

2017 APHL Annual Meeting – Providence, RI – June 11-14, 2017

Poster Abstracts

P-01

Investigation of a Canine Parvovirus Outbreak using Next Generation Sequencing

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Canine parvovirus (CPV) outbreaks can have a devastating effect in communities with dense dog populations. The interior region of Alaska experienced a CPV outbreak in the winter of 2016 leading to the further investigation of the virus due to reports of increased morbidity and mortality occurring at dog mushing kennels in the area. Twelve rectal-swab specimens from dogs displaying clinical signs consistent with parvoviral-associated disease were processed using next-generation sequencing (NGS) methodologies by targeting RNA transcripts, and therefore detecting only replicating virus. All twelve specimens demonstrated the presence of the CPV transcriptome, with read depths ranging from 1.5X – 7,566X, genome coverage ranging from 44.8% - 96.5%, and representation of CPV sequencing reads to those of the metagenome background ranging from 0.0015% - 6.7%. Using the data generated by NGS, the presence of newly evolved, yet known, strains of both CPV-2a and CPV-2b were identified and grouped geographically. Deep-sequencing data provided additional diagnostic information in terms of investigating novel CPV in this outbreak. Combining NGS data with serology results (not shown) provided strong diagnostic evidence that this outbreak most likely arose from unvaccinated or under-vaccinated canines, not from a novel CPV strain incapable of being neutralized by current vaccination efforts.

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P-02

Analytical Performance of H/UPLC-coupled MSMS Assays for Monitoring Vitamin D Levels in a NIST Standard Material

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The monitoring of Vitamin D levels (or more specifically, metabolites of the related Vitamins D2 and D3) – a fat soluble pro-hormone – is increasingly preferred by laboratories using mass spectrometry due to its reportedly higher accuracy over immunoassays (Carter GD & Phinney KW., 2014 Clin Chem; Roth JH, Schmidt-Gayk H, et al., 2008 Ann Clin Biochem). Here we demonstrate a customizable LC-MSMS method for measuring 25(OH) D3 and 25(OH)D2 levels and compare their analytical performances for precision, linearity, throughput/assay time and accuracy against the NIST standard material, SRM 972a. Our method combines solvent extraction and protein precipitation to isolate 25(OH) D2/D3 analytes followed by their derivatization using PTAD (4-Phenyl-1,2,4-triazoline-3,5-dione) for enhancing MSMS sensitivity, and either HPLC or UPLC customized reversed-phase separation prior to MSMS analysis of each analyte on a triple quadrupole mass spectrometer. Stable-isotope labeled internal standards are added during solvent extraction, thereby normalizing for sample preparation/instrumental variability.

The ratio of analyte levels (in the NIST material SRM972a) to internal standard signal was compared against that of a calibration curve to determine recovery of analyte concentrations by the two methods. We demonstrate comparable analytical performance across the assay range for both HPLC and UPLC methods, with the added benefit of time savings due to higher throughput by UPLC optimization. Detailed workflow and procedural details are provided for potential use either as a template or starting point for method optimization/development for those seeking to monitor Vitamin D levels by LC-MSMS.

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P-03

Comparison of Two Platforms for Measles and Mumps Reverse Transcription Real-time PCR

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Real-time PCR assays performed in public health laboratories may be infrequently run, unscheduled, requested as STAT, and run in low volumes. These assays include measles, mumps, norovirus, and Bordetella pertussis. The current Washington State Public Health Laboratory (WAPHL) assays for these pathogens are based on Qiagen extraction columns followed by nucleic acid amplification using an Applied Biosystems 7500 Fast Dx Real-Time PCR instrument. Another platform, the ARIES user-defined protocol (UDP), combines an FDA approved platform (ARIES, from Luminex) with the use of lab-developed test (LDT) assays. The ARIES platform accepts cartridges loaded with the specimen and custom primer/probe set, and performs a self-contained nucleic acid extraction followed by reverse transcription real-time PCR (RT-PCR) in under 2.5 hours. The master mix is optimized for Luminex's Multicode technology, but the platform is compatible with TaqMan based assays commonly performed in public health laboratories. We performed an initial comparison of the current WAPHL assays versus the ARIES UDP platform for measles and mumps. To evaluate the limit of detection (LOD) and linearity, serial 10-fold dilutions of Zeptomatrix virus culture fluid were tested. For measles, the LOD of the WAPHL assay was a 10⁻⁶ dilution of the Zeptomatrix material [0.3 tissue culture infectious dose 50 (TCID₅₀)/ml]. The ARIES assay had Ct values 4-5 cycles later than the WAPHL assay, which led to the LOD of the ARIES being a 10⁻⁴ dilution of the Zeptomatrix material (30 TCID₅₀/ml). Both assays showed good linearity, with an average change in Ct of 3.5-3.6 for each 10-fold dilution. For mumps, the LOD of the WAPHL assay was a 10⁻⁵ dilution of the Zeptomatrix material (10 TCID₅₀/ml). Similar to measles, the ARIES mumps assay had Ct values 3-4 cycles later than the WAPHL assay, which led to the LOD of the ARIES assay being a 10⁻⁴ dilution of the Zeptomatrix material (100 TCID₅₀/ml). Both assays showed good linearity. In these initial comparisons, the ARIES UDP platform showed good linearity but a higher LOD for measles and mumps. This may be due to differences in extraction, PCR mastermix, cycling parameters, or other aspects of the assay. Further investigation is needed to optimize the ARIES UDP platform for these assays. The ARIES UDP platform has the potential to simplify workflow and decrease turn-around-time for RT-PCR assays; however, as currently tested, the sensitivity of ARIES is too low to justify switching to the ARIES UDP platform for measles and mumps RT-PCR testing.

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P-04

Applications of Next Generation Sequencing in a Local Public Health Laboratory - The Benefit of Innovative Partnering

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Background: Next-generation sequencing (NGS) is opening opportunities for improved microbial detection, and advanced genomic analysis, thus revealing renewed insight into microbial impacts on humans and environment. Public health laboratories are in the unique position to explore and integrate NGS use to accelerate infectious disease surveillance, real-time outbreak investigations, and strain typing. During definitive microbial pathogens identification in complex clinical and environmental matrices, NGS will also generate information on antimicrobial resistance (AMR) markers for future targeted detection.

NGS projects: The City of Milwaukee Health Department Laboratory has partnered with academic and private sector researchers to conduct a variety of NGS applications. These include: 1) understand genomic diversity in gut microbiota upon 16S rRNA-based metagenomic analysis of human fecal microbiome from diarrheal outbreaks; 2) efficient and improved detection of multi-drug resistant *M. tuberculosis* complex from immigrants residing in the U.S. using full-gene sequencing and 3) elucidating mechanisms of resistance in light-irradiated Methicillin-Resistant *Staphylococcus aureus* by whole genome sequencing.

Conclusion: Use of NGS was critical for efficient and improved detection of drug resistant markers, understanding genomic diversity and in elucidating mechanism of resistance in irradiation treatment failures. State and local PHLs who are routinely using advanced molecular detection techniques like real-time PCR and sequencing, have the opportunity to explore innovative partnerships and unconventional funding supports. Availability of federal funding, data analysis and bioinformatics resources at public health laboratories will be critical for sustained and cost effective NGS practices.

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P-05

Molecular Surveillance of HCV Infection in Alaska Using Global Hepatitis Outbreak and Surveillance Technology (GHOST)

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Purpose: Hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States, and injection drug use is becoming the leading factor for HCV acquisition. Like other states, Alaska also observes a drastic increase in HCV cases in the past few years, particularly among young adults with a history of injection drug use. To meet this challenge, we aim to further develop infrastructure and improve our capacity in HCV advanced molecular detection, through the application of next generation sequencing (NGS) technology.

Setting: The Alaska State Public Health Virology Laboratory (ASVL) is the only public health laboratory in Alaska that tests HCV infection, which currently tests over 6,000 serum specimens per year for HCV infection from all regions in Alaska. The majority (~60%) of specimens tested in ASVL for HCV infection

are those from correctional centers and public health centers located in rural communities. ASVL is one of the four state public health laboratories currently participating in the CDC pilot GHOST projects and has been actively involved in CDC training and adopting GHOST system since 2015.

Technology used: The Global Hepatitis Outbreak and Surveillance Technology (GHOST) is a new web-based system developed by the CDC's Division of Viral Hepatitis that harnesses the power of novel bioinformatics technology and automatically performs a comprehensive analysis of HCV sequencing data via a computerized cloud basis. ASVL has adopted CDC-developed assays and methodology for the HCV NGS testing using GHOST.

Outcomes: The new CDC guide for HCV infection testing recommends testing algorithm to include an initial test with an FDA-approved test for HCV antibodies, followed by an FDA-approved nucleic acid test (NAT) intended for the detection of HCV RNA in serum or plasma if the initial serological assay is reactive. We have adopted this new HCV testing algorithm in addition to adding NGS to test those specimens that have HCV RNA detected but are unable to be genotyped. This approach can significantly reduce the cost of HCV testing since the HCV positive rate ranges from 3% to 15% of all clinical specimens and only HCV positive specimens need to be further tested by NGS. ASVL obtained NGS capacity in 2014 and since has been validating NGS in the testing of various human viral pathogens. In 2015, we re-organized ASVL to establish a new section of sequencing using NGS to replace the viral culture section and began to participate in CDC Pilot GHOST project.

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P-06

Identification of Integrase Drug Resistance Mutations within NYC HIV-1 Positive Specimens

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In support of the Ending the Epidemic (ETE) plan issued by New York State in 2014, NYC DOHMH Public Health Laboratory brought on HIV-1 genotyping and drug resistance mutation analysis. These data provide tools to aid in the suppression of viral load and track transmission in HIV-1 positive patients. We had analyzed over 100 randomly selected specimens from New York for viral load and drug resistance to protease/reverse transcriptase inhibitors. However, a new class of drugs, integrase strand transfer inhibitors (INSTI) were approved as part of combination antiretroviral therapy in 2007 with additional drugs approved in 2012, and 2014, Raltegravir (RAL), Elvitegravir (EVG), and Dolutegravir (DTG), respectively.¹ Due to the recent rollout, nominal data exists on the occurrence of integrase (IN) mutations conferring drug resistance. Therefore, we examined INSTI resistance in the same 100 HIV specimens, which were collected between June and November of 2016. Our methods also included analysis of mutations that confer resistance to allosteric integrase inhibitors (ALLINI), a novel class of IN inhibitors. Resistance mutations were identified using the ViroSeq HIV-1 Genotyping System 2.0 kit; kit instructions were followed according to FDA guidelines for extraction, reverse transcription, PCR, sequencing, and analysis (CELERA/Abbott Molecular). We used the Applied Biosystems' 3500 Genetic Analyzer (Waltham, Massachusetts) for automated sequence detection and identified mutations through deviations from the reference sequence HXB2 using the ViroSeq HIV-1 Genotyping Software v3.0. Successful RT-PCR amplification and sequencing analysis was obtained for 87 (87%) of the RNA specimens. No major primary resistance mutations were detected. Major accessory resistance mutations were identified in 14 (16%) of the 87 specimens and included E157Q (10; 11.5%), L47M (2;

2.3%), V151I (1; 1.1%) and A128T (1; 1.1%). Subtype and strain identification was performed using HIV BLAST (<https://www.hiv.lanl.gov/>). Our study included mostly subtype B infections (92%), but we also detected C (1%), CRF01_AE (1%), CRF02_AG (5%), and CRF44_BF (1%). The E157Q mutation was only found in patients with subtype B (6/10) or CRF02_AG (4/10) infection. Furthermore, two specimens harboring E157Q mutations in the IN gene were found to have major resistance mutations to either protease and/or reverse transcriptase inhibitors. We found multiple specimens with IN mutations that lead to decreased susceptibility to RAL and EVG and one specimen with a mutation (A128T) that can confer resistance to ALLINI drugs.^{2,3} These subtyping data indicate that the E157Q mutation may have been transmitted. Given that some of these drugs were released as late as 2014 and the ALLINIs are yet to be released, the prevalence of resistant mutations is concerning and highlights the need for continuous monitoring of resistance by clinicians and public health programs.

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P-07

Development of a Multiplex TaqMan probe-based Real-Time PCR Assay for Detection of *mcr* genes

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Plasmid-mediated *mcr* genes conferring colistin resistance are emerging worldwide. The first case of *mcr-1* was reported in China in November 2015 by Liu et al. McGann et al. reported the first U.S. case of *mcr-1* in April 2016, and since, *mcr* variants such as *mcr-1.2* and *mcr-2*, have been reported from Europe. Colistin is a last resort treatment option; therefore rapid detection is crucial to stem the spread of mobile colistin resistance genes. Our aim was to develop and evaluate a multiplex real-time PCR assay that could be implemented to screen isolates submitted to the CDC for different *mcr* variants. We further evaluated the assay using surveillance isolates submitted to CDC for antimicrobial susceptibility reference testing. Oligonucleotide primers and probes were designed according to published sequences (GenBank accession numbers NG_0504417 and NG_051171) to amplify a region of 106 and 100 bp of *mcr-1* and *mcr-2*, respectively. Primer specificity was assessed through a BLASTN search. Primers designed to target *mcr-1* should also detect *mcr-1.2*, as *mcr-1.2* and *mcr-1* sequences differ only by a single nucleotide polymorphism at position 8 (A to T). Previously established 16S rDNA primers and probe were used as an endogenous control. TaqMan probes were labeled with FAM (*mcr-1*) and HEX (*mcr-2*) together with a BHQ quenching dye. PCR reactions contained 1x KAPA Probe Fast qPCR Kit, 0.5 μ M of each primer, 0.25 μ M of each probe, 2 μ l template DNA and molecular grade water to a final volume of 20 μ l. Thermal cycling conditions were: 3 min at 95°C, followed by 35 cycles at 95°C for 3 sec and 60°C for 30 sec. Amplification, data acquisition and data analysis were performed using a 7500 Fast Real-Time PCR System (Applied Biosystems). Repeated tests of *mcr-1* and *mcr-2* positive controls produced exponential amplification curves; variant *mcr-1.2*, was successfully detected using the *mcr-1* primer/probe set. Amplification efficiency was determined to be 98.2% and 96.4% for *mcr-1* and *mcr-2*, respectively. The assay was validated against a set of 25 isolates, including 19 negative isolates to ensure specificity. The assay was further used to retrospectively screen 290 Enterobacteriaceae surveillance isolates displaying a colistin minimum inhibitory concentration of ≥ 2 μ g/ml. All isolates were negative for *mcr* genes. We developed a multiplex real-time PCR assay that can be used for the rapid and accurate detection of all currently described *mcr* genes. Continued surveillance and monitoring is

critical to provide more accurate estimates of the prevalence of *mcr* genes and to rapidly inform public health action to limit further global dissemination of colistin resistance.

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P-08

Simultaneous Detection of Four Human Malaria Species from Whole Blood or Dried Blood Smears

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Malarial disease is found worldwide with important public health implications. In spite of extensive eradication efforts, there is still a high mortality rate, especially in children. Identification of malarial infections to the species level is most important in endemic regions of Africa, Asia and the Americas. The 'gold standard' in malaria diagnostics is still microscopy but this method is not sensitive at low levels of parasitemia or with mixed infections when one species predominates. Reading slides at very low parasitemia is a challenge even with highly trained and experienced microscopists and leads to false negative results. More sensitive methods are required as cases of low parasitemia occur which allows for continued transmission of the malarial parasite. We developed a multiplex real-time PCR assay that can identify the most common malarial species that infect humans. The real-time PCR assay is performed on DNA extracted from whole-blood specimens and can simultaneously detect *P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale curtisi* and *P. ovale wallikeri*. The gene target is the 18S rRNA gene and the limit of detection is 23 gene copies per PCR reaction. The assay identifies mixed infections in patient samples and was shown to be 100% specific when tested against a panel of pathogens that are found in blood. This method is rapid, accurate, inexpensive and very sensitive for detection of *Plasmodium* species in patient samples. In addition to whole blood, the assay can be used with DNA extracted from dried blood scraped off of Giemsa-stained slides. This is especially useful in cases where whole blood samples are difficult to obtain and store, or when only blood smears are available. **Conclusion:** The multiplex real-time PCR has been used to identify *Plasmodium* species in over a thousand clinical samples submitted to the Wadsworth Center NYS public health lab over a five year period. It has proven to be a very robust, accurate, cost effective and sensitive method for identification of malaria infections at the species level.

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P-09

Validation of a Molecular-based Rapid Diagnostic for Coccidioidomycosis (Valley Fever)

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Coccidioidomycosis is a common causative agent of community-acquired pneumonia in the southwestern United States. It is increasingly becoming a public-health problem because of the

unprecedented population growth observed in this area and the large number of individuals with suppressed immune systems. Standard of care, diagnostic methods used to detect *Coccidioides* species include microscopy, serology, culture and histopathology of tissues. However, these methods present with different performance related problems, most notably delay due to culture time. In pursuit of a better performing and safer method, DxNA developed the PathoGene® *Coccidioides* Assay. This assay is a highly sensitive real-time (RT) PCR assay that is intended to be implemented in clinical laboratories for the diagnosis of coccidioidomycosis (pending FDA 510(k) clearance). The RT-PCR reactions are conducted on the GeneSTAT system following sample preparation and DNA extraction. Total assay time is four hours from sample preparation (2.5 hours) to testing samples (1.5 hours) on the analyzer. To comply in part with FDA recommendations, the performance of this assay was evaluated using both prospective and retrospective samples. This validation was conducted using remnants of bronchial alveolar lavage (BAL) fluid. Our site was one of three sites involved in this stage of the commercial assay validation. At our site, 88 prospective patient samples and 2 retrospective frozen samples were tested. Additionally, two pilot assessments were conducted: (1) To determine assay performance in the presence of confounding respiratory organisms and (2) to observe assay performance using different commercial extraction kits. In the clinical study, the assay demonstrated prospective specificity of 100% and sensitivity of 100%. Results from our pilot studies showed that the assay performed better when the Qiagen QIAamp? DSP DNA Mini Kit (reference kit) was used for BAL DNA extraction. The presence of other respiratory organisms had no effect on assay performance. In comparison to fungal cultures, which take 5-12 days to isolate *Coccidioides* spp. and 21 days to finalize negative cases, results from this validation study provided us with diagnostic values within four hours (identifying/ruling out cases of coccidioidomycosis). The implementation of this diagnostic assay in the clinical setting should contribute to earlier diagnosis and subsequent treatment of patients as well as reduce the exposure rates from culturing these organisms in the laboratory.

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P-10

Tennessee Department of Health Laboratory Services Implementation of Genexpert MTB/RIF Testing in Non-sputum Sources

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Objective: A study was undertaken to compare recovery rates of *Mycobacterium tuberculosis* in non-sputum sources. Cepheid (the manufacturer of the GeneXpert MTB/RIF kit) only has FDA approval for testing sputum sources. TDH Laboratory Services wanted to evaluate non-sputum sources for the following reasons: 1. *Mycobacterium* can disseminate throughout the body and to various body fluids. It may present at detectable levels prior to the development of respiratory symptoms. 2. Frequently, a non-sputum source may be the only specimen available for testing and therefore may be the only chance for laboratory confirmation of infection.

Study Design: Non-sputum sources received between July 2014 - September 2015 were tested on GeneXpert. Sources varied from: bronchial washings, lymph nodes, urine, stool, blood, CSF, bone marrow and endotracheal aspirate. Twenty-five non-sputum specimens were received from various hospitals and health departments throughout the Tennessee. Specimens tested included both positive

and negative specimens by fluorochrome smear. GeneXpert results were compared to reported culture results.

Results: Specimens tested for GeneXpert MTB/RIF had smear results ranging from negative to 10+. Seventeen specimens were reported as smear negative, GeneXpert negative and no growth by culture. Eight specimens had smear positive results with 6 positive GeneXpert results (2 negative). Five out of six positive GeneXperts had culture confirmation of Mycobacterium tuberculosis complex; 1 was contaminated and unable to identify further. The contaminated culture had a previous sample test positive for MTBC. Two GeneXpert negative results were confirmed as *M. intracellulare*. 100% correlation between the Positive GeneXpert and culture results.

Conclusions: Reliable results can be obtained from non-sputum sources utilizing GeneXpert MTB/RIF. Therefore, GeneXpert testing will be routinely performed on acceptable respiratory and non-respiratory specimens received for Mycobacteriology Smear and Culture testing. Non-sputum sources will also have the following disclaimer added: This test has been approved by U.S. Food and Drug Administration for analysis of sputum specimens. Performance characteristics from specimen types other than sputum have been determined by TDH Laboratories Services.

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P-11

Public Health and Corrections: A Model of Program Collaboration and Service Integration

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Objective: In 2009, CDC's National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) introduced a service mechanism called "Program Collaboration and Service Integration" (PSCI). Public health programs provide categorical services to persons who have multiple related disease risks, but often miss significant opportunities. PCSI's strategic priority strengthens collaboration across disease program areas at the client level. Incarcerated populations have higher risk for HIV/AIDS, STDs and TB due to increased risk of disease transmission. Incarceration provides important opportunities for disease surveillance, diagnosis, treatment and prevention. In October 2015, the TB Elimination Program, HIV/STD & Viral Hepatitis Program, Information Technology Services Division, and Laboratory Services of Tennessee Department of Health (TDH) collaborated with the Tennessee Department of Correction (TDOC) to screen all new inmates for TB infection, HIV, syphilis, gonorrhea and chlamydia. The collaborative efforts and results of TDH's and TDOC's implementation of intake screening for TB, HIV, and STDs for all inmates entering the TDOC system are described.

Study Design: Multidisciplinary planning included feasibility, resource assessment, protocol development, intake flow analysis, information technology installation, staff training and data analysis at two intake prisons in Tennessee – The Tennessee Prison for Women and Bledsoe County Correctional Complex.

Results: Following pilot testing at both facilities, from December 2015 through May 2016 a total of 16,166 tests for five diseases were obtained. The aggregate test positivity rates were: TB infection – 5.0%; HIV infection – 0.8%; syphilis infection – 1.0%; gonorrhea infection – 2.2%; and chlamydia infection – 0.2%; positivity rates differed by gender.

Conclusion: A unique multi-program and agency collaboration successfully implemented integrated prison intake screening for five (5) diseases of public health importance in Tennessee – including Mycobacterium tuberculosis. Multi agency collaboration continues and testing for additional diseases is being explored.

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P-12

Changing Diagnostic Practices for Detection of Enteric Infections in Clinical Laboratories—FoodNet, 2012–2016

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Background: The landscape of diagnostic practices for enteric pathogens has undergone a dramatic shift in the past 4 years. In March 2012, the Foodborne Diseases Active Surveillance Network (FoodNet), an active population-based sentinel surveillance system for laboratory-confirmed enteric infections, began conducting semi-annual surveys of all clinical laboratories that serve patients in its catchment area. The survey includes questions regarding the methods to detect 7 enteric pathogens to assess diagnostic testing practices, identify changes, and understand impacts of changes on surveillance.

