favor: 8; abstained: 0; against: 0; absent: 4 (see Attachment 2 for final voting results)

- Discussion of results for all other proposed QC ranges did not result in any proposed changes. A motion was made by Dr. Thomas Shryock (1st) and Dr. Martinez (2nd) to approve the modifications proposed for the next revision of VET01 (updated presentation slide #107), the proposed modifications to VET08, Table 5B (updated presentation slides #108-109), noting the modification of the QC range for tetracycline for *H. somni* ATCC® 700025 that was revised from 0.5-2 µg/mL to 0.25-2 µg/mL following VAST Subcommittee discussion, which the Subcommittee approved the motion as shown below.

In favor: 8; abstained: 0; against: 0; absent: 4 (see Attachment 2 for final voting results)

The decision was passed, however, a 5-day post-meeting electronic vote was sent to the 4 members absent from the 15 June 2019 meeting), who were asked to review and provide their vote electronically between 17-21 June 2019 (see Attachment 2 for final voting details). The proposed changes for including MHF-Y media preparation and updated testing conditions for *A. pleuropneumoniae* and *H. somni* will be made in the VET01 (**Action Item**) and changes in testing conditions and QC ranges for *A. pleuropneumoniae* and *H. somni* in MHF-Y will be made in VET08 (**Action Item**).

Additionally, they proposed that a Supplement Update be published prior to the next editions of VET01 and VET08 in order to offer earlier direction to laboratories. Given the poor performance of VFM and the current extended backorder on Supplement C, it was stressed that action needs to be taken as soon as possible. A mockup of Table 5B showed MIC QC ranges for *A. pleuropneumoniae* and *H. somni*. Dr. Miller suggested adding a comment to note the change of testing medium from VFM to MHF-Y. Dr. Shryock (1st) and Dr. Martinez (2nd) moved to accept the proposals as laid out by the working group, with the following voting results.

In favor: 8; abstained: 0; against: 0; absent: 4 (see Attachment 2 for final voting results)

Discussion continued on the topics of how best to inform laboratories of the change from VFM to MHF-Y and on the overlap of publication timelines to ensure that there would not be conflicting standards. Agreement was reached that the fastest method to send information to laboratories would occur by making the edits to the documents and communicating the changes via the existing process for "corrections" and revision memos could be sent out to all purchasers. The plan further developed to send out 2 revision memos, 1 memo to detail the media change and the revised QC ranges in VET08, and a 2nd memo to outline the methodology revisions to VET01. Dr. Shryock (1st) and Dr. Sinnott-Stutzman (2nd) moved that the Subcommittee on VAST should send out 2 revision memos as discussed,

	<p>with the following voting results:</p> <p>In favor: 8; abstained: 0; against: 0; absent: 4 (see Attachment 2 for final voting results)</p> <p>Further discussion occurred as to whether a supplement needs to be sent out in addition to the revision memos. Dr. Ian Morrissey stated that he believed a supplement would be viewed by laboratories as a more official change to the standards. Dr. Morrissey (1st) and Mr. Sweeney (2nd) moved to publish a supplement as well as revision memos. Vote: 7(approve)-1(reject) (Dr. Sinnott-Stutzman didn't see a need for a supplement if revision memos were to be sent out to all purchasers.) CLSI senior management will be consulted for the path forward (Action Item).</p> <p>In favor: 8; abstained: 0; against: 0; absent: 4 (see Attachment 2 for final voting results)</p> <p>Members considered how soon to make MHF-Y the only approved standard, recognizing that time is required for manufacturers to begin production of MHF-Y and that some laboratories may have large quantities of VFM in stock such that it would place a financial strain upon them if CLSI were to immediately instruct against the use of VFM. Dr. Morrissey proposed that wording in the revision memos and supplement recommend use of MHF-Y with a note that VAST will no longer be supporting QC for VFM. A straw vote passed 8(approve)-0(reject). Information on VFM and VFM QC ranges will not be included in future editions of VET01 (ie, VET01, 6th edition) and the VET08 (ie, VET08, 5th edition) (Action Item).</p> <p>The VAST Subcommittee thanked and applauded the VFM WG for their efforts over the past 6 years that will now enable transition to the improved MHF-Y testing medium.</p>
17.	<p>Other business</p> <p>Dr. Lubbers reminded everyone that all votes taken during the meeting will be sent out for 5-day electronic vote by members who were absent. Having no other points for discussion, Dr. Lubbers informed attendees that the next face-to-face meeting of the VAST Subcommittee is tentatively scheduled for 23-24 January 2020 in Tempe, Arizona, USA.</p>
18.	<p>Adjournment</p> <p>Dr. Lubbers thanked the VAST Subcommittee members, advisors, reviewers, and meeting guests for their time and contributions. The meeting was adjourned at 11:45 AM CDT.</p>

