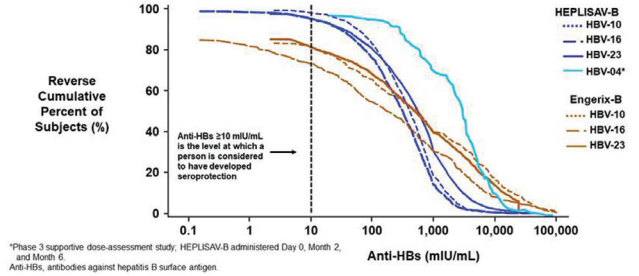
Background. HEPLISAV-B® [hepatitis B vaccine (recombinant), adjuvanted] uses a cytidine phospho-guanosine (CpG) oligonucleotide or "1018," a Toll-like receptor 9 agonist, as an adjuvant. Engerix-B® [hepatitis B vaccine (recombinant)], as well as other hepatitis B vaccines, use alum. HEPLISAV-B, a 2-dose vaccine given at Weeks 0 and 4, was recently approved for use in adults ≥18 years for the prevention of hepatitis B. Approval of HEPLISAV-B was based on three pivotal phase 3 noninferiority trials, comparing it with Engerix-B, a 3-dose vaccine given at Day 0, Day 30, and 6 months. Immunogenicity and safety results for these trials, HBV-10, HBV-16 and HBV-23, have been published previously; the safety of HEPLISAV-B was generally similar to Engerix-B.

Methods. The 3 randomized trials were observer-blinded and collectively included subjects aged 18–70 years. Immunogenicity analysis based on antibody against hepatitis B surface antigen (anti-HBs) levels were based on the per-protocol analysis. Presented here are reverse cumulative frequency plots of anti-HBs serum concentrations for the 3 trials.

Results. Across the trials, reverse cumulative frequency plots of anti-HBs concentrations showed a higher proportion (>90%) of HEPLISAV-B subjects developed a seroprotective antibody level (anti-HBs levels ≥10 mIU/mL) compared with Engerix-B subjects (80% to ~90%). A higher proportion of HEPLISAV-B subjects had anti-HBs levels between 10 mIU/mL and 1,000 mIU/mL. While a higher proportion of Engerix-B subjects had anti-HBs levels >1,000 mIU/mL, a significantly higher proportion of Engerix-B subjects did not develop seroprotective antibody levels. The response curves indicate a more consistent immune response with a higher percentage of subjects achieving seroprotection with less variability for HEPLISAV-B compared with Engerix-B, which showed a more variable response and fewer subjects achieving seroprotection.

Conclusion. HEPLISAV-B, using a CpG adjuvant, results in a higher percentage of persons achieving seroprotection and produces a more uniform and consistent induction of protective antibody levels than Engerix-B, an alum-adjuvanted vaccine.

Reverse Cumulative Frequency Plot of Anti-HBs Concentration for HEPLISAV-B Week 24 and Engerix-B Week 28 in HBV-10, HBV-16, and HBV-23 (Per-Protocol Populations)



Disclosures. **R. N. Hyer**, Dynavax Technologies Corporation: Employee and Shareholder, Salary and Stock options. **R. Janssen**, Dynavax Technologies Corporation: Employee and Shareholder, Salary and Stock options.

2288. Adherence to Hepatitis B Screening and Treatment Guidelines in Oncology Patients Starting Anti-CD20 Therapy

Anusha Govind, MD[1]; Nathan L'Etoile, MS[2]; Roberto Fratamico, MD[3]; Joanne Filicko-O'Hara, MD[3] and Joseph DeSimone Jr., MD[1]; [1]Infectious Disease, Thomas Jefferson University Hospital, Philadelphia, Pennsylvania, [2]Thomas Jefferson University Hospital, Philadelphia, Pennsylvania, [3]Medical Oncology, Sidney Kimmel Cancer Center, Philadelphia, Pennsylvania

Session: 244. Miscellaneous Vaccines
Saturday, October 6, 2018: 12:30 PM

Background. Hepatitis B virus (HBV) reactivation is a common complication in the treatment of oncology patients when using anti-CD20 monoclonal antibodies (MABs) such as rituximab, obinituzumab, and ofatumumab. In such patients, the reaction of HBV is seen in up to 70% who are HBV DNA positive. Antiviral therapy in high-risk patients has been shown to improve outcomes.