Methods: We compared data collected from FoodNet laboratory surveys conducted March 2012 and October 2016. Statistical significance was defined as $p < 0.05$ for 400 laboratories that tested for Campylobacter in 2012 versus 2016, those exclusively using culture decreased from 90% to 72%, those exclusively using CIDs significantly increased from 8% to 24%, and those using both remained similar (2% vs. 4%). Comparing the >390 laboratories that tested for Shiga toxin-producing Escherichia coli (STEC) or Shiga toxin in 2012 with 2016, those exclusively using culture for STEC O157 decreased from 47% to 22%, those exclusively using Shiga toxin-detecting CIDs increased from 16% to 29%, and those using culture for O157 with a test for Shiga toxin increased from 37% to 49%. Among the laboratories that tested for Salmonella, Shigella, Vibrio, or Yersinia in 2012 versus 2016 those using CIDs increased from =1% to 11%, 10%, 13%, and 11% respectively. The proportion of laboratories that use commercial DNA-based syndrome panels increased from 0% in 2012 to 13% in 2016, with the first reported usage in 2013.

Conclusion: Our findings show a marked shift in diagnostic practices with a significant increase in the number of laboratories that have discontinued culturing and an increase in the number using CIDs. The declining availability of patient specimens for reflex culture and pathogen isolation limits the ability of public health officials to monitor trends, detect outbreaks, monitor antimicrobial resistance, and attribute illnesses to specific sources

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P-13

Whole Genome Sequencing Analysis of Clinical Shiga Toxin-Producing Escherichia Coli O157 Strains from Washington State in 2016

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Shiga toxin-producing Escherichia coli serotype O157 is a major foodborne pathogen causing severe illness and many outbreaks worldwide. The mosaic genomic structure of STEC O157 genome and diversity among different strains may indicate that obtaining whole genome sequences would be necessary for subtyping different STEC O157 strains. We demonstrated the successful implementation of whole genome sequencing (WGS) analysis in public health applications as part of the routine workflow which includes PFGE testing. Whole genomes of 26 clinical STEC O157 strains were sequenced using Illumina MiSeq platform and uploaded to NCBI in Washington State during 2016. Whole-genome based phylogenetic trees were constructed using SNP analysis methods to compare the differences between these STEC strains and the reference EDL 933 isolate. Other genomic information, such as plasmids and virulence genes, antimicrobial resistance genes, MLST types and predicted serotypes were also revealed using Center for Genomic Epidemiology (CGE) server. Preliminary findings showed that some of these STEC strains were lack of stx1 genes. Different plasmids were also detected among these strains. Phylogenetic differences among these strains were also distinguished by kSNP tree analysis. The results indicated that whole genome sequencing analysis method could be successfully implemented in a public health laboratory for routine STEC testing.

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P-14

Automated Solution for the Simultaneous Detection of Non-treponemal and Treponemal Antibodies: A Paradigm Shift in Syphilis Diagnosis

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Introduction: The incidence of syphilis infection has increased over the last decade in various populations including men who have sex with men (MSM). Diagnosis of infection typically involves a combination of non-treponemal and treponemal assay results. While non-treponemal assays such as RPR continue to require extensive hands on time, treponemal assays have been semi- or fully automated. Here we describe an evaluation of the Bio-Rad BioPlex 2200 Syphilis Total & RPR Assay, an automated solution for the simultaneous detection of both non-treponemal and treponemal antibodies with on-board RPR titer capability.

Methods: A total of 1217 samples including 210 syphilis test-ordered, 118 medically diagnosed, 315 HIV positive samples, 296 pregnancy samples and 278 retrospective RPR/VDRL positive samples were evaluated using the Bio-Rad BioPlex 2200 Syphilis Total & RPR Assay. BioPlex Syphilis Total results were compared to a composite comparator result obtained using the DiaSorin LIAISON Treponema Screen assay, BD Macro-Vue Rapid Plasma Reagin (RPR) Test and Fujirebio SERODIA-TP-PA. Conversely, BioPlex RPR results were compared directly to those obtained using the BD Macro-Vue RPR Test. In addition, 96 qualitative RPR positive samples were titered using both the BioPlex RPR onboard dilution procedure and the BD Macro-Vue RPR Test.

Results: The BioPlex Syphilis Total showed an overall positive and negative agreement of 98.7% (534/541) and 98.5% (665/675) respectively when compared to the comparator result for all sample populations including syphilis test-ordered, medically diagnosed, HIV positive samples, pregnancy samples and retrospective RPR/VDRL positive samples. Within the same sample populations, the total positive and negative agreement between the BioPlex RPR and the BD Macro-Vue RPR was respectively 97.1% (401/413) and 96.3% (774/804). For the 96 positive RPR samples that were titered, the total percent agreement (within ± 1 titer) between the BioPlex RPR and BD Macro-Vue RPR was 86% covering a range of 1:1 to 1:256. Furthermore, the BioPlex RPR showed 100% titer reproducibility (within ± 1 titer) with titer precision of $< 8\%$.

Conclusions: The fully automated BioPlex 2200 Syphilis Total & RPR Assay showed high agreement with the DiaSorin LIASION Treponema Screen, BD Macro-Vue Rapid Plasma Reagin (RPR) Test and Fujirebio SERODIA-TP-PA. The BioPlex 2200 Syphilis Total & RPR Assay may be a suitable alternative for laboratories looking to consolidate their syphilis testing while improving workflow and labor savings.

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P-15

Cryptosporidiosis; What is the Gold Standard for Detection?

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Cryptosporidium is a pathogenic parasite that can cause severe diarrhea and gastrointestinal distress. Typically, infection is caused by ingesting water, or food, that has been contaminated with fecal matter. Microscopy is the current gold standard for the detection of Cryptosporidium in stool for many public health laboratories. Microscopic detection, however, can be limited by parasitemia level and takes skilled personnel to recognize the morphological features of Cryptosporidium oocysts. In this study we compared the current standard of microscopy to 1) the Alere Cryptosporidium antibody based method 2) the BioFire FilmArray GI panel and 3) a lab developed real-time PCR multiplex assay. Samples that were identified by hospital or commercial labs as positive for Cryptosporidium were submitted to the NYSDOH Wadsworth Center for confirmation. Samples that were positive (n=20) by Modified Acid Fast (MAF) and/or Direct Fluorescent Antibodies (DFA) microscopy were also tested by antibody, GI panel and real-time PCR which resulted in sensitivities of 80%, 95% and 100% respectively. Samples that were microscopy negative (n=72) were also analyzed using the comparative methods. Results show that using microscopy alone can result in false negatives as 15 samples were determined to be positive by both the GI panel and the real-time PCR. The Alere assay gave positive results for only 4 out of the 15. In addition to the 15 positive specimens detected by both molecular methods the real-time PCR assay detected an additional six samples that were confirmed via conventional PCR and sequencing to be positive for Cryptosporidium. When comparing all platforms for sensitivity, capacity and cost, the real-time PCR multiplex assay showed the best performance with great sensitivity, high through-put and low cost. For this sample set the Alere assay gave the lowest sensitivity. The FilmArray and real-time PCR assays have comparable sensitivity, however the combination of through-put and cost of testing makes the real-time PCR multiplex assay more desirable for a public health laboratory.

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P-16

Community Analysis of Environmental Healthcare Surfaces using Next Generation Sequencing

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The contribution of environmental contamination from patient room surfaces to acquisition and transmission of healthcare-associated infections has not been well-defined. This pilot study characterized microbial communities on high-touch, non-critical healthcare surfaces using next generation sequencing technology. Samples were collected from rooms of patients isolated for multidrug-resistant bacterial infections. 16S rDNA was extracted and hypervariable regions V1-V2 were amplified and sequenced using the Illumina MiSeq platform. Amplicon reads were clustered into Operational Taxonomic Units (OTUs) at 97% sequence similarity and identified by aligning centroid sequences against the GreenGenes database. Analysis of similarities (ANOSIM) was performed on distance matrices to test whether groups were significantly different by OTU composition. Concordance (percent agreement), between culture and sequence data was evaluated: *Acinetobacter baumannii* 51.3% *Klebsiella pneumoniae* 87.5%, *Staphylococcus aureus* 52.5%, and *Enterococcus* 66.3%. For cleaning product, there was a difference among the top ten family-level OTUs between rooms cleaned with bleach and those cleaned with a quaternary ammonium compound for surfaces not in direct contact with the patient, (ANOSIM $R = 0.66$, $p = 0.005$). For patients isolated for MRSA, *S. aureus* was sequenced from 45.1% of rooms; *Enterococcus* was sequenced from 23.1% of rooms where the patient was isolated for VRE. Overall, the microbiota on surfaces in bleach-cleaned rooms had larger proportions of Gram positive bacteria, including those that resemble skin microbiota, whereas quaternary ammonium compound-cleaned rooms had larger proportions of Gram negative bacteria, including those that resemble enteric microbiota. We could not confirm viability through sequencing and directionality between patient and environment could not be assessed. However, these data support that cleaning products likely impact the environmental microbiota and that the environment may play a critical role in transmission pathways. This study demonstrated that next generation sequencing technology is a valuable tool and, with further validation regarding burden and associations with colonization and infection, will be critical for evaluating the contribution of the environmental microbiota in transmission studies and healthcare-associated outbreak investigations.

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P-17

Implementation of QuantiFERON®-TB Gold Screening of Whole Blood Specimens in a Local Public Health Laboratory

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Fairfax County Health Department Laboratory (FCHDL) is a local public health laboratory located in the Northern Virginia (NoVa) region of the Commonwealth of Virginia. Fairfax County is a highly diverse community and home to many large ethnic populations. One-third of all the TB cases in the Commonwealth of Virginia reside in Fairfax County, making the interferon gamma-release assay (IGRA) a valuable diagnostic test for our population. In 2014, FCHDL successfully implemented QuantiFERON®-TB

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Gold (QFT) testing of whole blood specimens for Latent Tuberculosis Infection (LTBI) utilizing the Dynex DS2® ELISA platform. The QFT assay is based on a synthetic mixture of peptides, simulating ESAT-6, CFP-10, and TB7. 7, which stimulate cells to release interferon-gamma (INF-γ) in heparinized whole blood. Plasma is then tested for the presence of INF-γ produced in response to these peptide antigens associated with M. tuberculosis infection. FCHDL implemented QFT testing in a structured manner composed of three phases, allowing the laboratory to maintain control over aspects of training and testing, including pre-analytic, analytic, and post-analytic processes. Phase 1 served as a pilot program, consisting of training four laboratory technologists on QFT protocols utilizing the Dynex DS2® platform. At the same time, nursing staff at one of our clinic locations were trained on the proper collection, handling, and transportation procedures for QFT samples. FCHDL couriers were trained on the appropriate handling and transportation requirements for maintaining the integrity of QFT specimens. Once all training was completed and the method verified, testing was implemented. Phase 2 expanded training, testing, and courier services to the remaining Health Department clinic sites. Phase 3 entailed the purchase and deployment of incubators and data-loggers to allow for incubation on site. Training was provided to clinic staff, and competency assessed by laboratory personnel prior to implementation of on-site incubation of QFT samples. FCHDL's ability to maintain control over all processes involved in QFT testing, from staff training and competency assessment through collection, handling, incubation, transportation, testing, and reporting of results, has resulted in a high level of quality testing as evidenced by low indeterminate rates achieved. The successful implementation of QFT testing has allowed FCHD to replace the less specific tuberculin skin test (TST) with QFT testing for all eligible individuals ages five and up, resulting in a reduction of false positive tests and an increase in adherence to latent TB treatment. Implementation of QFT testing has increased accuracy of testing and has resulted in a significant cost savings to the county through the elimination of unnecessary chest x-rays and LTBI drug therapy.

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P-18

Construction, Communication and Collaboration: State Public Health Laboratory NGS Gap Analysis and Minnesota's Experience Bridging the Gap

X. Wang, A. Taylor, D. Boxrud and S. Vetter, Minnesota Department of Health, St. Paul, MN

When state public health laboratories started marching into the era of next-generation sequencing (NGS) for high resolution pathogen characterization, the accumulation of enormous amount of sequencing data brought the urgent need for bioinformatics in order to untangle complex datasets, mining pathogen biological information and translate fragmented sequencing reads into useful epidemiological interpretation. In December, 2016, The Minnesota Department of Health-Public Health Laboratory (MDH-PHL) teamed up with APHL and other four state PHLs, conducted an assessment within 27 public health labs nationwide in order to evaluate the capacity of NGS. At the time of the assessment, 24 state public health laboratories were still in the early stage of start performing WGS for the purpose of advanced molecular detection. Two state public health laboratories were still waiting for their first sequencer. Regarding WGS data analysis, the lack of bioinformatics tools and personnel, as well as difficulties of working with state IT department, was the most significant challenge. One way MDH-PHL was able to overcome some of these barriers was with the help a APHL-bioinformatic fellow, Dr. Wang. As the first APHL-CDC bioinformatic fellow who serves at state public health lab, Dr. Wang

was deeply involved in the building of Minnesota PHL bioinformatic infrastructure by collaborating with Minnesota Supercomputing Institute (MSI) and Minnesota IT Department (MNIIT). Here, insights and experiences are provided in order to advance other public health laboratories' NGS progress. In summary, it was a mix of collaboration and much communication to increase NGS capacity.

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P-19

Non-O157 STEC stx and eae Subtyping and Rare stx2 Subtypes Characterization by Whole Genome Sequencing (WGS)

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Shiga toxin-producing *Escherichia coli* (STEC), one of the most important foodborne bacteria, is a major threat to public health. An estimation of 96,500 O157 and 168,690 non-O157 STEC infection cases were reported each year, result in more than 3600 hospitalizations and 30 deaths due to diarrhea and Hemolytic Uremic Syndrome (HUS) (Scallan et al., 2011). For Minnesota Department of Health (MDH) non-O157 STEC monitoring, Shiga toxin (stx), an AB5 toxin that largely target renal epithelial cell and causing apoptotic cell death, as well as eae gene, which facilitates adhesion of the bacterium within the cecal epithelial cells, are two of interests. Evidences have shown that different stx subtypes have various contribution to HUS. Certain stx subtypes are also associated with increased virulence while eae's significance associated with STEC's pathogenicity is still largely unknown. Here we used traditional PCR methods to detect stx and eae gene. In addition, whole genome sequencing (WGS) as well as in house developed bioinformatics analysis were performed in order to further subtype those two genes. Within 380 non-O157 STEC isolates that collected from year 2015 to 2016, the dominant stx subtypes are stx1a and stx2a with the frequency of 72% and 28% respectively, while eae subtypes are more dispersedly distributed. Ten cases which the discordant results between PCR and WGS were identified, indicating the potential detection limitation of traditional PCR method. A rare stx2 gene sequence, with only 90% similarity to the closest subtypes and three amino acid deletions at the end of eae subunit A, was characterized. This study indicated the importance and significant discriminatory power of whole genome sequencing in the public health laboratory foodborne disease epidemiological monitoring.

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P-20

Concurrent Comparison of Two Real-time PCR Assays for the Detection of Zika Virus RNA in Clinical Specimens from an Outbreak

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In the summer of 2016, the state of Florida reported the first cases of autochthonous transmission of Zika virus in the continental United States. In response to the outbreak, the Florida Department of Health's Bureau of Public Health Laboratories (BPHL) provided laboratory support by testing the

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resulting increased volume of specimens and providing rapid results to public health officials. During the height of the outbreak, two of the three state public health laboratories in Florida (Jacksonville and Tampa) utilized the real-time RT-PCR assay described by Lanciotti and colleagues (2007). The BPHL-Miami implemented the Centers for Disease Control's Trioplex Real-time RT-PCR Assay for the simultaneous detection of Zika, Dengue, and Chikungunya viruses. In September of 2016, BPHL-Miami undertook a small study to compare the results of both assays to ascertain whether one performed substantially better than the other. Over a period of two weeks, specimens submitted for testing to the BPHL-Miami were tested using both assays. During this time, 343 whole blood, serum, and urine specimens were received and extracted using two different automated platforms. The resulting extracts were tested on the same day using both RT-PCR assays and the Ct values compared.

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P-21

Rapid Implementation of Zika RT-PCR Testing in Anticipation of an Outbreak Response: Lessons Learned at the Bureau of Public Health Laboratories-Miami

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During the first seven months of 2016, the Florida Department of Health (DOH) identified 321 travel-related cases of Zika virus infections amongst residents and visitors to Florida (Likos et al., 2016). Of the three laboratories of the Florida DOH's Bureau of Public Health Laboratories, only two locations (Jacksonville and Tampa) were supporting these investigations by testing specimens for Zika virus. In early July 2016, epidemiological and laboratory evidence began to mount toward autochthonous transmission of the virus in a limited area in Miami-Dade County, Florida. In response, BPHL-Miami began preparations to perform high-throughput testing of specimens to support an outbreak response. By the end of July, BPHL-Miami had implemented the Centers for Disease Control and Prevention's Trioplex Real-time RT-PCR Assay and was prepared to test the high volume of specimens associated with the forthcoming outbreak and provide timely, sustained support for the ensuing epidemiological investigations. From July to December 2016, BPHL-Miami tested approximately 6,000 specimens by real-time PCR. During this period, several workflow changes were made to adapt the testing process to the optimum configuration for the high volume of specimens the laboratory was experiencing. Herein, we report the lessons learned as a result of this experience and offer a model for high-throughput laboratory testing.

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P-22

Urosurvey as a Public Health Tool to Identify Locally-Acquired Cases of Zika Virus: Experiences of the Bureau of Public Health Laboratories-Miami

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On August 1, 2016, the Centers for Disease Control and Prevention (CDC) issued a health advisory notice in response to a newly identified area of vector borne transmission of Zika virus in Miami-Dade County. Much of the evidence garnered to support this public health action was provided through a joint effort of the laboratorians and epidemiologists of the Florida Department of Health (DOH) following a survey of the community immediately surrounding the separate workplaces where two otherwise unrelated cases of Zika were identified. Initially, urine specimens were collected from the households within a 150-meter radius and later expanded to determine the extent of spread of the virus. Results from this urosurvey provided additional information and context for the initial outbreak of Zika virus in Miami-Dade County. In addition to identifying additional cases for follow-up, the data gained from the urosurvey aided in establishing the tentative boundaries for the ensuing epidemiological investigation. Urosurveys have since been used in Florida to investigate sporadic cases of Zika virus infection and to determine the extent of the potential area of transmission. The urosurvey has proven to be an effective tool to identify both symptomatic and asymptomatic cases and guide further public health actions. Here, we present the experiences of the BPHL-Miami with providing high-volume testing support for the epidemiological investigations of locally-acquired Zika virus.

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P-23

Trace Metals Analysis in Low Volume Samples Using Inductively Coupled Plasma Mass Spectroscopy

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Techniques developed at our laboratory for trace element analysis in low volume samples can make this challenging application a routine procedure. Analysis of sample volumes of < 1mL for trace metals typically requires specialized sample handling, making the analysis difficult to incorporate into the normal workflow. Our laboratory recently developed a protocol for the determination of copper in plasma using the standard Integrated Sample Introduction System (ISIS) on an Agilent ICP-MS. Our approach utilized 50µL of plasma and was validated in compliance with FDA-GLP. Significant figures of merit for copper were a working range of 2-10,000ng/mL, bias of -3%, measurement uncertainty of 12%, and recovery of a commercial Certified Reference Material at "Low" and "High" ranges were within target limits for the duration of the study. Of note was that the duration of the analytical signal using our approach was in excess of 45 seconds, which would permit 6-8 additional elements to be added to the assay with no additional effort. This approach could be expanded to incorporate other toxic elements such as arsenic, cadmium, chromium, lead, mercury, and thallium for analysis. Conversely, the technique could be adapted to perform analysis of a single element of 10-20µL sample volume. A notable application for this approach would be the determination of trace elements in newborns and infants or patients where sample volume is typically small. Applications for ICP-MS, already used in state and local public health laboratories, can be expanded with low volume analysis for a variety of related applications including toxic elemental analysis for food safety, biomonitoring, water, and agriculture security.

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P-24

An Analysis of Technologies and Recent Tools to Provide a Food Testing Roadmap

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Recent industry measures and technological advances result in greater needs for educational and training references. These are expedited through information sharing among academia, government, industry, and public health laboratories, especially state and local. In part to reduce the 48 million people affected by foodborne illness annually, new regulations have impacted requirements for risk-based preventative controls, including environmental monitoring and supply chain traceability. Approximately 19% of annual foodborne illness fatalities are caused by listeriosis, with foods such as frozen fruits and vegetables, cheese, ice cream, and ready-to-eat products like salads being major contributors to recent recalls. During these recall investigations, it was discovered that *Listeria* had been proliferating in the manufacturing environment due to insufficient contamination control and microbiological monitoring. Several different pathogen diagnostic technologies may be used orthogonally to improve process and contamination control, including ATP swabbing, ELISA-based test kits, nucleic acid based detection technologies, and whole genome sequencing (WGS). These detection, identification, and characterization tools, along with educational and training references, can be used to provide a food testing roadmap that helps reduce the risk of contamination and foodborne illness. Our presentation includes an analysis of available tools and technologies focusing on *L. monocytogenes* that can be applied to existing assessments such as the APHL yardstick assessment tool and related references.

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P-25

Using a Capability Maturity Model as a Process and Strategy to Enhance Research Programs in Public Health Laboratories

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Establishing successful research programs, especially through competitively awarded external funding, is a major challenge for many state and local public health laboratories both in the United States and across the world. Many of these institutes lack a specific mission to perform, document, and publish novel scientific research which hinders their ability to access financial resources and retain highly qualified staff. Gaps in identifying research funding opportunities; pursuing and securing awards; conducting and completing research projects; and publishing results need to be addressed in order to strengthen and grow public health research capabilities. Assessing existing research capabilities can be challenging, due to the process' resource-intensive nature and lack of a standardized evaluation method. The Capability Matrix Model (CMM), often used for strategic planning in business and technology, is a process used to enhance performance by describing three levels of capability (initial, managed, and optimized). An organization can assess its current capability ("as is") and form an actionable strategy for its next level ("to be"). CMM can be applied to establish initial best practices,

define metrics, and measure outputs and success rates. Existing, basic metrics to measure laboratory research success, such as the number of peer-reviewed publications and grant funding awards, are often used to determine the quality of a research program. However, these metrics do not show how efficient an existing practice is and whether it is repeatable and optimized. We suggest that CMM provides a framework for effective strategic planning of public laboratory research capabilities. This presentation will provide information from a pilot survey of research institutes in under-resourced areas intended to better understand their existing research capabilities and practices, with an eye towards implementation of CMM to optimize these processes. The processes used to obtain these data and the associated analysis can be equally applied to benefit both state and local public health laboratories in the US and those in under-resourced areas. Moreover, US laboratories often support or are twinned with their counterparts in under-resourced settings. Thus, the use of a consistent approach to measure laboratory research success will further enhance these collaborations and allow best practices to be easily shared.

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P-26

Utilizing the Annual All-Hazards Survey to Identify Funding and Programmatic Support Issues in CDC-PHEP Funded Public Health Laboratories

S. Abrams, D. Kim, J. Rosalez and C. Mangal, Association of Public Health Laboratories, Silver Spring, MD

Objective: The Association of Public Health Laboratories (APHL) issues an annual survey to 54 Centers for Disease Control and Prevention (CDC) Public Health Emergency Preparedness (PHEP) funded public health laboratories (PHLs) to identify funding and programmatic shortcomings faced by our nation's laboratories.

