641. Evaluation of the FilmArray Pneumonia Panel and Potential Impact of Antimicrobial Use on Patients in a Trauma and Medical Intensive Care Unit

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Background. Organisms causing infections of the lower respiratory tract in hospitalized patients can lead to high morbidity and mortality. Identification of the agents of pneumonia allows implementation of appropriate antimicrobial therapy and fast and accurate results are essential for the application of the correct antimicrobial regimen.

Methods. For 6 months results of quantitative bronchioalveolar lavage (Q-BALs) respiratory cultures, ordered as a standard of care for patients in our intensive care unit, were compared with the results obtained by a new multiplex molecular assay for the detection of lower respiratory tract pathogens, the FilmArray pneumonia panel (PP). The panel offers semi-quantitation of the bacterial targets that were compared with the quantitative results of the Q-BALs. Additionally, a retrospective chart review was performed to examine whether there would be any difference in the timing of appropriate antimicrobial therapy if the results of the panel were to be available for those patients. Appropriate antimicrobial therapy was determined according to the institution protocol for treatment of patients for ventilator-associated pneumonia based on the results of the quantitative cultures

Results. Thirty-six unique patients Q-BALs were run and of those there was 82% agreement on the detected targets between cultures and PP. Six targets were not detected by the panel (yeast, *S. maltophilia*, Streptococci, *Salmonella* spp.). *M. catarrhalis*, *S. agalactiae* and 3 viral targets were detected only by the panel. There was 100% agreement between the panel detected resistance markers and the culture isolates susceptibilities. Of the 36 patients, 12 were excluded because their medical records were not available for review. Of the 24 reviewed, 8 (33.3%) would have de-escalation in their antibiotics use at least 24h earlier due to the PP result. Eight (33.3%) would have no potential change in therapy and 8 (33.3%) could have inappropriate escalation or continuation due to reporting of potential pathogens by the PP but recorded as normal flora by cultures.

Conclusion. The use of PP would lead to a reduction of unnecessary antimicrobial therapy in 1/3 of the patients examined. However, quantification of organisms otherwise reported as normal flora may lead to unnecessary treatment and requires education of staff to understand the results of the assay.

Disclosures. **All authors:** No reported disclosures.

642. Higher Diagnostic Accuracy with Ultrasensitive Detection of *Helicobacter pylori* Stool Antigen Using Single-Molecule Counting Technology

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Background. Current diagnostic methods for *Helicobacter pylori* infection include fecal antigen tests, ^{13}C-urea breath test, and gastric biopsy. The breath test is limited by poor specificity and the fecal antigen tests by poor sensitivity. We have developed a prototype assay for detection of *H. pylori* antigen in human stool, powered by ultrasensitive Single Molecule Counting technology, and compared the analytical performance to a commercially available enzyme-linked immunoassay (EIA) antigen test.

Methods. The Singulex Clarity *H. pylori* antigen assay incubates diluted stool with capture and fluorescent-labeled detection antibodies. After incubation and wash steps, fluorescent molecules are eluted and single-molecule fluorescence measured by detected events (DE′). Analytical performance was compared with a commercial EIA (Premier Platinum HpSA® Plus, Meridian Bioscience, Inc.) using serial dilutions of *H. pylori* control (~37,500–1.7 ng/mL) and high positive stool (signal to noise ratio >2). Clinical performance was evaluated using two cohorts, one had 10 EIA-negative and 10 EIA-positive samples and the other 13 high positives (> 0.500 at 450/630) and 5 low positives near the EIA cutoff (0.100–0.500 at 450/630). One sample was excluded due to discordant EIA results, and three to reader flags.

Results. The lower limit of detection of the Clarity *H. pylori* assay was 1.7 ng/mL and the EIA 1,250 ng/mL (IFU: LOD 4.67 ng/mL). A high positive stool sample was detectable by the Clarity *H. pylori* assay diluted 1:10,000,000 and by the EIA 1:10,000. The Clarity *H. pylori* assay showed a 729-fold increase in lower limit of detection and 1,000-fold increase in endogenous antigen lower limit of detection compared with the EIA. Clarity signal ranged from 46–665 DE' for EIA-negative samples and 487,484–576,747 DE' for EIA-positive samples.

Conclusion. The Singulex Clarity *H. pylori* antigen assay may have orders of magnitude higher analytical sensitivity than the commercial EIA and demonstrated 100% positive agreement and 100% negative agreement on detection of *H. pylori* antigen in human stool samples. The ultrasensitive Clarity *H. pylori* assay has the potential for high sensitivity and specificity to improve current diagnostic options for *H. pylori* infection; however, additional multicenter studies are required.