Methods. This retrospective review evaluated patients at Thomas Jefferson University Hospital who received rituximab, obinituzumab, or ofatumumab as a component of hematologic malignancy therapy between 2013 and 2016. We determined the number of patients who had appropriate HBV testing prior to therapy, the number who received appropriate antiviral therapy, and the number who developed reactivation of HBV and their outcomes.

Results. 402 patients received one of the above anti-CD20 MABs between November 2013 and December 2016. Of these 402 patients, 52 (13.4%) did not have either HBsAg or HBcAb performed prior to anti-CD20 therapy. 39 (9.7%) patients had positive HBsAg or HBcAb prior to therapy. Of these 39 highrisk patients, only 16/39 (41.3%) were placed on appropriate antiviral therapy. Two of the 39 high-risk patients (5.1%), who were not started on antiviral therapy, developed HBV reactivation as a complication of anti-CD20 MAB therapy.

Conclusion. A significant number of patients were not appropriately screened with HBV markers prior to anti-CD20 therapy for hematologic malignancies at our institution. In addition, less than half of highrisk HBV patients received appropriate antiviral therapy. System-wide changes are anticipated to improve this process at our institution.

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

2289. Accuracy of a Rapid Multiplex PCR Plus a Chromogenic Phenotypic Test Algorithm for the Detection of ESBL and Carbapenemase-Producing Gram Negatives Directly From Blood Cultures

Shawn Vasoo, MBBS, MRCP, D(ABIM), D(ABP)[1]; Pei-Yun Hon, BSc[2]; Sharon S.H. Wee, BSc[3]; Jonathan W.Z. Chia, MBBS[4]; Shehara M. Mendis, MBBS[5]; Ezlyn Izharrudin, MBBS[1]; Ray J.H. Lin, MBBS, MRCP[1]; Po-Ying Chia, MBBS, MRCP[1]; Rees C.S. Sim, BSc[6]; Mark I.C. Chen, MBBS, MMed, PhD[2]; Angela Chow, MBBS, MMed, MS, PhD[2]; Joanne Yoong, PhD[7]; David Lye, FRACP, FAMS, FRCP[2]; Christine Teng, MS[8]; Paul Tambyah, MBBS, MD, FSHEA[9]; Ritu Banerjee, MD, PhD[10]; Robin Patel, MD, FIDSA, D(ABMM)[11] and Partha P. De, MBBS, FRCPath[4]; [1]Infectious Diseases, National Center for Infectious Diseases and Tan Tock Seng Hospital, Singapore, Singapore, [2]National Center for Infectious Diseases and Tan Tock Seng Hospital, Singapore, Singapore, [3]Clinical Research and Innovation Office, Tan Tock Seng Hospital, Singapore, Singapore, [4]Department of Laboratory Medicine, Tan Tock Seng Hospital, Singapore, Singapore, [5]Tan Tock Seng Hospital, Singapore, Singapore, [6]Infectious Diseases, Tan Tock Seng Hospital, Singapore, Singapore, [7]Saw Swee Hock School of Public Health, National University of Singapore, Singapore, Singapore, [8]National University of Singapore, Singapore, Singapore, [9]Division of Infectious Disease, National University Hospital, Singapore, Singapore, [10]Division of Pediatric Infectious Diseases, Vanderbilt University, Nashville, Tennessee, [11]Divisions of Clinical Microbiology and Infectious Diseases, Mayo Clinic, Rochester, Minnesota

Session: 245. Molecular & Sequence Based Diagnostics
Saturday, October 6, 2018: 12:30 PM

Background. We studied the multiplex PCR panel (BioFire Blood Culture ID panel, "BCID") with phenotypic testing using the Rosco Diagnostica Rapid ESBL Screen kit 98022 (RE) and the Neo-Rapid CARB kit 98024 (RC) for extended-spectrum β-lactamase (ESBL)/carbapenemase producing Gram negative bacilli (CPGNB) detection directly from blood culture bottles, in patients with Gram negative bacteremia.