Study Design: The survey covered the 12 month period of the CDC PHEP Cooperative Agreement for Fiscal Year 2015, between July 1, 2014 and June 30, 2015. An online survey containing 36 questions was administered to laboratory contacts in 54 different PHLs across the USA between September and December 2015. All 50 states, Washington, D.C., Puerto Rico, Los Angeles and New York City, participated in the study. Questions addressed demographics, funding and workforce, planning and response, and different threats (biological, chemical, and radiological) among each PHL.

Results: All 54 PHLs completed the survey. Funding: The majority (57%) of PHLs experienced funding cuts from the previous fiscal year, with the most common impacts including the inability to expand capabilities for new assays and tests (58%), being unable to purchase service contracts necessary to maintain critical equipment (48%), and lacking adequate funds to purchase necessary equipment (42%). Funding issues also lead to 42% of PHLs being unable staff and 26% reducing or completely halting training courses and outreach activities.

Planning and Response: Only one-fourth of laboratories indicated that they had a cross-border contact with Canada or Mexico, while all but one indicated specimen submission and testing collaboration with both the FBI and sentinel clinical laboratories. 91% responded that they had the capability to handle a significant surge in testing lasting up to 8 weeks. During the period surveyed, PHLs sampled almost 165,000 different Laboratory Response Network specimens.

Threats: Only 39% of PHLs provided biosafety training, with 77% indicating funding as a major barrier to providing training. Over one-fourth of PHLs lacked a biosafety professional, while 9% experienced a decrease in capability to detect chemical threats, overwhelmingly due to the loss of personnel (80%).

Conclusions: PHLs continue to face major issues in light of decreased funding, placing excessive burden on health departments and their employees. This resulted in less training opportunities for staff and the inability to obtain updated technology needed to detect a wide range of threats. While the overall impact on the health of the population is hard to quantify, without swift changes to increase support for PHLs, the potential for a devastating public health emergency lurks ahead.

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P-27

The Laboratory Response Network in Action: A Collaborative Effort to Revise the Original Bioterrorism Response Guide for Clinical Laboratories (Bioterrorism Blue Book)

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In 2001, the CDC published a sentinel laboratory (lab) resource titled, "Bioterrorism Response Guide for Clinical Laboratories" which was printed in a blue notebook and became commonly known as "the BT Blue Book" and served as a primary reference for presumptive and safe recognition of biothreat agents in a clinical lab. The original version was never updated from CDC, although some State Public Health Laboratory Bioterrorism Training Coordinators (BTCs) and State Training Coordinators (STCs) updated the guide based on ASM Sentinel Lab Protocol revisions, and for their own State-specific Sentinel Lab Trainings. All BTCs and STCs were surveyed to inquire about the status and use of the guide and it was determined that the sentinel labs still used it and it was in need of a significant update. An initial collaboration was formed between CDC and APHL to revise the guide with help from the Training Coordinators, the APHL Sentinel Lab Training Collaborative Workgroup, and with steering oversight from the APHL Sentinel Lab Partner and Outreach Subcommittee and ASM. Shoolah Escott (formerly with CDC and now with the MA SPHL) became the project lead to update the entire guide and established her team of content developers and reviewers. The comprehensive 2 year revision project began in the fall of 2014, and in November 2016 an updated guide titled, the "Clinical Laboratory Preparedness and Response Guide" was released. The revision team was comprised of over 20 state public health laboratorians, and several staff from APHL, ASM and CDC participated in designing the layout, writing and editing the content. The updated guide is over 330 pages containing significant sentinel lab updates to the biothreat organisms, job aids, checklists, and an expanded all-hazards scope to include chemical and radiological threats. Many clinical lab regulatory references such as OSHA's Bloodborne Pathogens standard, and requirements for packaging and shipping were also added. The new guide allows for state specific contact and public health related information to be provided and has several national resources for general lab preparedness. Biosafety, biosecurity, and risk assessment content was added to help align with outreach from both ELC and PHEP grant measures. The new "Clinical Laboratory Preparedness and Response Guide" will serve as a primary reference once again for the next generation of sentinel labs and the SPHL trainings and outreach efforts. The new guide is available electronically to aid in the search functionality and increased usage, and is a single resource reference providing a summary of clinical lab preparedness. All states have access to the same information, ensuring a nationwide, consistent, standardized, and coordinated emergency response. The new guide will assist the public health laboratory system in preparing and responding more quickly and efficiently to public health and lab emergencies.

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P-28

Strengthening Biosafety and Biosecurity: APHL Convenes Regional Workshops

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Recent industry measures and technological advances result in greater needs for educational and training references. These are expedited through information sharing among academia, government, industry and public health laboratories, especially state and local. In part to reduce the 48 million people affected by foodborne illness annually, new regulations have impacted requirements for risk-based preventative controls, including environmental monitoring and supply chain traceability. Approximately 19% of annual foodborne illness fatalities are caused by listeriosis, with foods such as frozen fruits and vegetables, cheese, ice cream, and ready-to-eat products like salads being major contributors to recent recalls. During these recall investigations, it was discovered that *Listeria* had been proliferating in the manufacturing environment due to insufficient contamination control and microbiological monitoring. Several different pathogen diagnostic technologies may be used orthogonally to improve process and contamination control, including ATP swabbing, ELISA-based test kits, nucleic acid based detection technologies, and whole genome sequencing (WGS). These detection, identification, and characterization tools, along with educational and training references, can be used to provide a food testing roadmap that helps reduce the risk of contamination and foodborne illness. Our presentation includes an analysis of available tools and technologies focusing on *L. monocytogenes* that can be applied to existing assessments such as the APHL yardstick assessment tool and related references.

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P-29

Re-use of Electronic Laboratory Reporting (ELR) HL7 Messages for Zika Reporting to the Laboratory Response Network (LRN)

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The Laboratory Response Network (LRN) was established in 1999 to support laboratory testing for biological threat agents, later adding chemical threat agents. The network's infrastructure has also been leveraged for emerging infectious disease (EID) responses, namely Severe Acute Respiratory Syndrome (SARS), Middle East respiratory syndrome coronavirus (MERS-CoV), Ebola and most recently for Zika in 2016. The LRN began rolling out its Zika Triplex assay in March 2016. It soon became clear that the increased data volume would place a burden on the laboratories. The data generated for the Zika response was expected to far exceed the data volume of any other pathogen previously supported by LRN. To aid in reducing the data burden on the laboratories, the LRN Data Exchange (DE) Team

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proposed repurposing a widely used data stream that laboratories routinely generate to enable case reporting to their local health departments: the standard Health Level 7 (HL7) message for Electronic Laboratory Reporting (ELR) to Public Health. Reusing this message (stripped of any patient information) would maximize data capture while minimizing the effort required by laboratories. In July 2016 the LRN DE Team implemented system enhancements for the LRN data flow at CDC, including the addition of a Mirth data integration engine. The Mirth component allowed for dynamic message mapping, which would enable the LRN to accept a variety of HL7 message profiles and protocols and meant that changes could be made quickly with low effort. The LRN DE Team began Zika ELR pilot activities with LRN laboratories. Two pilot laboratories – New York State and Virginia -- went live with ELR messaging for their Zika data to the LRN in October 2016. The Alabama LRN laboratory came on board soon after in December 2016. Several other laboratories are on track to go live in 2017. The Zika-related system enhancements stand to improve the LRN's overall data interoperability with the acceptance of standard data message profiles other than the customized LRN HL7 message. This new process is deployable and reproducible for future EID events, and it should significantly decrease the amount of time needed for a laboratory to go live with standard messaging for EIDs. As the LRN continues its support of EIDs, such as Zika, Ebola, and MERS-CoV, this type of flexibility will ensure that the network can keep pace with the data demands of public health emergencies.

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P-30

From the Front Lines to the Laboratory: Essential Partnerships in the Laboratory Response Network for Responding to Biological and Chemical Threats

T. Wolford, Association of Public Health Laboratories, Silver Spring, MD

This poster will present on the capabilities of the Laboratory Response Network (LRN) and partners to prepare for and respond to biological and chemical threats. The poster will describe all-hazards approaches for preparing and responding to unknown threats, training and outreach to first responder communities and the role of partnerships in joint biological and chemical threats preparedness and response. All-hazards approaches for unknown threats allows the LRN to prepare for and respond to threat events effectively while utilizing resources efficiently. As funding, technologies and staffing in the LRN change, partnerships and resource sharing are increasingly important in mounting effective threat responses. The poster will allow attendees to share experiences and best practices for joint LRN preparedness and response activities.

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P-31

Leveraging Multi-State Analytical Capabilities – Biomonitoring in the Four Corners States: An update

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Objective: The objective of this study is to develop new and expand existing laboratory-based biomonitoring programs in the four corners states of Arizona, Colorado, New Mexico and Utah to assess the extent and nature of human exposures to environmental toxicants that have the potential to cause harm and to help prevent diseases resulting from such exposures.

Methods: The Four Corners States Biomonitoring Consortium (4CSBC) was formed to conduct biomonitoring projects to address environmental health issues that are of common concern. The Consortium members comprise representatives from the laboratory and environmental health programs of each state and are currently working on five projects. Each laboratory used existing equipment from the LRN-C Chemical Threat (CT) program to capitalize on existing infrastructure and build new capabilities and capacity for the biomonitoring projects. The analytical workload for the projects was distributed among four laboratories.

Results: 757 urine samples have been collected. Sample collections, analyses, results return, and risk communication are in progress.

Project status: 1. Identify exposure from heavy metals in well drinking water through simultaneous analysis of urine well water to assess exposure: Validated methods for 6 heavy metals (arsenic, cadmium, manganese, mercury, selenium and uranium) in urine. Successfully participated in external PT programs. Participant recruitment, urine and water collection, and analyses of samples are on-going. States have results return package and risk communication processes in place. Results are being sent to participants. Arsenic speciation method in progress. 2. Identify exposure from domestic use of 2,4-D herbicide through biomonitoring urine for 2,4-DCP: Validation of method for 2,4-DCP, 2,5-DCP in urine is complete. Sample collection, shipping, and analysis are on-going. 3. Identify exposure from p-DCB containing disinfectants, deodorants, or pesticides by biomonitoring urine for 2,5-DCP: Method validated. Sample collection, and analysis are on-going. 4. Identify exposure from phthalates in food and domestic use products by testing for phthalates in urine: Method validated for phthalate metabolites. Sample collection, shipping, and analysis is on-going. Results return and risk communication on-going. 5. Identify exposure from pyrethroid containing insecticides by testing for pyrethroid metabolites in urine: Method validation in progress.

Conclusions: The 4CSBC is proving that regionalization of public health laboratory assets is a working model for biomonitoring activities. By spreading the workload amongst the four labs the consortium was able take advantage of staff and instrument availability within each laboratory to the benefit of the consortium as a whole. "

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Implementation of a Targeted Study Examining the Association between Urinary Arsenic and Uranium and Private Well Water

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Maximum contaminant levels (MCLs) have been set for public drinking water supplies under the Safe Drinking Water Act; unfortunately no such regulations exist for private well water. This is alarming given more than 40% of New Hampshire's population relies on private wells, which is significantly higher than the national average of 15%. Due to this exposure as well as New Hampshire's agricultural history, the New Hampshire Public Health Laboratories (NH PHL) Biomonitoring Program is examining the association between urinary arsenic and uranium and well water. The Targeted Arsenic and Uranium Public Health Study covers select towns known to be at high risk for arsenic ground water contamination. The study received exempt approval from the Biomedical Research Alliance of New York institutional review board and was launched in 2016. Qualified participants meet with study staff where they receive education about the study and their responsibilities; review and sign an Informed Consent form; and receive sample collection materials. An exposure survey is given to capture demographic information as well as possible occupational, recreational, health, and nutritional exposures. To incent participation, water samples from each household are tested by the NH PHL for a panel of potential contaminants. The enrollment and interview processes will be discussed in further detail during the presentation. Urine specimens are creatinine adjusted and tested for total arsenic, uranium, and speciated arsenic when indicated. Speciation and water analytes chosen will be discussed in further detail during the presentation. This study is ongoing. Urine analysis reports will be returned at the conclusion of the study so participants can compare their results to the 50th and 95th percentiles found in the study and found nationally. Water reports are returned as soon as they have been finalized. Town meetings will be held to discuss results and answer questions. This poster will discuss the successes and challenges of this study, which will aid in the design and implementation of the NH state-wide biomonitoring surveillance program.

Financial and technical assistance is being provided through cooperative agreement with the Centers for Disease Control and Prevention (CDC) Division of Laboratory Sciences at the National Center for Environmental Health RFA EH14140202. The contents of these pages do not necessary represent the official views of the CDC.

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P-33

A Semi-Automated Sample Preparation for Polychlorinated Biphenyls (PCBs) in Human Serum for Trace Level Analysis by Gas Chromatography Tandem Mass Spectrometry (GC/MS/MS)

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Polychlorinated biphenyls (PCBs) are man-made aromatic hydrocarbon chemicals that were once manufactured as lubricants and coolants found in transformers and capacitors. PCBs were found to be persistent in the environment and bioaccumulate in the fatty tissues of the human body, which raises toxicity concerns. Even though PCBs were banned in the U.S. in 1977, some old electrical equipment

may still contain PCBs. Because of its persistent nature in both the environment and the human body, PCBs have been listed as one of the environmental chemicals that are monitored in the CDC National Health and Nutrition Examination Survey (NHANES). It is important to assess people's exposure to toxic substances, such as PCBs, and to develop advanced laboratory methods for the biomonitoring Massachusetts program. As part of a cooperative agreement with CDC, Massachusetts State Public Health Laboratory (MA PHL) developed a semi-automated method for sample preparation of PCBs in human serum for trace level PCB analysis by GC/MS/MS. PCBs are extracted from serum using liquid-liquid extraction, followed by an automated solid phase extraction (SPE) cleanup via the Gilson GX-274 Liquid Handler using Gilson 0.5 g silica gel cartridges, and sample extracts are concentrated using a high vacuum centrifugal evaporator called the GeneVac. The semi-automation procedure has increased sample throughput and productivity, improved robustness, and produced more consistency. This method is also very sensitive and has a lower limit of quantification (LLOQ) of 0.01 parts-per-billion (ppb).

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P-34

The Analysis of Water for Perfluorinated Compounds using Automated Solid Phase Extraction

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Perfluorinated compounds (PFCs) are of increasing concern as they are detected in environmental and human samples. Originally thought to be inert compounds, they are long-lived and may cause tumors and endocrine effects. They bioaccumulate so continued exposure may be especially hazardous. The measurement of PFCs was included in the Unregulated Contaminant Monitoring Program 3 (UCMR-3) and occurrence evaluated in drinking water across the US. US EPA Method 537, which passes 250 mL of water through a cartridge and subsequent analysis with LC/MS/MS, was developed to support this effort. As reports of PFC contamination continue to draw headlines, the need for a simple and automated analysis becomes more critical. This work evaluates the development of automated methodology for EPA 537. Background levels and the need to develop a system that will minimize contamination will be discussed. A range of water samples will be analyzed and challenges and results presented.

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P-35

Automated Solid Phase Extraction and Quantitative UHPLC Analysis of Cannabis Compounds in Food Matrices

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With the recent legislation that legalized the recreational use of marijuana in some states, and the medicinal use of marijuana in many more, there is a fast-growing need to develop standardized analytical techniques to assess the potency of cannabis plants and edibles. Sample preparation is one of the most significant challenges, especially as it pertains to the analysis of edibles such as brownies, cookies, chocolate bars, and gummy bears that have been prepared with cannabis plant extracts. This poster describes the development and optimization of a sample preparation and solid phase extraction method to quantitatively analyze cannabis compounds in edibles, focusing on automated procedures to increase precision, and exploring the sensitivity and accuracy of the complete workflow when combined with UHPLC analysis using a PDA detector.

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P-36

Assessing Environmental Exposure of Expecting Women in New Jersey to Toxic Metals, Polychlorinated Biphenyls, and Perfluorinated Compounds

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Heavy metals and persistent organic pollutants (POPs) including polychlorinated biphenyls (PCBs) and perfluorinated compounds (PFCs) readily cross the placental barrier and can lead to negative birth, early childhood, and lifelong outcomes including reduced gestational periods, birth weights, head and abdominal circumferences, neurological and endocrine disorders, neurodevelopmental disabilities, behavioral disorders, fetal mortality and more¹⁻¹³. Current testing in children is limited to lead testing when children reach 9 months with no prenatal screening for metals or POPs in New Jersey. Instituting such a program would allow state, local, and healthcare officials to identify contamination routes and to address select elevated levels prior to birth¹⁴⁻¹⁶. Scientific literature estimates encouraging early intervention provides a \$17-\$220 return per \$1 spent on Pb abatement and \$700-\$1000 return per \$1 spent on Hg testing by reducing the need to treat preventable exposure related developmental diseases^{3,4}. This project will quantify maternal blood metals and POP levels to allow for and encourage early intervention in order to reduce developmental damage to fetuses and young children. The project will focus primarily on expectant women living in urban, low-income communities heavily impacted by industry, living in older housing, or who can be considered high-risk based on diet. This pilot project will 1) confirm whether or not the selected populations are at higher risk of exposure, 2) confirm that the selected interventions for Pb and Hg following CDC and ACOG guidelines reduce the exposure, and 3) provide valuable insight into whether prenatal screening for exposure to environmental contaminants is worth further investigation while possibly actively improving health outcomes (outcomes of this population will be compared to those of another study that did not receive intervention). Briefly, expectant mothers from the select populations will be recruited as early in the 1st trimester as possible through participating OB/GYN offices. An initial blood draw will be taken and analyzed by NJDOH to

determine exposure. Elevated Pb and Hg levels will trigger a combined response from NJDOH, local health departments, the patients' care providers, and other collaborators to address the exposure. Follow up testing will be performed to confirm efficacy of intervention on maternal levels and birth outcomes will be collected to establish efficacy of intervention in regards to fetal development.

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P-37

Comparative Performance of a New Method, Legiolert™, vs. Standard Methods for the Quantification of Legionella pneumophila in Potable and Nonpotable Water Samples

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Legionella pneumophila is a Gram-negative bacterium that is commonly found in both potable and nonpotable water systems and can cause a severe pneumonia-type illness termed Legionnaires' Disease. A key step in mitigating L. pneumophila risk is to perform routine monitoring to quantify the presence of L. pneumophila, for which there are several methods in routine use internationally. In this study we compared the performance of standard plate-based culture methods defined by the CDC, Standard Methods, or ISO to Legiolert™, a quantitative MPN-based culture method. Independent field trial data was generated in both North America and Germany. To compare a Legiolert 100mL potable water protocol to method ISO-11731-1/2 for examination of 100mL of potable water, 1604 German potable water samples were analyzed by 4 commercial laboratories yielding 290 yielded data pairs. Mean relative difference analysis as per ISO-17994 methodology revealed better sensitivity for Legiolert (+35.3%) and the specificity was 96.4% (1102/1143 positive wells confirmed by subculture). To compare a Legiolert 10mL potable protocol to method SM9260J for examination of 10-500 mL of potable water, 491 U.S. potable water samples were analyzed by 1 commercial laboratory yielding 74 data pairs. A two-tailed Wilcoxon Signed Rank test (used for non-parametric data) revealed higher sensitivity ($\text{Prob}>|S| = |S| = 0.2488$ vs. the CDC method ($n=92$) and $\text{Prob}>|S| = 0.7278$ vs. SM9260J ($n=49$)). A two-tailed t-test was also run and revealed no statistical difference vs. either standard method. The specificity was 95.5% (378/396 positive wells confirmed by subculture). In summary, each of the test methods were either equivalent to or less sensitive than Legiolert for L. pneumophila quantification in these water matrices. Legiolert has a counting range of 1-2272 (MPN) compared to petri plates which are = 200 (CFU), requires no secondary confirmation, has a greatly simplified setup, and is highly repeatable and reproducible. Given these characteristics and performance statistics, routine test facilities are encouraged to examine their process to determine whether Legiolert can enhance their throughput and accuracy.

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P-38

A Comparison of Creatinine and Specific Gravity to Correct for Urinary Dilution in a Biomonitoring Study

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The New Hampshire Public Health Laboratories (NH PHL) utilizes biomonitoring to evaluate state and community-level exposure to environmental chemicals. The Targeted Arsenic and Uranium Public Health Study assessed arsenic and uranium in urine because a high percentage (>40%) of New Hampshire's population obtains their residential water from private wells. These wells are not subject to regulations under the Safe Drinking Water Act and as such, they may contain unsafe levels of arsenic and uranium. A 2009 NH PHL study found more than 30% of private well water tested contained arsenic concentrations above the maximum contaminant level. Urine is an ideal matrix to measure exposure to arsenic and uranium; however, an adjustment for urinary dilution is needed to compare results among biomonitoring study participants. This correction is also important when comparing study data to other populations. Creatinine is typically used in biomonitoring studies to adjust metabolite concentrations in differently diluted urine specimens. It is a useful correction for urinary dilution because of its relatively constant daily production though age, sex, and muscle mass may lead to differences in creatinine production. Urine specific gravity is an alternative method that can provide information on the hydration level of participants based upon the amount of solute present in the urine. Our objective is to compare these methods for correcting urine concentrations of arsenic and uranium from participants in an ongoing biomonitoring study. The preliminary results will be presented.

Financial and technical assistance is being provided through cooperative agreement with the Centers for Disease Control and Prevention (CDC) Division of Laboratory Sciences at the National Center for Environmental Health RFA EH14140202. The contents of these pages do not necessarily represent the official views of the CDC.

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P-39

Getting the Lead Out: Keeping Hoosiers Healthy

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In an effort to improve lead screening for children younger than seven years old, a new training was developed in 2015 by the Indiana State Department of Health (ISDH) Laboratories Outreach and Training Team, partnering with the ISDH Lead and Healthy Homes Program. The training targets local health departments and pediatricians' offices, specifically to increase low screening rates and improve specimen collection techniques. Additionally, case management training was added as a compliance requirement of Indiana Code 410 IAC 29. The Blood Lead Collection and Case Management Training was delivered to all 10 preparedness districts in Indiana in 2015 and 2016. A total of 213 public health nurses, pediatricians, and other clinicians were trained. To date, 74% of Indiana's counties have attended the training, and the Kirkpatrick Model of evaluation has identified an overall 39.6% increase in learning. Furthermore, all attending local health department personnel have been properly trained and are compliant with the Indiana Code for case management training as of November 2016. This training will remain in the Outreach and Training Team's portfolio for compliance purposes. In 2016, the ISDH was asked to assist in the first of three urgent situations involving lead contamination and children at

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risk. A Howard County school corporation and one school in Marion County reached out for help, followed by an entire community in Lake County. The ISDH responded by organizing mass screening clinics capable of collecting more than 300 specimens per day in Howard and Marion Counties. Lake County's soil contamination required a lengthier response and additional school and community screenings. The ISDH Laboratories, Preparedness, and Environmental Health Divisions responded to all three public health emergencies. Blood lead specimens were collected from a total of 2,698 people; of which 17.2% were children younger than 7-years old. Children whose results confirmed >5 ug/dL were placed in case management. Awareness of environmental contaminants and simple screening will help keep children healthy. Appropriate training for local health departments and pediatricians' offices ensures proper collection and transport of specimens to testing facilities and provides accurate point-of-care testing. This, in turn, facilitates timely access to case management and environmental investigations, and ultimately, to healthier children.

