2018 APHL Annual Meeting
Pasadena, CA
June 2-5, 2018

Poster Abstracts

P-01

ABSA International Outreach -- What Can We Do For You?

M. Downing, ABSA International, Mundelein, IL

The 2015 Ebola outbreak highlighted the need for robust biorisk management programs in the public health sector and the importance of cooperation between various specialties and organizations. ABSA (The American Biological Safety Association) International and APHL continue to cooperate and communicate on biosafety and biosecurity topics. One critical area is attracting, training and maintaining qualified biosafety officers (BSOs).The poster concentrates on the relevance of a biorisk management program to public health laboratories, potential biosafety career paths, and how to become a recognized expert in the biorisk management field. Many public health BSOs are nervous about job security relative to the Ebola Readiness grants; they need to know that trained BSOs are rare, credentials are available and there are many learning and job opportunities available to them. ABSA International provides programs to assist Biosafety Officers in their job and career, including educational opportunities, professional credentialing, laboratory accreditation, a public health list-serve open to all, mentoring, a job placement board, the infectious agent risk group database, educational/networking opportunities through ABSA regional affiliates, and outreach and cooperative opportunities, among others. Brochures and information of all of these topics will be included in the poster presentation and a knowledgeable ABSA International representative will be available for questions.

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P-02

Electronic Test Order and Result

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With a surge in Zika testing in 2016, and typical laboratory workflows resulting in over 60 steps to test a single specimen, the need became clear for a new approach. APHL has been funded by ONC to enhance existing Electronic Test Order and Result capabilities and functionalities across laboratories with the advent of a Lab Web Portal. Designed to streamline testing and accommodate high-volume requests in testing with emerging infectious disease threats, the portal allows epidemiologists to prioritize testing within laboratories, grant approval, and communicate with the submitter as needed. This poster will

feature some of the unique capabilities of the Lab Web Portal, and will demonstrate how its use can improve laboratory testing processes.

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P-03

Development of a Human Pathogen Specific Next Generation Sequencing Assay

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Purpose: Hepatitis C virus (HCV) infection is the most common chronic blood-borne infection in the United States, and injection drug use is becoming the leading factor for HCV acquisition. Overall, at least 3.5 million people are currently infected with HCV, and approximately 75% people infected with HCV are unaware of their infection. 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. Without immediate intervention, this nation-wide opioid epidemic/substance abuse, and related HCV prevalence in rural communities like most of Alaska, will become unmanageable.
Setting: The Alaska State Public Health Virology Laboratory (ASVL) is the only public health laboratory in Alaska that tests HCV infection, which currently tests ~6,000 serum specimens per year for HCV infection from all regions in Alaska. These specimens are tested using FDA-approved serological assay (i.e. Ortho HCV Version 3.0 ELISA Test System) and are further confirmed as HCV RNA positive using GenMark HCV Genotyping Assay. In addition, we are developing a specific HCV assay using next generation sequencing (NGS) technology.
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. In addition, we developed a method called "Preferential Amplification of Pathogenic Sequences (PATHseq)", which can be used to greatly enrich pathogenic sequences in NGS libraries.
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 add NGS to test those HCV antibody positive specimens. 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. Since 2016, ASVL has been validating NGS in the testing of HCV and began to participate in CDC/APHL Pilot GHOST project. We also aim to develop a HCV specific NGS assay using our proprietary method.

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P-04

Effects of the BioRad BioPlex 2200 Human Immunodeficiency Virus Ag-Ab Assay Results on Current HIV Testing Algorithms

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As laboratories move to adopt fully automated analyzers for common serological screenings, many are turning to BioRad's BioPlex 2200 instrument. The BioPlex 2200 is described as a multiplex flow immunoassay intended to simultaneously detect and differentiate various combinations of biological targets. The BioPlex 2200 HIV Ag-Ab assay, unlike other 4th generation HIV assays, is capable of differentiating positive HIV-1 antibodies (Groups M & O) from HIV-2 antibodies and/or HIV-1 p24 antigen in a single test using this newer technology. The Alaska State Virology Laboratory (ASVL) in Fairbanks, AK adopted the BioPlex 2200 early 2017 and can report on the BioPlex 2200 performance in terms of false positivity and its effects on the current HIV testing algorithm recommended by the Centers for Disease Control and Prevention (CDC). Out of the 2,904 sera screened for HIV, twelve specimens were positive on the BioPlex 2200. Only five of the specimens were able to be confirmed on the Geenius and were considered truly positive. All negative Geenius results were referred to the Wadsworth Center in New York for HIV RNA testing. All RNA tests were negative suggesting initial false positivity on the BioPlex 2200 HIV Ag-Ab assay. ASVL reports that all true positive results had index values (IDX) of >150 whereas false positive results were $\leq$ 4. We suggest a particular threshold of < 4 IDX on the BioPlex 2200 HIV Ag-Ab assay to determine if Geenius confirmation can be waived in order to proceed to RNA testing sooner, further reducing the cost of HIV confirmation.

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P-05

Resources for Sentinel Clinical Lab Partnerships

S. Abrams, Association of Public Health Laboratories, Silver Spring, MD

The Association of Public Health Laboratories (APHL) provides key resources to public health laboratories (PHLs) through the Sentinel Laboratory Partnerships and Outreach Subcommittee (SLPOS) to assist members in their ability to effectively communicate with and provide guidance to sentinel clinical laboratories. In fiscal year 2018, along with input from the American Society for Microbiology (ASM) and the Centers for Disease Control and Prevention (CDC), SLPOS members developed and updated resources that focus on the critical linkage between public and private laboratories. New activities this year encompassed updating the Sentinel Level Clinical Laboratory Definition, which articulates the role of sentinel laboratories in the Laboratory Response Network (LRN) and outlines the responsibilities of LRN Reference PHLs in support of sentinel clinical laboratories; review of and updated design to the Biothreat Agent Bench Cards for Sentinel Clinical Laboratories and the affiliated Bioterrorism Agents Poster, which are a detailed yet easy to use resource to assist laboratorians with quick identification of certain Tier 1 Select Agents; publication of scientific data illustrating the safety and accuracy of MALDI-TOF technology; and participation in newly formed Clinical Laboratory Partners Workgroup, which is led by the CDC/Division of Laboratory Systems and provides an opportunity for CDC and professional laboratory organizations to collaborate to address the needs of clinical and public

health laboratories and to facilitate improved communication between the public health and private sector. The resources developed by the members of SLPOS are integral in aiding communication between PHLs and their local sentinel clinical laboratories. They are vital in support of the mission in assisting with quick and accurate detection of public health threats.

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P-06

Funding Laboratory Preparedness and Response

S. Abrams, Association of Public Health Laboratories, Silver Spring, MD

The capabilities needed for a laboratory to prepare for and respond to incidents relies on its ability to operate properly. Funding remains a persistent concern among many member laboratories. This year marks the 15 year history of the PHEP funding cooperative agreement, which provides funding to many of our member laboratories across the country. It serves a critical need to help ensure that laboratories are funded for emergency preparedness initiatives. This abstract details preparedness and response funding, highlighting the history of the Public Health Emergency Preparedness (PHEP) funding and how it is critical in ensuring our nations laboratories operate effectively when faced with the next public health threat. It describes how funding sources support PHEP capabilities for Emergency Operations Coordination and Public Health Laboratory Testing, detailing recent public health events that relied on PHEP resources. The Association of Public Health Laboratories (APHL) Public Health Preparedness and Response program utilizes PHEP funding to accomplish goals outlined by these capabilities. This presentation will exhibit the need for an emergency response fund and how this approach benefits member laboratories when urgent funding circumstances occur. It will also show the 15 year history of PHEP funding, accomplishments and ongoing challenges such as evolving funding formulas. Specifics will be provided for how differing state public health laboratories utilize PHEP funding, such as the unique funding challenge approach of the Washington, DC laboratory. In addition, it will describe how the Texas laboratory utilizes PHEP resources to support a network of 10 Laboratory Response Network member laboratories.

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P-07 - Withdrawn

P-08

Evaluating Progress Achieved through a Two-Year Quality Assurance Laboratory Mentor Program

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Objective: From May 2015 to June 2017, the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC) in collaboration with the World Health Organization Regional Office for Europe (WHO Euro) and the Southeast European Center for Surveillance and Control of Infectious Diseases (SECID) conducted an influenza laboratory quality assurance mentorship program. The primary goal was to help laboratories systematically implement a quality monitoring system and enable laboratories to achieve WHO National Influenza Center (NIC) recognition. Initially supported for 1 year, the program was extended to a second to help move remaining action items to completion and increase the number of laboratories ready for NIC assessments. This poster provides updated data from the end of Year 2 (Y2).
Study Design: Four mentors from US public health laboratories were paired with 6 laboratories from 5 countries. Mentors and countries worked in partnership to address quality management weaknesses, NIC requirements, and recommendations from previous laboratory assessments. In Y2, required communications were decreased from once per month to once per quarter. Mentors shared templates and example documents, reviewed draft documents and provided general advice and reminders. Results of progress achieved were compiled at the end of Year 1 (Y1) and previously reported. Each laboratory created a Y2 action plan with priority items to complete by the program conclusion.
Results: During Y1, mentees identified 159 action items compared to 121 identified for Y2.. At the conclusion of Y2, the laboratories marked a total of 85.8% of action items as being in-progress or completed compared with an 83.0% completion rate for these same groups in Y1. Montenegro achieved NIC recognition in 2017 and two additional laboratories are on track for NIC assessments in 2018. The poster will evaluate the entire two year program and compare Y1 and Y2 progress.
Conclusion: Similar to the first year of the program, we saw progression of many of the planned activities. The accountability offered by regular interaction and the interpersonal relationships built in the first year of the program were key to progress achieved in the second year. The southeastern European mentor program served as a proof of concept for regional mentor programs and led to the CDC and APHL initiating a second iteration of the program in Africa in summer 2017.

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P-09

The 2017 APHL Membership Survey: Results Are In!

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Introduction: Every 2 -3 years, APHL administers a member satisfaction survey seeking responses and feedback from all APHL members. In 2017, the membership survey was administered between the dates of January 25, 2017 and February 23, 2017.

Methods: Survey was sent to all APHL members. The Membership Department provided the content for the questions and added new types of questions namely on assessing the real value of APHL membership and member engagement both now and in the future. Survey questions covered members' satisfaction levels with a variety of APHL products and services. Survey was administered by APHL's Institutional Research Program.
Results: Response rate for the survey was 31% (265). Of the 265 who responded, the highest numbers of respondents were in the state institutional member category (51.3%). Satisfaction with APHL membership was very high, with > 99% of respondents saying they were satisfied with their benefits. Likewise, the satisfaction rating for interactions with APHL staff was 97.3% (excellent or good rating). Publications, email blasts, My APHL and continuing education top the list of APHL products and services of which respondents were very satisfied or satisfied. With regards to APHL's intangible resources, the top three were communication/marketing of the value of public health laboratories (88.4%), professional collaboration with colleagues (87.3%) and legislative advocacy (83.7%). On the valuation of APHL and its role, most people strongly agreed or agreed with being proud to be a member of APHL, recognition that APHL strengthens public health laboratory effectiveness, APHL being the liaison with federal partners and the provision of valuable collaboration/networking opportunities. The qualitative analysis of open-ended questions yielded results that mirrored what was seen in the quantitative responses.
Conclusion: Although most responses were positive, the results of this survey have shown that additional promotional activities are required for those opportunities with lower levels of familiarity to the membership. In addition, the results also identified other areas of improvement that the Membership Department will address in the near future.

Acknowledgements: Deborah Kim, MPH, former director, APHL Institutional Research Program, Sara Woldehanna, MA, MS, manager, Program Evaluation, APHL Institutional Research Program and Jacob Rosalez, manager, APHL Institutional Research Program for their contributions to the development, delivery and evaluation of the survey and its results.