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643. Comparison of Multiplex Polymerase Chain Reaction (PCR) and Routine Culture for the Detection of Respiratory Pathogens in Pneumonia Patients

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Background. The identification of causative pathogens in pneumonia can be challenging, and conventional culture methods can take up to 72 hours. However, rapid microbiologic tests identify organisms within hours. The Biofire®Filmarray ((bioMérieux, North Carolina) Pneumonia Panel was recently approved by the FDA. The multiplex PCR system identifies 33 targets from sputum and bronchoalveolar (BAL) samples, which include 18 bacteria, 8 viruses, and 7 antibiotic resistance genes. The purpose is to compare the panel to routine culture methods for the detection of respiratory pathogens in patients with pneumonia in a 794-bed teaching hospital in northwest Ohio.

Methods. We retrospectively screened all hospitalized intensive care unit patients who met clinical and radiological criteria of pneumonia using electronic medical records between November 2018 and February 2019. Adult patients who had respiratory cultures collected within 7 days were included. Repeat specimens were excluded. Routine cultures were performed using the laboratory's standard procedure, and Pneumonia Panel testing was performed according to manufacturer instructions.

Results. Fifty-nine respiratory or 13 BAL and 46 sputum specimens were evaluated. There was no discrepancy between culture and PCR in 63% (37/59) samples. One (8%) BAL and 10 (22%) sputum specimens had additional pathogens detected by PCR. There was a discrepancy between culture and PCR in four (31%) BAL and seven (15%) sputum samples. The largest discrepancy was noted amongst Serratia marcescens (4/59 or 7%) and Haemophilus influenzae (6/59 or 10%) species. Only one sputum culture had Legionella detected by PCR. Additionally, 17 specimens had a virus detected either alone or with another bacterial pathogen by PCR. For the resistance genes, KPC was detected by PCR but not by Modified Carbapenem Inactivation Method (mCIM) test. The mecA gene was detected in six of seven (86%) of methicillin-resistant *Staphylococcus aureus* (MRSA) isolates. CTX-M was detected in Serratia and *Klebsiella pneunomiae* in two samples; however, the organisms were not isolated in culture.

Conclusion. The Pneumonia Panel can identify additional bacteria that did not grow in culture. This panel can rapidly identify pathogens and potentially reduce unnecessary antibiotic use.

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644. Comparative Evaluation of ETEST® ERV bioMérieux with the CLSI Broth Microdilution Method for Eravacycline MIC Determination

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Background. Eravacycline (XERAVA™) is a novel, FDA and EMA-approved fully-synthetic fluorocycline antibiotic developed by Tetraphase Pharmaceuticals Inc. for the treatment of complicated intra-abdominal infections (cIAI) including those caused by multidrug-resistant (MDR) pathogens that have been highlighted as urgent public health threats by the US CDC and the WHO.

The new ETEST ERV strip (MIC range 0.002 – 32 μg/mL) has been developed by bioMérieux and calibrated vs. the broth microdilution reference method (BMD) as described by the Clinical and Laboratory Standards Institute (CLSI) to determine the minimal inhibitory concentration (MIC) of eravacycline against Enterobacterales and *Enterococci.* The aim of the study was to compare ETEST ERV to the CLSI BMD method on a panel of 166 strains comprising 131 Enterobacterales and 35 *Enterococci.*

Methods. Quality control was performed with the CLSI QC strains *E.coli* ATCC 25922 and *E.faecalis* ATCC 29212. The ETEST ERV strip was applied on a Mueller–Hinton agar plate previously seeded with a 0.5 McF bacterial suspension. After incubation for 16–20H at 35°C, the reading was performed using the bacteriostatic mode i.e.,80% of growth. The FDA-approved breakpoints were applied (S≤0.5μg/mL for Enterobacterales and S ≤0.064 μg/mL for *Enterococci*).

Results. The MIC essential agreement was 99.4% at ±1 dilution for the whole panel and the category agreement was 96.4% with 4.8% Major Errors (1 *E. coli*, 2 *K. pneumoniae,* 1 *K.aerogenes,* 1 *C. koseri*, 1 *E. faecalis*), all at ±1 dilution around the single breakpoint. No Very Major Error (VME) was observed.

Conclusion. In this study, the new ETEST ERV strip has been found to be substantially equivalent to the CLI reference method. MIC end-points appear easier to read in comparison to the reference method. With a 15-dilution MIC range and simplicity of use, ETEST ERV could represent a valuable tool for MIC determination and an alternative to the BMD reference method. ETEST ERV will undergo clinical studies to seek IVD FDA clearance and CE marking. For Research Use Only. The performance characteristics of this product have not yet been established.

Disclosures. **All authors:** No reported disclosures.

645. Singulex Clarity Norovirus Assay (In Development) Provides Ultrasensitive Detection of Norovirus Genogroups I and II

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