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P-40

The Development of a Biomonitoring Participant Questionnaire to Inform Public Health Interventions

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Biomonitoring is the measurement of chemicals or their metabolites in biological tissues or fluids, such as blood or urine. It provides an estimate of an individual's exposure to environmental chemicals, which once compared to comparison values, becomes a powerful tool for both public health surveillance and intervention. When developing a participant questionnaire for the large scale surveillance of environmental exposure to chemicals, it is important to collect participant information (e.g., demographics, occupational history, hobbies, diet) in a manner that is considerate of the potency (toxicology) of the measured analytes. We describe the development and implementation of an approach that is informed by such considerations, and allows individual-level biomonitoring results to be personalized based on evidence-based exposure reduction interventions.

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P-41

A Biomonitoring Study to Examine Baseline Exposures to Six Toxic Metals in a Geographically Representative Population in Virginia

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The Commonwealth of Virginia is a geographically diverse state spanning from the Appalachian Mountains to the Atlantic Ocean. Within Virginia are small farming and mining communities, large cities and urban areas, military installations and shoreline fishing and recreation areas; each with its own unique environment. Virginia is rich in natural resources including coal and many minerals with large

deposits of uranium in the southern and western regions. Although uranium mining is not permitted in Virginia, studies have shown drinking water contamination ranging from trace levels to more than twice the EPA allowable maximum contamination limit (MCL) of 30 µg/L. Prolonged exposure to high levels of uranium can lead to many health issues including renal damage. Exposure to uranium, along with beryllium, barium, cadmium, thallium and lead is being assessed by the Division of Consolidated Laboratory Services (DCLS) through a Biomonitoring study by analyzing urine samples collected from volunteers. Volunteers representing students, faculty and staff are recruited from community college campuses throughout Virginia in order to obtain a geographically representative population from which to compile data. The Virginia Community College System consists of twenty-three community colleges serving distinct regions of the state. Since students, faculty and staff typically live and work within these regions; environmental exposures to chemicals are expected to be representative of the general population. Creatinine corrected urine metal concentrations are presented by location and other demographics.

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P-42

Development of a Residual Solvent Standard for Propane, n-butane, or Iso-butane in Edible Medical Marijuana Products

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In Massachusetts, medical marijuana products are evaluated for residual solvent contamination if a solvent has been used in the production of the retail product (i.e., in the extraction of oil from plant product). The product is tested by a private analytical chemistry laboratory and the measured levels of residual solvents are compared to the respective upper limit standard. As a regulatory framework, DPH adopted the upper limits established by the United States Pharmacopeia (USP Chapter <467>) and the International Conference on Harmonization (ICH, 2011). These USP Chapter <467> recommendations, however, do not describe a specific standard for the hydrocarbon gasses n-butane, iso-butane, and propane. In the absence of USP guidance, DPH derived an acceptable upper limit using an exposure assessment methodology. Briefly, when using this approach, DPH first evaluated the typical exposure to hydrocarbon gas residue in foods (e.g., propane, butane and iso-butane) based on an assessment of daily food consumption patterns, daily oil consumption estimates, and an estimate of fried food intake. Based on conservative (health-protective) estimates of a level of typical hydrocarbon exposure in foods and a probable maximum daily consumption of cannabis oil, DPH developed an exposure-based upper limit residual solvent standard for propane, n-butane, or iso-butane or a high-purity (>99%) blend of these three hydrocarbon gases.

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P-43

Creating Best Practices for the Submission of Actionable Food and Feed Testing Data Generated in State and Local Laboratories

Y. Salfinger¹, K. Wangsnest², R. Randolph¹, S. Shea¹, K. Larson¹; ¹Association of Public Health Laboratories, Silver Spring, MD, ²Arizona State Public Health Laboratory, Phoenix, AZ

Laboratory accreditation has been identified as a critical element for ensuring the integrity and accuracy of food testing results. The ISO/IEC 17025:2005 standard establishes a minimum threshold of acceptance for activities and systems in the laboratory and stresses the importance of establishing a quality management system, which aims to improve the laboratory's ability to produce consistently valid test results. Around the country, many state and local governmental food and feed testing laboratories have been working towards achieving ISO/IEC 17025 accreditation. Accreditation instills confidence in laboratory data; many regulators will not take action on data if the laboratory is not accredited or if the method is not included on the scope of accreditation. However, some governmental laboratories operate in an environment in which ISO accreditation may not be fiscally justifiable. Food and feed testing may be performed only in rare instances, the volume of routine testing may be very low, or the requests received may be for esoteric testing that would fall outside the scope of accreditation. In the case of food or feed safety emergencies, newly developed methods for immediate and timely response to an event (e.g., melamine, oil spill contaminants, etc.) may fall outside of the laboratory's scope of accreditation, and yet it may be very important to share and act upon results from these analyses. The APHL Data Acceptance White Paper is intended to assist laboratories in identifying those specific policies, procedures, and records that should be in place in order to share such food and feed data.

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ISO/IEC 17025 Accreditation Costs of Food and Feed Testing Laboratories under the FDA ISO Cooperative Agreements

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Project Purpose: To determine the costs associated with accreditation for state food and feed testing laboratories across the country through a survey mechanism. As we near the end of the US Food and Drug Administration (FDA) five-year Cooperative Agreements for ISO/IEC 17025 accreditation, sustainability is becoming very important for both FDA and the state laboratories. The costs of accreditation can vary from laboratory to laboratory, depending on the size, staffing, location, and testing methods of the laboratory. APHL will survey and interview the food laboratories involved in the FDA ISO Cooperative Agreements and some that were unfunded to achieve ISO accreditation to determine the costs of achieving, maintaining, and expanding the scope their accreditation. These survey results will inform FDA and any other laboratories interested in pursuing ISO accreditation of the costs incurred by similar laboratories and also provide information on the various ways that laboratories around the country have met the ISO standard.

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P-45

APHL Quality Management Training Series

Y. Salfinger¹, M. Valbracht², C. Mangioine³; ¹Association of Public Health Laboratories, Silver Spring, MD, ²University of Iowa State Hygienic Laboratory, Iowa City, IA, ³New York State Department of Agriculture and Markets, Albany, NY

The goal of the Quality Management Training Series (QMTS) is to provide the laboratory community with a comprehensive set of quality management learning tools. QMTS provides timely and consistent quality management training for new laboratory hires and refresher training for veteran staff, taking the burden off of Quality Managers. The materials primarily consist of online modules containing presentations, documents, best practice guidance, and quizzes; the modules are customizable and can be tailored to the specific needs of a laboratory. Pre-recorded, in-depth webinars are also available to supplement the training modules. Who should use the QMTS? This series is particularly appropriate for laboratories seeking initial accreditation or expanding their current scope of accreditation, but the trainings are intended for all who wish to improve their understanding and use of quality management systems. How was the QMTS created? APHL collaborated with Quality Managers at ISO/IEC 17025:2005 accredited laboratories that perform food and feed testing. Link:

https://www.aphl.org/programs/food_safety/laboratory-accreditation/Pages/Developing-Training.aspx

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Using a SharePoint Site to Communicate Laboratory and Epidemiologic Information on Whole Genome Sequencing of Enteric Pathogens: The New York State Department of Health Experience

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Results from whole genome sequencing (WGS) have been communicated between laboratorians and epidemiologists over the past four years within the New York State Department of Health (NYSDOH). Information communicated is specific to surveillance and cluster detection for enteric organisms. Results of WGS cluster analysis were initially shared via email and in word documents, but have evolved to uploading surveillance and cluster information into a SharePoint site that is accessible to both laboratorians and epidemiologists. Data, text descriptions, and images (i.e phylogenetic trees) are included on the site. In addition to patient metadata associated with each isolate of interest, the site shows the epidemiological rationale for the sequencing request, the laboratory analysis and interpretation of the WGS data, and the epidemiological outcome. The SharePoint site has become an efficient and flexible conduit for communicating between laboratorians and epidemiologists resulting in a simpler workflow, which may serve as a best practice by other agencies.

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P-47

Assessment of Laboratory Networks and Systems in Uganda: Paving the Way for Policy and Planning, and Global Health Security Agenda Implementation

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Background: The Global Health Security Agenda (GHSA) is an initiative by over 40 countries to collectively combat global infectious disease threats and accelerate the achievement of the 2005 International Health Regulations. The Association of Public Health Laboratories (APHL), in collaboration with the Amsterdam Institute for Global Health Development (AIGHD) and the African Society for Laboratory Medicine (ASLM), designed and piloted the LABNET scorecard: a tool to assess the performance of national laboratory networks and systems using a maturity scale across various laboratory standards. This scorecard provides an initial assessment to identify underperforming or developing areas preventing the achievement of the nine laboratory core capabilities identified in the GHSA Initiative essential for a robust public health laboratory network. The scorecard compliments the Joint External Evaluation by evaluating national laboratory networks and systems specifically. The first “official” assessment was requested by Uganda MOH and conducted In May 2016.

Method: In May, 2016, the LABNET scorecard was used for a laboratory assessment conducted by the MOH and APHL, funded by the Centers for Disease Control and Prevention (CDC). APHL provided technical support through its members and facilitated the LABNET scorecard self-assessment of Uganda national laboratory networks and systems. Zero to five colour-coded scores were assigned by the MoH committee for each of the 9 core capabilities. Results were validated by the APHL team through on-site visits of representative facilities within the tiered network. A full evidence-based report with recommendations was submitted to MOH.

Results: The average percentage of core capability achievement towards the standards was 41%; lowest percentages for core capabilities 7 (quality=28%) and 9 (priority diseases=24%), highest percentage for core capability 6 (infrastructure=55%). Seventy nine percent of the total questions scored one out of a possible five.

Discussion: The analyses and unique colored scoring system provided an objective baseline overview of the Ugandan national health laboratory system and network functionality as well as an effective visual aid for prioritization of needs. Tailored interventions focusing on critical gaps will be conducted under the leadership of the newly appointed Uganda National Health Laboratory Services (UNHLS). The situational and root-cause analysis guided the development of the National Laboratory Policy, the National Laboratory Network Strategic Plan and the UNHLS Strategic Plan. Follow up assessments will monitor laboratory services performance and improvement over time, and will also address GHSA gaps based on documented evidence. This unique process will serve as a model for other countries to assess gaps and monitor performance improvement of national laboratory systems and networks.

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Suspected Measles Outbreak in Plateau State, Nigeria, 2012-2015: A Secondary Data Analysis

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Background: Measles has remained a major cause of death among under five children despite the availability of a safe and affordable vaccine. In 2014, there were 114 900 measles deaths globally. The case fatality rate of measles in developing countries is 3–5%. Despite efforts to vaccinate eligible children, measles outbreaks continue to occur in Nigeria. A population herd immunity of 95% is required to interrupt transmission in endemic areas. This is yet to be achieved in Nigeria. **Objectives:** To determine the extent, most affected population and the annual trend of the measles outbreak in Plateau State between 2012 and 2015.

Methods: A four-year retrospective review of line listed measles data was carried out for the seventeen Local Government Areas (LGA) in Plateau State. Data was cleaned and analyzed using Microsoft Office Excel version 2007. Descriptive statistics was performed on the cleaned data. Variables extracted and analyzed include: age, sex, LGA, date of onset of rash, number of valid measles vaccine taken, and outcome of illness. Counts, mean and proportions were determined. Graphs and charts were used to show time, person and place relationships. Association between three exposure variables (sex, vaccination status and no. of measles vaccine given) and the outcome of measles infection was determined using 2x2 table. Confidence limit was set at 95%.

Results: A total of 1189 records were reviewed between 2012 and 2015. Of these 416(35%) had incomplete records and were excluded from the analysis. A total of 773 suspected measles cases were obtained. Males constituted 54 % (415). Proportion of under-five was 58% (446) while oldest case was 51 years. Overall case fatality rate was 1.9% (under-five CFR 1.4%). Wase LGA recorded highest number of cases while Jos East recorded least. Jos North recorded the highest number of mortality. Proportion of laboratory confirmed cases was 0%. The OR for the association between sex and outcome of illness was 0.77 (CI 0.28-2.11) while the RR of the association between vaccination status and outcome of illness was 0.26 (CI 0.08-0.81). **Conclusion:** Between 2012 and 2015 a propagated suspected measles outbreak occurred in Plateau State involving all 17 LGAs; overall case fatality rate of 1.9% and 1.4% amongst fewer than fives. The most affected age groups were those aged 13-24 months old. The outbreak showed a seasonal trend with cases reaching a peak between February and April every year and vaccination was found to improve the outcome of illness.

Recommendations: 1. Efforts should be intensified to vaccinate all eligible persons. 2. Measles vaccination should include all who missed vaccination during childhood. 3. Provision of health education and supplementary immunization activities to citizens during peak periods (February to April) annually. 4. Need to establish a public health laboratory in the State for confirmation of cases.

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Prevalence of HIV Among Newborns Aged 1 To >36 Weeks For Early Infant Diagnosis In Sierra Leone Tested at the Central Public Health Reference Laboratory

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Background: Early infant diagnosis (EID) which is part of the national mandate sponsored by National Aids Secretariat of Sierra Leone in the Ministry of Health and Sanitation and authorized to screen newborns of suspected or identified HIV positive mothers. The newborns are tested at 1 to >36 weeks of age to determine HIV status using a HIV-1 RNA Reverse Transcriptase (RT) Real-Time Polymerase Chain Reaction (PCR). When treatment is initiated at an early stage outcomes are better.

Objective: To determine the degree of HIV positivity in various children between the ages 1 to >36 weeks ages presenting for testing at the Central Public Health Reference Laboratory (CPHRL).

Methodology: From September 2015 to December 2015, one hundred and fifty eight (n=158) Dry Blood Spot (DBS) samples from children 1->36 weeks after birth were collected from entry points at various regions in the country: Western, Northern, Southern, and Eastern Districts as part of the Expanded Program of Immunization (EPI), Children's Ward, Prevent of Mother to Child Transition (PMTCT), Out Patient Department (OPD), Therapeutic Feed Centre (TFC), WFP World Food Program. Blood samples were tested for HIV-1 RNA using the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Test (manufactured in USA; Roche Diagnostics GmbH Sandhofer Strabe 116 68305nMannheim, Germany). Samples are collected and sent to National HIV Secretariat (NAS) Kingharm Road, Freetown, and sent for analysis to the Central Public Health Reference Laboratory. DBS samples eluted with 1100µL Specimen Pre-Extraction Reagent (SPEX) were loaded in the COBAS® AmpliPrep/Taqman Instrument and processed by the automated machine according to manufacturer's instruction. The reverse transcriptase real-time nucleic acid amplification test quantitates HIV-1 RNA in human blood. Specimen preparation is automated for amplification and automated detection.

Results: Of the 158 samples tested, 115 were negative (72.8%) and 43 were positive (37.4%). Four were with ages and of this four two were positive and two were negative. Only two samples were received without location, and both were negative. There were 27 positive samples males, and 16(40%) were female. As the age of patients' increases, the prevalence increased in children between the ages 19-36 weeks.

Conclusions: Of the 158 DBS been analyzed, 37.4% showed positive and more are males than females. Surveillance has increased, but there is the possibility of bias. The level of positivity for HIV appeared lower before the Ebola outbreak (2012), and after the Ebola (2016) there appears an increase. Analysis is ongoing and several possibilities exist to explain the increase: more active surveillance; potentially change in surveillance; true increase in HIV incidence and prevalence.

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Distribution of Influenza Virus by Sex in the Four Sentinel Sites in Sierra Leone from 2011-2013

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Background: In Sierra Leone, the cases that are brought to the sentinel sites are mostly children below the age of 5 and this is not usually representative of the amount of people affected by the virus; Moreover, serious problems related to flu can happen at any age, but some people are at high risk of developing serious flu-related complications if they get sick. This includes people 65 years and older, people of any age with certain chronic medical conditions (such as asthma, diabetes, or heart disease), pregnant women, and young children. - www.cdc.gov

Methods: At the sentinel sites specimens were collected from patients that met the case definition for either ILI (fever >38°C, Cough with onset within the last 7 days, Sore throat, Fatigue) or SARI (standard case definition including hospitalization) For SARI cases, specimens were collected from all patients that met the case definition. However, for ILI cases a systematic sampling approach ensured that the collection of specimen was from every fourth (4th) patient. All specimens were transported to the laboratory using the viral transport medium under the required cold chain storage. The specimen collection was within 7 days of the onset of symptoms and consent was always taken from the patient or guardian concerned. The RT-PCR was used to analyze all the specimen at the laboratory using the Standard Operating Procedures for testing.

Results: A total of 1791 samples were analyzed for the three (3) years. From the total samples analyzed, 106 (5.9%) of the samples were positive for the 3 years. A yearly breakdown shows that in 2011, a total of 59 (3.3%) samples were positive [38(2.1%) males and 21(1.1%) females] whilst in 2012 there was a decrease in the number of positive cases 43 (2.4%) samples with 18 (1.0%) males and 25 (1.4%) females. 2013 had only 4 (0.2%) positive cases with 1(0.05%) male and 3 (0.17%) females. Out of the total positive cases recorded, 57 (3.2%) male children and 49(2.7%) female children were affected.

Conclusion: The population of Sierra Leone is estimated at approximately 7,075,641. Out of this population, 3,473,991 are males whilst 3,601,650 are females -Statistics Sierra Leone 2015 According to the result above we can see that male children are mostly affected by the virus as compared to female which is not representative of the country's population Therefore the following arguments can be put forward concerning the result: 1. More male children visit the sites more than females. 2. The systematically chosen ILI cases (every 4th patient) also would affect the outcome of the most sampled sex. 3. Male children are given more attention than female children. Further studies can be done to find out the reasons why males are affected more than females.

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P-53

Comparative *Mycobacterium tuberculosis* Culture and DNA Isolation Methods for Next Generation Sequencing: Time, Cost, Quality of NGS Data

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Mycobacterium tuberculosis (MTB) whole genome sequencing (WGS) data has the potential to better guide patient care and public health interventions. In 2016, the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC) Division of TB Elimination (DTBE), initiated a pilot program to enroll public health laboratories to contribute to WGS of MTB using next generation sequencing (NGS) in support of outbreak investigations. NGS data must be of sufficient quality to provide good coverage across the entire genome for optimal strain characterization and enable detection of potential point mutations in antibiotic resistance genes with high accuracy. There are few studies that directly compare the time and cost involved with different MTB DNA isolation methods in relation to the quality of NGS data generated. The State Hygienic Laboratory (SHL) performed a comparison of three nucleic acid isolation methods in order to evaluate the impact on DNA purity, library preparation, sequencing depth, uniformity of coverage, time and cost. The protocols compared were the CDC's method using the Zymo Research fungal/bacterial DNA MicroPrep kit, NY Wadsworth Center's protocol using the Bio-Rad InstaGene matrix and the MasterPure Complete DNA and RNA purification protocol from Epicenter. Additionally, we compared preparation of DNA from MGIT cultures to preparation directly from frozen isolate stocks that were shipped to SHL. The methods had different costs, ancillary instrumentation required, amount of DNA recovered and hands on time. However, we found that there was no apparent effect on NGS data produced relative to degree of fragmentation of the input gDNA, presence of RNA in the extract, or presence of potential contaminants affecting the A260/280 or A260/230 ratios (mostly in InstaGene extracts). This study shows that as a reference laboratory, SHL found that of the methods investigated, using the Bio-Rad InstaGene matrix protocol on frozen isolates (no culture) provided quality NGS data at the minimal cost and effort.

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P-54

An Overview of Antimicrobial Susceptibility of *Mycobacterium tuberculosis* Complex Isolates in NYC, 2015

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Background: The New York City Health Department's Public Health Laboratory (PHL) performs *Mycobacterium Tuberculosis* (MTBC) laboratory testing on all patient isolates submitted by the Department's TB Clinics, specimens submitted to PHL from NYC hospitals, and serves as a reference lab for other NYC clinical laboratories. Antimicrobial susceptibility testing (AST) is performed on all isolates positive for MTBC. We analyzed the susceptibility to first line drugs of patient specimens submitted to PHL for testing.

Methods: AST was conducted using standard laboratory methods. Data for this study were gathered using a structured query language (SQL) server reporting service (SSRS) report that links directly to data

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in the laboratory information system, STARLims, through a written electronic code. After the code for the SSRS report was written, extensive manual data cleanup was required in order to obtain the true number of unique isolates that underwent AST successfully in 2015. Once the data was compiled, susceptibility percentages were calculated for each first line antibiotic drug for TB treatment (ethambutol, rifampin, isoniazid, pyrazinamide, and streptomycin). Descriptive statistics were performed using Microsoft Excel and PowerPivot.

Results: Overall, 4,991 specimens were submitted to PHL in 2015 for TB testing. Of those, 474 (9.5%) were positive for MTBC and underwent AST successfully. Of those, 98%, 98%, 87%, 96%, and 92% were susceptible to rifampin, ethambutol, isoniazid, pyrazinamide, and streptomycin, respectively. Additionally, 2.3% displayed resistance to rifampin (n=11). Of specimens that displayed resistance to two or more first line antibiotic drugs (n=26), 3.6% displayed resistance to two first line drugs (n=17), 1.3% displayed resistance to three first line drugs (n=6), 0.4% displayed resistance to four first line drugs (n=2), and 0.2% displayed resistance to all five first line drugs (n=1). 1.9% of specimens overall (n=9) were resistant to both isoniazid and rifampin.

Discussion: While multidrug resistance is uncommon in NYC, TB isolates are frequently resistant to single agents, most notably isoniazid. However, isolates resistance to more than one agent is prevalent in NYC patients as well. Identification of drug resistance is important in order for NYC clinicians to modify patients' treatment regimens to drugs to which they are susceptible. Further analysis is also needed to determine how NYC clinicians adjust their patients' courses of therapy, if at all, to susceptibility data, and the impact drug resistance has on treatment success. Having knowledge of TB drug susceptibility through the use of a TB antibiogram may assist clinicians in making informed decisions about patient treatment before identification of the isolate is confirmed.