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P-10

APHL Biosafety Officer Leadership Workshop

M. Marsico, Association of Public Health Laboratories, Silver Spring, MD

In 2017 and 2018, the Public Health Preparedness and Response Program at APHL convened the Biosafety Leadership Workshop to facilitate the professional development of biosafety officers (officials) (BSOs) in state, local, territorial US Affiliated Pacific Island public health laboratories. In order to tackle the challenges of biosafety at its source, three APHL member laboratories graciously agreed to host these regional workshops: Hawaii State Laboratories Division, Arizona Department of Health Services and Florida Bureau of Public Health Laboratories, Tampa Branch. These four-day workshops convened BSOs by region and provided a forum that encouraged personal and professional growth with the overall goal to strengthen leadership skills. Participants gained an invaluable network and a broader skill set that directly benefits the individual, their laboratory, and ultimately, the greater public health laboratory system. Due to an ever changing and increasingly complex environment, public health laboratories need biosafety leaders who embrace change, manage people and processes efficiently and anticipate future

needs. Through skill development sessions on leadership, project management, public policy, communications including messaging and storytelling, building effective training programs and implementing evaluation measures, the workshop shaped BSOs into future leaders within the laboratory system. PACE credits and a certificate for completion of the program were given to the participants of the workshops. Overall, 37 attendees from 34 public health laboratories across the United States and US Affiliated Pacific Islands participated in these three workshops. The Biosafety Leadership Workshops have received positive reviews from attendees who plan to incorporate this training in their everyday roles as a BSO. APHL recognizes the evolutionary nature of these workshops and will continue to provide quality Biosafety and Biosecurity training opportunities to all its members.

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P-11

Biosafety Peer Network: Connecting the Dots in Biosafety

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Recent lapses in institutional biosafety and the 2014 Ebola outbreak have demonstrated the necessity to fill gaps and deficiencies that remain in the nation's biosafety apparatus. In 2016, the Association of Public Health Laboratories (APHL) established the Biosafety Peer Network. The free program partners state, local and territorial public health laboratories (PHLs) with each other that are funded via the Centers for Disease Control and Prevention (CDC) Domestic Ebola Supplement to the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement – Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments (CK14-1401PPHFSUPP15). The PHLs partnered were based on their current strengths in specified areas of biosafety and biosecurity. In the programs first and second year since being created, applications were accepted from 24 PHLs that were eventually twinned. Based on the twinning model, the PHL alternately visit the other's institution. The visiting lab spends approximately three days at the host PHL working closely with them on an agenda tailored to the needs of the visiting institution. Biosafety and biosecurity plans, occupational health programs, regulated waste management and sentinel clinical outreach are a few of the topics that are examined. Within three months, the roles are reversed, and the initial host travels to the other's facility. The Biosafety Peer Network facilitates mentoring and information sharing among biosafety professionals in PHLs. Analyzing the trip reports from the 24 twinned laboratories, we have seen PHLs improve the implementation of their respective biosafety and biosecurity programs. PHLs have initiated changes in their biosecurity plans, donning and doffing procedures, waste management protocols and sentinel laboratory outreach program to name a few. Finally, this program pools limited resources to strengthen biosafety and biosecurity nationwide to foster an environment of collaboration and community of practice among the relevant stakeholders as well as to develop a baseline level of competency in biosafety and biosecurity for all programs across all PHLs. The biosafety and biosecurity programs at these PHLs are more harmonized 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. APHL plans to continue this program in 2018 for another round, pairing additional PHLs across the United States.

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P-12

Analysis from the APHL 2016 and 2017 Biosafety and Biosecurity Surveys

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Recent events such as the Ebola Virus Disease have called attention to the climate of biosafety and biosecurity in public health laboratories (PHLs) around the US. During this response, significant gaps were identified in US laboratory biosafety practices. In 2015, the US Centers for Disease Control and Prevention (CDC) awarded APHL a $2.2 million Domestic Laboratory Biosafety for Ebola and other Highly Infectious Diseases Cooperative Agreement. Over the course of three years (2015 – 2018), APHL has strengthened biosafety across US laboratories by coordinating with CDC, state, local and territorial health departments and other partners to review biosafety practices, address identified gaps, develop and promote tools to help laboratorians improve biosafety practices, and assist PHLs with outreach to clinical labs. With the support of CDC funding, APHL conducted the 2016 and 2017 Biosafety and Biosecurity Surveys to the 62 state, local, territorial and US Affiliated Pacific Island (USAPI) PHLs that received $21 million in March 2015 via the CDC Domestic Ebola Supplement to the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement – Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments to identify current biosafety and biosecurity practices and gaps. These 62 PHLs include all 50 states, the District of Columbia, the five largest US metropolitan areas, and US territories and US Affiliated Pacific Islands (USAPI). The three year funding of $21 million aims to strengthen biosafety and biosecurity programs at PHLs and to assist these labs with outreach to clinical labs. Questions from both surveys were solicited in the areas of funding, workforce, biosafety competencies, risk assessments, biosafety/biosecurity drills or exercises, clinical lab outreach training and related resource needs. Additional questions in the 2017 Biosafety and Biosecurity Survey included funding questions related to maintaining biosafety programs after the three year funding period is concluded along with the effectiveness of the APHL developed resources. Key findings from both surveys included PHLs are utilizing the CDC funding to strengthen internal biosafety and biosecurity programs. Successes include implementing risk assessments, reaching out to sentinel clinical labs and delivering training courses to thousands of clinical laboratorians. The survey data shows that PHLs still face challenges such as inconsistent funding, a diminished workforce pool, limited guidance documents and limited buy-in from clinical labs. APHL via its Public Health Preparedness and Response staff and Biosafety and Biosecurity Committee (BBC) plans to utilize these survey findings to address the identified gaps and continue to provide support to PHL directors and biosafety professionals.

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P-13

Emerging Leaders Program (ELP) Theory of Change (2017-2018)
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Objective: Present the current Emerging Leader Program (ELP) Theory of Change (TOC) model that shows how the program envisions change in the public health system through leadership development and to highlight how the model is used for program improvement.
Design: A Theory of Change (TOC) is a model that explains how long-term change (outcome) is brought about in a program. The ELP TOC was created as part of the development of an evaluation plan to assess the ELP. Critical stakeholders including APHL staff and ELP alums were consulted to create the initial TOC. In addition, Most Significant Stories of Change (MSC) was used to collect stories from current ELP participants to further understand the change process; analysis of stories by project staff was used to further refine the Theory of Change.
Result: The ELP TOC envisions a PHL system with a community of leaders capable of meeting and addressing other system challenges. Starting with the potential of interested laboratorians, the program envisions changes at the individual, organizational and systems levels in a number of areas. At the individual levels, a number of interrelated and reinforcing changes are expected including: - Increased self-awareness and empathy for others; - Increased skills in communication, managerial abilities, team development, critical thinking, problem solving, decision making and team work; -- More confidence; Increased investment engagement and commitment, to public health; and, - Demonstrated leadership behavior. The program also supports the development of a network of PHL leaders that can facilitate problem solving between individuals as well as between organizations. This community of PHL leaders will also be equipped to advocate on behalf of the PHL system to ensure that PHLs have a place at the decision making table which will assure a systems approach to problem solving within the public health system. In addition to showcasing the relationships of the outcomes that the ELP program is trying to influence, the TOC is also used to guide evaluations by answering questions such as: - How does leadership development happen? - Is the program effective in its objectives?
Conclusion: The ELP TOC model is a living document that will continue to change as the ELP engages in ongoing discussions with key stakeholders. ELP program 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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P-14

Increased Use of 'Council to Improve Foodborne Outbreak Response' Products through Branding and Messaging
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The Council to Improve Foodborne Outbreak Response (CIFOR) was founded in 2006. The Council is a multidisciplinary collaboration of national associations and federal agencies working together to improve methods for detecting, investigating, controlling, and preventing foodborne disease outbreaks.

APHL is a founding member of CIFOR and our representatives have contributed to CIFOR guidelines, processes, and products that facilitate improved foodborne outbreak response. CIFOR is one of the only entities with representation across the entire spectrum of organizations, jurisdictions, geographies, and professions that focuses on foodborne outbreak response. With other member organizations, we collectively represent epidemiology programs, environmental health programs, public health laboratories, and regulatory agencies at the local, state and federal levels. The food industry is represented on the Industry Workgroup. All of these audiences are considered when creating CIFOR promotional materials. Although CIFOR guidelines, processes and products are widely available, the member organizations recognize a need to increase the use of these tools nationwide. The Promote Development Team, one of 4 core development teams within CIFOR, is tasked with promoting the use of CIFOR products and promoting CIFOR as a credible source of information for use by decision-makers. In 2017, The Promote Development Team created a CIFOR Marketing Plan to ensure consistency in our branding and messaging, coordinate marketing communications, be proactive in building awareness of the overall CIFOR mission/vision and innovatively market CIFOR. Activities include, building a new CIFOR website, designing branded templates for CIFOR documents and presentations, providing suggested web content for member organizations, disseminating end-user testimonials on the impact of CIFOR, distributing canned social media, blog, newsletter and email content on CIFOR and its products, presenting about CIFOR at annual meetings and conferences, and launching a CIFOR app. Examples of these activities are highlighted in this poster.

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P-15

Evolution of APHL's Informatics Technical Assistance Program

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An increasing number of public health agencies and organizations are attempting to build networks to share data that are pertinent to public health decision making across federal and state systems, and between public and private partners. However, the challenges of implementing such a data exchange in terms of planning an approach, reaching consensus among stakeholders, coordinating activities, tracking and resolving issues and working against an agreed-upon project schedule often inhibit the successful implementation of data exchange projects. APHL has offered informatics virtual and in-person technical assistance for the past ten years to help public health meet these needs. This poster will examine the evolution of technical assistance over the years and how APHL has helped public health laboratories and agencies understand, navigate and implement electronic data exchange that uses simple, effective standards based methods.

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P-16

Using APHL Tools to Inform Informatics Strategy

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As public health laboratories are required to meet increasing informatics requirements, they face crucial decisions about their overall informatics strategy. Decisions regarding LIMS upgrades or replacements, system interoperability, and defining functional requirements are often times difficult and require laboratories to have a comprehensive understanding and assessment of their current informatics capabilities. To help in these efforts, the Informatics Self-Assessment tool was designed to help laboratories assess strengths and gaps in their informatics capacity by addressing 19 critical lab operational areas. A laboratory can also measure the ability of its laboratory information management system (LIMS) or other software to meet basic requirements against APHL's "Requirements for a Public Health Laboratory Information Management System." This poster will examine the practical informatics tools APHL offers to its members to help them make informed decisions on their informatics activities and projects.

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P-17

Improving Technologies for Biological Threat Detection

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

The Laboratory Response Network for Biological Threats Preparedness (LRN-B) was formed in 1999 through a collaborative effort between the Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories (APHL). Originally comprising 17 laboratories, the LRN-B has since expanded membership to over 130 Federal, state and local governmental laboratories, international laboratories and sentinel clinical laboratories. Public health laboratories comprise 70% of the LRN reference level membership. A cornerstone of the LRN-B is its ability to rapidly and accurately detect biological threat agents. To that end, The LRN-B is continuously seeking the newest, most efficient and reliable technology for its testing needs. The network utilizes member laboratories to evaluate new technologies, ensuring buy-in from all parties and facilitates gathering input from labs with different regional peculiarities and needs. It also ensures repeatability of results when systems and test kits are distributed and used on a broad scale. In addition, CDC provides standard operating procedures, reagents and training to implement and maintain assays developed on these technologies. The LRN-B currently utilizes multiple technologies for the detection of biological threat agents, including polymerase chain reaction (PCR), time-resolved fluorescence (TRF) and a variety of automated extraction platforms. More recently, the LRN is exploring matrix-assisted laser desorption ionization – time of flight (MALDI-TOF) mass spectrometry with the goal of improving time to detection. As the technology progresses, APHL and CDC have collaborated with LRN-B member laboratories on multi-center validation studies, training courses and developing guidance for these detection technologies. This poster will discuss the technology collaborations to improve biological threat detection capacity and capabilities in LRN member laboratories.

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P-18

The Public Health Laboratory Systems Database (PHLSD): Moving Towards a Nationwide Public Health Laboratory Test and Equipment Directory

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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 use. Poster content will demonstrate how PHLs can benefit from using the PHLSD as a repository for their own data and as a searchable directory that allows for querying testing services across those PHLs that have submitted their data.

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. PHLs who complete test data entry will be able to obtain reports showing what tests are performed in other PHLs who have also completed their test data.

