

system (ACC, Accelerate Diagnostics Inc., Tucson, AZ, USA) provides microbial ID and susceptibility (AST) from positive blood cultures. Our objective was to determine ACC's potential to quickly ID bacterial pathogens directly from urine.

Methods: Remnant urine samples with >100K colony forming units (CFU)/mL of gram-negative bacteria as determined by quantitative plating were obtained from the clinical lab. 1.5ml of urine was dispensed into a capsule and loaded onto the Accelerate PhenoPrep™ module. This module automatically performs wash steps to separate bacteria from human cells and other debris. The processed sample was loaded onto ACC for analysis using a custom designed assay which detects the presence of bacteria and employs an *Enterobacteriaceae* family specific FISH probe. The results were compared to standard of care ID results.

Results: There were 10 *E. coli* and 1 *C. koseri* among the eleven samples tested. Baseline concentration of samples immediately prior to testing ranged from 2.5×10^6 to 1.08×10^{10} CFU/mL (average 4.19×10^9). After specimen processing, average concentration was 2.14×10^9 CFU/mL and average recovery was 42.83%. ACC detected bacteria and identified it as *Enterobacteriaceae* in 11/11 samples (100%). Average sample prep time was 55 min. Average time to *Enterobacteriaceae* ID was 8.6 hrs. Average total time to ID, including specimen processing, was 9.5 hrs.

Table 1: Results of Direct from Urine Testing

	Bacteria Detected?	Enterobacteriaceae Detected?	Concordance with clinical lab	Average total time to ID
Total n=11	11	11	100%	9.5 hrs
<i>E.coli</i> n=10	10	10	100%	
<i>C. koseri</i> n=1	1	1	100%	

Conclusion: ACC identified *Enterobacteriaceae* directly from remnant urine specimens in an average of 9.5 hours, approximately 24 to 48 hours faster than conventional methods. ACC was able to be adapted for use in urine samples. Future directions include improving the assay to identify bacteria to the species level and adding AST testing. This shows promise in providing fast actionable UTI diagnosis, allowing for tailored antibiotic therapy.

*This information concerns a use that has not been approved or cleared by the Food and Drug Administration.

Disclosures: Martin Fuchs, BSEE, MSEE, Accelerate Diagnostics (Employee) Steve Metzger, BA, Accelerate Diagnostics (Employee)

672. The Pediatric Endotracheal Aspirate Culture Survey (Petacs): Examining Practice Variation Across Pediatric Microbiology Laboratories in the United States

Andrea Prinzi, SM(ASCP), MPH, CPH¹; Donna Curtis, MD MPH²; Sarah Parker, MD³; Sonja Ziniel, PhD³; ¹University of Colorado Graduate School, Denver, Colorado; ²Children's Hospital Colorado, University of Colorado School of Medicine, Aurora, Colorado; ³Children's Hospital Colorado, Aurora, CO

Session: P-25. Diagnostics: Bacteriology/mycobacteriology

Background: In the absence of evidence-based laboratory guidelines, the workup and interpretation of tracheal aspirate (TA) cultures remains controversial and confusing within the fields of clinical microbiology, infectious diseases, and critical care.

Methods: Between January 22 and February 24, 2020, we conducted a national, web-based survey of microbiology laboratory personnel in free-standing pediatric hospitals and adult hospitals containing pediatric facilities regarding the laboratory practices used for TA specimens. We hypothesized that there would be substantial center-level variability in laboratory processes of TA cultures.

Results: The response rate for the survey was 48%. There was a high level of variability in the criteria used for all processes including specimen receipt, Gram staining and culture reporting. Nearly a quarter of respondents (23%) reject TA specimens based on Gram stain criteria, and 56% of labs require that a minimum number of Gram stain fields be reviewed prior to reporting results. Overall, non-academic hospital laboratories and pediatric-only laboratories are more likely to identify, report and perform susceptibility testing on organisms from tracheal aspirate cultures, regardless of organism quantity or predominance.

Conclusion: There is a substantial amount of process variability among pediatric microbiology laboratories that affects TA culture reporting, which is used to make treatment decisions. This variation within and among labs makes clinical outcome studies related to TA cultures very difficult. Research is needed to determine best laboratory practices for TA culture workup and to provide evidence for the development of clinical guidelines.

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673. Updated CLSI Ciprofloxacin Breakpoints from a Multicenter Assessment for Enterobacteriales, Salmonella spp. and Pseudomonas aeruginosa Using MicroScan Dried Gram Negative MIC Panels

Maria M. Traczewski, BS MT (ASCP)¹; Denise Beasley, BS¹; Amanda Harrington, PhD²; Sharon Desjarlais, BS²; Omai Garner, PhD, D(ABMM)³; Christine Haste, PhD⁴; Regina Brookman, BS⁴; Zabrina Lockett, MS⁴; Jennifer Chau, PhD⁴; ¹Clinical Microbiology Institute, Wilsonville, OR; ²Loyola University & Medical Center, Maywood, IL; ³University of California, Los Angeles, Los Angeles, CA; ⁴Beckman Coulter, West Sacramento, CA

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Background: Updated US FDA/CLSI ciprofloxacin breakpoints were evaluated against data from a multicenter clinical study with *Enterobacteriales*, *Salmonella* spp. and *P. aeruginosa* on a MicroScan Dried Gram-negative MIC (MSDGN) Panel. MIC results were compared to results obtained with frozen broth microdilution panels prepared according to CLSI methodology.