ACTION ITEMS June 2019			
No.	Description	Responsibility	Due Date
37.	Find a champion to work on a project proposal for developing (veterinary) breakpoint rationale documents and to look into what the FDA CVM WG has done and what can be addressed through rationale documents, VET08, and VET09 updates, and whether there any remaining gaps that are a priority for CLSI to address.	B. Lubbers M. Papich L. Moon	20 Aug 2019
38.	Post a Call for Volunteers within the VAST SC for a new Working Group (WG) on Veterinary Breakpoint Rationale.	B. Lubbers M. Papich R. Hunter L. Moon	15 Jul 2019

39.	Use template adapted from human AST breakpoint rationale documents to create example rationale documents, using information from several of the antimicrobial agents with breakpoints established by the GWG, for presentation to the subcommittee in January 2020.	M. Papich	13 Dec 2019
40.	Charge the new WG on Veterinary Breakpoint Rationale to look into what the FDA CVM WG has done and what can be addressed through rationale documents, VET08, and VET09 updates, and whether there any remaining gaps that are a priority for CLSI to address.	R. Hunter M. Papich	23 Jan 2020
41.	Revisit/revise proposal for veterinary breakpoints for staphylococcal isolates from dogs and cats for presentation in January 2020.	R. Bowden D. Diaz-Campos C. Burbick	23 Jan 2020
42.	Develop a plan to publish VAST Newsletter, like the AST Newsletter, as a tool to reach out to laboratories.	D. Diaz-Campos	23 Jan 2020
43.	Discuss and propose additional input to the VAST SC on how to handle the application of veterinary-specific breakpoints for " <i>E. coli</i> only to other <i>Enterobacteriaceae</i> (ie, rather than the default being to use human breakpoints for other <i>Enterobacteriaceae</i>).	M. Sweeney V. Sinnott-Stutzman	23 Jan 2020
44.	Update the proposed revised VET08, Table 1 to have separate columns for dogs and cats.	M. Sweeney V. Sinnott-Stutzman L. Moon	23 Jan 2020
45.	Reorganize VET08, Tables 2A-2J first by animal species, and then by agent in alphabetical order without grouping by antimicrobial agent class.	M. Sweeney L. Moon	23 Jan 2020
46.	Raise the issue to CLSI for allowing development of an interactive sortable document.	B. Lubbers D. Diaz-Campos	23 Jan 2020
47.	Review all breakpoint comments in VET08 for consistency (ie, use same wording when meaning is the same).	M. Sweeney M. Papich L. Moon	23 Jan 2020
48.	Compare the updated VET08 draft document Table 6 with Table 6 in M100 to ensure completeness.	M. Sweeney	23 Jan 2020
49.	Review VET08, Table 2D (now Table 2D) <i>Streptococcus</i> spp. for additional comments and/or clarifications in M100, Tables 2G, 2H-1, and 2H-2.	M. Sweeney	23 Jan 2020
50.	Review imipenem QC in VET08, Tables 4 and 5 and compare with M100, Tables 4 and 5 QC for consistency.	M. Sweeney	23 Jan 2020
51.	Review VET08, Appendix B (eg, remove "R" for ciprofloxacin from <i>Burkholderia cepacia</i> complex) and check all entries with M100, Appendix B.	M. Sweeney	23 Jan 2020
52.	Make the proposed changes for including MHF-Y media preparation and updated testing conditions for <i>A. pleuropneumoniae</i> and <i>H. somni</i> to VET01.	B. Lubbers M. Sweeney D. Bade L. Moon	1 Sep 2019
53.	Make the proposed changes to testing conditions and QC ranges for <i>A. pleuropneumoniae</i> and <i>H. somni</i> in MHF-Y to VET08.	B. Lubbers M. Sweeney D. Bade L. Moon	1 Sep 2019
54.	Consult CLSI senior management (VP and lead editor) for path forward for rapid communication (eg, revision memos) for addition of MHF-Y to VET01 and VET08, and/or updated supplement with new information.	B. Lubbers M. Sweeney L. Moon	1 Sep 2019

55.	Remove information on VFM and VFM QC ranges from future editions of VET01 (ie, VET01, 6th edition) and the VET08 (ie, VET08, 5th edition) because the VAST SC will no longer be supporting QC for VFM.	B. Lubbers M. Sweeney L. Moon	23 Jan 2020
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Respectfully submitted,

Robert Bowden, BS
Graduate student, Tufts University
VAST SC Committee Secretary (June 2019)

Lori Moon, MS, MT (ASCP)
Senior Project Manager, Standards
Clinical and Laboratory Standards Institute (CLSI)