Results: APHL held eight 1-hour webinars attended by 135 laboratorians from member PHLs in Fall 2017. Thus far, 17 state PHLs and 4 local PHLs have completed the PHLSD. Stories will be provided from PHLs on how they have used the reporting tools in their database for CLIA inspections and other benefits to submitting their testing data.

Conclusion: The PHLSD is creating a comprehensive national PHL test directory that offers a strategic approach for preparing for regulatory inspections, organizing, reporting and sharing information. 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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P-19

What We Know About State Public Health Laboratories Funding and Spending

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Background: In this time of diminishing budgets, public health laboratories (PHLs) need to be able to determine the status of their funding sources and plan to launch new revenue sources to respond to future changes. APHL has been collecting financial data from public health laboratories over several years and intends to provide insights on revenue and expenditure patterns that they may use for decision making and advocacy purposes.

Methods: Financial data from APHL's State Public Health Laboratories (SPHLs) Profiles Survey data was compiled for analysis. While most analyses were limited to data from the 2015 survey, data from 2010 was used for the analysis of changes over time. Due to low response rates during these years, local and agricultural and environmental laboratories were excluded. Descriptive and multivariate analyses were performed to answer the following questions: • What are the main sources of funding for SPHLs? What variations are observed? • How do SPHLs allocate their spending? • What trends over time are

observed in both funding and spending allocations? To ensure that the analysis addresses the needs of key stakeholders and includes appropriate interpretations, APHL member committees and key APHL staff were asked to provide feedback.
Results: A total of 37 SPHLs in 2010 and 29 SPHLs in 2015 participated in the survey. Most funding for SPHLs came from states dollars, followed by fee-for-service revenue and federal dollars. SPHLs spend most of their budget on personnel and the least amount on capital, with the rest spent on consumables and other spending categories. Variations in the proportions of funding by type of revenue sources, as well as spending patterns on different categories, were noted across regions, over time and by the size of state populations.
Conclusions: From the findings presented here, members will understand key SPHL funding trends, learn how SPHLs typically assign any scarce resources and be able to identify variations in both funding and spending allocations amongst other laboratories.

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P-20

The Contributions of Public Health Laboratories: How Systematic Reviews of Literature Focusing on Return on Investment (ROI) Can Help Justify the Value of your Laboratory Programs

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Background: In this time of diminishing budgets, laboratories need to show their value in order to obtain needed resources. Public health laboratories (PHLs) often have difficulty quantifying the value of the work done in public health laboratories. APHL is developing a return on investment (ROI) tool tailored to five public health laboratory (PHL) testing programs: tuberculosis (TB), influenza, PulseNet, newborn screening and Safe Drinking Water Act testing. Since the key component of the ROI model is published cost-benefit analysis, it is necessary to conduct transparent and comprehensive systematic reviews to identify and summarize the published economic literature on each selected PHL testing area. This poster summarizes the findings from a systemic review of the literature on the cost-benefit of TB programs.
Major Findings: There were a total of 8 articles that met the reviews eligibility criteria out of 650 identified through literature searches. The articles evaluated testing programs that varied in scope, geography, perspective, population characteristics as well as specific types of TB diagnostic tests used. We will report on the cost per test ($/test) for each of the evaluated laboratory tests, as well as benefits that were identified in a range of units, including societal costs averted ($) or hospital savings ($), and number of TB cases prevented or number of fewer days of TB treatment.
Conclusions: In this presentation, members will learn about the development of the return on investment (ROI) tool and the systematic reviews currently being conducted to provide the evidence base for the tool. Members will also find illustrative examples of the systematic review findings from TB testing programs. These findings will be used in the ROI tool but can also be used independently by PHLs, not only to have internal conversations on the cost of tests but to also advocate on the value of the public health testing program.

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P-21

Twelve Years of Strengthening Environmental Laboratories – What is the Impact?

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Starting in 2006, the US Environmental Protection Agency (US EPA) funded the Association of Public Health Laboratories (APHL) through two cooperative agreements to provide technical assistance and support that helps environmental laboratories to build capability and capacity to better respond to emergencies. During the first four-year cooperative agreement, funds were used for a variety of activities, including annual environmental laboratory conferences, laboratory standardization and method development workgroups, various trainings, and communications to connect environmental laboratories. The second cooperative agreement was awarded in 2011 and concluded November 30, 2017. During this time, APHL continued to play a leadership role by serving as an environmental laboratory sector liaison, organizing conferences, task forces and work group meetings, disseminating and sharing information and providing technical assistance through training opportunities. This poster will explore the quantitative and qualitative measures of this nearly twelve year partnership between US EPA and APHL, as well as its ultimate effect on strengthening environmental laboratories.

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P-22

Using Whole Genome Sequencing Data for Salmonella Serotype Prediction

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Texas Department of State Health Services (DSHS) Laboratory Service Section typically receives 3000-3500 Salmonella isolates each year. Currently, the laboratory performs serotyping on all Salmonella isolates received using molecular or conventional serotyping techniques, which are time consuming and costly. Since 2015, DSHS has been performing Whole Genome Sequencing (WGS) on foodborne bacteria, and thus generating an enormous amount of sequencing data waiting to be fully utilized. The free SeqSero software allows identification of Salmonella serotypes from raw sequencing reads. To determine the utility of using SeqSero to predict Salmonella serotype, we are performing a retrospective study comparing SeqSero analysis with our standard serotyping methods. SeqSero will be used to infer the serotypes from a pool of 2,300 Salmonella isolates sequenced in the lab between 2015 and 2017. The isolates we selected for this study are from PFGE clusters/potential outbreaks. These isolates were collected from routine Salmonella surveillance activities of food/food manufacture swabs. We predict a high concordance between SeqSero prediction and our standard methods. The raw sequence reads will be analyzed using the FDA/CFSAN GalaxyTrakr software. GalaxyTrakr utilizes the open-source Galaxy platform as a packaging tool, GUI, and integrates SeqSero and other analysis tools to host a runtime environment for bioinformatics projects. The analysis is performed on the GalaxtTrakr.org website. This project is on-going. Our preliminary results indicated a good concordance between SeqSero and our standard methods. We will expand our study to include up to 800 isolates and will present a final report with complete information at the APHL Annual Conference. For the isolates which produce

discrepancies between SeqSero and standard methods, we will examine the results to understand the limitations of SeqSero based serotype determination. The DSHS laboratory hopes to replace our current serotyping methods and implement routine sequencing of Salmonella isolates with WGS. This study will confirm the practicality of using SeqSero in serotype prediction and help establish criteria for when Seqsero should not be utilized for prediction. Using SeqSero for serotyping will shorten the total test time, reduce labor and cost, and make outbreak investigation more efficient.

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P-23

Whole Genome MLST-based Typing and Strain Nomenclature for Clostridium difficile Isolates

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Background: Clostridium difficile is a bacterium that causes symptoms ranging from diarrhea to life-threatening inflammation of the colon, most commonly affecting older or immunocompromised adults in hospitals or long-term care facilities. In recent years, C. difficile infections have become more frequent, severe and difficult to treat. Rapid typing and characterization methods are essential epidemiological tools to prevent and control infection. Although bacterial WGS has become feasible in smaller clinical laboratories, non-standardized data analysis remains a bottleneck for routine surveillance. In this work, we assessed wgMLST and wgSNP for C. difficile typing.
Materials/methods: We created a core (n=1999 loci) and pangenomic (n=6713 loci) schema based on 259 reference sequences reflecting the known diversity of C. difficile. Also capturing the accessory loci greatly increased the discriminatory power of the schema. Adding MLST, CWP, and loci associated with antibiotic resistance and virulence maximized consistency with classical typing methods. Assembly-free and BLAST-based algorithms determined locus presence and detected allelic variants. wgSNP further characterized defined clusters by mapping the reads to a reference chosen from within the cluster and filtering the variants. High-throughput data processing pipelines in BioNumerics® implemented both methods on publicly available data.
Results: We ran wgMLST on +1,500 samples to identify closely related clusters. We detected a wide diversity of samples and defined clusters at various allele difference cutoffs, allowing the creation of a stable strain nomenclature on the sample set. The defined thresholds determined 36 clusters for which additional resolution was obtained by running the wgSNP analysis, identifying linked clinical cases and linking additional metadata (e.g. date of isolation, geo information) to the results.
Conclusions: WGS combined with automated analysis pipelines holds great promise for bacterial epidemiological surveillance. The pangenomic schema for C. difficile includes over 8000 loci and allows for the detection of subtype- or outbreak-specific markers. BioNumerics® and integrated wgMLST and wgSNP functionality allows for accessible cluster analysis and typing of C. difficile isolates down to strain level.

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P-24

Gas Chromatography/Tandem Mass Spectrometry Analysis of Volatile Organic Compounds

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Our public health is greatly affected by our environment. Depending on where we live and work, we could be exposed to a variety of environmental contaminants; from the air we breathe, to the water we drink, to the soil on which we build our houses. At The Environmental Chemistry Laboratory in Pasadena, our mission statement includes striving to be leaders in analytical and environmental chemistry to protect California's people and environment from toxic harm. One class of compounds that we are interested in from a public health aspect is volatile organic compounds (VOCs). VOCs are a group of compounds with low boiling points (below 200?C), low to medium water solubility, and low molecular weights. They are anthropogenic (man-made) contaminants found in different matrices such as soil, waste water, and indoor air. Due to their prevalence and toxic nature, the Public Health Goal (PGH) in drinking water for various VOCs are in the very low µg/L and pg/L range, which emphasizes the need to enable detection of these compounds at very low levels. We have developed a GC/triple quadrupole mass spectrometric (GC/MS-QQQ) analysis for VOC quantitation using a dynamic multiple reaction monitoring method (dMRM). Samples are introduced using a purge and trap system. Our dMRM method allows for detection down to 0.5 µg/L with great selectivity and high sensitivity for desired compounds. Additionally, we can analyze 62 compounds in a single run, allowing for reduced analysis time.

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Gas Chromatography/Tandem Mass Spectrometry Analysis of Pesticides

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Our public health is greatly affected by our environment. Depending on where we live and work, we could be exposed to a variety of environmental contaminants; from the air we breathe, to the water we drink, to the soil on which we build our houses. At The Environmental Chemistry Laboratory in Pasadena, our mission statement includes striving to be leaders in analytical and environmental chemistry to protect California's people and environment from toxic harm. One class of compounds that we are interested in from a public health aspect is pesticides. Organophosphorus and organochlorine pesticides are neurotoxic and are the active ingredients in many insecticides used in agricultural, residential, and commercial landscape settings. After their use, pesticides can remain in the soil. Parathion, an organophosphorus compound, has a low oral LD50 of 3 – 8 mg/kg, which emphasizes the need to enable detection of these compounds at very low mg/kg or µg/kg levels. Traditional analysis relies on separation and detection of pesticides using gas chromatography coupled to a flame photometric detector (GC/FPD) or electron capture detector (GC/ECD). These techniques detect the signals from either the phosphorus or chlorine atoms and rely on a second column confirmation, resulting in a longer analysis time and a higher detection limit (>50 µg/kg). We have developed a GC/triple quadrupole mass spectrometric (GC/MS-QQQ) analysis for multiple compounds of interest that uses a dynamic multiple reaction monitoring (dMRM) method to enable specific mass detection of each compound, thus eliminating the second column confirmation. In addition, the dMRM method

allows for detection down to 1 - 2.5 μg/kg by minimizing interference from other compounds. The quantitation is based on specific mass and fragmentation pattern of each analyte of interest and is a very powerful method to analyze soil contaminants.

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P-26

Gas Chromatography/Tandem Mass Spectrometry Analysis of Polychlorinated Biphenyl Aroclors

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Our public health is greatly affected by our environment. Depending on where we live and work, we could be exposed to a variety of environmental contaminants; from the air we breathe, to the water we drink, to the soil on which we build our houses. At The Environmental Chemistry Laboratory in Pasadena, our mission statement includes striving to be leaders in analytical and environmental chemistry to protect California's people and environment from toxic harm. One class of compounds that we are interested in from a public health aspect is polychlorinated biphenyl (PCB) Aroclors. PCBs are multicomponent mixtures of different polychlorinated biphenyl congeners. Aroclors were used as coolant fluids in many electrical devices. Due to their stability, they are considered persistent organic pollutants and are probable human carcinogens, which emphasizes the need to enable detection of these compounds at very low mg/kg or μg/kg levels. There 209 congeners differ in the degree of chlorination of the parent compound. Traditional analysis relies on pattern recognition to identify the Aroclor mixture(s) in the sample using gas chromatography coupled to an electron capture detector (GC/ECD). This technique utilizes the distribution of chlorination of the Aroclors as a fingerprint to identify specific Aroclor mixtures. We have developed a GC/triple quadrupole mass spectrometric (GC/MS-QQQ) analysis for Aroclor determination that allows us to selectively choose specific congeners based on the mass transitions present for a given retention time. This allows for more accurate quantitation by minimizing the influence of coeluting analyte peaks and matrix interferences. We have used this technique to quantitate Aroclor mixtures in complicated matrices including metal shredder waste.

