No cross reactivity was observed with any of the malarial species tested. Babesia M01, Babesia dancani and all bacterial isolates tested were negative by the BMPCR. Intra-run, inter-run and day to day reproducibility of the assay was 100%.

Conclusion. The B. microti real time PCR assay developed by Northwell Health Laboratories is rapid, sensitive, specific and reproducible. With the sample to result turnaround time of 2.5 hours and hands on time of only 5 minutes per sample, BMPCR can be used as screening assay for B. microti in clinical laboratories.

Disclosures. All authors: no reported disclosures.

2009. A Novel Diagnostic Method for Malaria Using Loop Mediated Isothermal Amplification (LAMP) and MinION Nanopore Sequencer

Kazuo Imai, MD, PhD; Junya Yamagishi, PhD; and Takuya Maeda, MD PhD; 1Department of Infectious Disease and Infection Control, Saitama Medical University, Saitama, Japan, 2Center for Culture Independent Diagnostics and Research, Saitama Medical University, Saitama, Japan, 3Department of Internal Medicine, National Defense Medical College, Saitama, Japan, 4Department of Microbiology, Saitama Medical University, Saitama, Japan, 5Department of Medical Genome Sciences, University of Tokyo, Chiba, Japan, 6Global Station for Zoonosis Control, Hokkaido University, Hokkaido, Japan

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. Simply and accurately diagnostic tool for Malaria is required for clinical diagnosis and epidemiological survey. We have developed a novel diagnostic tool for Malaria using loop mediated isothermal amplification (LAMP) with MinION nanopore sequencer.

Methods. In this study, we have designed human Plasmodium parasites-specific LAMP primers targeting for the lesion of 18S rDNA gene, which were locating on the conserved sequences across all five Plasmodium species: Plasmodium falciparum, P. vivax, P. ovale (P. wallikeri and P. crusi), P. knowlesi and P. malariae, containing each species-specific sequence within F1-B1 primer pairs. The sensitivities were evaluated using 10-fold serially diluted plasmids harboring the sequences of 18S rDNA. We also applied our protocol to human blood samples collected and stored with FTA elite cards derived from 30 Malaria patients, who are clinically diagnosed as Malaria in Indonesia. Its analytical sensitivities and specificities were also evaluated while comparing the results of previously described nested PCR methods. Finally, we performed amplicon sequencing of our LAMP methods using MinION nanopore sequencer to identify each Plasmodium species.

Results. Our LAMP method could amplify all targeting 18S rDNA gene on clinical samples, obtained LAMP results were completely consistent with the results of nested PCR. Additionally, detections of Plasmodium species based on the sequence analysis with MinION were also consistent with the sequence of each constructed plasmid and could consistently confirmed its Plasmodium species with the highest homology of reference Plasmodiumparasite sequence.

Conclusion. Our innovative diagnostic technology with LAMP and MinION could become a powerful tool for identification of Plasmodium parasites even in resource-limited situation.

Disclosures. All authors: no reported disclosures.

2009. Accelerating Time to Pathogen-adapted Antibiotic Treatment through Culture-independent Antimicrobial Susceptibility Testing in Patients Suffering from Sepsis

Matthias Karrasch, MD; Marco Bender, none; Jennifer Geraci, DiplBiol; Frank Brunkhorst, MD; Bettina Löffler, MD; 1University Laboratory, Jena University Hospital, Germany, Jena, Germany, 2Medical Microbiology, Jena University Hospital, Germany, Jena, Germany, 3Center of Sepsis Control and Care (CSCC), Department of Anaesthesiology and Intensive Care Medicine, Jena University Hospital, Germany, Jena, Germany

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. Accurate and fast pathogen identification and consecutive antimicrobial susceptibility testing (AST) is of vital importance for patient outcome in patients suffering from sepsis.

Methods. The Accelerate Pheno® system is a new, fully automated, culture-independent diagnostic method for both pathogen identification (ID) and antimicrobial susceptibility testing (AST). We analyzed positive blood cultures from critically ill patients with new onset of sepsis according to the new sepsis guidelines, using both conventional standard methods (VITEK, MALDI-TOF) and Accelerate Pheno® system. ID/AST results of the Accelerate Pheno® system were not reported to treating physicians as part of our internal evaluation program.