Methods: MSDGN panels were evaluated at three clinical sites by comparing MIC values obtained using the MSDGN panels to MICs utilizing a CLSI broth microdilution reference panel. Data from the combined phases of efficacy and challenge included 803 *Enterobacteriales*, *Salmonella* spp. and *P. aeruginosa* clinical isolates tested using the turbidity and Prompt methods of inoculation. To demonstrate reproducibility, a subset of 12 organisms were tested on MSDGN panels at each site during reproducibility. MSDGN panels were incubated at $35 \pm 1^\circ\text{C}$ and read on the WalkAway System, the autoSCAN-4 instrument, and visually. Read times for the MSDGN panels were at 16-20 hours. Frozen reference panels were prepared and read according to CLSI methodology. FDA and CLSI breakpoints ($\mu\text{g/mL}$) used for interpretation of MIC results were: *Enterobacteriales* ≤ 0.25 S, 0.5 I, ≥ 1 R; *Salmonella* spp. ≤ 0.06 S, 0.12 - 0.5 I, ≥ 1 R; *P. aeruginosa* ≤ 0.5 S, 1 I, ≥ 2 R.

Results: Essential and categorical agreement was calculated compared to frozen reference panel results. Results for isolates tested during efficacy and challenge with Prompt inoculation and manual read are as follows:

Read Method	Essential Agreement (EA) %	Categorical Agreement (CA) %	Very Major Error (VME) %	Major Error (MAJ) %
<i>Enterobacteriales</i>	93.8 (646/689)	97.7 (673/689)	0.0 (0/146)	0.0 (0/535)
<i>Salmonella</i> spp.	100 (21/21)	95.2 (20/21)	0.0 (0/1)	0.0 (0/18)
<i>P. aeruginosa</i>	94.6 (88/93)	91.4 (85/93)	0.0 (0/29)	1.7 (1/58)

Conclusion: Ciprofloxacin MIC results for *Enterobacteriales*, *Salmonella* spp., and *P. aeruginosa* obtained with the MSDGN panel correlate well with MICs obtained using frozen reference panels using updated FDA/CLSI interpretive criteria in this multicenter study.

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674. Variations in Agreement and Epidemiological Cutoff Value (ECV) between Fosfomicin (FOF) Agar Dilution and Broth Microdilution Using Standard- and High-Inoculum Protocols for Klebsiella pneumoniae (KP)

Amanda R. Krueger, BS¹; Jady C. Anderson¹; Elizabeth C. Smith, BS¹; Morgan L. Bixby, BS¹; Hunter V. Brigman, BS¹; Elizabeth B. Hirsch, PharmD²; ¹University of Minnesota College of Pharmacy, Shoreview, Minnesota; ²University of Minnesota, Minneapolis, MN

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Background: FOF has been used in the treatment of multidrug-resistant (MDR) KP infections despite established susceptibility breakpoints. At present, agar dilution (AD) is considered the reference method for FOF while broth microdilution (BMD) is specifically recommended against despite its convenience over AD. We therefore sought to assess FOF activity against KP, along with essential and categorical agreement between AD and BMD methods to determine if BMD could be used as a reliable testing method.

Methods: Minimal inhibitory concentration (MIC) values were determined for a convenience collection of 69 KP isolates (59.4% MDR) from three US institutions. MIC testing was conducted in duplicate on separate days using AD and BMD methods; essential and categorical agreement were calculated using AD as the reference method. Fourteen isolates were also analyzed using high-inoculum AD ($10^{5.3-5.9}$ CFU/mL) similar to the BMD method. MIC values were categorized using Clinical and Laboratory Standards Institute (CLSI) interpretive criteria for *Escherichia coli* (≤ 64 mg/L, susceptible). ECVs were determined according to CLSI methodology.

Results: MIC values varied between methods, with MIC₅₀/MIC₉₀ values being 32/256 mg/L for AD and 128/256 mg/L for BMD. Using *E. coli* criteria, susceptible/intermediate/resistant rates were 82.6/2.9/14.5% (AD) and 44.9/21.7/33.3% (BMD). Essential agreement was 44.9% and categorical agreement was 60.8%. When using high-inoculum AD, MIC values were on average three-fold higher compared to standard-inoculum AD, with 10 of the 14 (71.4%) isolates brought into essential