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P-27

Evaluating Associations between PFAS Detected in Drinking Water and Human Serum in Northern California

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Per- and polyfluoroalkyl substances (PFASs) are a large class of anthropogenic and persistent chemicals, some of which bioaccumulate and are associated with testicular and kidney cancer, high cholesterol, ulcerative colitis, thyroid disease, and preeclampsia. Public concern regarding the ubiquity and potential toxicity of legacy and next-generation PFASs in drinking water has led to increased regulatory pressure

requiring more sensitive and selective analytical methods. Our previous study suggests drinking water could be a significant exposure route for PFASs in the general population (1). To evaluate any association between drinking water and serum PFAS concentrations, here we apply newly developed analytical methods to quantify PFAS in human serum and tap water collected from San Francisco Bay and Sacramento locations in Northern California. Using 0.25 mL of serum and 250 mL of water sample, the analyses were performed by using liquid chromatography (Nexera UFLC system, Shimadzu) coupled to a triple-quadrupole tandem mass spectrometer (SCIEX QTRAP 5500 MS/MS system). In both matrices, we were able to confidently measure 29 PFASs, including 10 out of the 12 analytes listed in EPA method 537: eight perfluoroalkyl carboxylic acids (PFCAs), six telomer acids (TAs), four perfluoroalkyl sulfonates (PFASs), four polyfluorinated phosphate esters (PAPs), three perfluororoctanesulfonamides (FOSAs), two telomer sulfonates (TSs), one perfluoroalkylphosphinate (PFPi), and one perfluoroalkyl phosphonic acid (PFAPA). Our drinking water method has detection limits sufficiently sensitive to comply with the 2016 USEPA Health Advisory Guideline for PFAS in water. Our preliminary data showed PFAS concentrations ranging between <MDL - 45.3 ng/L, with perfluoroalkylcarboxylic acids (e.g. PFOA) and perfluoroalkylsulfonates (e.g. PFOS) being ubiquitous in drinking water. Perfluoroalkyl phosphonic acids, polyfluorinated phosphate esters, and long-chain perfluoroalkyl carboxylic acids were also detected. Further investigation on the relationships between drinking water and resident serum for those PFASs detected is under way.

Disclaimer: The views expressed herein are those of the authors and do not necessarily reflect those of the Department of Toxic Substances Control [1] Environ. Sci. Technol. Lett., 2016, 3 (7), pp 264–269

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P-28

Comparison of Automated Extraction Methods Using the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panels

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Background: The CDC Human Influenza Real-Time RT-PCR Diagnostic Panel is used in real-time RT-PCR (rRT-PCR) assays on the Applied Biosystems® (ABI) 7500 Fast Dx Real-Time PCR system. The panel is configured in four separate kits. Each kit consists of oligonucleotide primers, fluorescently labeled hydrolysis probes, and controls that are used in rRT-PCR assays for the in vitro qualitative detection and characterization of influenza virus RNA in respiratory specimens from patients presenting with influenza-like illness (ILI) or from virus culture. Six RNA extraction methods have been approved for use with the CDC rRT-PCR Flu Panel: the automated Roche MagNA Pure LC Total Nucleic Acid Isolation kit, Roche MagNA Pure Compact RNA Isolation kit I, Qiagen® QIAamp Viral RNA manual extraction, Qiagen® RNeasy RNA manual extraction, Qiagen® QIAcube platform using Qiagen® QIAamp Viral RNA kit, and the BioMerieux NucliSENS easyMAG. In order to understand the performance of additional high and low throughput automated extraction methods used in domestic Public Health Laboratories (PHLs), we evaluated two additional automated extraction methods. The Qiagen EZ1 Advanced XL extraction platform using the EZ1 DSP Virus Kit and EZ1 RNA Tissue Mini Kit, and the Roche MagNA Pure 96 using the DNA and Viral NA Small Volume Kit.

Method: A study was performed to assess the reproducibility of the Roche MagNA Pure 96 and Qiagen EZ1 Advanced XL instruments. The Roche MagNA Pure 96 was evaluated with the Roche DNA and Viral NA Small Volume Kit. The Qiagen EZ1 Advanced XL was evaluated with the Qiagen DSP Virus Kit and the Qiagen RNA Tissue Mini Kit. A blinded panel of contrived samples containing a background of beta-propiolactone (BPL) treated A549 cells in Viral Transport Medium (VTM) was assembled by adding a BPL inactivated influenza A(H3N2) virus, A/Hong Kong/4801/2014. The samples included a moderate positive sample, a low positive sample near the established assay limit of detection for the CDC Influenza A Subtyping Kit, and a negative sample consisting of background A549 cells and VTM. Three separate testing sites were selected for each extraction instrument platform. The sample panel was tested 5 times by two different analysts at each site over five different days. Analysts performed extractions with the investigational instrument and method and tested the extracted nucleic acids with the InfA, H3, and RP assay markers from the CDC Influenza A Subtyping Kit using Invitrogen SuperScript™ and utilizing the ABI 7500 Fast Dx real-time PCR system. Samples were analyzed using the ABI SDS software version 1.4 with 21CFR part 11 compliant module. Results were compared side-by-side and with data generated using approved methods.
Results: The Qiagen EZ1 Advanced XL and Roche MagNA Pure 96 platforms with their respective reagent kits and paired protocols demonstrated 100% reproducibility (30/30 correct results per extraction platform) across multiple sites, analysts, and days. Both new platforms and methods performed comparably to methods previously qualified to be used with the CDC rRT-PCR Flu Panel assay.
Conclusions: Test results indicated that both the Qiagen EZ1 Advanced XL and Roche MagNA Pure 96 performed well under the conditions of this study. Qualification of additional RNA extraction procedures expands the options for domestic PHLs to use equipment already in place to perform testing for influenza. The data generated in this study supported FDA clearance of these two automated extraction platforms for influenza diagnostic testing using the CDC rRT-PCR Flu Panel.

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P-29

Epidemiology and Laboratory Capacity for Infectious Diseases Cooperative Agreement (ELC)'s Enhanced Biosafety Project: Progress toward Biosafety Milestones and Outcomes

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Objective: In March of 2015, CDC awarded $24.1 million to 63 state and territorial health departments to support public health laboratories (PHLs) and their clinical partners in improving laboratory biosafety practices for dealing with Ebola virus disease and other emerging infectious diseases. A set of eight indicators was used to evaluate the effectiveness of the project at making progress towards important biosafety milestones and outcomes.
Methods: Data collection on the eight quantitative indicators is ongoing, starting in March, 2015, and continuing through March, 2018. A descriptive analysis of indicators is conducted after each data submission. Additionally, ELC staff conducted calls with each PHL to discuss progress made on the indicators and work plan activities.
Results: PHLs reported progress in putting risk assessment (RA) policies in place (+19%). They met targets for improving staff certifications in packaging and shipping and staff competency for working in Biosafety Level 3 laboratories. Clinical laboratory partners made progress on all indicators, with more

improvement made on increasing staff certifications in packaging and shipping (+27%) compared to conducting RAs (+20%) and having policies in place to perform RAs (+26%).
Conclusions: PHLs have made progress on improving staff competency in biosafety practices and strengthened their ability to address biosafety issues. Gaps still exist in improving biosafety practices among clinical laboratory partners. Outreach to clinical laboratory partners was most successful when PHLs directly contacted partners via calls or site visits. PHLs cited staffing turnover and shortages as major challenges to sustaining improvements.

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P-30

Incorporation of Non-Influenza Respiratory Virus Detections from the Public Health Laboratory Interoperability Project into the National Respiratory and Enteric Virus Surveillance System

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National surveillance of non-influenza respiratory viruses (NIRVs) is essential to identify temporal and geographical trends for these pathogens in the US along with detecting re-emerging and novel viruses. Two national-level laboratory-based surveillance systems currently collect information on NIRVs. The CDC's National Respiratory and Enteric Virus Surveillance System (NREVSS) monitors the circulation of respiratory viruses including adenoviruses, coronaviruses, enteroviruses, metapneumovirus, parainfluenza viruses, respiratory syncytial virus, and rhinoviruses through voluntary reporting of antigen, culture, and PCR diagnostic test data primarily from university, hospital, and commercial laboratories. NREVSS collects weekly aggregate counts of tests, typically via manual entry, which does not allow for more detailed analyses of respiratory virus activity due to a lack of specimen-level epidemiologic data. The Public Health Laboratory Interoperability Project (PHLIP) and Public Health Lab Information System replacement (PHLIS2) are two mechanisms by which state and local health laboratories (PHLs), plus several other non-commercial laboratories, can report to CDC for the purposes of conducting influenza surveillance. It also routinely receives specimen-level NIRV testing results. Specimen-level test results along with descriptive patient information are reported automatically to CDC, and these data allow for detection of co-infections and more refined epidemiologic characterization than is possible with NREVSS. In an effort to streamline CDC's data sources, reduce PHLs' reporting burden, and enhance epidemiologic capacity, the Division of Viral Diseases (DVD) and Influenza Division (ID) are collaborating to increase reporting of specimen-level NIRV data via PHLIP or PHLIS2 and to incorporate these data into NREVSS. First, to determine if PHLIP data were appropriate for inclusion in NREVSS, data from four PHLs that reported to both systems were assessed for comparability. Next, an 11 additional PHLs reporting to PHLIP or PHLIS2 with robust NIRV test results not currently reporting to NREVSS were asked to share their data with DVD and to provide a secondary source of data to validate the messages. To date, DVD has validated data from these 15 labs and all are now reporting their specimen-level data to NREVSS exclusively through PHLIP or PHLIS2. Several more labs are currently undergoing validation checks and/or upgrading their messaging systems to include NIRV test results in their PHLIP or PHLIS2 transmissions to CDC. Collaborations that make reporting methods more efficient strengthens the relationship between CDC and participating laboratories, in particular state and local public health departments; helps maintain a robust surveillance system; and ultimately contributes to a better understanding of viral respiratory disease trends in the US.

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P-31

Flipping it Inside Out! Making Biosafety Training Available to Clinical and Public Health Laboratories

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In 2016, the Clinical Laboratory Improvement Advisory Committee declared "the matter of biosafety in clinical laboratories as an urgent unmet national need," and called upon US government to substantially increase the amount of guidance, training, and outreach on biosafety to the clinical laboratory community. Subsequently, the CDC Division for Laboratory Systems (DLS) and the Office of the Associate Director for Laboratory Science and Safety collaboratively made extensive progress to improve laboratory safety practices and procedures across the agency by expanding laboratory safety training as part of the safety initiatives outlined to address safety concerns for the agency. From 2016 – 2017, 20 new laboratory safety courses were released to the agency. However, their need and impact extends beyond CDC. The US Ebola response identified several critical gaps in laboratory safety. Access to free high-quality safety training applicable to the clinical and public health communities is often lacking. In 2017, DLS took the first step towards addressing this need by creating a process for "flipping" the newly developed safety training courses designed for use inside the agency into publicly available courses tailored to meet the needs of the clinical and public health laboratory communities outside of the agency. In coordination with biosafety representatives from the Association of Public Health Laboratories, the American Society for Microbiology, the American Biological Safety Association International, and the American Society for Clinical Laboratory Science, the first adapted course entitled, "Fundamentals of Working Safely in a Biological Safety Cabinet (BSC)" was released in June 2017. This basic-level eLearning course provides information on the safe use of BSCs through videos, interactive exercises, and job aids to enhance the learning experience. Utilizing a "superhero" themed communication campaign, the course was promoted through social media, outreach systems and other traditional methods. Within 6 months, 1728 learners successfully completed the course, obtained PACE credits, and gave the course an average rating of 4.62 out of 5 stars. During the 36 day BSC course communication campaign period the page views for the course went from 0 page views to a high of 51 page views per day, reaching 446 page views total for the period. As a result of the BSC course's success, DLS has lined up 2 additional courses to flip and release in 2018 with another 5 more in the queue. Our long term goal is to develop a competency-based safety training curriculum with easily accessible and innovative courses to strengthen preparedness of clinical and public health laboratories.