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P-55

Prevalence of *Trichomonas vaginalis* and *Mycoplasma genitalium* among Women in East Tennessee G. Dizikes, M. McWilliams and R. Steece, Tennessee Department of Health, Nashville, TN

Although public health laboratories routinely test for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG), in recent years it has become apparent that sexually transmitted diseases (STDs) can be caused by many other organisms. *Trichomonas vaginalis* (TV) is now recognized as the most common cause of non-viral sexually transmitted disease worldwide, but testing has been generally limited to point-of-care wet mounts, in spite of the availability of more sensitive nucleic acid amplified tests (NAATs). Another pathogen associated with widespread STDs is *Mycoplasma genitalium* (MG), and analyte-specific reagents (ASR) are now commercially available to perform NAAT testing for this disease causing agent. To determine the prevalence of TV and MG infection in women residing in east Tennessee, we have subjected 1,000 de-identified female specimens, previously tested for CT and NG on the Panther platform by the Hologic Aptima Combo 2 assay, to testing by both the Hologic Aptima TV assay and the ASR produced by Hologic for the detection of MG. The 1,000 specimens consisted of 785 urines, 192 endocervical swabs, and 23 vaginal swabs. The specimens were stratified by age (<20, 20-35, >35), county of origin, and (for Knox County) STD or family planning (FP) clinic. Overall the highest positivity was for MG (9.7%), followed by CT (8.9%) and TV (7.6%). NG positivity was 2.2%. As previously reported, older women (>35) had the highest positivity for TV (12.5%), but women 20-35 had the highest positivity for MG (11.4%). And, as expected, women < 20 had the highest positivity for CT

(11.7%). Positivity for NG was consistent at 2-2.5% through age 35, after which it dropped below 1%. In situations where the clinic of origin could be determined (STD or FP), positivity rates for all STDs were higher for women visiting STD clinics (23.3-25.6% for CT, TV, & MG; and 9.3% for NG). Interestingly, the highest positivity rate observed for FP clinics was 8.7% for MG, followed by 5.8% for CT. This situation may reflect the commonly asymptomatic nature of these STDs. Somewhat surprisingly, the positivity rate for TV in presumably asymptomatic women visiting FP clinics was only 2.9%, while the rate was 25.9% for TV in women visiting STD clinics. Since these women (i.e., those visiting STD clinics) were either symptomatic or the contacts of men diagnosed with either CT or NG, this high positivity rate suggests co-infection with TV and one of these other two STD-causing agents. Indeed, an analysis of the data shows that all iterations of double or triple infections involving these four organisms is greater than would be expected if their occurrences were independent events. It has been reported before that the presence of one STD predisposes an individual to additional urogenital infections, and this study bears that out for both TV and MG.

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Evaluation of the INSTI HIV-1/2 Antibody Test Performance Characteristics at the Point-of-Care Clinical Setting

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Project: To evaluate performance of the FDA approved, CLIA-waived INSTI HIV-1/2 Antibody Test (INSTI, BioLytical Lab Inc., Canada) and to compare them with Alere Determine HIV-1/2 Ag/Ab Combo and Clearview Complete HIV-1/2 Ab tests used in the STD clinic's current testing algorithm. FDOH Miami-Dade Laboratory is AHCA/CLIA-certified for moderate complex and waived testing, performing 4000 rapid HIV-1/2 tests annually in its high HIV-1 seroprevalence public health population.

Implementation: A total of 400 INSTI kits and control materials were provided by BioLytical Lab, Inc. A panel of 70 known plasma samples with varying levels of HIV-1 viral load and HIV-1 Ab s/co values were provided by the FDOH BPHL-Jacksonville. Whole blood samples were collected by venipuncture for routine screening from patients with unknown HIV status visiting STD clinic in October-November 2016. The Clinic's current algorithm includes initial HIV screening by Alere Combo followed by Clearview Complete for reactive results with confirmation at the BPHL-Miami per CDC recommended diagnostic algorithm (2014). Study samples were tested in the following order: Alere Combo first, then Clearview and INSTI with confirmation at the BPHL-Miami. Sensitivity, specificity and accuracy were calculated for each test.

Results: A total of 304 whole blood samples were tested, 1.64% (5/304) were preliminary HIV-1 Ab positive by all three tests, and 100% (5/5) were confirmed by the lab-based algorithm at the BPHL. 299 nonreactive specimens (100%) were confirmed as negative. 100% (70/70) of plasma panel samples were tested as Ab positive. No p24 Ag was detected by Alere Combo. On that limited number of samples (374) all three tests demonstrated 100% specificity, which is in concordance with INSTI product insert specifications and exceeds specificity for Alere Combo (99.7%) and Clearview (99.9%). Sensitivity was at 100% for all 3 tests that exceeds package inserts (99.9% for INSTI and Alere Combo and 99.7% for Clearview).

Lessons Learned: INSTI tests were easy to perform and interpret. Test procedure takes only 1-3 minutes and significantly improves patient and provider satisfaction with turn-around time for results. Short processing time allows more patients prescreened in a very busy STD clinic. HIV-1 antibody specificity and sensitivity were in concordance or exceeded manufacturers' tests specifications, although more data is recommended to identify acute/early infection. All three tests demonstrated high degree of accuracy and provided a reliable way to perform rapid HIV testing at point-of-care setting. Non-reactive prescreened specimens may not require additional testing unless possible acute HIV-1 infection is suspected. All reactive samples may be tested by secondary HIV rapid test with highest specificity to expedite the linkage-to-care process. Final confirmation should be done per CDC recommended algorithm.

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Rapid Detection of Mycobacterium tuberculosis Complex Species from Formalin-fixed Tissue Specimens by Pyrosequencing-based PCR Assay

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Mycobacterium tuberculosis (MTB) is an infectious agent of great public health concern because of high morbidity and mortality rates among high risk populations and the emergence of drug resistance. After years of steady decline, the incidence of active tuberculosis (TB) increased 1.6% from 2014. The timeliness and accuracy of diagnosis is critical for preventing disease transmission, selecting of appropriate antimicrobial treatment, and increasing the chances for patient survival. Often, due to clinical suspicion of non-infectious conditions such as lung cancer, lymphoma or sarcoidosis, specimens are not processed for culture and formalin-fixed, paraffin-embedded (FFPE) tissues are the only specimens available. Acid-fast (AFB) stains and immunohistochemistry (IHC) targeting mycobacteria can be performed on FFPE tissues, but cannot identify species. Variable histopathological features of tuberculosis infection often make it difficult to establish a diagnosis and initiate appropriate therapy, thus MTB molecular assays optimized for FFPE tissues are vital for accurate pathogen identification. We optimized and validated a pyrosequencing-based (PSQ) PCR assay targeting the IS6110 region for the detection of MTB complex species from fixed tissues, and tested FFPE tissues from 114 cases that were submitted to the Infectious Diseases Pathology Branch at the Centers for Disease Control and Prevention in 2015. Of 114 cases, MTB complex was identified in 47 by conventional Mycobacterium genus PCR and sequencing. The remaining 67 cases had clinical and histopathological suspicion of MTB complex species but conventional PCR results were negative or an environmental contaminant such as Corynebacterium was amplified by 16S rDNA PCR. DNA extracted from FFPE tissues from each of the 114 cases was tested by the IS6110 PSQ assay performed on Qiagen PyroMark Q24 system. All 47 (100%) conventional PCR positive MTB cases were also positive by the IS6110 PSQ assay. Nine of the 67 (12%) cases that were negative by conventional PCR were positive for MTB by the PSQ assay. In six of these nine cases, conventional PCRs and sequencing previously detected Corynebacterium spp. or M. gordonae, suggesting that MTB detection could be masked by other bacteria or environmental contaminants. Of these nine cases, four were also positive by mycobacterium IHC or AFB staining. This assay was able to detect MTB in multiple tissue types (lung, lymph node, brain, liver, spleen, heart, and

testis). The PSQ assay enhanced the sensitivity of MTB detection in FFPE tissues, demonstrated specificity for MTB, even in the presence of environmental contaminants, and is more rapid and cost-effective compared to conventional PCR and sequencing. The PSQ assay can be a useful adjunct for MTB diagnosis, particularly in cases where conventional specimens are unavailable for testing.

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P-58

A Regional Review of the Distribution of Measles and Rubella amongst Children in Sierra Leone from 2015 to 2016: A Laboratory-based Study

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Background: Pivotal to the strategic directional efforts to eliminate measles and rubella is a quality and reliable laboratory diagnosis to confirm occurrence and augment surveillance and outbreak response. From our records, laboratory confirmed measles and rubella for 2015 and 2016 summates to 231 and 127 cases respectively. Measles and rubella remain to be a serious viral disease common among children. As of 2013, it was estimated that, measles caused some 40,000 deaths annually in the African Region. In this study, we analyzed regional laboratory confirmed IgM positive cases of measles and rubella for the period of 2015 and 2016.

Methods: Regional measles and rubella laboratory confirmed cases from all the regions for the year 2015 and 2016 were analyzed. Samples are analyzed serologically by detection of measles and rubella immunoglobulin M (IgM) antibodies at the Central Public Health Reference Laboratory using Enzyme-Linked Immunosorbent Assay kit (Enzygnost for IgM; Siemens). A Bar chart was used to graphically describe regional distribution of confirmed measles cases for each region in the year 2015 and 2016. According to the adapted algorithm for diagnosis, all positive results for measles should be reported and not be tested for rubella. Only negative measles samples are tested for rubella; indeterminate (equivocal) samples for measles or rubella should be retested.

Result: The number of regions included in the analysis of the laboratory confirmed measles and rubella cases were four (4); East, West, North and South. Of 264 samples suspected of measles and rubella in 2015, 124 (47%) were positive for measles IgM, 11 (8%) of 131 analyzed were positive for rubella IgM. In 2016, 424 suspected measles/rubella samples were analyzed; 107 (25%) were measles IgM positive, and 118 (50%) of 235 samples analyzed for rubella were positive. Regionally from 2015 to 2016, Northern region sent 274 samples, of these 112 (41%) were positive for measles and 19 (18%) of 105 samples analyzed were positive for rubella. Southern region sent 184, of these 43 (23%) were positive for measles and 56 (48%) of 117 samples were positive for rubella. Eastern region sent 156 samples, of these 45 (29%) were positive for measles and 29 (58%) of 50 samples were positive for rubella. Western Area sent 74 samples, of these 31 (42%) were positive for measles and 15 (47%) of 32 samples were positive for rubella.

Conclusion: There is still an ongoing incidence of measles and rubella cases across the country with concurrent occurrences in all the regions. From these findings, it can be seen that the Northern region has high incidence rate as compared to others, although changing epidemiology is also observed. Average affected population is under 15 years.

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P-59

Expanding Mosquito Surveillance in Louisville Metro, KY, 2016

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Background: For 60 years, the Louisville Metro Department of Public Health and Wellness (LMPHW) has maintained a Mosquito Control Program. Environmental Health Specialists target over 300 sites in the Metro area for pre-treatment and on-going mosquito control beginning March/April and ending October/November of each year. Specially trained staff set traps and collect mosquitoes weekly. Mosquitoes are sorted by location, identified at the genus and species level, and then provided to the laboratory for screening by PCR methods. Between 2007 and 2015, Roche instruments and kits (MagNALyser Green Beads, MagNAPure Compact and LightCycler) were used to detect West Nile Virus (WNV). In 2016, the LMPHW Laboratory implemented CDC published TaqMan assays to screen mosquito pools for WNV, Zika and St. Louis Encephalitis (SLE) viruses using the analytik jena qTower3 instrument.

Methods: Traps used to collect mosquitoes included the CDC Gravid Trap and the New Standard Miniature Blacklight Trap. Contents of the trap collections are frozen, emptied from the collection container and then mosquitoes are sorted out from other insects. A subset of well-preserved specimens is removed for further speciation. Speciation is conducted using dichotomous keys of mosquitoes commonly found in Kentucky. Manufacturer's instructions were followed for disruption of mosquito pools (MagNALyser Green Beads) and RNA isolation (MagNAPure Compact). RNA was eluted in a final volume of 50 uL. For real time RT-PCR, CDC published TaqMan primers and probes were used in 25 uL final reaction volumes. WNV and Zika were combined into a duplex PCR reaction; however, SLE was a single PCR reaction. QuantaBiosciences qScript XLT One-Step RT-qPCR ToughMix was used for the master mix. Cycling conditions for WNV/ZIKA were as follows: cDNA synthesis 50°C for 30 minutes; Initial Denaturation 95°C for 3 minutes then 45 cycles of 95°C for 15 seconds followed by 60°C for 1 minute (scanning for FAM dye in Channel 1 and CY5 dye in Channel 5). Cycling conditions for SLE were: cDNA synthesis 50°C for 10 minutes; Initial Denaturation 95°C for 1 minute, then 45 cycles of 95°C for 10 seconds followed by 60°C for 1 minute.

Results: 300 pools were screened for the presence of WNV, Zika and SLE viruses using TaqMan assays and real-time PCR methodology. Of these 300 pools, 18 were positive for WNV and none were positive for Zika or SLE using these methods.

Conclusions: The use of TaqMan PCR reagents and the qTower3 allowed for expansion of the number of arboviruses that could be detected in mosquito collections. As a result of the real-time RT-PCR analysis, several sites in the Louisville Metro area demonstrated presence of West Nile virus, and thus targeted mosquito control activities were carried out in these locations. Future activities will include implementing additional virus targets and validating duplex PCR reactions.

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P-60

Effects of Changes to Indiana's CDR on the Enteric Laboratory

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Background: Indiana's Communicable Disease Rule (CDR) was updated December 25, 2015. One change to the CDR was in the isolates that are required to be submitted to the Indiana State Department of Health Laboratory (ISDHL). The major changes affecting the Enteric laboratory were the addition of *Shigella* spp and *Vibrio* spp as required isolate submission, as well as the requirement of submitting stool or broth specimens if culture independent diagnostic testing (CIDT) was used to identify the pathogen and the specimen was positive for *Salmonella*, Shiga-toxin producing *Escherichia coli* (STEC), *Shigella*, or *Vibrio*.

Methods: Approximately 1925 specimens were received at ISDHL in 2016 for enteric testing. The specimens received were isolates, broths, and stool specimens. Required submission according to the CDR includes *Salmonella*, STEC, *Shigella*, and *Vibrio*. The lab receives occasional requests for reference testing of organisms that are not part of the CDR. Specimens are received, processed and plated on selective media based on the pathogen identified by the submitting lab. If the specimen is confirmed positive, additional serotyping is completed to further characterize the submission. Isolates are then given to the Pulse-field Gel Electrophoresis (PFGE) and Whole Genome Sequencing (WGS) analysts to complete testing.

Results: The 5-year average (2011-2015) for specimens received in the Enteric lab is 1378 specimens, with a range of 1151 to 1571. The nearly 40% increase in submission, as well as the 10% increase in specimens that were not isolates, caused a large increase in work demands, including analyst hours and reagents. More than half of the submissions received as broth or stool were unable to be confirmed, and therefore an isolate was not available for further characterization by PFGE or WGS. An additional analyst was permanently relocated from another lab area to assist with the increased work demands. The increase in specimen load made it impossible to maintain PFGE for routine surveillance of *Shigella* isolates, so *Shigella* PFGE was discontinued in July and is only done by epidemiologist request for foodborne outbreaks.

Conclusions: The significant increase in specimen submission resulting from the CDR changes has been difficult to keep up with, especially during peak enteric season. Isolating pathogens from broths or stools requires significantly more time and reagents than when a specimen is received as an isolate. Prior to the change in the CDR rule, the laboratory was not included in the financial impact statement. No additional resources or personnel were allocated in response to the changes, and adaptations had to be made throughout the year. The experience stressed the importance of effective communication and joint planning between laboratory and epidemiology, and the need for a structured assessment of the public health benefits and cost associated with future rule changes.

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Developing Reusable Tools and Resources for HL7 Implementation – The NMI Experience

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APHL and the Centers for Disease Control and Prevention (CDC) recognize the significant challenges that electronic data exchange presents to public health agencies (PHAs) and their messaging partners. Even for agencies with a mature technical infrastructure and robust messaging capabilities, the implementation of a data exchange requires a substantial investment of technical and subject matter expertise. APHL and CDC continue to look for and develop tools, resources, and processes that messaging partners can use to implement, streamline, and maintain data exchanges. As part of the National Notifiable Diseases Surveillance System (NNDSS) Modernization Initiative (NMI), the APHL Informatics Technical Assistance (TA) Team developed a series of tools to support Public Health Agencies (PHAs) in electronic message implementation. An important component of CDC's surveillance strategy, NMI is designed to enhance the capabilities of NNDSS to provide more comprehensive, timely, and higher quality data for public health decision-making. CDC has partnered with APHL Informatics to provide technical assistance to PHAs that are implementing NMI case notifications messages to CDC. While working with PHAs, the TA Team developed reusable tools to 1) assess the alignment of the agency's data with the Message Mapping Guides (MMGs) developed by CDC, 2) design and perform the technical work needed to create the HL7 message, and 3) plan and manage the MMG implementation. APHL informatics subject matter experts (SMEs) in terminology and standards designed the NMI Implementation Spreadsheet to help program SMEs efficiently map information captured in the surveillance system to MMG data fields and identify and resolve any missing data elements. This Spreadsheet serves as the tool for message implementers within the PHA to build the HL7 message; it also documents system information for long-term maintenance. APHL Informatics SMEs in technical architecture and integration developed an HL7 template message creation route in Orion Rhapsody. PHA technical staff can load the route into Rhapsody and prepare custom mapping tables based on jurisdiction-specific data. Finally, SMEs in project management and business analysis developed the NMI Technical Assistance and Implementation Guidebook, which offers best practices for organizing the project and resources needed, identifies common implementation project risks and mitigation strategies, and provides step-by-step guidance to build the HL7 message. These resources are available to PHAs through CDC's NMI Technical Assistance and Training Resource Center. While these resources were developed for NMI work, many of the best practices and basic processes apply to any HL7 implementation effort. These resources may offer utility for public health jurisdictions as informational resources, and can serve as templates for future messaging projects.

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Modernizing Public Health Surveillance through Shared Services

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Background: Emerging challenges in public health surveillance include the proliferation of overlapping capabilities and independent systems that impede innovation and meaningful connections across programs. Recent calls from public health partners, Congress, and from within U.S. Centers for Disease Control and Prevention (CDC) call for the reduction of reporting burden on partners and improve efficiency within the agency. In response, CDC's Surveillance Strategy answers these calls. As an outgrowth of the strategy and taking advantage of partnerships with the CDC's Federally Funded Research and Development Center, the Surveillance Data Platform initiative (SDP) will offer shared software services on a cloud-based platform. SDP is laying the foundation for a future in which CDC programs could assemble services to create new capabilities in near real time, allowing a more agile response to public health needs.

Methods: CDC's Surveillance Leadership Board chartered cross-agency workgroups to provide recommendations for an integrated and interoperable surveillance data platform of shared services. The workgroups covered design principles, scope, and service priorities. From there, the SDP program team analyzed top challenges faced by CDC programs, gaps in capability, and existing services that could be shared across CDC and its partners. Based on factors such as cost, value to surveillance, and readiness of programs to use services, two services were selected for initial deployment: vocabulary and content-based routing.

Results: The vocabulary services are being designed in close collaboration with users to enable use of harmonized standards for new data collection, thus simplifying reporting for partners. Content-based routing services are focused on providing foundational capability for streamlined data flow into CDC, further reducing the reporting burden on public health partners. SDP development is iterative and user-centered. Working capability began in Aug. 2016, and is released every 2 weeks with close interaction from users. Preliminary results on reducing reporting burden on behalf of public health partners and time to create data collection tools will be available to present at APHL.

Conclusions: CDC is modernizing its use of informatics through shared services designed to support multiple public health surveillance systems. By engaging public health users throughout the design and development of the initial services, CDC aims to demonstrate the value and impact of shared services within public health. While SDP is in early stages, the initiative is committed to communication and collaboration throughout development and early implementation.

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Building Partnerships with Clinical Laboratories: An APHL Informatics Initiative

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Objectives: Define the unique partnerships APHL has formed with clinical laboratories. Describe the impact these partnerships have with electronic laboratory reporting and public health.

Background: The ability to share data efficiently and securely with diverse messaging partners is a critical capability of public health, however it is often difficult for the public health community to maintain multiple point-to-point electronic interfaces and accommodate ever-changing transport mechanisms. As a direct response to these challenges, APHL developed the Informatics Messaging Services platform (AIMS). AIMS is a secure, cloud based environment that accelerates the implementation of health messaging by providing shared services to aid in the transport, validation, translation and routing of electronic data. With the success of AIMS and new regulations to oversee health data exchange, new messaging partners, such as clinical laboratories, are seeking to capitalize on exchanging data with public health. Large clinical commercial laboratories account for 41% of all ELR volume and thus prove important to the exchange of laboratory data. Quest Diagnostics and Cerner's Reference Lab Network (RLN) are clinical laboratories APHL is working with through AIMS to send ELR to public health agencies. These projects have proven to accelerate data flow to public health and serve as an example of the relationships that can exist to integrate public health and clinical care.

Methods: APHL explored the data that currently flows between the clinical laboratories, AIMS and public health. This includes examining how the data flows and how much is flowing. APHL also examined those relationships by interviewing key contacts on these projects around how these initiatives impact their work.

Results: By creating partnerships between large clinical laboratories and public health, APHL has accelerated data flow between these two entities. Quest Diagnostics has 16 public health agencies in production which represents over 95,000 messages from Quest to public health agencies via AIMS. Cerner's Reference Lab Network has also been working with Kansas and Florida on ELR.

Conclusion: Partnerships between clinical and public health will continue to be a critical need. As a result of this work, the CDC national electronic laboratory reporting average will increase by roughly 8 percentage points. The Quest Diagnostics project alone will bring in a projected 2.5 million messages on a monthly basis via the AIMS platform. As more clinical laboratories become interested and start engaging with public health, the hope is that other messaging partners such as Labcorp will want to come to the table and play with public health.

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APHL AIMS Portal Architecture - Gateway to Enhanced Data Visualization and Interpretation

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Objectives: Describe the use of portal solutions to view message details and message content. Present the current challenge and describe how portal solutions will allow APHL to meet partner needs

Background: APHL Informatics Messaging System (AIMS) is a secure, cloud based environment that accelerates the implementation of health messaging by providing shared services to aid in the transport, validation, translation and routing of electronic data. While AIMS was initially a hub for data exchange, there has been a strong interest and need from partners to have access to solutions and tools that improve visualization of not only the data itself, but also summarization information about the data.

Methods: In collaboration with APHL partners, the need for robust portal solutions became evident to analyze messaging data and metadata (data about data). APHL identified this need through close relationships with those requesting to have additional insight into message flow. APHL has provided not only custom portal solutions, but also has leverage third party software-as-a-service (SaaS) portal and data visualization tools that integrate with the AIMS environment.

Results: By providing secure messaging portals to the CDC, public health and private corporations, APHL has delivered portal solutions to several key partners. Quest Diagnostics will be using our messaging dashboard to view live HL7 messages and summary data around message transmission. CDC's Advanced Molecular Detection (AMD) program uses a SaaS portal integrated with AIMS to track next generation sequencing runs. This SaaS portal not only provides the CDC with ability to view AMD data, but also provides public health with this visibility as well. Above are two examples, however there is a strong expectation to continue delivering portal solutions. For the Antibiotic Resistance Laboratory Network (ARLN), we are currently developing an upload portal that will accept public health lab generated CSV input files to be made available to the ARLN program at the CDC.

Conclusion: Secure portal solutions allow both public and private partners to track message status, store live data, visualize and interpret datasets, and provide an audit trail of actions taken within the portal. It has become very evident in recent years through projects such as Quest, Rabies and Advanced Molecular Detection that requests for similar portal solutions will continue in the coming years.

