640. Development of a Laboratory Verification Protocol for Concurrent Detection of Bacterial, Fungal, and Antimicrobial Resistance Genes in a Multiplex Syndromic Joint Infection Panel
Monica Cronin, MS; Taylor K. Fadgen, Bachelor of Science 1; Lisa Ogden, BS; Jeremy P. Green, BS; Stephanie A. Thatcher, MS; Rebecca C. Young, MS; Brandon Hoebel, BS; BioFire Diagnostics, LLC, Salt Lake City, Utah; ZeptoMetrix, LLC, Buffalo, New York.

Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Verification is a critical component of implementing a diagnostic test in a clinical lab and can be time consuming and costly. A verification protocol and organism panel were developed in collaboration with ZeptoMetrix, LLC to verify all analyte detections for the BioFire Joint Infection (JJ) Panel. The BioFire JJ Panel detects 31 pathogens and 8 antimicrobial resistance (AMR) genes associated with joint infections in synovial fluid specimens.

Methods. A protocol was developed using prototype NATTrol controls from ZeptoMetrix, synovial fluid, and the BioFire FilmArray 2.0 and the BioFire FilmArray Torch Systems. Control materials were tested in the presence of synovial fluid from pooled human donors. The 32 targets required for all analyte detections were divided into 5 pools of 6-7 analytes and then tested over multiple days on several systems.

Results. Preliminary outcomes were good with a cumulative positive detection rate of 100% (310/310) and expected negative detections of 99.3% (1182/1190) from 50 prototype BioFire JJ Panel test runs. ARMs were correctly identified in 50/50 (100%) replicates when a correlated bacterium was present. Unexpected detections of Streptococcus spp. (7/50) and Staphylococcus lugdunensis (1/50) were likely due to contaminants in the synovial fluid. Streptococcus spp. was confirmed by testing the synovial fluid in isolation.

Conclusion. Efficient performance verification may be achieved by combining 32 organisms/8 AMR into 5 pools and can be completed with 20 test runs in 4 days. The pool scheme provided multiple positive/negative detections per analyte and accurately detects AMR. The protocol and controls serve as a useful tool for providing reliable detections of targets over multiple days, operators and systems and offers a flexible solution for supporting verification needs.

The BioFire Joint Infection Panel is currently pending US FDA De Novo review. This product has not been evaluated by other global regulatory agencies for in vitro diagnostic use. Not available for sale. Panel menu subject to change.

Disclosures. Monica Cronin, MS, BioFire Diagnostics, LLC (Employee) Taylor K. Fadgen, Bachelor of Science, BioFire Diagnostics, LLC (Employee) Lisa Ogden, BS, BioFire Diagnostics, LLC (Employee) Jeremy P. Green, BS, BioFire Diagnostics, LLC (Employee, Shareholder) Stephanie A. Thatcher, MS, BioFire Diagnostics (Employee) Rebecca C. Young, MS, BioFire Diagnostics, LLC (Employee) Brandon Hoebel, BS, ZeptoMetrix, LLC (Employee)

641. Clinical Predictors of Hospital-Acquired Bloodstream Infections
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Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Hospital-acquired bloodstream infections (HABSI) are associated with increased mortality and decreased hospital quality metrics. This has led to an increased focus on blood culture stewardship. Little data exists regarding predictive factors of bacteremia in hospitalized patients. We aim to determine what clinical characteristics are predictive of HABSI.

Methods. This is a retrospective case-control study of 540 patients with positive blood cultures admitted to our health system between September 1, 2017, to September 30, 2019. All adults with a positive non-contaminant ENT culture (first isolate of a species per 30-day period) were included. We included age ≥ 18 years, hospital-acquired bloodstream infection (BCIDP) breakpoints defined as: susceptible (S), intermediate (I) or R to ertapenem (ETP), imipenem (IPM), meropenem (MEM) and/or doripenem (DOR) per commercial panels. Where available, MICs were interpreted using CLSI 2010 MIC breakpoints (µg/ml): ≤ 0.5 (S), 1-2 (I), ≥ 2 (R) for ETP and ≤1 (S), 2 (I), and ≥ 4 (R) for IPM/MEM/DOR. For evaluable ENT isolates we compared susceptibility results as reported by the facility to CLSI breakpoints.

Results. Overall, 77.4% (937,926,211,845) and 90.6% (2,157,785,238,812) non-duplicate ENT isolates with facility-reported susceptibility results also had interpretable MIC results for ETP and IPM/MEM/DOR, respectively (Tables). ETP S rates were 99.3% and 99.1% as reported by facilities and using CLSI criteria, respectively. S rates of other Carbs were 98.8% and 98.4% by facility reporting and CLSI criteria, respectively. Systematic application of CLSI breakpoints under-reported ETP and –R isolates by 24.2% and 16.4%, respectively, and identification of IPM/MEM/DOR and –R isolates by 31.3% and 22.7%, respectively.

Conclusion. Systematic application of CLSI breakpoints in 2016-19 would have had minimal impact on ENT S rates in the US. However, facility reporting failed to identify 18.8% of ETP I or R and 26.5% of IPM/MEM/DOR I or R isolates. The clinical implications of these observations are unknown. Facilities should know their local epidemiology, decide if under-reporting might be an issue, and assess if there is any impact on their patients.

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642. Evaluation of Rapid Blood Pathogen Identification Along with Antimicrobial Stewardship at an Academic Teaching Institution
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Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Bloodstream infections are a major cause of morbidity and mortality in hospitalized patients. Prompt initiation of effective antimicrobials are essential to optimize patient outcomes. New diagnostic technologies rapidly identifying bacteria, viruses, fungi, and parasites in infections of various body sites. The time a paucity of literature determining if stewardship programs run by a trained pharmacist with rapid diagnostics decreases time to optimal antimicrobial therapy.

Methods. This was a retrospective chart review of positive bloodstream infections identified via rapid diagnostic technologies. The EHR of admitted adult patients...