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Development of a Targeted Resequencing Approach to Identify and Characterize Pathogens in Respiratory Specimens from Unexplained Respiratory Disease Outbreak Responses

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Rapid identification of etiology is critical during respiratory outbreaks when early 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 public health laboratories during respiratory disease outbreak investigations. Since 2009, routine implementation of the TaqMan Array Card (TAC), a microfluidic real-time PCR array for multi-pathogen detection, has improved time to results and increased the proportion of outbreaks in which a probable etiology is identified to over 50%. Still, an etiology remains elusive in many outbreak investigations, and immediate results are limited to pathogen detection. Further testing is required in order to identify features that may direct vaccination recommendations, prescribing practices, or source attribution. To expand upon existing laboratory testing capacity, CDC, along with Minnesota and Massachusetts state public health laboratories (PHL), have developed a targeted resequencing approach that enables simultaneous pathogen detection and characterization, such as antibiotic and antiviral resistance determinants or strain types. Custom oligonucleotides are used to generate sequence-ready amplicon libraries for next-generation sequencing (MiSeq) analysis. Each state has contributed to the panel of assays through oligonucleotide design, performance assessment, and cross-evaluation of assays designed by the other sites. Together we have developed 41 total assays for identification (24), strain typing (14), or antimicrobial resistance determination (3). For all assays, the lower limit of detection was equivalent or superior to the corresponding real-time PCR assay performed on TAC. Following comprehensive performance evaluation in 96-well plate format, assays were evaluated for performance on a nanofluidic chip system (Wafergen SmartChip, Takara Bio Inc.). Testing of a panel of 6 mock specimens in 96-well plate at CDC, MA PHL, and MN PHL, as well as on the Smartchip at the manufacturer's facility yielded similar results. All pathogens spiked into each sample were detected by each site in both formats; in each case the expected amplicon comprised =90% of recovered cleaned sequence reads. Multiple data analysis strategies, including both whole read and kmer based methods, were compared to maximize accuracy of read identification, minimize computing time, and capture naturally-occurring variants. Engagement of state laboratories has helped to increase genomic and informatics capacity at highly functional PHLs that may serve as regional centers for future URDO investigations. Comprehensive regional laboratory testing may improve determination of etiology by reducing the time from sample collection to testing.

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Laboratory Confirmation of Enterotoxigenic Escherichia coli Detected by Culture-Independent Diagnostic Tests — Minnesota, 2015–2017

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Enterotoxigenic Escherichia coli (ETEC) is a common cause of travelers' diarrhea and can cause foodborne disease outbreaks. Historically, clinical laboratories have not tested for ETEC because diagnostic methods were not available. Increasingly, diagnostic testing is shifting from culture-based methods to culture-independent diagnostic tests (CIDTs), which can detect ETEC. However, molecular and culture confirmation is imperative for public health surveillance and identification of ETEC outbreaks; ETEC is a reportable pathogen in Minnesota, requiring clinical laboratories to submit isolates or clinical samples. To improve ETEC laboratory surveillance, we confirmed ETEC in CIDT-positive samples and measured the association between ETEC confirmation and duration of sample transport. During 2015–2017, Minnesota Public Health Laboratory (MN-PHL) received 263 fecal samples positive for ETEC by the CIDT, FilmArray® GI Panel (Biofire Diagnostics), 7 days after collection. Among the 97 samples selected for ETEC isolation, 62 (64%) were positive. ETEC PCR and culture confirmation rates were low for ETEC-positive CIDT samples, and were dependent on the number of days in transport after sample collection. Low rates of ETEC-positive CIDT samples confirmed by PCR and culture suggests the likelihood of false positive results by CIDTs. This study highlights the importance of receiving fecal samples soon after detection and the need for public health laboratories to confirm the presence of ETEC in CIDT-positive samples to conduct surveillance and outbreak investigations.

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Collaborative Recovery Efforts to Restore Public Health Laboratory Testing Following Landfall of a Category 4 Hurricane in the Tropics — Puerto Rico, 2017

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Background: On September 20, 2017, Hurricane Maria severely damaged the Puerto Rico Department of Health (PRDH) building infrastructure, resulting in immediate and long-term impacts to public health laboratory capacity. Working with PRDH, the CDC Restoration of Services Team began interagency recovery and restoration efforts at affected facilities, in conjunction with FEMA, USACE, EPA, and FDA. Testing for seven laboratories (Rabies, Influenza, Tuberculosis, Bacteriology, Sexually Transmitted Diseases (STDs), Milk, and Water) was affected across four locations.

Methods: Working with PRDH laboratory subject matter experts (SMEs), the CDC Team inventoried and procured essential supplies for the laboratories. The CDC Team also assisted PRDH staff with implementing quality management system (QMS) modules to increase accuracy, reliability, and timeliness for specimen shipping and tracking. The QMS provided support toward long-term recovery and complemented PRDH's emergency preparedness and readiness plans.

Results: More than 117 essential laboratory consumables and instruments needed to restore testing were identified. By January 5, 2018, CDC Foundation had ordered 97% and PRDH had received 54% of these items. Three standard operating procedures were created for specimen shipping, specimen

tracking, and the receipt and installation of new equipment, including calibration and servicing of instruments. The impact on CLIA testing was mitigated in consultation with the Centers for Medicare and Medicaid Services (CMS), who issued a temporary waiver for proficiency testing. By December 2017, testing had resumed for the Rabies and STDs laboratories.
Conclusions: Diagnostic capabilities at local public health laboratories are at risk during natural disasters. Public health laboratories can be secured using the immediate and long-term strategies developed by the CDC Team. Public health laboratory mitigation strategies were developed that can be adapted to various emergencies or disaster responses.

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Respiratory Virus Seasonality in the US, 2007-2017: An Overview from the National Respiratory and Enteric Virus Surveillance System

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Background: Lower respiratory illness remains a leading cause of morbidity and mortality in the US among young children, the immunocompromised and older adults. Many respiratory illnesses are associated with viruses reported to the National Respiratory and Enteric Virus Surveillance System (NREVSS). Since 1984, NREVSS has collected aggregate results routinely performed at public health, private and reference laboratories across the US to depict the national and regional activity among the primary etiologic agents of respiratory illness other than influenza. NREVSS includes results from antigen, virus isolation and molecular assays reported weekly from July 1 to June 30 of the following year. Understanding seasonality of respiratory viruses helps inform decisions related to the timing and selection of treatment, prevention, and prophylactic interventions. We reviewed and summarized these data to provide insight into the regional and annual patterns of respiratory virus circulation and trends in utilization of respiratory viral diagnostics.
Methods: We assessed the volume and frequency of reporting, types of reporters, and weekly test results for the following pathogens during 2007-2017: respiratory syncytial virus (RSV), parainfluenza viruses (PIVs 1-4), RV/EV (rhinovirus/enterovirus), human metapneumovirus (HMPV) and human coronaviruses (CoVs 229E, NL63, HKU1, OC43).
Results: During July 2007 - June 2017, approximately 20 million respiratory tests results were reported from 1222 laboratories; approximately 32%, 22% and 47% were antigen, virus isolation and molecular diagnostic assays, respectively. A median of 73% of laboratories reported at least 26 of 52 weeks over the 10 surveillance years analyzed. Participating laboratories in all 50 states, the District of Columbia and Puerto Rico reported in select years, with a median of 51 states or territories reporting each surveillance year. Of the 1222 laboratories reporting during this period, 86% were clinical hospitals, 5% military hospitals/clinics, 4% pediatric hospitals/clinics, 3% local or state public health laboratories, and 1% reference facilities. RV/EV, RSV, PIV 1-4, and HCOVs circulate in discernable annual patterns as assessed by both antigen and molecular assay results. The primary fall/winter viruses are CoVOC43, CoVNL63, RSV, and PIV1, 2 and 4, whereas PIV3 and HMPV predominate in the spring/summer months. RV/EV has a high peak in fall/winter and a less prominent peak in spring/summer. CoV229E, CoVHKU1, PIV1 and PIV2 appear to peak biennially during fall/winter.

Conclusions: NREVSS is an important surveillance system that provides information on national and regional respiratory virus activity. Year-round surveillance of respiratory viruses using various diagnostic methods allows timely identification of virus activity, baseline circulation patterns, and trends in testing practices.

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Evaluating the Flocked Swab as a Tool to Sample and Recover Healthcare Pathogens from Nitrile Gloves

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Flocked swabs are commonly used in healthcare for collecting clinical specimens for diagnosis and surveillance purposes. Manufacturers claim their charged fibers hold and release organisms efficiently, with some claiming superior performance for environmental sampling as well. In working toward developing a standardized, efficient hand and glove sampling and recovery method, we compared the use of a representative nylon flocked swab (eSwab™, Copan Diagnostics, Inc.) to a cellulose sponge, the Sponge Stick (3M™), as potential glove sampling devices. Nitrile gloves were inoculated with a carbapenem-resistant Klebsiella pneumoniae (KPC), methicillin-resistant Staphylococcus aureus (MRSA), and Clostridium difficile spores (CD) suspended in Artificial Test Soil (Healthmark Industries, Inc.) to simulate body fluids. Inocula (50µl of 104 CFU/mL or 103 CFU/mL for vegetative cells and 105 CFU/mL or 104 CFU/mL for the CD spores) were spread along each of the four fingers and across the top of the palm and allowed to dry for 10 minutes, then sampled with one flocked swab, two flocked swabs, or a Sponge-Stick (SS). Sampling devices were processed, eluents cultured, then enumerated, and the percent recovery determined. We saw no significant difference between using one or two swabs to sample a single glove ($p > 0.05$). The SS performed significantly better than flocked swabs when recovering CD (SS 48.4%, eSwab 18.3%; $p=0.05$) and KPC using a 104 inoculum (SS 4.5%, eSwab 1.6%; $p=0.05$). However, there was no significant difference between flocked swabs and SS when recovering MRSA and KPC using a 103 inoculum with the mean recoveries ranging between 8.1% and 13.6%.These results suggest that flocked swabs could be a useful and easy to use tool in sampling some organisms from gloved hands in the field as compared to other common sampling devices. Additional work is needed to evaluate multiple organic loads, glove types, and additional organisms before a standardized method is developed. These data inform researchers, epidemiologists and infection control personnel as to options for sampling gloved hands in a healthcare setting.

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Lab-Aid: A New Endeavor for CDC to Provide Field Laboratory Assistance to Public Health Laboratories

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Background: CDC's Laboratory Leadership Service (LLS) fellowship program prepares early-career laboratory scientists to become future public health laboratory leaders. Fellows acquire and apply skills in laboratory quality management, biosafety science, and leadership through on-the-job service at CDC and other public health laboratories. Lab-Aid provides a new mechanism for a public health authority to request short-term laboratory assistance from CDC. Lab-Aids focus on addressing partners' laboratory needs and can include urgent public health responses and other laboratory capacity building requests.
Processes: A Lab-Aid must be requested by the authority of a public health laboratory, which describes the public health problem to CDC. A team consisting of CDC subject matter experts (SMEs), at least one LLS fellow, and a field supervisor will be identified and form the Lab-Aid team to work with the requesting agency. Before a Lab-Aid is approved, objectives need to be clearly defined and roles and responsibilities of the Lab-Aid team specified among stakeholders. An LLS fellow is deployed to the field under the supervision of at least one SME and works with the team to provide technical support and training and make recommendations based on Lab-Aid objectives. After Lab-Aid completion, the laboratory can request CDC's continued collaboration and assistance. Lab-Aid
Experiences: Lab-Aids have been implemented in both emergency response and under capacity building requests. LLS fellows were deployed to assist the Puerto Rico Department of Health with specimens transport and evaluate and restore essential laboratory services after Hurricane Maria. An LLS fellow was requested to help a state laboratory develop a comprehensive laboratory response plan for Legionella outbreaks based on a safety risk assessment and evaluation of the state's existing water management plans, after which targeted trainings will be delivered to address gaps and a readiness exercise based on the response plan will be conducted. Experience and lessons learned from Lab-Aids will be shared.
Discussion: Input from APHL and state and local laboratory partners will be helpful to ensure the quality of services provided by LLS fellows, improve efficiency of requesting Lab-Aids, and facilitate successful implementation of Lab-Aids as a new endeavor for CDC to provide field laboratory assistance. In addition, the benefits and challenges associated with LLS fellows participating in Lab-Aids to achieve the field training essential for future public health laboratory leaders and strengthen relationships among CDC SMEs and state and local partners will be explored.