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Highlighting APHL Toolkits through the Member Resource Center

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APHL committees and programs have developed a variety of tools for laboratories to help manage their workload more efficiently, identify gaps, and collect organizational information. APHL members are either not aware of the tools or have not seen the benefits of using them. The APHL Knowledge Management Committee (KMC), local laboratories, and APHL staff collaborated in marketing and promoting the usage of these toolkits to its members with alignment to the APHL Member Resource Center (MRC). The MRC is a web-based tool developed by APHL that offers resources to help strengthen the operation of all types of health laboratories. APHL programs including Institutional Research, Communications, Information systems, Quality Systems, Informatics, and Membership have been updating and improving the MRC, specifically by making the submission process easier and the search functionality more user friendly. This poster highlights some of the most frequently used toolkits by our members, demonstrated recent improvements to the MRC and search techniques to find the toolkits. In addition, tips and tricks on utilization of the MRC site will be shared with the attendees along with input from members and APHL staff. To view the rest of the toolkits, please visit www.aphl.org/MRC.

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Using a Decision Matrix to Guide Strategic Planning & Resource Allocation

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With emerging diseases and conditions, rapid changes in molecular and information technology, and continued need to effectively maximize existing resources, public health laboratories are in need of readily available tools that can guide strategic decision-making and resource allocation. We developed and used a comprehensive decision matrix tool that allows laboratory leaders and managers to evaluate public health laboratory programs, projects, and testing divisions using objective criteria supported through verifiable data. The backbone of the matrix is based on five key organizational systems: 1) Purpose/Mission/Strategy; 2) Finance; 3) Operations; 4) Workforce; and 5) Customer. Each organizational system includes subcategories such as existing legal authority, political and partnership support, financial performance, unique services and predictable volumes, current capabilities, impact to population health, and reliability/performance. Using a numbered ranking, PHLs can readily evaluate and compare any existing or future program, project, or testing service. The tool allows for executive leadership analysis, as well as from perspective of both testing divisions and support offices. Highest scores are potential for strategic priorities following development of a business plan/tactical plan with balanced scorecard. Mid-level scores provide opportunity to strengthen as a future growth through the formation of a new Community of Practice (experts brought together to enable continuous health and environmental topical/programmatic scanning and evaluate opportunities). Lowest scores are potential for deeper evaluation on whether those resources should be re-allocated following the findings of a risk assessment/analysis. The completed tool can be updated annually as part of the organization's strategic planning and budgeting process, and provides a data-driven, organized and concise summary of all major organizational activities.

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Applying Business Development Tools to Public Health Laboratory Strategy

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Proven business development tools, such as business models, business plans, and project management are a practical resource to help drive strategy within the private sector. We adopted and modified these tools to support the need of public health laboratories. Using the Plan-Do-Check-Act (PDCA) cycle, we implemented a Decision-Matrix methodology (Plan), Deep Dive (Do), Management Control (Check), and Implementation (Act). The Decision-Matrix allows laboratory leaders and managers to evaluate public health laboratory programs, projects, and testing divisions using objective criteria supported through verifiable data. Highest scores are potential for strategic priorities following development of a business plan/tactical plan with balanced scorecard. Outcomes from the Decision-Matrix are input into the Deep Dive, which brings laboratory experts together to identify Value Streams, and areas of growth or contraction using principles from the Malcolm Baldrige Criteria, ALOU (Advantages, Limitations, Opportunities, Uniqueness), and key Business Plan elements. Outcomes from the Deep Dive are evaluated for appropriate resource allocation and budget support through Management Control. The final step in the model, once the business plan and associated resources have been approved, incorporates project management practices and development of a Balanced Scorecard to assure successful implementation of the business plan, achievement of key milestones, and accountability to executive leaders. This poster will share the models and tools employed, and provide examples on application of use. Adoption of business development tools within a PDCA cycle for public health laboratories provides a proven roadmap to successfully develop and implement organizational strategy through clearly defined and objective criteria.

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Informatics Self-Assessment Tool: 2017 Reboot

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The Informatics Self-Assessment Tool is a web-based application designed to help laboratories identify, evaluate, and communicate their specific strengths and needs. By synthesizing labs' data across 19 different capability areas, it is able to paint a comprehensive picture of the nation's PHL informatics infrastructure. Earlier this year, APHL released an updated version of this tool, and would like to share its findings and results based on participation of laboratories in the Spring of 2017.

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Towards a More In-depth Understanding of State Public Health Laboratories

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Objective: Using data obtained from a variety of APHL surveys from 2010 to 2016, the Institutional Research (IR) program will describe and provide new insights on state public health laboratories (SPHLs).

Project Design: The IR program will utilize data garnered from APHL surveys to answer the following research questions: what do SPHL funding and expenditure allocation look like, what does the SPHL workforce look like, what types of services do most SPHLs provide, what type of quality control processes do SPHLs employ, and what networks do SPHLs belong to.

Methods: Data utilized for this project will come from a variety of longitudinal and cross-sectional APHL surveys such as the All Hazards Laboratory Preparedness Survey, Biosafety and Biosecurity Survey, Comprehensive Laboratory Services Survey, and Zika Virus Testing Survey. Univariate, bivariate and multivariate analysis were performed.

Results: The timeline for completing analysis is April 2017. An in-depth analysis plan has been developed and data has been compiled. Next steps include completing the analysis and seeking feedback from member laboratories on interpretation of findings. These findings will be presented on this poster.

Conclusions: The findings from this analysis can be used by member laboratories to assess the factors that influence key outcomes. In addition, APHL program staff can use this to advocate on behalf of SPHLs with funders, policy makers and the public. Targeted reports and a variety of other products for public policy makers and the public may be generated.

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Towards a New Culture of Evaluation at APHL

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Objective: To describe the process of APHL's efforts to develop a comprehensive evaluation plan for the Association, showcase specific evaluation activities that were implemented during this past year, and discuss lessons learned.

Design: APHL is committed to understanding and assessing its effectiveness for supporting the public health laboratory system. APHL employed the CDC framework for program evaluation to develop an Association wide evaluation plan. The CDC framework for evaluation outlines six steps (from engaging stakeholders to ensuring use) and four quality criteria (accuracy, feasibility, propriety and utility). The following methods were used to engage and build consensus among key stakeholders (APHL staff, CDC staff and APHL members) between February and June 2016: • Capacity development trainings of APHL staff on evaluation approaches and methods • Key informant interviews with 22 APHL senior staff to understand APHL's need for evaluation • One focus group discussion with CDC senior staff to understand CDC's needs for evaluation findings • Facilitated group discussions with more than 10

groups to build the APHL Theory of Change. • Online survey of all APHL staff to solicit relevant evaluation questions • Document reviews of relevant reports and literature

Results: APHL submitted an evaluation plan to CDC in June 2016. The plan outlines an evaluation approach that is particularly suited for a complex capacity development organization. Theory-based evaluations articulate a model (theory of change) that explicitly states how a program (APHL) is planning to bring about needed change (outcomes) and then tests this theory. It aims to answer the “how” and “why” of change in addition to the “if”. Subsequently, the plan has been used to guide a variety of evaluation activities including the development of monitoring and evaluation (M&E) plans for specific programs, implementation of internal organizational activity assessments, and identification of baseline metrics for public laboratory system utilizing existing data.

Conclusion: APHL has successfully modeled the development of a stakeholder driven evaluation plan that is both relevant and feasible. This evaluation model can be adapted in other public health laboratory settings to facilitate organizational learning and highlight effectiveness of activities. "

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APHL Theory of Change (2016-2017)

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Objective: To present the current APHL Theory of Change model that shows how APHL envisions its impact on the public health system.

Design: A Theory of Change (TOC) is a model that explains how long-term change (outcome) is brought about in a program. A Theory of Change is modeled in a causal framework of necessary outcomes (“preconditions”) that need to exist for long-term outcomes to be achieved. The APHL TOC was created as part of the development of the 2016 APHL evaluation plan. Critical stakeholders including APHL staff, members, and CDC staff were consulted through more than 30 key informant interviews and facilitated group discussions. In addition, relevant documents, including internal project reports and published literature were reviewed. Finally, an advisory group, made up of eight APHL staff volunteers, was formed to guide the use and refinement of the APHL TOC.

Result: The APHL TOC envisions changes that result in a healthier world. It is based on the principle that better population health outcomes will result from evidence-based decision making as a consequence of better surveillance. This in turn is predicated on: • A functioning public health laboratory (PHL) system • A public health laboratory system that is integrated and working effectively with other public health system components and • Timely data exchange. The TOC describes how APHL envisions it will contribute to a functioning PHL system that is working more effectively with other public health actors to provide accurate and timely data for public health decision-making. It also highlights other processes beyond the sphere of APHL’s influence that contribute to improved population health outcomes (e.g., effective regulatory and enforcement systems, more accessible and effective health care services, more effective medicines or vaccines, etc.). In addition to outlining outcomes of interest and their interrelationships, the TOC conveys the key strategies that APHL uses to facilitate change, including research, collaborations, advocacy, technical assistance, education and public-private partnerships.

Conclusion: The APHL TOC model is a living document that will continue to change as APHL engages in ongoing discussions with key stakeholders. APHL will also utilize the TOC to guide its evaluation efforts

and findings will be used to review the validity and comprehensiveness of the model and its underlying assumptions.

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Characterizing Current Public Health Laboratory Workforce

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Objective: To describe the composition of the national workforce, identify key recruitment and retention factors, and utilize findings for future workforce development efforts.

Project Design: Data collected in 2016 from 1653 laboratorians from state, local, agricultural and environmental PHLs is used to benchmark and trend workforce capacity and capabilities. The survey asked questions regarding retention, recruitment, job satisfaction and salary.

Results: Survey results will describe and characterize the composition of the national PHL workforce and gain laboratorian perspective on issues regarding recruitment, retention and job satisfaction.

Preliminary findings indicated that 65% of laboratorian are female of white ethnicity (75.3%), with 57% holding a bachelors, and 18% intend to leave a PHL career in less than 2 years. Although only 39% are satisfied or very satisfied with their pay, 78% indicated high level of job satisfaction. Further will explore factors that will influence retention as well as other issues to inform future workforce development efforts to better serve the interests of PHLs.

Conclusion: Shortages in the PHL workforce at every level have been plaguing the community for decades. The impact of these shortages at the leadership level are even more pronounced. Factors such as aging workforce, salaries and technological advances challenge our ability to keep up. Impactful data from APHL workforce surveys will provide insight to the current attitudes and perspectives as well as leveraging data to inform strategies to address future workforce needs.

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Building a Smarter Information Management System – Enhancing CDC’s Influenza Partner Portal to Support Detection and Response to Infectious Disease Outbreaks

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The Influenza Partner Portal (IPP) is an information management system that was launched last year by the CDC’s Influenza Division to facilitate tracking and management of laboratory reagent distribution to over 600 labs supported by the International Reagent Resource (IRR) program. Since its initial launch, IPP has expanded to support surveillance reagents for non-flu pathogens including RSV, MERS, and other priority infectious disease threats in Global Health Security Agenda participant countries. IPP is also playing a central role in the Zika Emergency Response by facilitating IRR’s provision of Zika ancillary

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reagents. As the volume and complexity of interactions between CDC and its many public health laboratory partners grows, so does the demand for smarter solutions to efficiently manage and ensure the accuracy of underlying data. To that aim, CDC has enhanced IPP with functionality to support improved data visualization, data analysis, and stakeholder engagement; components that are critical to infectious disease outbreak preparedness and response. IPP leverages Microsoft Dynamics Customer Relationship Management (CRM) software, integrated with Outlook and SharePoint, to connect parallel data sources and streamline communications. The first IPP module launched in 2016 to support the IRR reagent distribution program and created a strong foundational platform for the collection and triage of the large number of laboratory requests received by the Influenza Division each year. It also supports stakeholder communications. For example, an email from a state epidemiologist regarding a surge in reported influenza cases can be directly linked to a pending IRR order to enable expedited shipping of needed diagnostic reagents. Enhancements made during 2017 provide additional functionality to support CDC's data analysis and to better communicate information to improve internal operations and rapid decision-making. CDC has also incorporated data visualization software to facilitate the interpretation of the underlying data. This capability enables IPP users to create interactive data visualizations and supports real-time reporting capabilities. A summary dashboard with quick filter options allows IPP users to immediately update graphs and tables that can be incorporated into status reports and metrics. IPP's added functionality allows CDC investigators and response team leads to directly manage its reagent distribution data to generate graphics and summary reports that improve their understanding of the underlying trends and support communication of developing priorities to strategic decision-makers and leadership. These enhancements are critical to facilitating rapid response to infectious disease outbreaks domestically and internationally, and ultimately align with CDC's goal to reduce disease burden and mortality from preventable disease.

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Harmonizing Public Health Data: The Knowledge Management Challenge

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Centers for Disease Control and Prevention (CDC) and its partners have identified improving efficiency and effectiveness of public health surveillance as a top priority. CDC is developing a Surveillance Data Platform of shared services to help modernize systems and eliminate unnecessary redundancies in reporting toward the goal of improving quality, timeliness, and availability of critical information to the public health system. A major challenge in realizing these improvements is the variety of public health data that CDC collects from many sources. Improved harmonization of public health data would 1) Reduce the reporting burden on state and local health authorities, who now must submit overlapping data in many different formats; and 2) Improve CDC's analytic capability, for example, by allowing different programs to more easily use data. This poster presentation presents five facets of SDP. 3) Describes the importance of data standardization and harmonization to public health. We will describe the principal stakeholders and how they would benefit from improved standards management and harmonization (SMH) processes. We present an augmentation of the standard Public Health Surveillance Lifecycle that shows the impact of SMH on each phase of the lifecycle. Second, we present the main findings from an analysis of the current state of standards management and harmonization at CDC. A

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major finding was the need for better knowledge management to ease both the development of new data standards as well as the adoption and evolution of existing standards. Third, we describe the features of improved knowledge management for SMH, including a description of the stakeholders and their needs for improved, tools, processes, and governance. Finally, we describe CDC's ongoing efforts to improve SMH, including the approach to knowledge management, progress to date, challenges, and lessons learned relevant to a broad range of public health agencies.

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Integrated Whole Genome MLST and SNP Analyses in BioNumerics Applied to Publicly Available *Campylobacter jejuni* and *C. coli* Isolates

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Introduction: Illnesses caused by bacterial foodborne pathogens continue to be a serious health issue worldwide. In laboratory-confirmed cases of infection, *Campylobacter jejuni* (about 90% of cases) and *Campylobacter coli* (about 10% of cases) are considered to be one of the most significant bacterial causes of human gastroenteritis worldwide. Molecular subtyping methods for detecting *Campylobacter* outbreaks have mainly been pulsed-field gel electrophoresis (PFGE) and PCR-RFLP. However, at present, rapid and cost-effective generation of whole-genome sequence (WGS) data offer a considerable advantage as the ability to rapidly extract relevant information from large sequence data files can considerably speed up detection and containment of an outbreak.

Methods: In this study, two subsequent approaches for high resolution WGS-based molecular typing were taken. First, whole genome multilocus sequence typing (wgMLST) was applied to WGS data from over 1000 publically available strains from clinical or chicken-related sources to detect clusters of highly related strains. A typing scheme was created by extracting all coding regions from a set of reference organisms, resulting in a set of discernible wgMLST loci. Two independent allele calling approaches are applied, an assembly-free and a BLAST-based allele calling algorithm, to determine locus presence and detect allelic variants in a quality-controlled manner. Subsequently, a cluster defined by wgMLST can be further characterized by whole genome single-nucleotide polymorphism analysis (wgSNP). The wgSNP pipeline, tuned to reduce false positives while maximizing resolution, detects SNP variants by mapping the WGS reads to a reference sequence chosen from within the cluster to further maximize resolution. For both pipelines, calculation-intensive data processing steps were performed on the BioNumerics® Calculation Engine, deployed locally or in the cloud.

Results: wgMLST is suitable for the rapid analysis of large datasets, making it a useful technique for outbreak surveillance, while wgSNP can provide additional resolution increasing the confidence in detected clusters. In this case, it allowed us to quickly identify clinical cases related to chicken that might have previously gone unnoticed.

Conclusions: The application of two complementary approaches, wgMLST and wgSNP, to a virtually unlimited number of samples, managed by a single software platform that also stores traditional data and metadata, opens many perspectives for food safety and public health monitoring programs. Moreover, the possibility to extract traditional typing data, resistance and virulence data from wgMLST schemes reduces the total analysis time and cost, and may lead to more efficient outbreak detection.

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Bridging the Gap: Building Strong Communication between Laboratory and Informatics Staff

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One of the key products of public health laboratories is the data they produce. As such, the management and exchange of that data is a key component of a successful laboratory. As laboratories increase efficiency and move away from paper based systems, the role of informatics staff grows more critical to the overall mission of the laboratory. While some informaticians transition to information management directly from the laboratory bench, many come from an IT background and lack a clear understanding of public health and laboratory science. In order for the informatics team to design robust systems that work with laboratory workflows rather than contrary to them, efficient communication between laboratory and informatics staff is vitally important. To ensure success, laboratory staff must often dedicate time and expertise to informatics projects, such as the implementation of Laboratory Information Management System (LIMS) software, the generation of electronic messages or the design of data warehouses. Informatics staff may include business analysts, developers, messaging specialists and database administrators, all of whom require various degrees of interaction with laboratory staff to complete these projects successfully. All levels of laboratory staff need to provide input on informatics projects including describing their daily workflow, communicating quality assurance needs, and determining scope and budget. Communicating effectively requires a willingness to learn the basics of informatics, and to teach the fundamentals of laboratory processes to informatics staff. Common understanding and a willingness to “meet in the middle” are key components of communication for both informatics and laboratory staff. This level of communication is developed by understanding each other’s limitations and motivations. Clearly defining a project’s scope and requirements in language that is understandable by all stakeholders saves time and avoids interruptions of informatics projects. By developing and maintaining clear lines of communication between laboratory staff and informatics staff, the chances of a successful, timely and correctly budgeted project increase.

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Beyond Biosafety and Biosecurity: Bioquality as a Fundamental Culture of Successful Laboratories Worldwide

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A robust Quality Management System (QMS) is critical to a successful diagnostic laboratory. The manner in which laboratories and professional organizations define QMS creates a gap requiring a broader term

encompassing more than the system; we propose Biological Quality or rather Bioquality. The case for Bioquality will be made by defining the discipline in a culture of organization, contrasts drawn with QMS, and comparisons with current definitions of Biosafety, Biosecurity, and Biorisk management. QMS is a practice, a systematic process-oriented approach to meeting quality objectives (CLSI); whereas, Bioquality is the guiding principle that translates practice into the pragmatic QMS implementation encompassing the laboratory's organizational culture associated with QMS. Too often QMS dictates a procedural list of regulatory requirements governing a laboratory, whereas Bioquality takes into consideration the scope of human input engaging both traditional and cultural attitudes with the flexibility to ensure quality as an essential component of the biological laboratory's values. This inside approach creates a healthy QMS which is incorporated throughout policies, processes and procedures. It not only produces concrete or definitive deliverables and products, but also interpretive data and deliverables. To laboratorians, QMS is the behavior in normal settings within the scope of specific regulations; however when faced with behavioral decisions outside specific regulations, Bioquality is the culture or a 'way of thinking' ensuring quality is sustained. Bioquality addresses the moment of decision affecting the quality and integrity of deliverables. Furthermore, QMS takes a leap of faith to sustainability assuming a successful laboratory is executing regulatory guidelines and continually improving the processes by revising SOPs, employing newer trainings, and building on past difficulties, an iterative process. Bioquality seeks to embed these principles within the minds of all laboratory workers as part of the laboratory culture. Similar to Biosafety and Biosecurity (BS&S), and Biorisk management components as overarching principles guiding regulatory standards, a term to supersede the QMS, specifically within biological laboratories, is likewise needed. As a thorough understanding of BS&S and biorisk management are critical to all who enter a laboratory, so is Bioquality as a holistic approach to quality. Biological quality (bioquality) is a needed discipline for an internal cultural framework through which a biological laboratory can promote, implement and advocate a strong QMS as well as create the culture of quality decision making.

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Design Considerations for the Reporting of Laboratory Analyses of Cannabinoids and Contaminants in Marijuana Products to Public Health Regulatory Agencies

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Medical marijuana products that are sold in Massachusetts are required to be tested for contaminants and cannabinoid content by private analytical testing laboratories. The laboratory records from these private analytical testing laboratories are submitted to the Massachusetts Department of Public Health (DPH) and evaluated for a determination of compliance with health-based standards. A standardized reporting tool was developed by DPH to integrate the information from the laboratory client (Registered Marijuana Dispensaries) and the analytical testing laboratories. This standardized reporting tool ensures the creation of a laboratory record that meets international quality standards (ISO 17025), in a manner that is timely, accurate, and understood by all stakeholders. The standardization of a laboratory reporting tool across laboratories allows for the rapid assembly of large amounts of data, facilitating a capability to track and analyze trends in the characterization of medical marijuana products. The reporting tool was developed to consider linkages to enterprise systems such as Laboratory Information Management Systems as well as compliance-based software for tracking marijuana distribution in the state.

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Examples of Uses of the Public Health Laboratory Systems Database

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Objective: Provide public health laboratory (PHL) stakeholders with an update on the progress of the Public Health Laboratory System Database (PHLSD) and provide information on its utilization. Poster content will demonstrate how PHLs can benefit by using the PHLSD as a repository for their data and for improving recordkeeping for regulatory inspections, personnel vacancies, tests, and equipment inventory.

Project Design: The PHLSD is a web-based tool developed by APHL with support from CDC, which enables PHLs to enter and access information on their regulatory and testing capabilities. The PHLSD provides “one-stop shopping” for querying testing services across PHLs. Once PHLs complete data entry, the database provides PHLs who completed the data with updated list of tests conducted and access to an equipment inventory to prepare for inspections by accrediting agencies. There is continuing work to ensure that reporting features align with PHL needs for CLIA inspections and the search functions effectively identify PHLs with related testing services.

Results: This new database provides a central repository for both external and internal information sharing, real-time and comprehensive information on the capabilities of PHLs, and improved reporting capabilities including recordkeeping for CLIA audits. Stories will be provided from PHLs on how using the database provided accurate reports on personnel and test data that could be shared with their CLIA inspectors and laboratory personnel.

Conclusion: The database is creating a comprehensive national PHL test directory that offers a strategic approach for preparing for regulatory inspections, organizing, reporting, and sharing information, as well as increasing the efficiency of PHL information management. This will allow for greater transparency, enhance opportunities for collaboration, inform interoperability efforts, and provide a resource in times of emergency or surge.