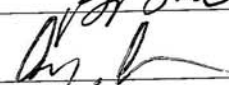


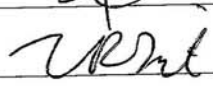


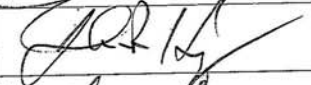
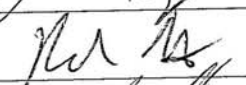
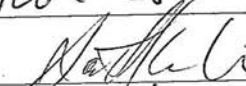

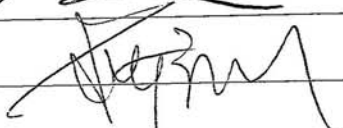
Donald Bade, BS
President, Microbial Research, Inc.
VFM WG Chairholder

Cory Langston, DVM, PhD
Professor, Mississippi State University
Education WG Recording Secretary

Maria M. Traczewski, BS, MT (ASCP)
Director, The Clinical Microbiology Institute
VET08 WG Recording Secretary

Meeting: Subcommittee on Veterinary Antimicrobial Susceptibility Testing
 Date: Friday, 14 June 2019

Attendees Sign-in Sheet

Name	Email	Signature
Akli, Djamell		
Bade, Donald J.	sne	
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biomerieux.com

Meeting: Subcommittee on Veterinary Antimicrobial Susceptibility Testing
Date: Friday, 14 June 2019

Attendees Sign-in Sheet

Name	Email	Signature
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MARTINEZ, MARILYN	Marilyn.Martinez@FDA.HHS.gov	M. Martinez
Fritzsche Tom	has in spirit only!!	

Meeting: Subcommittee on Veterinary Antimicrobial Susceptibility Testing
Date: Saturday, 15 June 2019

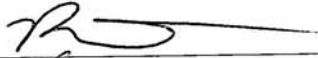
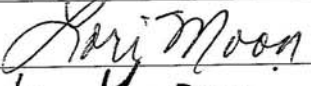
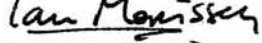
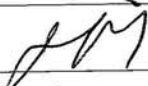
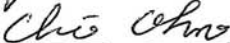
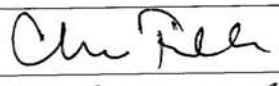

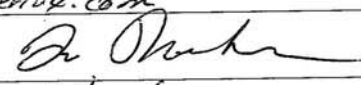

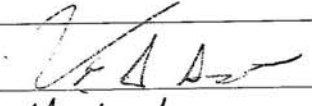

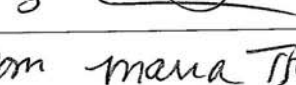
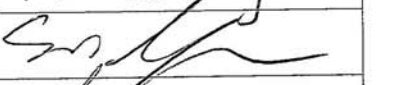


Attendees Sign-in Sheet

Name	Email	Signature
Akli, Djamell		
Bade, Donald J.	<i>Don</i> <i>same</i>	<i>Donald J. Bade</i>
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Marchand, Sakurako	sakurako.marchand	<i>Sakurako Marchand</i>

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Meeting: Subcommittee on Veterinary Antimicrobial Susceptibility Testing
Date: Saturday, 15 June 2019

Attendees Sign-in Sheet

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MARTINEZ, MARILYN	marilyn.martinez@fda.hhs.gov	

Subcommittee on VAST Voting Records from 14-15 June 2019 Meeting

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Attachment 2

Generic WG Breakpoint Presentation #2	Approve horse ampicillin breakpoints and comment(s) proposed for inclusion in VET08, Table 2A and 2B	<p>(1) The following clinical breakpoints were proposed to be added for ampicillin in horses for <i>Enterobacteriaceae</i> in Table 2A: S ($\leq 0.25 \mu\text{g/mL}$), I ($0.5 \mu\text{g/mL}$), R ($\geq 1 \mu\text{g/mL}$) and for <i>Staphylococcus aureus</i> in Table 2C: S ($\leq 0.25 \mu\text{g/mL}$), I ($0.5 \mu\text{g/mL}$), R ($\geq 1 \mu\text{g/mL}$).</p> <p>(2) Additionally, a Susceptible breakpoint is currently listed for <i>Streptococcus equi</i> subsp. <i>equi</i> and subsp. <i>zooepidemicus</i> in Table 2D: S ($\leq 0.25 \mu\text{g/mL}$) (no I or R breakpoints), and a dosage regimen comment is proposed, as shown below:</p> <p>"(X) Ampicillin breakpoints were determined from an examination of MIC distributions of isolates and PK-PD analysis of ampicillin in horses after administration at a dose of 22 mg/kg IM or IV every 12 hours."</p>	C. Langston/ M. Martinez	11 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	1 (M. Sweeney)	0	5* (on 14 June 2019: M. Fielder, X. Li, I. Morrissey, S. Simjee, D. Trott)	Yes
Comments: Negative vote due to conflict of interest.								
VET08 WG Presentation (Table 1)	Approve proposed plan for revising VET08, Table 1 (Test/Report Groups)	<p>The proposed plan is approved for revision of VET08, Table 1:</p> <ul style="list-style-type: none"> Group A - Veterinary specific breakpoints (BP) Group B - Veterinary-specific BPs that are considered drugs of last resort, which is proposed to include ceftazidime, piperacillin-tazobactam, and potentially levofloxacin Group C - Human and dog-only breakpoints (Note: "dog" later removed) Group D - Agents for which QC ranges exist but not clinical BPs Group E - Formerly Group D drugs, which are drugs that may be tested and reported if an isolate is resistant to drugs in A, B, C. BPs are human BPs. <p>NOTE: Subject to future review and approval.</p>	N/A (Straw poll)	12 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	0	0	4* (on 15 June 2019: M. Fielder, X. Li, S. Simjee, D. Trott)	Yes
Comments:								