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Improving the Collection and Management of Human Samples Used for Measuring Environmental Chemicals and Nutrition Indicators

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Biomonitoring is widely recognized as an important tool for assessing people's nutrition status and exposure to natural or man-made chemicals in the environment. By measuring substances or their

biomarkers in human specimens, such as urine, blood, or serum, public health officials and scientists may be able to identify nutrition deficiencies and unusual or potentially harmful exposures that cause disease or increase disease risk. When conducting biomonitoring studies, use of specific and sensitive analytical methods is critical to ensure accurate exposure or nutrition assessment. For accurate performance of the methods, biological specimens must be collected and managed in a manner that preserves their quality and minimizes external contamination. The Centers for Disease Control and Prevention (CDC) developed *Improving the Collection and Management of Human Samples Used for Measuring Environmental Chemicals and Nutrition Indicators* to describe important factors for obtaining and using high-quality samples in studies that assess environmental exposures and nutrition status. This newly available resource is intended for use by epidemiologists, laboratorians, and other health scientists in state or local public health programs that are involved in the design and implementation of human biomonitoring studies. General and test-specific considerations are included in this document for key components of sample handling including required materials, sample collection and processing, storage, and transport. These factors highlight the importance of seeking laboratory input at the earliest stage of study design. CDC and the Association of Public Health Laboratories (APHL) continually work to establish, expand, and improve biomonitoring science by providing technical resources to programs conducting or planning biomonitoring work. Recognizing these important considerations can minimize external pre-analytical contamination risks, ensure analyte integrity, and promote accurate exposure and nutrition assessments. This document also supports APHL's National Biomonitoring Network goal to ensure the quality and consistency of national biomonitoring measurements.

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At Your Fingertips: Laboratory Workforce Development and Training Resources of CDC's Division of Laboratory Systems

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CDC's Division of Laboratory Systems (DLS) provides leadership and support to enhance the clinical and public health laboratory workforce through initiatives that strengthen recruitment, retention, management, and training. Several resources and activities are helping individual scientists, organizations, and laboratory communities prepare to meet the needs of the 21st century laboratory workforce. Training courses and programs, which are available in person and virtually, help scientists learn evolving practices, combat emerging threats, and improve their safety and quality of practice. The training offered is innovative and convenient, featuring state-of-the-art video and graphics production in a variety of formats. Over 30 free courses across a variety of topics are offered each year. Participants regularly rate courses positively and the majority report implementing new or improved laboratory procedures as a result of training. All training courses can be accessed at www.cdc.gov/labtraining. The 2015 Competency Guidelines for Public Health Laboratory Professionals were published through a collaboration between DLS and APHL (www.cdc.gov/labcompetencies); and these are intended to form the foundation for training and workforce development initiatives. The Competency Guidelines help improve the workforce in a variety of ways, including providing a guiding framework for: producing education, training, and fellowship programs; identifying worker roles and job responsibilities; assessing individual performance and organizational capacity; and guiding staff professional development. A robust suite of tools and resources – the Competency Implementation

Toolbox-- is now available to help laboratories implement behavior-based competencies into laboratory and human resource practices. DLS has also recently embarked on a Workforce Assessment of Laboratory Communities (WALC), an effort to identify critical training and workforce development needs and gaps within the national clinical and public health laboratory communities. This effort will better position DLS along with its public health laboratory and clinical laboratory partners to develop, implement, and coordinate effective training programs and workforce development initiatives that address challenges in the workforce. A wealth of training and workforce development resources are currently accessible to the public or are in development to help support a competent, prepared, and sustainable national and global laboratory workforce.

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Expanding Public Health Laboratory Capacity to Combat the Threat of Antibiotic-Resistant Neisseria gonorrhoeae: Antibiotic Resistance Laboratory Network, 2016 – 2017

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Background: Antimicrobial susceptibility testing (AST) is not routinely performed for patient diagnosis and management of uncomplicated gonorrhea. Nonetheless, AST is critical for public health actions including preparedness, surveillance, and control of antibiotic-resistant Neisseria gonorrhoeae (AR-Ng). The threat of AR-Ng, categorized as “urgent” by the Centers for Disease Control and Prevention (CDC), has further highlighted the need to increase AST activity. In 2016, CDC established the Antibiotic Resistance Laboratory Network (AR Lab Network) to support national lab capacity to detect and prevent the spread of AR threats. One of the goals of the AR Lab Network is to build and maintain capacity for N. gonorrhoeae AST at the state public health labs.
Methods: In an effort to increase AR-Ng detection capacity, 4 of the 7 regional labs in the AR Lab Network are funded to perform AST on up to 20,000 N. gonorrhoeae isolates per year. Gonococcal isolates are obtained from patients presenting at 32 clinics that participate in CDC’s Gonococcal Isolate Surveillance Project (GISP), enhanced GISP, and the new AR gonorrhea response program, Strengthening the U.S. Response to Resistant Gonorrhea. These 4 labs perform agar dilution AST for ceftriaxone (CRO), cefixime (CFX), azithromycin (AZM), tetracycline, penicillin, gentamicin, and ciprofloxacin to determine the minimum inhibitory concentrations (MICs). Isolates with MICs ≥ 0.125, ≥ 0.25, or ≥ 2 mg/ml to CRO, CFM, and AZM, respectively are considered “alert” isolates and are subjected to further examination and archival storage at CDC. These labs also have capacity for whole genome sequencing (WGS) on up to 5,000 N. gonorrhoeae isolates per year for analysis of AR markers.
Results: Washington State, Maryland, Tennessee, and Texas public health labs successfully competed to perform AR-Ng testing. The Laboratory Reference and Research Branch at CDC provided laboratory support, AST training, and proficiency testing panels to expedite capacity building. AR-Ng activities were initiated at all 4 labs by the end of 2017. From January-November 2017, AST was performed on 6,671 N. gonorrhoeae isolates, and 290 identified alert isolates were sent to CDC. A majority of the identified alert isolates displayed elevated MIC for AZM. These 4 labs also performed WGS on 337 N. gonorrhoeae isolates.

Conclusions: The remarkable ability of N. gonorrhoeae to develop antibiotic resistance, in conjunction with the waning antibiotic arsenal against this pathogen, have necessitated public health action to increase AST laboratory capacity. In 2017, the CDC successfully implemented a robust program at 4 regional labs, within the AR Lab Network, to monitor AR-Ng. The AR Lab Network is a national effort to both maintain traditional culture-based AST and expand genomic monitoring of AR markers in N. gonorrhoeae.

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Developing a Framework for a Quality Management Systems Training Curriculum for CDC Research Laboratories

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Background: The Centers for Disease Control and Prevention (CDC) aims to enhance the agency's culture of quality, safety and excellence in science by implementing Laboratory Quality Management Systems (LQMS). CDC laboratories engage in investigational research activities ranging from infectious and non-communicable diseases to environmental and occupational health. This diversity presents a challenge in instituting standardized LQMS training, as it can be hard to translate quality standards to actions relevant to the activities of laboratory staff. Our objective was to translate the view of LQMS from big picture guidelines to real, applicable bench-side practices, empowering laboratories to align their research activities with external accreditation or certification standards.
Methods: The Laboratory Leadership Service Class of 2016 (LLS 2016) collaborated with the CDC Office of the Associate Director for Laboratory Science and Safety (OADLSS) to develop a framework for a training curriculum tailored to research laboratories. We developed the training around the concept that producing Sustainable, Trustworthy, Accurate and Reproducible (STAR) data is the foundation of all CDC laboratory research. LLS 2016 identified key domains that were common amongst all research laboratories in which quality management practices are essential for producing STAR data. Specific, plain language components for each domain were developed and measureable outcomes for each component were identified. Components were mapped to International Organization for Standardization (ISO) 9001:2015 QMS requirements, CDC/APHL QMS competency guidelines, and Clinical and Laboratory Standards Institute Quality System Essentials (QSEs). To align training with staffing needs, we assigned personnel to functional roles based on their activities and responsibilities.
Results: LLS 2016 generated a quality domain matrix outlining six core laboratory domains: Materials & Resources, Processes & Procedures, Data, Personnel, Facilities, and Improvement. The matrix relates quality domains to ISO standards and QSEs. We developed a LQMS training matrix based on roles within the research laboratory linking quality domains and training delivery formats. We created case studies that relate the quality domains and STAR principles to everyday activities of research laboratory staff to contextualize LQMS concepts.
Conclusions: The training matrices provide a framework to guide future LQMS curricula development by OADLSS. This work addresses the critical need for standardized, agency-wide LQMS training for CDC

laboratory staff. We highlight the importance of developing programs and materials that are simple and understandable, framing quality as an integral part of conducting STAR research rather than as a separate activity.

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Surveillance Trends and Prevalence of Carbapenemase-Producing Enterobacteriaceae and other Carbapenemase-Producing Organisms in Washington State, 2012-2017

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Background: Carbapenemase-producing Enterobacteriaceae (CPE) and other carbapenemase-producing organisms (CPO) like Pseudomonas and Acinetobacter spp. are increasingly common causes of healthcare-associated infections. CPE and CPO isolates are often multidrug-resistant resulting in limited therapeutic options and poor clinical outcomes; moreover carbapenem-resistance (CR) can spread rapidly by horizontal gene transfer and clonal expansion amongst Gram-negative bacteria. Taken together, CPE/CPO pose significant public health concerns and systematic surveillance and prevalence studies are critical for tracking resistance and coordinating response. Objective. Washington State Public Health Laboratories (WAPHL) began carbapenamase testing and surveillance for CR Gram-negative organisms in Oct. 2012 to study prevalence and distribution of carbapenemase genes, support infection prevention, and capture population-based CPE/CPO infection incidence in WA State.
Methods: Bacterial isolates meeting the latest surveillance case definition of that time were solicited from clinical labs and tested using a phenotypic assay to detect carbapenemase production, if available (i.e. Modified Hodge Test or later the Modified Carbapenem Inactivation Method), and PCR to identify the five most common carbapenemase genes, KPC, NDM, OXA-48, VIM, and IMP. Additionally, case-patient investigations were completed on carbapenemase-positive cases to determine suspected carbapenemase source(s). It should be noted that surveillance case definitions and testing methods have evolved over time and the data presented here captures results from various practices used between 2012-2017.
Results: From Oct. 2012 - Dec. 2017, a total of 1,186 unique CR-isolates were tested at WAPHL. Enterobacter spp, were most common (38.8%), followed by Pseudomonas spp. (23.6%), E. coli (20.8%), Klebsiella spp. (11.1%), other Enterobacteriaceae (2.8%), and Acinetobacter spp (2.9%). Overall, 105 isolates (8.9%) were positive for a carbapenemase by PCR. Klebsiella spp. were most likely to be carbapenamase-positive. A carbapenemase was detected in 36.4% CR-Klebsiella spp., compared to 15.2% in Other CR-Enterobacteriaceae, 12.1% in CR-E. coli, 3.0% in CR-Enterobacter spp., 5.9% in CR-Acinetobacter spp, and 2.1% in CR-Pseudomonas spp. KPC was the most common carbapenemase detected (42.9%), followed by NDM (34.3%), OXA-48 (15.2%), VIM (2.9%), SME (2.9%), and IMP (1.9%). In WA, healthcare was the most likely source of KPC, while international healthcare or travel were probable sources of non KPC-carbapenamases.
Conclusions: CPE/CPO testing and surveillance are critical to determine prevalence and coordinate infection prevention of CR within an institution, state, or region. We report here that KPC, the most prevalent mechanism in the US, accounts for over a third of the carbapenemases in WA State.