Results. Accelerate Pheno® system correctly detected 74 pathogens [Gram-negative (GN) (n = 27), Gram-positive (GP) (n = 47)] straight out of 84 positive blood culture bottles. Gram-negative (GN) pathogens were identified as E. coli (n = 15; concordance rate 90%), K. pneumoniae (n = 7; 71.4%), S. marcescens (n = 3; 100%), E. cloacae (n = 2; 50%), P. mirabilis (n = 1; 100%) and P. aeruginosa (n = 1; 33%). Gram-positive pathogens were identified as CNS (n = 24; 82.6%), S. aureus (n = 15; 88.2%), E. faecium (n = 6; 100%) and E. faecalis (n = 2; 100%). The Accelerate Pheno® system generated a GN-AST result in 70.4% (19 of 27 samples) and a GP-AST result in 61.7% (29 of 47 samples) when compared with routine AST. Growth control, analysis and mechanical failure led to reduced results in comparison to conventional ID/AST. Accelerate Pheno® delivered correct MIC-results for most of the panel antibiotics [e.g., meropenem: 83.3%; gentamicin: 88.9%, etrapenem: 100%].

Conclusion. The use of the Accelerate Pheno® system significantly improved time-to-ID/AST and would have led to reduced time-to-treatment in patients suffering from sepsis if results would have been reported. The system currently lies to some weakness in the detection of polymicrobial and streptococcal infections but due to the short hands-on-time, culture-independent and fast generation of results, it represents a promising new diagnostic method for the consecutive antibiotic treatment of septic patients.

Disclosures. All authors: no reported disclosures.

2009. T-Cell Immunity Panel Measures CMV-Specific CD4 and CD8 T-Cell Responses

Cory B. Lutgen, BS; Linda Flebbe-Rehwaldt, PhD; Steve Kleboeker, PhD; Viracor Eurofins Clinical Diagnostics: Employee, Salary; Shigefumi Maesaki, MD PhD; Kathie Steffens, BS, MA and Michelle Altrich, PhD

Viracor Eurofins Clinical Diagnostics, Lee's Summit, Missouri

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. Infection and disease from human cytomegalovirus (CMV) is a major complicating factor for both solid organ and hematopoietic stem cell transplant recipients. Antiviral therapy is often used to control CMV infections, but presents problems of toxicity, antiviral resistance and excessive costs. Currently, treating physicians are limited in the information and data available to assess a patient's ability to control a potential CMV infection post-transplant. Recent studies have shown that measuring a patient's CMV specific T cell mediated immunity may provide valuable information concerning CMV infection/disease in transplant patients and may aid in determining which patients need antiviral therapy.

Methods. For this purpose, a flow cytometry assay was developed to determine the percentages of CD4+ and CD8+ T cells that respond to stimulation with CMV antigen pools. CMV specific response is based upon the cellular activation surface marker CD69 in conjunction with IFNγ, TNFα, and IL-2 cytokine production. Three CMV antigens were used to assess patient immunity: a whole viral lysate, a peptide pool of pp65, and a peptide pool of IE-1.

Results. Our data indicate that CD8 T cells respond primarily to the pp65 and/or IE-1 peptide pools while the CD4 T cells respond primarily to the viral lysate. Detection of both CD4 and CD8 responding populations at levels above background, ≥ 0.2% of the parent population, indicates that a patient's immune system has previously been exposed to CMV. Validation of 23 CMV seropositive samples demonstrated immune responses below 0.2% (when excluding underlying, unrelated immune responses). Included for each sample is a positive (Staphylococcal Enterotoxin type B) control to assess patient's overall ability to mount an immune response and negative (media) control to capture the presence of an underlying immune response.

Conclusion. This assay evaluates a patient's pre-existing CMV specific T cell immunity and their global T cell function.

Disclosures. C. B. Lutgen, Viracor Eurofins Clinical Diagnostics: Employee, Salary; L. Flebbe-Rehwaldt, Viracor Eurofins Clinical Diagnostics: Employee, Salary; S. Kleboeker, Viracor Eurofins Laboratories: Employee, Salary; S. Maesaki, Viracor Eurofins Clinical Diagnostics: Employee, Salary; J. Rodgers, Viracor Eurofins Clinical Diagnostics: Employee, Salary; K. Steffens, Viracor Eurofins Clinical Diagnostics: Employee, Salary; M. Altrich, Viracor Eurofins Laboratories: Employee, Salary

2009. Application of Laser Light Scattering Technology in Rapid Diagnosis of Urinary Tract Infections and Antimicrobial Susceptibility Testing in a Tertiary Children's Hospital

Tam Yan, PhD; Samia Naccache, PhD; Andrew Tomaras, PhD; Javier Mestas, PhD; and Jennifer Duen Bard, PhD

Pathology and Laboratory Medicine, Children's Hospital Los Angeles, Los Angeles, California, 1BacterioScan, Inc., St. Louis, Missouri

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. Timely and accurate microbiology testing is crucial in the diagnosis and management of urinary tract infections (UTIs). The ability to rapidly screen for potential UTIs can lead to early rule out and judicious use of antimicrobial therapy. This study examines the application of laser scattering for bacterial detection and antimicrobial susceptibility testing (AST) directly from urine.