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National efforts to Improve Laboratory Quality and Safety in Clinical and Public Health Laboratories

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Clinical laboratory testing is performed in more than 200,000 Clinical Laboratory Improvement Amendments (CLIA) certified sites, warranting national standards, guidance, and training that support effectiveness and reliability of clinical laboratory science and medicine. The mission of CDC’s Division of Laboratory Systems (DLS) is to strengthen the nation’s clinical and public health laboratory system by

continually improving quality and safety, data and information science, and workforce competency. DLS accomplishes its mission through multidisciplinary collaborations with partners and stakeholders, including managing the Clinical Laboratory Improvement Advisory Committee. Through partnership with APHL, DLS is working to support the sustainability of the nation's public health laboratories; areas of focus include workforce development, regional network strategies, a national test directory and informatics. DLS collaborates with ASM and other professional organizations as part of our Laboratory Medicine Best Practices (LMBP) Initiative to address quality improvement practices of interest to the laboratory and healthcare community. The division's laboratory training website provides easily accessible learning resources. Through CDC TRAIN, laboratory professionals can register for live and on-demand courses, obtain continuing education credits, and notifications of new courses. Since 2015, DLS has published guidelines on diverse topic areas including developing an individualized quality control plan, quality practices in next generation sequencing, laboratory professional competencies, and an Informatics Self-Assessment Tool. Ten formal CLIAC recommendations have been submitted to HHS that address interoperability of laboratory information, laboratory safety, integration of laboratory medicine into health care, and non-invasive prenatal testing. Seven LMBP systematic reviews have been published including a review on Practices to Increase Timeliness of Therapy for Inpatients with Bloodstream Infections. In 2016, DLS distributed free tools to 3,798 laboratories that help assure the quality of waived testing and test results, and disseminated an educational booklet to 3,063 laboratories on recommended practices for provider-performed microscopy procedures. DLS' laboratory training website has >300 course offerings with >18,900 registrants in FY16; 92% indicated training objectives aligned with their training needs. DLS and partners have developed practice guidelines and trainings for a national audience. In 2017, DLS will publicly release many new CDC biosafety courses, and expand its engagement on laboratory biosafety. Through continued collaboration and active engagement with the laboratory community, DLS can collectively strive for exemplary laboratory science and practice across clinical care and population health.

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LEANing towards Efficiency in the TB Laboratory

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At the Scientific Laboratory Division, TB testing involves multiple sections. The Specimen Receiving Section receives and accessions the specimens, the General Microbiology Section processes and tests specimens through microscopy and culture, while the Molecular Biology Section conducts PCR on both raw specimens and culture. We have been having continual issues meeting CDC targets and internal measures despite some internal changes. Our laboratory applied for and was selected, by APHL, for a LEAN Assessment that was conducted by LEAN experts from Abbott Laboratories. The objectives were improved turnaround time through implementation of LEAN processes, improved resource utilization, thus improved patient care. Here we present the results of the assessment and our endeavors to bring these recommendations into our workflow. The assessment revealed a total potential increased capacity of 165% with a time savings of 49% among all sections. Data management, quality control, and technology were identified as areas for improvement.

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Practical Applications Using the APHL Return on Investment Tool

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Objective: The objectives of this poster presentation are to 1) describe the concepts and relevant formulas of the Return on Investment (ROI) tool and 2) share the potential uses and benefits of the tool's outputs and examples of how the findings can be used by public health laboratories (PHLs).

Project Design: The ROI tool is designed to assess the return on investment (ROI) for five tests including influenza, tuberculosis, PulseNet, newborn screening and Safe Drinking Water Act programs. For each of these test areas, the tool estimates the laboratory's ROI by mapping laboratory expenditures, test volume and FTE data onto published cost-benefit analysis. Data was collected from 11 pilot sites including six state sites (Utah, Arizona, Minnesota, New York-Wadsworth, New Hampshire and Iowa) and five local laboratories (Tulare, Monterey and Riverside Counties, California; Fairfax County, Virginia; Alaska Environmental).

Results: The tool's outputs include laboratory level efficiency metrics such as cost per test and productivity (FTE/test) and system level program cost effectiveness (i.e. the dollar saved for dollar invested for the overall program). The potential uses of these outputs are multiple. PHLs can monitor laboratory level metrics across time and compare themselves with similar laboratories. They can also use the tool to analyze the factors that contribute to efficiencies in order to make strategic programmatic decisions. Finally, the findings offer a sense of the dramatic benefit that public health laboratories offer and can be used to communicate the importance of PHL services to decision makers, partners, stakeholders and policy makers.

Conclusion: The conceptual underpinnings of the ROI tool will be explained. Illustrative examples highlighting the potential uses and benefits of the tool's outputs will be shared from pilot site experiences. The ultimate goal in collecting and analyzing personnel, financial and testing volume data through this tool is to provide PHLs with information for decision making and communication of their value to critical stakeholders.

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A Biosafety Risk Assessment Comparing Laboratories that support Acute Care and Critical Assess Hospitals in Nebraska

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Introduction: Nebraska, a rural state with a population of 35 miles from another hospital) and Acute Care Hospitals (ACH, >25 inpatient beds with personnel available 24/7 to provide diagnosis, care, and treatment of acute conditions or injuries). This project involved performing biosafety risk assessments at laboratories supporting both CAH and ACH and comparing the results of the assessment between the two facility types.

Methods: The biosafety risk assessment was conducted using both observations and an in-house developed questionnaire. The questionnaire was comprised by using templates provided by the Association of Public Health Laboratories and assessment examples from several states with modifications.

Results: A total of 64 risk assessments were conducted at 57 CAH and 9 ACH. The results showed that all laboratories were Clinical Laboratory Improvement Amendments (CLIA)-certified and participated in a proficiency testing program. All ACH hospitals participated in the College of American Pathology Program (CAP). This difference was evident when most of the CAH did not have a documented quality management program, a required component of CAP. Personnel protective equipment was generally available but not always used by the CAH laboratorians. Major safety concerns for both CAH and ACH were the lack of centrifuges with sealed rotors or safety cups (none had sealed rotor and most did not have safety cups available) and the lack of chemistry core analyzers with closed system analysis (only 11% of the ACH and 0% of the CAH had this available). Another major finding was the lack of biosafety cabinets for CAH to process specimens (only 28% had cabinets available). Overall, biosafety compliance for the ACH was at 76% while the CAH was at 44%.

Conclusions: The results of these risk assessments showed that safety compliance needs improvement at both ACH and CAH support laboratories. A major finding was the lack of biosafety practices at CAH with their ability to handle specimens that might contain a high-risk pathogen as their capacity to be front-line hospitals. Future activities will target training directed for these front-line hospitals to improve laboratory safety. Additional assessments to recognize, mitigate risks and improve overall safety practices for both CAH and ACH are planned.

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Laboratory Acquired Infections, Exposures and Near Misses: Tools and Case Studies from the New Mexico Scientific Laboratory Division

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Lab acquired infections (LAIs) in the laboratory setting are very serious and can result in severe illness and death. However, they are believed to be underreported in the literature and often undetected in the workplace. One reason biosafety exists is to prevent LAIs or at the least minimize their probability. Studies, from various sources, have demonstrated that reporting of near misses, along with performance of risk assessments and training can significantly decrease the likelihood of LAIs, and lab

accidents. One of the compounding factors is that numerous laboratories are lagging in the development of robust biosafety programs that improve practices. In an effort to bridge this gap, the CDC awarded funds to state public health laboratories so they might hire a designated biosafety officer to strengthen biosafety programs both internally and within sentinel laboratories. One focus of these biosafety officers is to establish formal risk assessment SOPs and help perform risk assessments. Here, we describe the risk assessment SOP, risk assessments, biosafety cabinet disinfection protocol, and other tools we have developed for use both internally and by sentinel laboratories. We will also discuss the lessons learnt through examples of recent exposures and LAIs in our laboratory.

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APHL Biosafety Peer Network: Paired for the Future

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In 2016, the Association of Public Health Laboratories (APHL) established the Biosafety Peer Network, commonly known as the Visiting Biosafety Official Program. The purpose of this program is to twin state, local, territorial and US Affiliated Pacific Islands (API) public health laboratories (PHLs) with one another to facilitate mentoring and information sharing among the biosafety officials (BSOs). The overall objective of the Biosafety Peer Network is to strengthen biosafety and biosecurity across PHLs. It is anticipated that through the free and mutual exchange of practices and procedures both participating laboratories will improve and enhance the implementation of their respective biosafety and biosecurity programs. Furthermore, it will harmonize the biosafety and biosecurity programs at several different PHLs due to their common source of guidance. This standardization among different organizations is beneficial in many aspects such as implementing new procedures and communication between partners. Finally, this program will pool limited resources to strengthen biosafety and biosecurity in laboratories nationwide as well as foster an environment of collaboration and community among the relevant stakeholders. The strategy for implementation is that initially one laboratory will take the role of the hosting laboratory while the other laboratory will take the role of the visiting laboratory. The visiting BSO will spend approximately three days navigating the hosting laboratories facility and will work closely with their partnered BSO. During this time they will be guided by a personalized agenda that will cover a variety of topics, such as biosafety and biosecurity plans, occupational health programs, regulated waste management and sentinel clinical outreach. Within three months of this initial visit, the roles of the twinned labs are reversed, with the initial hosting laboratory going to the initial visiting laboratory's facility while working closely with their BSO. For this first round, 12 state PHL BSOs have been twinned, for a total of 6 pairs. The laboratories are twinned according to their responses on an application as well as based on their current strengths and proficiencies in specified areas of biosafety and biosecurity. The visits for the first round of twinned laboratories began in January 2017. For this first round of twinning, all lodging and per diem is covered by APHL through its cooperative agreement with the Centers for Disease Control and Prevention (CDC). It is anticipated that this program will be continued through 2018.

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Laboratory Biosafety and Biosecurity Partners Forum-Strength in Cooperation

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On September 19th 2016, the Association of Public Health Laboratories (APHL) in partnership with the Centers for Disease Control and Prevention (CDC) convened the Laboratory Biosafety and Biosecurity Partners Forum to facilitate information exchange among various federal partners and other stakeholders engaged in evaluating and improving clinical laboratory biosafety and biosecurity practices in the United States. This Forum included fourteen diverse partners, to include representatives from federal agencies such as the CDC, Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS), as well as associations that represent and/or accredit clinical laboratories such as the Joint Commission, Clinical Lab Management Association (CLMA), American Association for Clinical Chemistry (AACC), American Association of Bioanalysts (AAB), COLA, and the American Society for Clinical Pathology (ASCP) to list a few. This Forum enabled these key stakeholders to discuss policies, practices, gaps and improvements with the overall goal of sharing timely information to improve biosafety and biosecurity in the nation's clinical laboratories. The actions of this forum and their on-going activities will be discussed in detail.

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SAFELab: Integrating Technology and Quality to Enhance Laboratory Safety

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Laboratory safety is a constantly evolving field due to the increasing complexity and associated risks of scientific research. Moreover, regulatory and institutional compliance requirements continue to increase to protect public health. As such, Public health laboratories have looked into ways to integrate available technologies to help improve quality and safety strategies and minimize the additional levels of effort to ensure compliance. To answer this need, Booz Allen Hamilton has developed a technological platform, called SAFELab, which is designed to facilitate the convergence of training, access control, and other quality management processes while decreasing the burden of additional documentation and reporting. SAFELab alters the laboratory management and laboratory research experience by documenting procedures without leaving the biological safety cabinet, capturing key metrics in an auditable platform, passively tracking samples and inventory, tracking and monitoring personnel, and delivering real-time alerts that ensure adherence to protocols and help prevent safety breaches.

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A Biological Risk Assessment of Neisseria species Reference and Research Activities

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Background: Select urethral isolates from the CDC Gonococcal Isolate Surveillance Project (GISP) are routinely sent to the CDC Laboratory Reference and Research Branch (LRRB) for antimicrobial-resistance and possible genetic analyses after they are presumably identified at submitting GISP Laboratories. Identification involves culture on selective medium, Gram stain, morphologic assessment and oxidase reaction. This identification scheme is sufficient for urethral isolates collected from men with urethral discharge suggestive of *Neisseria gonorrhoeae* (Ng) infection since other bacteria are not typically associated with symptoms. However, urethral *Neisseria meningitidis* (Nm) isolates have sporadically been identified from patients reporting urethritis symptoms commonly experienced during gonorrhea infection. There is a slight chance that Nm isolates were misidentified as Ng since they share similar characteristics. To address safely working with submitted isolates that are presumably Ng but may occasionally contain Nm, a laboratory risk assessment (RA) was conducted.

Methods: All Standard Operating Procedures (SOPs) and workflows involving *Neisseria* species isolates at LRRB were evaluated to identify common hazards. The RA involved laboratory staff working with *Neisseria* species isolates, supervisors and leadership. We identified a total of 17 activities that may lead to an accidental exposure. The likelihood and consequences of each hazard were assessed using the LRRB RA Tool, which was adapted from various published RA methods to assist in hazard identification, likelihood, consequences and mitigation strategy evaluation.

Findings: Cell inoculation and harvesting, nucleic acid purifications, and MIC testing were considered to be of highest risk for accidental exposure to infectious bacteria in staff performing these steps, which included but are not limited to splashes, aerosolization, and spills. However, mitigation strategies currently in place including BSL-2 practices and facilities, SOPs for Ng isolate handling, and PPE such as laboratory coat, eye protection and gloves were judged as satisfactory in minimizing personal risk.

Conclusions and future plans: Based on the recommended biosafety practices with *Neisseria* species and the evaluation of risk at LRRB, the overall risk is considered low. Additional mitigation strategies were identified in an effort to further reduce risk: 1) additional biochemical characterization to positively identify Ng, 2) containers for the transport of culture plates and frozen isolate stocks, 3) cap locks during high temperature incubations, 4) substitution of glass pasteur pipettes, 5) specifying BSC use for specific protocol steps, 6) update and optimize SOPs to reflect the changes made, 7) develop separate SOPs for work with confirmed Nm strains, and 8) training of laboratory staff for new or updated procedures.

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Improving Timeliness: Tracking Newborn Screening Specimens from Birth to Storage

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Do you know how many babies have been born in your state so far this year? Do you know how many specimens are in transit to your lab right now? Would that information at your fingertips help you to

ensure no babies are missed and no specimens go missing? In many jurisdictions, newborn screening (NBS) laboratory staff know children are being born but do not have an exact denominator of the births. Waiting for a report from Vital Statistics may be too late to ensure every baby is screened. They may never know how many specimens are in transit to their lab and where they originated. Current NBS information systems have gaps, including notifying the NBS program when a baby is born and where samples are, before and after screening. Can informatics solve these problems? Absolutely. Track-Kit Newborn Suite is a new software system that brings together the pre-analytical NBS information needed by all stakeholders. The system captures demographic details on every baby born in the jurisdiction. Track-Kit Newborn Suite tracks every specimen from the moment it is collected to the time that laboratory results are reported and keeps an audit trail of specimen storage and destruction. The end result is an integrated system that saves time and enables sharing critical information. Each stakeholder has their own secure portal, including hospitals, laboratories, physicians, kit distributors, the state program, and most importantly, parents. If a sample doesn't arrive at the lab within a specified time, staff are notified and can see where it originated and when it was last scanned, to find it quickly and avoid further delays. Lab and hospital staff benefit from faster data capture, more reliable data and improved access to information. The state program gets a global view for better transparency and accountability. Even parents can access location- and language-specific resources via their portal. Everyone is kept informed as appropriate and is alerted of any problems so prompt action can be taken to stay on track and optimize timeliness. OZ Systems and STACS DNA collaborated to produce Track-Kit Newborn Suite. OZ Systems has been dedicated to solving NBS information technology challenges since 1996. STACS DNA has been delivering sample tracking software to public laboratories since 2000. The two companies marry baby-tracking and sample-tracking perspectives to provide a complete end-to-end NBS information system.

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MicrobeNet: Revolutionizing Bacterial Reference Identification

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Introduction: Since its deployment in 2013, MicrobeNet has been a vital tool for aiding the identification of bacterial and fungal pathogens in State Public Health labs, hospitals, medical centers and universities, laboratories in the US and worldwide. MicrobeNet is a free, online, virtual pathogen reference laboratory that was created to connect the public health scientist to the CDC, saving time, money and lives.

Methods: MicrobeNet's ability to reduce pathogen identification costs and identification time originates from its three CDC curated, searchable modules. The MicrobeNet 16S BLAST module introduced first in 2013, contains over 7,000 16S, rpoB, gyrB, and ITS loci. This module lets users BLAST a bacterial or fungal sequence against MicrobeNet, either by copying and pasting a sequence, uploading a FASTA file, or using ThermoFisher's Micro-Bridge tool. MicrobeNet then connects to a CDC hosted BLAST service and uses the BLASTN algorithm against the CDC-curated database for identification. The second module centers on phenotypic searches. Launched in 2015, users can create their own virtual test tube rack, enter in their biochemical results and perform a more accurate biochemical testing identification. Biochemical results are compared against a set of CDC - curated matrices (phenotypic database) and an

identification and confidence score is returned to the user. In 2016, using a Linux based service provided by Bruker Daltonics, the MALDI-TOF proteomic fingerprint module was launched to provide users with access to CDC pathogen database specifically designed to bridge gaps within Bruker Daltonics' database, as well as provide additional representation for rare and unusual pathogens which have minimal coverage.

Results: MicrobeNet has grown quickly since 2013 where 950 users joined this year making the total user number 1,185. These users represent 624 different organizations in the US and internationally. 3,567 identification matches were reported back to the users with 833 of those hits coming from US State Public Health Labs. US Public Health Labs have used MicrobeNet to help with recent outbreak pathogens such as Elizabethkingia anophelis and Candida auris. The top three species that were identified by US PHLs in 2016 were Nocardia nova, Dolosigranulum pigrum, and Nocardia farcinica.

Conclusion: MicrobeNet's three modules – DNA sequence BLAST, phenotypic, and MALDI-TOF - help reduce costs and identification times. MicrobeNet is a revolutionary clinical tool that will instantaneously connect PHL's to CDC's curated collections of microbial data. As we look to the future, modules will be added that will include antibiotic resistance modules, whole genomes and taxonomy databases, to serve the needs of US Public Health Labs and global public health efforts.

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P-91

Leeches, Scopes, and Implants, Oh My! – The Clinical and Environmental Microbiology Branch's Primary Specimen Testing Capacities for Outbreak Investigations

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As medical practice improves, facilities serve an increasingly fragile patient population vulnerable to microbial exposure, transmission, and infection by unusual organisms from unusual sources. Thus, outbreak investigators may encounter items in the patient care environment that require specialized collection methods, which in turn present laboratorians with a bewildering array of primary specimens to process, many of which do not have validated testing methods. For this reason, the Clinical and Environmental Microbiology Branch (CEMB) of the Centers for Disease Control and Prevention (CDC) provides laboratory expertise and support to state and regional public health partners investigating healthcare-associated outbreaks, with an emphasis on emerging antimicrobial resistant organisms. The laboratory, in conjunction with epidemiologists located within the Division of Healthcare Quality Promotion, provides logistical support in the form of email and phone consultations regarding hypothesis development, sampling supplies and testing strategies, methods sharing and training, and shipping logistics. Sample processing guidance and execution by CEMB includes, but is not limited to, swabs, wipes, implanted and reusable medical devices, intravenous and compounded medications, water, plumbing fixtures, soil, small animals, human remains, breast milk, cosmetics, and other complex matrices which may contain competing organisms and compounds which may inhibit the recovery of the suspect organism. As many of these procedures are either modifications of existing procedures or custom-made, the use of quality control measures such as field blanks and process controls is implemented. Recovered suspect organisms are then characterized by species identification, resistance mechanism testing, and comparison to any available patient isolates by genotyping. The laboratory's most frequently used procedures are standardized and optimized to improve yields and shared to strengthen environmental testing by our partners advancing the nation's public health response

capacity. These findings, their interpretation in conjunction with epidemiological information, and implied transmission pathways are then reported to the laboratory's public health partners for implementation of potential control measures and interventions to protect patients.

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Additional Zika Cases Identified in Expanded Window for Zika NAAT and IgM Testing in New York City

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Background: As the main Zika testing laboratory of a city with a large population that frequently travels to Zika affected countries, the Public Health Laboratory at the New York City Department of Health and Mental Hygiene (DOHMH) received and tested 14,771 serum and urine specimens for nucleic acid amplification testing (NAAT) and IgM antibody testing from January 2016 through December 2016. CDC's current testing algorithm recommends NAAT for specimens collected from pregnant patients within 14 days of symptom onset or possible exposure from travel or unprotected sex with a traveler and IgM for specimens collected from 14 to 84 days from onset or exposure. New York State expanded testing criteria for pregnant and non-pregnant patients. This included testing all pregnant women who traveled to areas with Zika virus transmission any time during pregnancy. As a result, DOHMH received many specimens that were outside the testing recommended by CDC.

Methods: Data for specimens from NYC residents tested in 2016 were obtained from our DOHMH's laboratory information system and surveillance system. Data from 684 serum and urine specimens with positive results by NAAT or IgM were used to assess time from onset of symptoms to specimen collection among symptomatic persons with positive Zika tests and date of last travel from a Zika affected country to collection among asymptomatic persons with Zika positive tests.

Findings: Thirteen (3.6%) of 363 Zika NAAT-positive urine specimens were collected outside of the 14 day window after symptom onset – with a maximum of 45 days between symptom onset and specimen collection. Ten (8.9%) of 113 Zika NAAT-positive serum specimens were outside of the 14 day window with a maximum of 93 days. Twelve (7.6%) of 158 IgM positive serum were collected after 84 days with a maximum of 184 days.

Interpretation: Most Zika positive specimens at DOHMH were detected within the suggested testing windows provided by CDC. Still, the detection of Zika in specimens collected outside of the initial CDC recommended window suggests the virus may remain detectable longer than expected. Our data show that by accepting and testing specimens that were outside testing recommendations, we detected Zika that might not have otherwise been detected. While other factors including laboratories' ability to handle increased specimen volume should be considered before expanding recommendations, a lenient and expanded testing window may be beneficial in detecting more positive patients.

Funding: Fund for Public Health in New York City, Epidemiology and Laboratory Capacity (ELC)

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P-93

Council for Outbreak Response: Healthcare-Associated Infections and Antimicrobial Resistant Pathogens (CORHA): Building Capacity for Public Health and Healthcare to Improve Outbreak Detection, Response and Prevention

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Healthcare-associated Infections (HAIs) including antimicrobial resistant (AR) pathogens cause hundreds of thousands of illnesses and deaths among U.S. patients each year. Despite significant progress, patients are still experiencing preventable harms related to outbreaks and other adverse events from delayed recognition of infectious diseases with the potential for healthcare transmission, unsafe healthcare practices, contaminated drugs, and medical device risks. Consistent and coordinated approaches are needed to speed-up detection of emerging threats, development of tools to support outbreak investigations, prevent outbreaks from spreading, and better inform prevention activities. To address these needs, CDC's Division of Healthcare Quality Promotion funded the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists (CSTE) to co-lead the Council for Outbreak Response: HAI/AR (CORHA). Council membership includes ASTHO, CSTE, CDC, and the National Association of County and City Health Officials (NACCHO), APIC and SHEA. The Council will function as a multidisciplinary collective representing the interests of healthcare consumers, the medical community, state, local and territorial public health authorities, professional associations, and federal agencies. In 2016, CORHA finalized a strategic plan and governance and developed operational bylaws. CORHA also formed workgroups tasked with identifying standardized and coordinated approaches to detection, reporting, investigation, and control of infectious disease outbreaks and exposure events within healthcare facilities and in various ambulatory care settings. In 2017, CORHA workgroups will develop practical guidance for outbreak detection and investigation and promoting CORHA's mission. CORHA will be recruiting representation from public health and clinical laboratories to help define public health, clinical, and commercial laboratory best practices to support outbreak detection and response. Laboratorians play a crucial role in detecting and reporting of emerging infections and outbreaks in healthcare settings. Their future engagement with the council will be crucial to achieving the mission of CORHA.