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Quality Assurance of Qualitative DNA Detection Assays for Long-term Surveillance Studies of Human Papillomavirus

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In 2006, the US Food and Drug Administration approved the first human papillomavirus (HPV) vaccine. Since 2005, the Chronic Viral Diseases Branch (CVDB) has tested for HPV genotypes in over 80,000 specimens to measure the impact of vaccination in US surveillance studies. For reliable monitoring of trends, quality assurance of the assays is vital. CVDB uses multiple processes and controls to assure the performance of qualitative assays for detection of over 30 HPV genotypes. Fidelity of manually read line blot results are ensured by independent double reading and double database entry. Assays include probes for human ß-globin as an endogenous positive control, and the frequency of inadequate samples (HPV negative and ß-globin negative) is monitored. Reference samples are run in parallel on current and new lots of kits to bridge lot-to-lot performance. Water blanks are processed with specimens as negative controls for cross-contamination. Positive HPV controls indicate a successful assay run. Ten percent of samples are re-assayed to determine reproducibility, and when different types of assays are run on the same samples, assay concordance is determined. Laboratory personnel are trained and evaluated under a quality management system. Since 2007 participation in the WHO HPV LabNet Proficiency Studies has provided an independent assessment of assay performance. Assay results are reviewed quarterly in summary reports before data is submitted to partners. The quality assurance process has led to valuable insights and interventions. In a 2016 comparison between kit lots, the newer lot had weaker signal intensity and lower reproducibility than the current lot in use. Assay procedures were adjusted to maintain performance standards. Approximately 9 months later the vendor reported manufacturing issues. Non-conforming events with water negative controls contaminated with DNA have led to refinement of assay procedures, instrument maintenance and additional training of personnel. Quality assurance can also identify issues that originate outside the laboratory. In the first quarter of 2016, the number of inadequate results for one study tripled from the previous 3 year trend from 6% to 18%. The issue was traced to one clinical collection site. The staff were retrained and the inadequate rate returned to baseline. Quality assurance helps to ensure the reliability of HPV genotyping results to measure the impact of vaccination. Future directions include consolidating assay results of different studies into a single relational SQL database and automating summary report creation to track more nuanced data trends and for more frequent monitoring reports.

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Genomic Sequence Analysis of Common Legionella pneumophila Sequence Types Recovered from Healthcare Facilities

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Hospitals and long-term care facilities may contain large, complex water systems which can become colonized with Legionella leading to cases of healthcare-associated Legionnaires' disease (LD). Individuals in healthcare facilities often have underlying conditions making them more susceptible to LD. The case fatality rate for healthcare-associated LD is approximately 25%. During outbreak investigations of LD, isolates recovered from clinical specimens and environmental water samples can be analyzed with whole genome MLST (wgMLST) to characterize their genetic relatedness. Detection of highly related isolates can help support the confirmation of specific sources of LD infection and inform the development of water management programs. We analyzed the genetic relatedness of environmental isolates recovered from 2 facilities (located in Georgia and Illinois) where clinical isolates from individuals with confirmed or suspected healthcare exposures were also available. In the Georgia facility, L. pneumophila Sequence Types (ST) 1 and 36 were recovered, however, available clinical isolates belonged to ST1. wgMLST analysis revealed that environmental ST1 isolates recovered from samples taken nearly 6 months apart and clinical isolates recovered in previous years shared >99% identical alleles. Similarly, ST1 and ST36 isolates were recovered from the Illinois facility, however, clinical isolates belonged to ST36. Genomic analysis of the clinical isolates and ST36 environmental isolates recovered from samples collected over 3 consecutive years revealed that the isolates shared >99% identical alleles. These data support the notion that some common L. pneumophila sequence types can persist in healthcare facilities and highlight the need for genome sequence analysis of isolates obtained from large, complex water systems in an effort to find ways to reduce the risk of Legionella growth and transmission. The findings and conclusions in this presentation are those of the authors and do not necessary represent the official position of the Centers for Disease Control and Prevention.

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Review of Requests to Exclude Attenuated Strains of Select Agents and Modified Select Toxins from the HHS Select Agent Regulations

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Background: The Centers for Disease Control and Prevention, Division of Select Agents and Toxins (DSAT) regulates the possession, use, and transfer of select agents and toxins, which have the potential to pose a severe threat to public health and safety as part of the Federal Select Agent Program (FSAP). The U.S. Department of Health and Human Services (HHS) select agent regulations include criteria for

the exclusion of select agents and toxins from these regulations (42 CFR §§ 73.3, 73.4). An entity may request the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. DSAT reviews the exclusion request by conducting a risk assessment to determine whether the attenuated strain or modified toxin retains the potential to pose a severe risk to public health and safety. In this study, DSAT surveyed the number and types of requests reviewed and decisions rendered between calendar years (CY) 2003-2017 to exclude an attenuated strain or modified toxin.

Materials and Methods: DSAT conducted a census of data variables from a DSAT Microsoft Access database that contained the following information: number of exclusion requests received by DSAT between CY 2003-2017, whether an exclusion was granted or denied based upon established criteria, the type of facilities that submitted exclusion requests, and the specific select agent and toxin requested for exclusion.

Results: DSAT reviewed 79 requests to exclude a select agent or toxin between calendar years 2003-2017. Twenty-four percent (n = 19) of all exclusion requests were denied because the attenuated select agent or modified toxin still had the potential to pose a severe risk to public health and safety. Seventy-six percent (n =60) of the exclusion requests were approved because the attenuated strain or modified toxin no longer had the potential to pose a severe risk to public health and safety. Attenuated strains of Francisella tularensis (n = 7), Brucella abortus (n = 6), and Burkholderia pseudomallei (n = 18) were the most frequently requested select agents for exclusion. Botulinum neurotoxin (n = 7) was the most frequently requested select toxin for exclusion. The list of excluded select agents and toxins may be found at www.selectagents.gov.

Conclusion: DSAT routinely reviews requests to exclude attenuated select agents or modified toxins from the requirements of the select agent regulations to determine whether they retain the potential to pose a severe threat to public health and safety. The exclusion provisions in the select agent regulations encourages work with variants of select agents and toxins that pose less of a biosafety and security risk to public health.

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Enterprise-level Risk Assessment in the Public Health Laboratory: A Case Study from a Prospective Polio-Essential Facility

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Background: We present an interdisciplinary team-based approach for risk assessment in a public health laboratory setting. We describe, as a case study, an exercise conducted at the Polio and Picornavirus Laboratory Branch (PPLB) at the Centers for Disease Control and Prevention (CDC), in preparation for a request for certification as a Polio-Essential Facility. The objectives of this exercise were to (1) identify risks to staff safety, (2) identify risks to biosecurity, and (3) inform strategic risk management planning, to minimize poliovirus facility-associated risk after eradication of wild polioviruses.

Methods: We formed a task force composed of laboratory scientists, a quality specialist, a safety specialist, and leadership to review laboratory procedures and applied process analysis to classify them into a network of core activities. We developed a custom risk assessment tool to identify hazards to

biosafety, biosecurity, and quality, and reached a consensus about each hazard's relative likelihood and consequences by core activity.
Results: Our enterprise-level risk assessment identified no high-risk hazards, formally documenting the strengths of the existing PPLB biorisk management system. However, through this process we identified additional opportunities to further mitigate moderate- and low-risk hazards. This risk assessment informed the optimization of several PPLB workflows and facilitated the strategic engagement of partners in CDC occupational health, physical security, and facilities services.
Conclusions: Engaging scientists, safety specialists, and quality specialists simultaneously not only promoted comprehensive evaluation of hazards, but effectively coupled hazard identification with strategic planning for risk mitigation. Furthermore, leadership engagement facilitated the implementation of risk management plans, particularly those that required engagement of key players outside the laboratory. We propose that this model is broadly applicable for risk assessment in any public health laboratory.

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Facility Assessments Rapidly Identify Public Health Laboratory Needs following Hurricane Maria – Puerto Rico, 2017
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Background: Hurricane Maria interrupted public health laboratory services provided by Puerto Rico Department of Health (PRDH), including proficiency and diagnostic testing, surveillance, and analysis of water and milk. In response to a request for assistance from PRDH, CDC collaborated with APHL and USACE, FEMA, and HHS/ASPR to perform systematic assessments. The objectives were to assess short-term and long-term PRDH laboratory needs.
Methods: The PRDH system includes a central public health laboratory facility and the Biological and Chemical Emergencies Laboratory (BCEL) in San Juan and satellite facilities in Arecibo, Mayaguez, and Ponce. Beginning October 13, 2017, APHL scientists and the Restoration of Services Team, including laboratory scientists from CDC, FEMA liaison, CDC senior public health advisor, and USACE engineers, visited PRDH laboratories. Sites were systematically evaluated over the next six weeks to assess the hurricane's impact on facilities, environmental health, and operational capacity. Independent assessments from CDC and response partners were synthesized in the context of biosafety and laboratory quality management systems principles to strategically identify critical structural, resource, and operational needs.
Results: The assessments identified structural and resource challenges to restoring services. Short-term needs included critical structural repairs (e.g. roof damage ranging from 1%-30% surface area), repair of essential equipment damaged by loss of power, and replacement of essential reagents (69% and 92% of laboratories affected, respectively). Long-term needs included restoration of power, facility

reconstruction, mold remediation, and equipment re-qualification. Laboratory needs analysis based on the Quality System Essentials framework informed strategic recovery efforts.
Conclusions: These assessments demonstrate a collaboration between PRDH, CDC, and response and recovery partners including APHL, FEMA, USACE, and HHS/ASPR. Integrated analysis of the facility assessments facilitated the transition to the recovery phase and laid the groundwork towards restoring PRDH laboratory capacity.

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New Online Course to Help Laboratory Professionals and Healthcare Providers Improve Preanalytic Processes of Biochemical Genetic Testing

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Introduction: Biochemical genetic tests are associated with a wide range of preanalytic variables, including test selection and ordering, patient conditions, quality and timing of specimen collection, handling of test requests and specimens by referring laboratories, specimen transport, and communications with healthcare providers, patients, and collaborating laboratories. Studies have shown that the preanalytic phase might be the most error-prone during the total testing process in many laboratory disciplines including genetic testing.
Method: CDC published a guideline “Good Laboratory Practices for BiochemicalGenetic Testing and Newborn Screening for Inherited Metabolic Disorders” in 2012 (http://www.cdc.gov/mmwr/pdf/rr/rr6102.pdf). Since 2013, CDC has been collaborating with the Association of Public Health Laboratories (APHL) to help genetic and newborn screening laboratories in their quality improvement activities. Findings from two discussion groups held in 2013 identified a need for training to supplement the guideline (https://www.aphl.org/aboutAPHL/publications/Documents/CDCRecommendationsGoodLabPractices_OCT2014.pdf). To meet this need, a new online training course titled “Good Laboratory Practice Recommendations for Biochemical Genetic Testing: Preanalytic Phase” was developed under the APHL-CDC cooperative agreement to help laboratory professionals and healthcare providers improve preanalytic practices for biochemical genetic testing.
Results: This multimedia online course is now publicly available on CDC TRAIN website at https://www.train.org/cdctrain/course/1072447 as of December 2, 2017. The course consists of 3 lessons on quality assurance for test requisitions, specimen collection and submission; laboratory-clinician communications; and preanalytic quality assessment. Several case scenarios are included to illustrate how the recommended practices can be used to improve preanalytic quality and patient outcomes. After completing this course, participants will be able to recognize the role of each stakeholder group in the preanalytic processes, choose the procedures that are consistent with regulatory requirements and good laboratory practices, select indicators for preanalytic quality assessments, and explain the communication needs of each stakeholder group. Continuing education credits are available from this course free of charge, including 1.5 hours of the ASCLS P.A.C.E. credit and 1.5 contact hours for Florida Laboratory Licensees.

Conclusions: The quality improvement practices discussed in this course will be helpful not only for biochemical genetic testing but also for many other laboratory areas. Feedback from the participants will be closely monitored and course evaluation results will be presented at this meeting.