Methods. Residual urine samples collected for routine culture were tested using the BacterioScan® 216Dx® UTI System and 216R AST System. Continuous collection of overnight urine patient samples generated growth curve and then bacterial AST results were calculated. Further analysis ruled out mixed flora at lower concentrations, and "qualified" samples were identified directly from the software. Growth control, analysis of light refraction patterns generated growth curve that was used to determine whether the BacterioScan™ 216Dx™ UTI System and 216R AST System. Continuous collection of overnight urine patient samples generated growth curve and then bacterial AST results were calculated.

Results. A total of 106 patients were sampled. Average AST time was 2.5 hours with 100% growth control. Four of the 106 samples were classified as uninterpretable due to limited growth. A total of 53 different bacterial species were identified, including 46 different Gram-positive bacterial species. A total of 32 different antibiotic susceptibility results were generated. The sensitivity and specificity of the BacterioScan™ 216Dx™ UTI System and 216R AST System was 100% for the 106 samples tested.

Conclusion. Laser light scattering technology offers an alternative approach for the rapid diagnosis of UTIs and initial antimicrobial susceptibility testing in a Tertiary Children's Hospital setting.
2092. Development and Characterization of a Synthetic DNA, NuVersa, to Be Used as a Standard in All Quantitative PCR Reactions for Molecular Pneumococcal Serotyping

Pumkinson Sakai, MD, PhD; Griffin Sonaty, MPH; Keith Kligman, MD, PhD; Fitida** and Jorge Vidal, PhD; 1Hubert Department of Global Health, Rollins School of Public Health Emory University, Atlanta, Georgia; 2Pneumonia, Bill & Melinda Gates Foundation, Seattle, Washington

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. Identification of Streptococcus pneumoniae (Spn) and its more than 90 serotypes is routinely conducted by culture and Quellung reactions. Quantitative (q)PCR technology has been developed for molecular detection, including serotyping by lytA assay, and assays targeting 78 serotypes. Reactions require genomic DNA from every target to prepare standards, which can be time consuming. In this study we developed a synthetic DNA molecule as a surrogate for genomic DNA and present new single-plex qPCR reactions to increase molecular detection to 94 pneumococcal serotypes.

Methods. Single-plex qPCR reactions (N=11) that detect 16 pneumococcal sero-types/serogroups were developed and concentration of primer and probe optimized to obtain the highest efficiency by between 90% to 110%. Specificity for the target serotype/serogroup of these new reactions was investigated using a collection of strains belonging to our laboratory and strains kindly donated by the “StepLab” at GDC. A synthetic DNA (NuVersa, ~8.2 kb) was then engineered to contain all available qPCR targets for serotyping and lytA, NuVersa was cloned into pUC57-Amp-modified to generate pNuVersa (~10.2 kb). Standards prepared from pNUversa and NuVersa were compared against standards made out of genomic DNA.

Results. Specificity of these new reactions was confirmed, and after optimization, the obtained limit of detection (LOD) was between 2 and 20 genome equivalents/ reaction. Molecular studies demonstrated that linearity (R²>0.982) for NuVersa (R²=0.991) and efficiency of qPCR reactions using synthetic DNA were similar to those utilizing chromosomal DNA (R²=0.981). Quantification, however, with plasmid pNUversa (Y=Int=4.30 x 1.12) was affected whereas using synthetic NuVersa (Y=Int=4.83 x 1.3) was comparable to genomic DNA (Y=Int=3.9 x 0.62).

Conclusion. We validated new single-plex reactions that, together with published qPCR reactions, now make possible to detect and quantify 94 pneumococcal serotypes/serogroups. NuVersa can be utilized as a control in most, if not all, published single-plex qPCR reactions for the identification (i.e., detection), and quantification (i.e., genome equivalents) of pneumococcal serotypes.

Disclosures. All authors: No reported disclosures.