Methods. The RE and RC kits were evaluated in a verification phase with 98 blood cultures, comprising 43 spiked with GNB: 23 *Escherichia coli*, 9 *Klebsiella pneumoniae*, 7 *Enterobacter cloacae*, 2 *Serratia marcescens*, one *Pseudomonas aeruginosa*, one *Acinetobacter baumanii* complex with varying resistance genotypes (11 CTX-M-15, 5 CTX-M9, one SHV-18, one SHV-3, one TEM-10, 3 IMI, 4 IMP, 4 KPC, 2 NDM, one OXA-23+OXA-51-like, 3 OXA-232, one OXA-48, one SME-1, 2 VIM-1, 2 AmpC from reference and clinical isolate banks, and ATCC 25922), and 54 clinical blood cultures with GNB (5 phenotypic ESBL-positive, one KPC, 48 no known β-lactamase). In a prospective phase, a further 123 clinical blood cultures positive for GNB were tested simultaneously with the BCID, RE and RC kits.

Results. In the verification phase, the RE kit detected 24/25 of ESBL-positive samples (sensitivity 96%, specificity 99%). The RE kit did not detect the 2 AmpC-producers, and was positive for a *K. oxytoca* isolate, which are known to produce chromosomally encoded β-lactamases. The RC kit detected 11/22 of CPGNB (sensitivity 50%, specificity 100%). It missed IMI, OXA-23+OXA-51-like, OXA-232, OXA-48, SME-1 and VIM CPGNB (weak carbapenemases), but detected NDM, KPC, IMP. In the prospective phase, the RE kit detected 20/20 ESBL-positive blood culture samples (sensitivity 100%). The single OXA-48 positive sample was detected by both the RE and RC kits. The 123 blood cultures had a total of 125 panel-represented targets detectable by BCID. The BCID detected 124 /125 (missed one *K. pneumoniae* in a polymicrobial bacteremia), and there were 2 *Proteus* false-positives (sensitivity 99%, specificity 98%). No KPC-positive samples were detected by BCID.

Conclusion. An algorithm comprising the BCID and the RE/RC kits applied to positive blood cultures allows both rapid and accurate pathogen identification and detection of ESBLs and some carbapenemases (e.g., KPC, NDM, IMP). This may allow the institution of timelier, directed therapy.

Disclosures. **S. Vasoo**, bioMerieux: Grant Investigator, Research support. Rosco Diagnostica: In-kind support, Research support. **R. Banerjee**, Accelerate Diagnostics, Biomerieux, BioFire: Grant Investigator, Research grant and Research support. **R. Patel**, CD Diagnostics, BioFire, Curetis, Merck, Hutchison Biofilm Medical Solutions, Accelerate Diagnostics, Allergan, and The Medicines Company: Grant Investigator, Research grant - monies paid to Mayo Clinic. Curetis, Specific Technologies, Selux Dx, GenMark Diagnostics, PathoQuest and Genentech: Consultant and Scientific Advisor, Consulting fee - monies paid to Mayo Clinic. ASM and IDSA: Travel reimbursement and editor's stipends, Travel reimbursement and editor's stipends. NBME, Up-to-Date and the Infectious Diseases Board Review Course: Varies, Honoraria. Mayo Clinic: Employee, Salary.