Attachment 2

VET08 WG Presentation (Tables 2A-2J Reorganization)	Approve proposed reorganization of VET08, Tables 2A-2J, with revised Test/Report Groups (eg, A, B, C) integrated	The reorganization of VET08, Tables 2A-2J is approved as presented (and reviewed positively by beta-testing laboratories), with the inclusion of the revised Test/Report Groups (eg, A, B, C) per the revisions to VET08, Table 1. NOTE: VET08, Tables 2A-2J are subject to future review and approvals.	N/A (Straw poll)	12 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	0	0	4* (on 15 June 2019: M. Fielder, X. Li, S. Simjee, D. Trott)	Yes
Comments:								
VFM WG Presentation	Approve proposed 4-dilution QC range for <i>A. pleuropneumoniae</i> ATCC® 27090 for cefquinome.	The 4-dilution QC range for <i>A. pleuropneumoniae</i> ATCC® 27090 for cefquinome is approved as originally proposed.	I. Morrissey/ M. Martinez	12 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	0	0	4* (on 15 June 2019: M. Fielder, X. Li, S. Simjee, D. Trott)	Yes
Comments:								
VFM WG Presentation	Approve change to proposed QC range for <i>H. somni</i> ATCC® 700025 for tetracycline from 0.5-2 mg/mL to 0.25-2 mg/mL.	The revised QC range for <i>H. somni</i> ATCC® 700025 for tetracycline from 0.5-2 µg/mL to 0.25-2 µg/mL is approved.	I. Morrissey/ M. Martinez	12 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	0	0	4* (on 15 June 2019: M. Fielder, X. Li, S. Simjee, D. Trott)	Yes
Comments:								

Attachment 2

VFM WG Presentation	Approve the proposed modifications for the next revisions of VET01 and VET08.	The proposed modifications (eg, MHF-Y media as an alternative to VFM) for the next revision of VET01 (updated presentation slide #107) and the proposed modifications new QC ranges for <i>A. pleuropneumoniae</i> ATCC® 27090 and <i>H. somni</i> ATCC® 700025 be added to VET08, Table 5B (updated presentation slides #108-109), noting the modification of the QC range for tetracycline for <i>H. somni</i> ATCC® 700025 that was revised from 0.5-2 µg/mL to 0.25-2 µg/mL.	T. Shryock/ M. Martinez	12 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	0	0	4* (on 15 June 2019: M. Fielder, X. Li, S. Simjee, D. Trott)	Yes
Comments:								
VFM WG Presentation	Approve the plan to rapidly communicate the newly-approved MHF-Y media and new QC ranges for <i>A. pleuropneumoniae</i> ATCC® 27090 and <i>H. somni</i> ATCC® 700025.	The proposal to rapidly communicate the newly-approved MHF-Y media and new QC ranges for <i>A. pleuropneumoniae</i> ATCC® 27090 and <i>H. somni</i> ATCC® 700025 in a VET01 Revision Memo and VET08 Revision Memo similar to the recent M100-S29 revision memo for changes to daptomycin BPs for humans is approved (the specific text for the Memos will be drafted and sent for review by the VAST Subcommittee members and advisors, and approval by the VAST Subcommittee members before distribution).	T. Shryock/ V. Sinnott-Stutzman	12 (D. Diaz-Campos, M. Fielder, C. Langston, X. Li, S. Marchand, M. Martinez, I. Morrissey, T. Shryock, S. Simjee, V. Sinnott-Stutzman, D. Trott)	0	0	4* (on 15 June 2019: M. Fielder, X. Li, S. Simjee, D. Trott)	Yes