2093. The DISCOVER Trial: Application of the Karius Plasma Next-Generation Sequencing Test for Pathogen Detection in Stem-Cell Transplant Patients

Monica Fung, MD, MSc, MPH; 1Hin Wong, BS; 2Desiree Hollemon, Karius, Inc., Redwood City, California, USA; 3Pneumonia, Bill & Melinda Gates Foundation, Seattle, Washington; 4Consulting fee Forge Therapeutics; 5Consulting fee Pfizer; 6Consultant, Consulting fee Spero Therapeutics; Consultant, Consulting fee Fuminori Sakai, MD, PhD; 1Griffin Sonaty, MPH; 1Keith Kligman, MD, PhD; 1Fitida** and Jorge Vidal, PhD; 1Hubert Department of Global Health, Rollins School of Public Health Emory University, Atlanta, Georgia; 2Pneumonia, Bill & Melinda Gates Foundation, Seattle, Washington

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. The 216Dx UTI System could be utilized as a screening platform to rule out UTIs within 3 hours, with AST available after an additional 2–6 hours for suspect UTI positive samples. This could potentially prevent unnecessary antibiotic therapy. Preliminary data are promising but testing of additional clinical samples is warranted.

Disclosures. A. Tomaras, Karius, Inc.: Employee, Salary; 4Consulting fee Fuminori Sakai, Karius, Inc.: Employee, Salary; 6Consultant, Consulting fee Pfizer; 5Consultant, Consulting fee Spero Therapeutics; Consultant, Consulting fee Fuminori Sakai, Karius, Inc., Redwood City, California, USA; 3Pneumonia, Bill & Melinda Gates Foundation, Seattle, Washington

2094. Futility of Centor Score (CS) for Predicting Group A Streptococcal (GAS) Pharyngitis in an Adult Hyper-endemic Native American (NA) Population

Ryan Close, MD, MPH** and James B. McAuley, MD, MPH, DTM&H, FIDSA** 1Indian Health Services, Whiteriver, Arizona; Pediatrics, University of Pennsylvania, Philadelphia, Pennsylvania; 2Rush Medical College, Chicago, Illinois

Session: 237. Diagnostics - Novel Diagnostics
Saturday, October 7, 2017: 12:30 PM

Background. Prevalence of GAS pharyngitis among adults is 5% to 15% in the general population. Methods using clinical criteria and laboratory testing to diagnose GAS have not been evaluated in Native American (NA) populations with a higher prevalence than the general population.

Methods. Prompted by an apparent increase (10-15x above national rates) in incidence of GAS pharyngitis in 2016 we conducted a comprehensive epidemiologic study of GAS. Part of this evaluation included GAS pharyngitis. From January to March 2017, we collected a Centor score (CS), throat swab for culture and rapid antigen test (RAT) for all adults ≥18 years presenting with sore throat. For comparison, we also reviewed our electronic health record (EHR), identifying all adults with RAT on file from Jul to December 2016.

Results. From July to December 2016, 224 (33.5%) adults with sore throat had a positive RAT. From January to March 2017, 268 adults had RAT and culture performed: 86 (32.1%) and 85 (31.7%) were positive by RAT and culture, respectively. Comparing adults 18–44 years and ≥ 45 years, odds of culture positive GAS pharyngitis for young age group were 2.00 (C.I. 1.06–3.88, P = 0.023). RAT alone was 75.4% sensitive and 88.0% specific. Comparing adults18–44 years to ≥ 45 years, RAT was less sensitive (70.1% vs. 94.4%) and less specific (86.6% vs. 90.6%) in the younger group. The adding RAT plus CS to patient’s course (40% of cases) can potentially change specificity (91.3% vs. 88.0%) or sensitivity (74.7% vs. 75.3%). A higher CS increased the odds of a positive GAS culture. Tonsillar exudates (89.9%) and fever (51.9%) were the most and least sensitive criteria, respectively. Absence of cough (50%) and pharyngeal erythema (95%) are most and least specific criteria, respectively.

Conclusion. GAS was confirmed in > 30% of cases by RAT on both retrospective review of the EHR and prospectively via RAT or culture. These rates are significantly higher than what is reported in general population. Young age was associated with culture positive GAS. The high sensitivity of exudates and high specificity of absence of cough indicates this criteria may be helpful in deciding which adults are most likely to have GAS. Higher CS did increase odds of GAS positive culture, but the addition of CS to RAT did not significantly alter sensitivity or specificity in this population.

Disclosures. All authors: No reported disclosures.