2290. Identification of Pathogens in Synovial Fluid Samples With an Automated Multiplexed Molecular Detection System

Benedicte Pons, PhD[1]; Corinne Jay, MS[1]; Thibault Martin, PhD[1]; Isabelle Sothier, Ms.[1]; Helene Savelli, MS[1]; Bart Kensinger, PhD[2]; Frédéric Laurent, PharmD, Professor[3]; Lelia Abad, MS[3]; Caitlin Murphy, PhD[4]; Arryn Craney, PhD[4]; Bryan Schmitt, DO[5]; Amy Waggoner, MS[5]; Susan Butler-Wu, PhD[6]; Cristina Costales, PhD[6]; Jennifer Bien-Bard, PhD D (ABMM)[7]; Javier Mestas, PhD[7]; Jaime Esteban, PhD[8]; Llanos Salar-Vidal, MS[8]; Amanda Harrington, PhD[9]; Samuel Collier, Mr[9]; Amy Leber, PhD[10]; Kathy Everhart, MS[10]; Joan-Miquel Balada-Llasat, Pharm D, PhD[11]; Jarid Horn, Mr[11]; Stephane Magro, Mr[1] and Kevin Bourzac, PhD[2]; [1]Molecular Biology R&D, Biomerieux, Grenoble, France, [2]BioFire Diagnostics, LLC, Salt

Lake City, Utah, [3]Hospices Civils De Lyon, French National Reference Center for Staphylococci, Lyon, France, [4]University of Nebraska Medical Center, Omaha, Nebraska, [5]Pathology and Laboratory Medicine, Indiana University, Indianapolis, Indiana, [6]Keck School of Medicine, Los Angeles, California, [7]Children's Hospital Los Angeles, Los Angeles, California, [8]Department of Clinical Microbiology, Foundation Jimenez Diaz, Madrid, Spain, [9]Loyola University Medical Center, Maywood, Illinois, [10]Department of Laboratory Medicine, Nationwide Children's Hospital, Columbus, Ohio, [11]Clinical Microbiology, The Ohio State University Wexner Medical Center, Columbus, Ohio

Session: 245. Molecular & Sequence Based Diagnostics
Saturday, October 6, 2018: 12:30 PM

Background. Bone and Joint Infections (BJI) have high morbidity and are difficult to treat infections. Culture-based diagnosis is limited in its ability to recover fastidious bacteria and because several organisms can be involved; culture times of up to two weeks may be necessary for certain bacteria. The sensitivity of culture is also negatively impacted by antibiotics received before surgery. Alternatively, molecular methods offer a promising improvement for the diagnosis of BJI. The goal of this study was to evaluate a development version of Biofire® Bone and Joint Infection (BJI) Panel (bioMerieux SA, BioFire Diagnostics, LLC) using synovial fluid samples.

Methods. 121 synovial fluid specimens were collected from patients with suspected bone and joint infection in a pilot evaluation. All specimens were collected and tested in culture by the sites using their standard of care practices; in parallel, a leftover volume of 200 µL was tested on the BJI panel. BJI panel results were then compared with culture and discordant results were investigated using a comparator assay (PCR/sequencing).

Results. 49 synovial fluid specimens (40%) were positive by culture vs. 72 with the BJI panel (59%). Of the 97 positive detections by the BJI panel, 58 were concordant with culture; the 39 additional organism detections were in majority confirmed by PCR/sequencing. Lastly, two false negative results corresponding to the same sample are under investigation.

Conclusion. The BJI Panel was able to identify most of the pathogens detected by culture. The majority of additional detections observed were confirmed by PCR/sequencing. While sites are currently enrolling more synovial fluids samples, these preliminary data suggest that a multiplexed molecular test may be more sensitive than culture to detect pathogens in synovial fluid specimens.

The data presented in this abstract have not been reviewed by FDA or other regulatory agencies for In Vitro Diagnostic use.