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Investigating Unexplained Respiratory Disease Outbreaks: Laboratory and Epidemiologic Resources Available through the Centers for Disease Control and Prevention URDO Working Group

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Respiratory illness remains a leading cause of morbidity and mortality both in the United States and globally, yet identification of etiology remains a significant challenge, particularly for non-sterile site specimens. Rapid ascertainment of etiology is particularly critical in the context of respiratory outbreaks of unknown etiology when targeted interventions may be effective for halting disease transmission. The

Unexplained Respiratory Disease Outbreak (URDO) working group at the Centers for Disease Control and Prevention (CDC) provides laboratory and epidemiologic support to state, local and international public health laboratories during investigations of respiratory disease outbreaks of unknown etiology. A number of resources have been developed and are publicly-available on the URDO website, including tools for investigating outbreaks, determining differential diagnoses, and collecting and handling appropriate clinical specimens. From 2007-2016, the URDO working group assisted in 100 outbreaks. In addition to providing telephone and email consultation, support was provided through conference calls with the working group (69%), on-site epidemiologic investigation (11%), and laboratory assistance (76%); etiology was confirmed in 40 out of 76 outbreaks (53%), of which 9 (23%) had more than one etiology identified. Non-influenza respiratory viruses (24%), *Mycoplasma pneumoniae* (16%), Influenza A (16%), and *Bordetella pertussis* (10%) were among the most frequently attributed pathogens. Routine implementation of the TaqMan Array Card (TAC) for multi-pathogen detection has improved time to results and increased the proportion of outbreaks in which a probable etiology is identified. Still, only half of all outbreak investigations reveal an obvious pathogen. CDC is often consulted late in local outbreak investigations, at which point appropriate specimens may no longer be available. To improve identification of etiology, CDC, in conjunction with state health laboratory partners, is currently developing a targeted resequencing approach to amplify and sequence target regions for specific pathogen detection at the genus and species level, as well as to interrogate for relevant characteristics, including antimicrobial resistance determinants, genotyping, or other significant genetic traits or single nucleotide polymorphisms that may impact diagnosis, treatment, or intervention strategies. This updated sequence-based approach holds promise to improve the proportion of outbreaks in which an etiology is identified, decrease time to results, give more complete information about the infections, and guide specific outbreak response efforts.

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P-95

Environmental Protection Agency - Overview of Regional Laboratory Network

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The U.S. Environmental Protection Agency (EPA) Regional Laboratories are state-of-the-art, full-service environmental laboratories delivering analytical services, field support, quality assurance and data review, and expert technical assistance. Ten Regional Laboratories individually support the 10 EPA regions while also collaborating to form a highly effective Regional Laboratory Network (RLN). The location and contact information for each laboratory is presented and provides a visual map of the EPA Regional Laboratory Network. More specific information is available at <https://www.epa.gov/aboutepa/regional-science-and-technology-rst-organizations>. Annually, the Regional Laboratory Network reports highlights of accomplishments. These reports are available at <https://www.epa.gov/aboutepa/annual-reports-epas-regional-laboratory-network>.

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The Northern Plains Consortium: A Partnership from Laboratory to Leadership

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Background: The Public Health Laboratories (PHLs) in Idaho, Montana, North Dakota, South Dakota and Wyoming share demographic characteristics that lead to common challenges. Since its formation, the NPC has actively worked to identify, prioritize, and address areas of need. Here we highlight key activities of the NPC with an emphasis on shared testing services and succession planning via the regional Emerging Leaders Program (ELP).

Methods: To address mutual agreements regarding shared testing services between the NPC states, a Memorandum of Understanding (MOU) was drafted to define the objectives of the NPC and demonstrates the value of regional organizations. In addition to shared services, regional and onsite trainings have been developed and provided for employees and consortium members. At these workshops, experts in topics such biosafety practices and whole genome sequencing provide hands-on training and give examples of the importance of improving biosafety standards and new technology advancements in the laboratory. Lack of workforce development opportunities for public health laboratory employee has been a topic of discussion for many years amongst the NPC states. In 2015, an inaugural regional emerging leaders program (ELP) was created to provide leadership training to staff in all five states. The regional ELP program was modeled after APHL's national ELP and the ASCLS leadership providing leadership webinars, onsite meetings, and group activities for the participants. Using regional ELC support and networking grant funds from APHL, a second cohort will start in April of 2017 and will end in December of 2017.

Results: NPC members have successfully shared low volume testing services, thereby increasing capability and decreasing costs. The first regional ELP cohort finished its training and project in the spring of 2016 and will continue into 2017. The focus on leadership training and team building exercises for laboratory employees that may not otherwise have the opportunity to experience will be a main theme.

Conclusion: The NPC represents a regional effort to improve public health laboratory systems and increase efficiencies. Activities have included: development of a shared services MOU, sharing of knowledge and resources to meet Ebola supplemental grant deliverables, as well as a regional Emerging Leaders Program (ELP) based on APHL's national curriculum. These activities demonstrate a grassroots effort to share services based on efficiency and need, and the continuation of the NPC ELP aims to improve leadership skills for PHL staff that might not otherwise have access to leadership training. The NPC serves as a successful model for regional networks to expand access to leadership training, increase efficiency and enhance capability.

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Increasing Access to Laboratory Training and Education in a Rural State

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In 2016, the ND LRN BT workshop was converted from an in-person workshop to an online training. This poster will highlight the accomplishments of this project, summarize the logistics of creating and implementing the workshop, and communicate lessons learned and plans for the future of online training courses at the ND DoH, Laboratory Services. In previous years, only a select few laboratorians were able to attend the in-person workshop each year due to space and budget constraints. We will also display data that shows how implementing the online workshop increased our attendance numbers, thereby increasing our outreach capabilities.

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Assessing and Enhancing the Public Health Epidemiologist/Laboratorian Relationship

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In 2014, the Council of State and Territorial Epidemiologists (CSTE) and the Association of Public Health Laboratories (APHL) held two joint workshops to bring public health laboratorians and epidemiologists together from different parts of the U.S. to increase understanding and develop tools to help jurisdictions enhance these important partnerships. The resulting recommendations from these workshops were drafted as three separate worksheet checklists: 1) Improving Data Processes; 2) Sharing Standard Operating Procedures (SOPs); and 3) Training and Toolkits. Action on promoting this information was delayed due to the public health laboratory and epidemiology response to the recent Ebola and Zika virus outbreaks. In 2016, an APHL workgroup condensed these worksheets into a single checklist that was used to survey public health laboratories to assess their existing epidemiologist/laboratorian relationships. The survey was performed online using Qualtrics software and surveyed 26 public health laboratory managers distributed across the U.S. (five local laboratories, 19 state laboratories, two “other” laboratories) on their practices in the previous two years on how they communicated with their public health epidemiologist counterparts in the areas of shared data processes, SOPs, and training. Responses to questions were categorized as Yes, No, Yes – but >2 years ago, or Not Applicable. In 2017, the APHL workgroup will develop and distribute a toolkit for public health laboratories that includes these survey results, the worksheet checklists, relevant reference information on the Council to Improve Foodborne Outbreak Response (CIFOR), a public health epidemiologist/laboratorian competency crosswalk, and other best practices.

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P-100

Public Health Lab's Role in Indiana's Rapid Response Team

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Introduction: Rapid Response Teams (RRT) are multi-agency and multi-disciplinary teams comprised of federal, state, and local partners working together to respond to food emergencies. Often referred to as the 3-legged stool, the collaboration between the environmental investigators, laboratory, and epidemiology relies heavily on communication among each other. In 2012, Indiana State Department of Health Laboratories (ISDHL) became involved in the initial development of Indiana's RRT by reviewing ISDH Food Protection Program's (FPP) communication procedure and attending newly formed meetings with the RRT main players. The increased communication brought to light gaps in food sample collection and sampling supply issues that ISDH Laboratories could help improve.

Methods: Since 2014, only a limited number of food samples were submitted by local health departments (LHD) in response to outbreak investigations. To more effectively understand why LHDs were not collecting samples and submitting them for testing during outbreak investigations, the ISDH Food Microbiology Lab supervisor, in coordination with ISDH FPP staff, created an online survey for the LHDs focused on demographics, sampling resources, supplies, and training. Recommendations for improvements to communication procedures between ISDH FPP, ISDH Labs, and LHDs, will be developed once the survey answers are analyzed in February 2017. In 2012, ISDH FPP purchased sampling supplies, many of which have gone unused. Others are unsuitable for sample collection. The ISDH Food Microbiology Lab supervisor performed two separate root cause analyses to address the reasons for unused supplies and supplies unsuitable for sample collection. Final answers to the "5 Whys" root cause analysis determined the following: • Use improved, stickier seals • Use containers specifically designated for collecting liquid samples • Distribute various sizes of boxes to minimize shifting of the contents within the box. • Determine expectations for purchasing sampling supplies. After extensive follow-up meetings between ISDH Labs and ISDH FPP to discuss the findings, a plan of action was agreed upon to immediately address supplies within ISDH and investigate avenues to improve interactions with LHDs.

Conclusion: Planned changes will be presented at the Indiana Environmental Health Association annual conference in spring 2017. LHDs will have an opportunity to see the improvements and make any suggestions to expand on those changes. The effectiveness of ISDH Labs' involvement in the RRT will be assessed based on a decrease of sample rejections and an increase in sample submissions from LHDs. Additional improvements that ISDHL would like to pursue are continued communication with LHDs and more frequent requests for supplies from ISDH FPP field staff and LHDs.

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The FDA-CDC Antimicrobial Resistance Isolate Bank: A Resource for the Public Health Community

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Background: Antibiotic resistance (AR) is a growing threat to public health that jeopardizes our ability to successfully treat infections. Essential in the response to this global health crisis is the development of new diagnostic assays that would enhance our ability to rapidly detect emerging resistance and the discovery of new antimicrobial agents that would help us treat these infections. Development of new diagnostic assays and drugs requires the availability of diverse collections of clinically relevant antimicrobial-resistant microorganisms to serve as challenge for validation and use to support review and decision-making by the U.S. Food and Drug Administration (FDA).

Methods: In collaboration with and funding from the FDA, the Centers for Disease Control and Prevention (CDC) launched the FDA-CDC AR Isolate Bank in July 2015. The AR Isolate Bank is a curated repository composed of panels of drug-resistant and -susceptible microbes. A full profile of species identity, antimicrobial susceptibility patterns based on reference testing, PCR-based determination of resistance genes, and whole genome sequence (WGS) information is provided for each pathogen. WGS data generated by Illumina or PacBio platforms are uploaded to the National Center for Biotechnology Information. Isolates are provided at no cost (except for shipping) to requesting organizations (<https://www.cdc.gov/drugresistance/resistance-bank/index.html>).

Results: To date, the bank contains 429 isolates in 12 different panels comprised of carbapenem-resistant Enterobacteriaceae (CRE, 164 isolates), *Staphylococcus aureus* (14), *Neisseria gonorrhoeae* (50), *Pseudomonas aeruginosa* (44), *Acinetobacter baumannii* (41), *Candida* species (52), and additional Enterobacteriaceae (64). Incorporation of isolates with newly emerging AR mechanisms (e.g., mcr-1 and isolates that are non-susceptible to recently marketed antimicrobials) provides public health partners with access to the most up-to-date information on mechanisms of resistance. WGS data will enable better understanding of the mechanism of resistance and correlation between the phenotype and genotype. To date, 839 panels including 36,934 isolates have been provided to more than 300 organizations. Requesting organizations have included diagnostic manufacturers developing new assays, pharmaceutical companies testing new antimicrobial agents, academic institutions developing new technologies, and hospitals and state public health labs seeking to validate tests before use for patient care.

Conclusions: The AR Isolate Bank has been highly utilized since its launch and is a valuable tool that will improve our ability to detect emerging threats, assist in the FDA regulatory review process, facilitate validation of diagnostic tests, and contribute to the development of life-saving therapies for hard-to-treat pathogens.

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P-102

Development of an eLearning Module to Address the Public Health Financial Management Subcompetencies of Budget and Resource Management at the Beginner and Competent Levels

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Competency guidelines for public health laboratory professionals were published in MMWR in 2015. These guidelines describe the knowledge, skills and abilities required to perform at beginner, competent, proficient and expert levels. The 9th cohort of the APHL Emerging Leader Program identified a gap in financial management knowledge and skills among public health laboratory staff, leaving them underprepared to take on higher level leadership positions. This knowledge gap falls under the management and leadership (MDL) domain. Pilot studies determined targeted subcompetencies; 3.01 Budgets and 3.05 Resource Management, and targeted proficiency levels; beginner and competent and would be most beneficial for laboratory staff. Twenty current public health laboratory employees and 14 cohort members completed a survey developed by Cohort 9 to assist in narrowing the scope of the project. Questions included assessing gaps in financial management at different competency levels (beginner, competent or proficient), perceived competency levels in financial management, ranking the least and most important subcompetencies, and most effective delivery methods for employees' professional development in financial management. Based on these survey results, an instructional designer was consulted. Additionally, the cohort completed an environmental scan of existing training materials/tools, grouped them by subcompetency, and evaluated the level of modification needed. The gap analysis revealed an across the board acknowledgment that public health laboratorians are generally not well equipped in education or experience to address financial management duties. The perceived competencies of the survey participants were mostly at the beginner to competent level at the start of their current positions and ranged from beginner to expert at the time of the survey. Budgets and Resource Management were the subcompetencies identified as most important. All learning methods (mentoring, providing tools, web-based, classroom and combination) received very similar ratings overall. This is not unexpected and reflects differences in personal learning styles. The 9th cohort of the APHL Emerging Leader Program has focused a project to develop financial management training (MDL 3.0) to attract and retain high performing public health laboratory leaders. The two subcompetencies that will be addressed are 3.01 Budgets and 3.05 Resource Management. The level to which these subcompetencies will be targeted are beginner and competent. With the assistance of an instructional designer, an eLearning Module was developed. The next steps are to deploy the eLearning Module and make them available for the public and members to use. This project provides high-potential bench employees and existing laboratory supervisors/managers an opportunity to gain or enhance their financial management skills.

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Developing and Improving Laboratory Skills

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Government laboratories continue to have concerns about workforce development and the retention of institutional knowledge as the workforce ages and more individuals leave taking key knowledge with them. In this project, we have developed a technical skills training resource tool that has been developed by public health professionals for public health professionals and other laboratory workers. Using the Competency Guidelines for Public Health Laboratory Professionals (MMWR, Supplement / Vol. 64 / No. 1), which includes agriculture, environmental, and clinical laboratories, as the foundation, a workgroup has created a central location for training materials to address this need. This project ties into other projects that are also in development, such as the Quality Management System (QMS) training modules. This is an opportunity to show how we can grow the laboratory workforce and how Public Health Laboratorians can learn about this new and valuable resource that can assist with workforce development. Having a freely available public resource that captures some of the basic skills that laboratorians need to know while providing trainings that meet the Competency Guidelines gives laboratorians a reliable training source and lab supervisors more time to spend on complex skill training.

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Tools and Resources for Competency-Based Products to Strengthen Workforce Practices

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In May 2015, Competency Guidelines for Public Health Laboratory Professionals was published in the Morbidity and Mortality Weekly Report. The document is a master guide to associate competencies with every work activity in the laboratory and is the foundation for strengthening processes and activities that support professional and workforce development. A number of tools and resources are now available that help promote and aid in the multifaceted process of integrating the competencies into workforce practices.

Implementing behavior-based competencies has benefits in both recruiting and retaining successful employees. Position descriptions and defined career paths created using the competency guidelines can be indispensable tools during recruitment of potential employees. Managers will benefit from hiring employees that are well-informed about current and future expectations, and competency tools can provide for a systematic evaluation to assess performance and track an employee's personal development. Current employees can also benefit, as individuals can use the competency guidelines to perform self-assessments, define personal training needs, and assist in reaching career goals by following a competency-based career ladder or path as part of their professional growth plan.

To help facilitate the integration of these competency guidelines into workforce practices, 5 work teams comprised of public health laboratory professionals developed a variety of implementation tools and resources. The teams created: a) communication materials (videos, educational brochures) encouraging

the implementation of competency-based products and helping guide a process for implementation; b) spreadsheet tools for developing competency-based position descriptions, career ladders, performance assessments and training needs assessments; c) a sample career ladder and sample position descriptions; as well as d) a survey to assess and engage academic stakeholders regarding knowledge about, and interest in, integrating the Competency Guidelines into their education programs. These tools and resources have been combined into a Competency Implementation Toolbox, which is posted on the APHL Public Health Laboratory Competencies website.

Competencies improve the workforce by providing a guiding framework for producing education and training programs, identifying worker roles and job responsibilities, and assessing individual performance and organizational capacity. A robust suite of tools and resources is now available to help implement behavior-based competencies into laboratory and human resource practices, and early adopter public health laboratories are finding value in the incorporation.

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Implementation of Zika Screening on Mosquito Pools in a Local Public Health Laboratory in Collaboration with State Partners

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Zika virus (ZIKV) is a member of the genus *Flavivirus* and is currently known to be transmitted by *Aedes* mosquitoes. Although ZIKV is not a novel virus, it became a growing concern throughout the Americas in May 2015 due to evidence suggesting ZIKV is linked to an increased incidence of microcephaly in infants born to mothers infected with the virus. In support of the Disease Carrying Insects Program (DCIP) of the Fairfax County Health Department (FCHD) in Virginia, which has a well-established mosquito surveillance program, the FCHD Laboratory implemented real-time RT-PCR (rRT-PCR) testing of mosquitoes known to potentially transmit ZIKV in July 2016. The rRT-PCR protocol, primer/probe sequences and ZIKV culture strain PRVABC59 (GenBank Accession #KU501215, CDC lot# TC01088) were obtained from the Center for Disease Control (CDC) to validate the assay at the FCHD Laboratory. A screening primer set and confirmatory primer set were validated. Known positive and negative controls were created using clean *A. albopictus* mosquito pools spiked and not spiked with ZIKV culture, respectively. Accuracy and precision were evaluated, and the assay performed with at least 90% agreement to expected results. The FCHD Laboratory worked closely with state laboratory partners at the Virginia Division of Consolidated Laboratory Services (DCLS) during the validation process to share results and to ensure laboratories maintained consistent State-wide testing methods. This collaboration involved the exchange of samples to further strengthen both laboratories' validation of the ZIKV assay and accelerate implementation of this method in response to the potential threat of mosquito transmission of Zika in Virginia.

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Implementation of a Mentored Professional Development Program in Laboratory Leadership and Management in Zambia

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Overview: Laboratories need leaders who can manage their resources effectively, maximize the laboratory's capacity, communicate effectively with stakeholders and ensure their laboratory meets the service delivery needs of the community. To address this need, we created the Certificate Program in Laboratory Leadership and Management (CPLLM), an in-service program for mid-career laboratory managers and directors. Its purpose is to teach leadership and management skills to laboratory staff in supervisory positions, with the goal of enabling participants to make substantive and impactful improvements in laboratory testing quality and operations. It employs a mentored, blended learning approach utilizing both in-country and online training, and participants complete 5 courses and a laboratory improvement Capstone Project over the course of 9 months. The program was developed in 2013 at the University of Washington and has been implemented in 10 countries in the Middle East and North Africa in 2014 and in Zambia from March-December 2016.

Program Design: The CPLLM is delivered through 2 in-person meetings and 4 distance-learning courses, and program curriculum is organized and managed in a robust learning management system called Canvas™ which is capable of delivering diverse multimedia content, enabling discussion, group collaboration and communication, and surveying learner capacity and enabling course and program evaluations. The curriculum addresses key competencies such as: laboratory quality management, laboratory systems, leadership skills and management practices, analysis and communication of laboratory information, law and regulation of laboratory practice, and appropriate implementation of diagnostic technology. Participants also complete a Capstone Project, which is an applied effort towards improving their home laboratory operations and visibility in the health system. In addition, each participant is paired with a local or regional mentor who helps create and sustain a supportive and positive learning environment for each of the participants throughout the entire program.

Program Implementation in Zambia, 2016: 17 laboratory managers from 16 national referral and provincial level hospital laboratories were selected in February 2016 through a competitive nomination process and 8 senior mentors from Zambia, Botswana and Zimbabwe were also recruited and paired with participants. The CPLLM Orientation and Laboratory Systems course was delivered in March. Following this meeting, participants returned to their laboratories to conduct a comprehensive internal laboratory audit using the SLIPTA checklist and complete the 4 online courses. SLIPTA audit results allowed participants to identify gaps in quality management in their laboratories and develop individualized Capstone Projects based on these findings and other gaps in their laboratory's service delivery. Over the following 8 months, participants developed project proposal work plans and implemented their projects, culminating in a second internal audit of their laboratories in October and a 20-page project report and presentation summarizing their work and results at the program finale meeting in November.

Conclusions: The CPLLM is an effective in-service blended-learning solution that strengthens the skills of laboratory directors and managers and encourages networking and collaboration, strengthening the laboratory system at the national and regional levels.

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The Role of the Laboratory Response Network (LRN) during the 2016 Zika Virus Outbreak

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In January 2016 the Centers for Disease Control and Prevention (CDC) activated the Emergency Operations Center (EOC) to respond to the global Zika virus outbreak. State and local public health laboratory preparation was essential for testing travelers arriving in the US from Zika-affected areas. CDC collaborated with FDA to obtain Emergency Use Authorizations (EUA) for an antibody-based assay (Zika MAC-ELISA) and real-time RT-PCR assay (Trioplex rRT-PCR Assay). The Zika MAC-ELISA was deployed to detect anti-Zika antibodies in patient specimens. The Trioplex rRT-PCR Assay (Trioplex) detects Zika, dengue, and chikungunya virus RNA in symptomatic patient specimens. The LRN was uniquely positioned to deploy these assays due to infrastructure which allows for production and distribution of laboratory reagents using quality systems. The LRN provided verification panels, protocols and customer support for these EUA assays. LRN laboratories quickly and successfully adopted the CDC EUA assays with 62 labs implementing the Zika MAC-ELISA and 79 labs implementing the Trioplex by December 2016.

From assay deployment (February 2016 for Zika MAC-ELISA and March 2016 for Trioplex) through December 2016, over 55, 000 individual test results had been reported to the LRN. Of those results, 59% were for the Zika MAC-ELISA (6.7% positive, 1.6% inconclusive, 91.7% negative), 41% were Trioplex results. Of the Trioplex results, 7.1% of the test results were positive for one of the viruses in the panel. Of these Trioplex positives 92.7% were positive for Zika virus, 6.4% for dengue virus, and 0.9% for chikungunya virus. LRN laboratories had the option of reporting test data from these two assays throughout the emergency response through several mechanisms. The LRN laboratories were able to report results to the LRN Program Office utilizing an LRN module within their laboratory information management systems (LIMS), electronic laboratory reporting (ELR) using HL7 messaging or the use of Results Messenger, a LRN dedicated reporting system.

The data reported to the LRN Program Office during the 2016 Zika response informed CDC and EOC leadership and allowed the LRN program to monitor reagent usage and testing demand. Public health laboratories worked closely with CDC to implement complex testing algorithms to support patient care. Because little was known regarding the epidemiology and pathology of the Zika virus, testing algorithms evolved as more data were gathered. Despite the evolving information, LRN laboratories proved to be adaptable and were able to provide reliable diagnostic testing for thousands of suspect patients.

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