Disclosures. **B. Pons**, bioMerieux: Employee, Salary. **C. Jay**, bioMerieux: Employee, Salary. **T. Martin**, bioMerieux: Employee, Salary. **I. Sothier**, bioMerieux: Employee, Salary. **H. Savelli**, bioMerieux: Employee, Salary. **B. Kensinger**, bioFire a bioMerieux company: Employee, Salary. **F. Laurent**, BioFire (bioMerieux company): Investigator, Research support. **L. Abad**, BioFire (bioMerieux company): Investigator, Research support. **C. Murphy**, BioFire (bioMerieux company): Investigator, Research support. **A. Craney**, BioFire (bioMerieux company): Investigator, Research support. **B. Schmitt**, BioFire (bioMerieux company): Investigator, Research support. **A. Waggoner**, BioFire (bioMerieux company): Investigator, Research support. **S. Butler-Wu**, BioFire (bioMerieux): Investigator, Research support. **C. Costales**, BioFire (bioMerieux company): Investigator, Research support. **J. Bien-Bard**, BioFire (bioMerieux): Investigator, Research support. **J. Mestas**, BioFire (bioMerieux): Investigator, Research support. **J. Esteban**, BioFire (bioMerieux): Investigator, Research support. **L. Salar-Vidal**, BioFire (BioMerieux company)): Investigator, Research support. **A. Harrington**, BioFire (bioMerieux company): Investigator, Research support. **S. Collier**, BioFire (BioMerieux Company): Investigator, Research support. **A. Leber**, BioFire (bioMerieux company): Investigator, Research support. **K. Everhart**, BioFire (bioMerieux company): Investigator, Research support. **J. M. Balada-Llasat**, BioFire (bioMerieux company): Investigator, Research support. **J. Horn**, BioFire (bioMerieux company): Investigator, Research support. **S. Magro**, bioMerieux: Employee, Salary. **K. Bourzac**, BioFire a bioMerieux company: Employee, Salary.

2291. A Real-Time Sequencing Approach for Simultaneous Metagenomic and Transcriptomic-Based Diagnosis of Infectious Diseases

Benjamin Briggs, MD, PhD[1,2,3]; Scot Federman, BA[2,3]; Xian Ding Deng, PhD[2,3]; Wei Gu, MD, PhD[2,3]; Guixia Yu, BS[2,3]; Claudia Sanchez San Martin, PhD[2,3]; Steve Miller, MD, PhD[2,3] and Charles Y. Chiu, MD, PhD[2,3,4]; [1]Department of Pediatrics, Division of Infectious Disease, University of California, San Francisco, San Francisco, California, [2]Department of Laboratory Medicine, University of California, San Francisco, San Francisco, California, [3]UCSF-Abbott Viral Diagnostics and Discovery Center, San Francisco, California, [4]Department of Internal Medicine, Division of Infectious Disease, University of California, San Francisco, San Francisco, California

Session: 245. Molecular & Sequence Based Diagnostics
Saturday, October 6, 2018: 12:30 PM

Background. Recent studies have demonstrated the utility of metagenomic next-generation sequencing (mNGS) and RNA gene expression sequencing (RNA-Seq) for identifying causes of infections. Although these approaches have been largely tested to date using established sequencing platforms such as the Illumina HiSeq, the use of nanopore sequencing on the MinION sequencer (Oxford Nanopore Technologies) is attractive given rapid library preparation and real-time analysis of sequencing data resulting in accelerated sample-to-answer turnaround times.

Methods. We have developed a rapid molecular concatemerization library approach to increase the throughput of the nanopore sequencer analysis for metagenomic and RNA-Seq approaches. We have also developed a pipeline (SURPI*rt*, "Sequence-based ultra-rapid pathogen identification, real-time") that allows for real-time, simultaneous metagenomic and transcriptomic analyses on the same sample.

Results. With the use of molecular concatemerization library approach, we show that metagenomic and transcriptomic data generated on the MinION are comparable to those on the Illumina platform, yet can be collected and analyzed in significantly less time (6 hours vs. 2–3 days).

Conclusion. Here we demonstrate simultaneous metagenomic and RNA-Seq analyses on a nanopore-based sequencing platform with real-time analysis of results. We foresee that this approach could be leveraged into a rapid screening test for diagnosis of infectious diseases in both hospital and field settings.

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

2292. Comparison of Molecular Assays for the Diagnosis of Pertussis

Joshua Otiso, MPH, MLS (ASCP); Sherilynn Vogel, MT (ASCP); Gary W. Procop, MD and Sandra S. Richter, MD; Department of Laboratory Medicine, Cleveland Clinic, Cleveland, Ohio

Session: 245. Molecular & Sequence Based Diagnostics
Saturday, October 6, 2018: 12:30 PM

Background. Pertussis is a vaccine preventable disease caused by *Bordetella pertussis* with highest mortality observed in infants. Rapid diagnosis allows prompt treatment and administration of prophylaxis to those at high risk of severe disease. Molecular assays are commonly used for diagnosis because of the long turn-around time and reduced sensitivity associated with culture of samples obtained >2 weeks after symptom onset. We compared the workflow and performance of two molecular assays for the detection of *B. pertussis* from nasopharyngeal (NP) swab specimens.

Methods. NP swabs in universal transport media submitted to Cleveland Clinic for *B. pertussis* testing are routinely tested by the AmpliVue Bordetella assay (Quidel). The AmpliVue utilizes helicase-dependent amplification targeting the insertion sequence IS481 and detection in a lateral flow device. Remnant specimens (n = 112) were stored at -70° C until IRB approval was obtained for this study. The Simplexa™ Bordetella Direct PCR assay (DiaSorin Molecular) targeting IS481 for detection of *B. pertussis* and IS1001 for identification of *Bordetella parapertussis* was performed on the LIAISON MDx instrument. The Simplexa and AmpliVue results were compared. To arbitrate discordant *B. pertussis* results or positive results for *B. parapertussis* (not included in the AmpliVue assay), samples were sent to DiaSorin for sequencing. Sensitivity and specificity were determined for each assay's detection of *B. pertussis* based on sequencing as the reference method for discordant samples.

Results. Positive results for *B. pertussis* were detected for 14 specimens by AmpliVue and 18 specimens by Simplexa. Discrepancy analysis by sequencing confirmed 4 *B. pertussis* positive specimens detected only by Simplexa and one false-positive result for each assay. The sensitivities of AmpliVue and Simplexa were 76.5% and 100%, respectively. The specificity of both assays was 98.9%. Positivity rates were 27% for 48 children ≥1 year, 4% for 25 infants, and 8% for 39 adults tested. The Simplexa *B. parapertussis* target detected in one child's specimen was confirmed by sequencing.

Conclusion. Compared with AmpliVue, the Simplexa assay required less hands on time and provided detection of more specimens containing *B. pertussis*.

Disclosures. **S. S. Richter**, bioMerieux: Grant Investigator, Research grant. BD Diagnostics: Grant Investigator, Research grant. Roche: Grant Investigator, Research grant. Hologic: Grant Investigator, Research grant. Diasorin: Grant Investigator, Research grant. Accelerate: Grant Investigator, Research grant. Biofire: Grant Investigator, Research grant.

2293. Evaluation of Three Rapid Molecular Assays for the Detection of Group A *Streptococcus*

Eric Beck, PhD[1]; Patricia Ross, BS[1]; Ashlee Clow, BS[1]; Jennifer Larson, MS[2]; Prina Patel, BS[2]; Sarah Siason, BS[2]; Matthew Drozd, BS[2]; Pankaj Patel, MS[2] and Michael Costello, PhD[2]; [1]Microbiology, ACL Laboratories, West Allis, Wisconsin, [2]Microbiology, ACL Laboratories, Rosemont, Illinois

Session: 245. Molecular & Sequence Based Diagnostics
Saturday, October 6, 2018: 12:30 PM

Background. Group A *Streptococcus* (GAS), the primary causative agent of bacterial pharyngitis, is most commonly diagnosed with a rapid antigen test performed at the point of care followed by bacterial culture, if negative. Final test results may not be available for 24–72 hours, which can delay the time to therapy and cause patients to miss additional work or school days. Recently, rapid molecular tests, including some that are CLIA-waived, have become available allowing providers to obtain results within a timeframe similar to rapid antigen tests, but with accuracies comparable to traditional culture. The purpose of this study was to evaluate the performance of the Alere™i Strep A test, Roche cobas® Strep A test, and the Cepheid Xpert Xpress Strep A Test (RUO Version) compared with the OSOM Group A Streptococcus rapid antigen test and traditional bacterial culture. All molecular tests are either currently or in the process of obtaining CLIA-Waived status and can be completed in less than 25 minutes.

Methods. The current testing process in our healthcare system (AdvocateAuroraHealth) is to collect oropharyngeal swabs with both a traditional swab and an ESwab (Copan). The traditional swab is used for rapid antigen testing