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An Analysis of Laboratory Response Network for Biological Threat Preparedness (LRN-B) Member Laboratory Test Data, 2009-2016

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Created in 1999, the objective of the Laboratory Response Network for Biological threat preparedness (LRN-B) is to ensure an effective response to bioterrorism by helping to improve the nation's public health laboratory infrastructure. A biothreat incident, which may be an intentional attack or an introduction of a novel, emerging infectious disease, could occur anywhere in the United States. Therefore, a comprehensive public health plan for response is critical. The success of associated response activities will depend on rapidly and accurately identifying the biothreat agent associated with the event. The use of electronic reporting systems to rapidly communicate laboratory results has been utilized throughout the existence of LRN-B. Here we describe a subset of biothreat test data from LRN-B member laboratories from 2009-2016.LRN-B member laboratories have the ability to test for multiple biothreat agents. The number of tests performed by LRN-B laboratories for biothreat agents has doubled in the past eight years, increasing from approximately 2700 tests in 2009 to almost 6000 tests in 2016. Over the past eight years, LRN-B member laboratories have tested and reported results from an average of 686 environmental samples per year including white powder-like substances such as those contained in letters that reference anthrax. Since 2009, LRN-B member laboratories have reported testing an average of 887 samples for B. anthracis per year. Since 2010, the average percent positivity of samples for B. anthracis has averaged 0.3% with only two samples reported positive from 2014-2015. The percent positivity of samples for biothreats such as Brucella species, F. tularensis, and Y. pestis have increased in the time period analyzed in this study. LRN-B member laboratories performed and reported more than 4600 tests for Brucella species from 2009-2016, with the number of tests performed increasing each year. Increases in testing volume may be related to increasing animal and human populations and the connection between the health of people, animals, and the environment. Since many recent risk assessments highlight the zoonotic origin of most emerging infectious diseases in humans, developing and maintaining testing capability and capacity for these organisms is critical to public health protection. LRN-B member laboratories have demonstrated superior capability and capacity in managing the increases in testing volume through the past eight years. However LRN-B must continue to be a high priority in order to provide continued, real-time monitoring for biothreat agents.

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Initial Public Health Laboratory Response in Puerto Rico after Hurricane Maria — Puerto Rico, 2017

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Background: Hurricane Maria caused significant damage to Puerto Rico Department of Health (PRDH) laboratory buildings and equipment, rendering them largely inoperable. Consequently, PRDH was unable to detect and diagnose many infectious diseases that may affect Puerto Rico's 3.5 million US citizens. In response to a request for assistance by PRDH, the CDC Infectious Disease and Medical Countermeasures Task Force Laboratory Team (Lab Team) sought to establish an alternative approach to laboratory testing to restore disease surveillance.
Methods: The Lab Team deployed to Puerto Rico to implement a system for shipping specimens to the continental US for surveillance, confirmatory, or diagnostic testing of five high priority infectious diseases (rabies, influenza, leptospirosis, salmonella, and tuberculosis). The Lab Team collaborated with CDC Foundation to coordinate specimen shipments, partnered with CDC, APHL, and state laboratories for testing, and created a secure mechanism to report results to PRDH.
Results: Within 27 days of Hurricane Maria, the Lab Team identified 16 CDC and state health laboratories to perform specimen testing and began shipping specimens. During October 17, 2017 - December 20, 2017, the Lab Team facilitated the transport of 1,306 specimens for testing. This novel, sustainable transport system allowed Puerto Rico to re-initiate disease surveillance and identified 138 cases of high priority infectious diseases. Testing results allowed PRDH to investigate cases, identify additional suspect cases, and target public health messaging for food and water safety, prevention of leptospirosis, and the importance of influenza vaccinations, as well as continued vigilance in diagnosing and treating tuberculosis.
Conclusions: The Lab Team developed and implemented a sustainable specimen transport system that reestablished clinical testing and surveillance of priority infectious diseases in Puerto Rico, and informed public health interventions. This is an unprecedented example of federal, state, and territorial collaboration to re-establish specimen testing and disease surveillance for an entire jurisdiction.

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Whole-Genome Sequencing Analysis of Neisseria meningitidis from the Urethritis Clade Causing Conjunctivitis in a Newborn Delivered by Cesarean — New York, August 2017

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Neisseria meningitidis (Nm) is a leading cause of bacterial meningitis, and is identified as a rare cause of newborn conjunctivitis linked to perinatal transmission from a genitally or nasopharyngeally colonized parent. Additionally, since 2015, it has been associated with outbreaks of urethritis. On August 31, 2017, Montefiore Medical Center isolated a nongroupable Nm (NmNG) from the eye of an infant aged 3 days with conjunctivitis. The infant was born to a healthy mother in a New York City (NYC) hospital, by

cesarean section done due to prolonged rupture of membranes. For in-depth molecular characterization of the strain responsible for the disease and to determine the genetic similarity to circulating strains, we used whole-genome sequencing (WGS) and phylogenetic analysis. We used phylogenetic analyses to compare the sequences with publicly available Nm sequences and available NYC sequences collected for outbreaks and sporadic case investigations. Genomic analyses confirmed that the conjunctivitis isolate was phylogenetically part of the Nm urethritis clade with between 20-50 single nucleotide polymorphisms (SNP) differences. Moreover, the isolate possessed specific molecular characteristics found in the emerging clade of NmNG associated with an increase of urethritis cases in Ohio and Michigan. This novel clade belongs to sequence type 11/clonal complex 11, a hyperinvasive lineage that has caused meningococcal outbreaks. Further in-depth characterization found that the isolate possessed specific characteristics from urethritis-associated Nm genomes including multigene deletion at the capsule locus, causing its NG phenotype and the presence of the aniA gene, a gonococcal-acquired gene suspected to allow survival in anaerobic environments. Vaginal and nasopharyngeal swabs were collected from the mother to determine potential carriage and transmission, but no cultures were recovered. Our investigation demonstrates that an isolate belonging to the Nm urethritis clade has caused neonatal conjunctivitis. Modes of transmission are not fully understood for this clade, and future investigations of Nm recovered from nonsterile sites (e.g., urogenital and oropharyngeal sites) for patients with non-invasive disease will be important to increase our understanding of non-invasive Nm. State and local health departments should consider investigating Nm conjunctivitis among newborns to more fully understand the clinical implications, modes of transmission, and epidemiologic evolution of this emerging urethritis clade.

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Analysis of Microbial Diversity - A Novel Metagenomic Approach to Decipher Beach Microbiome

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Introduction: Microbial ecology of recreational beach waters is one of the most underexplored ecosystems, often disrupted by anthropogenic activities, particularly in summer months. Here we deciphered microbial ecology of three Milwaukee beaches using state of the art whole genome shotgun metagenomics to explore microbial diversity, community resistome, virulome and their possible implication to public health.
Methods: A total of 18 pooled water samples were selected based on disparity between findings by Colilert and qPCR methods. Samples were collected during summer 2016 at three Milwaukee area beaches- Bradford, McKinley and South Shore. DNA extractions of 100 ml filtrates were performed using Fecal DNA kit (Zymo Research). dsDNA quantification was performed using Qubit 4 Fluorometer. Lyophilized SmartBeads (BioGx, Inc.) were used for E. coli. Nextera XT library prep protocol was used to generate fragment libraries followed by 150 bp paired end sequencing on Illumina HiSeq4000, generating an average of 40M read pairs per sample. CosmosID bioinformatics platform was used for multi-kingdom microbiome analyses and profiling of community resistome and virulome.
Results: Diverse population of bacteria (n=645), fungi (n=14), parasites (n=20), viruses and bacteriophages (n=21) are identified in all samples. Chao diversity index indicated diverse bacterial

population on a given day as compared to fungi, protists, and viruses. Proteobacteria (60-68%), Actinobacteria (24-27%), Bacteroidetes (4-7%), Firmicutes (0.6-1%), Verrucomicrobia (0.6-2%), Cyanobacteria (0.3-2%), Planctomycetes (0.6-0.9%) represents the dominant bacterial and Basidiomycota (36-89%) and Ascomycota (11-64%) as dominant fungal phyla detected among all three beaches. Bacterial load of 0.5% at Bradford, 0.8% at McKinley and 0.04% at South shore beach was observed. However, top five abundant microbial strains (Hot Spots) were found in South shore beach, followed by McKinley, and Bradford beach. Heatmaps were generated for bacteria, fungi and protist using relative abundance of organisms. Principal Component Analysis based on covariance between bacterial community among each pair of samples demonstrated close clustering between Bradford and McKinley samples indicating greater microbiome similarly between these two areas whereas South Shore samples were clustered away from those. Community resistome profiles demonstrate presence of genes associated with Aminoglycoside resistance in all samples, indicating possible environmental reservoir of Aminoglycoside resistance developed by Gram-negative bacteria.
Conclusion: Metagenomic sequencing approach to explore microbial communities offered critical inside, both on ecological and public health perspectives, and underscore the crucial need for more frequent microbiome analysis of waters people encounter on the shoreline.

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A Semi-Automated Method to Analyze, and Report Data from Neisseria gonorrheae Antimicrobial Susceptibility Testing

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Introduction: The Milwaukee Health Department Laboratory (MHDL) uses the SoftLab/SoftMic platform from Soft Computer (SCC) for all LIS-based operations in the lab. The platform includes a front-end GUI interface for daily lab operations and a back-end database that can be queried via Microsoft Access. We designed a system of two MS Access queries coupled to three simple programs in the Python programming language that together accomplish the task of compiling, analyzing, and validating lab test results for both NAATs, cultures and susceptibility testing for Neisseria gonorrheae monthly.
Methods: Queries were designed in MS Access to return results based on lab test type, order #, patient ID #, dates collected, received, and finalized, clinic where sample was collected, result including MIC values for AST analysis if available, and other internal quality measures. Results were exported to CSV format and used as input for Python programs. Python programs were designed to compute the number of each specimen type for positive and negative results, the turnaround time of culture-positive samples undergoing Etesting for AST, and order numbers that do not match between the LIS GUI interface and the MS Access database. SCC SoftMic Epidemiology Reports were generated in the usual manner to cross-check test order mismatches, and SoftMic Micro Reports were used to diagnose the cause of any mismatches discovered.
Results: Implementation of the present method eliminated lab side data entry errors for specimen and test counts, incorrect date entry, and miscalculation of turnaround times. The method also flags about 5 test orders per month with incorrect clinic or collector codes. By pulling LIS values directly from the database using an SQL query, transcription errors are eliminated. Similarly, by coding in the formulae

needed to compute metrics such as turnaround time in working days and tallies of infection by specimen site by clinic, calculation errors are eliminated once the code is validated.
Discussion: The task of compiling laboratory metrics was formerly done manually, requiring laboratorians to transcribe values from the LIS into an Excel spreadsheet, make calculations based on those values, and report them on a separate form. This method introduced many sources of error, including data entry error, calculation errors, and the propagation of errors through multiple calculations. The method also provided an unforeseen benefit by identifying test orders with incorrect clinic codes, which results in over- or underreporting of clinic metrics if left uncorrected. Overall, the method saves laboratorians' time, reduces errors, and helps validate data integrity within the LIS.

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Evaluation of Five Test Methods for Syphilis Screening, Serodiagnosis and Titer Determination in Contra Costa County

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Syphilis infection rates are rising in California, especially in high risk populations. Management of patient outcome and infection control requires prompt and accurate identification of early and active syphilis infections. Traditionally, laboratories screen for antibodies common to infection, but not specific to Treponema pallidum; reactive specimens are tested for T. pallidum-specific antibodies. Seeking increased automation and specificity, new technologies make a case for algorithm reversal: screen for treponemal antibodies and confirm with non-treponemal antibodies. We evaluated traditional and reverse testing algorithms that incorporate the Bio-Rad Laboratories BioPlex 2200 Syphilis Total and Rapid Plasma Reagin (RPR) assay, which detects treponemal and non-treponemal antibodies. In our current traditional algorithm, we screen with RPR; reactive specimens reflex to quantitative Venereal Disease Research Laboratory test (VDRL) and Treponema Pallidum Particle Agglutination assay (TPPA). We evaluated 359 samples by manual RPR (Arlington Scientific, Inc.) and BioPlex 2200 Syphilis Total &RPR. Samples reactive by manual RPR reflexed to VDRL (Becton Dickinson) and TPPA (FujirebioSERODIA). We initially tested 203 samples with each treponemal and nontreponemal assay (excludingVDRL). We tested 156 samples with each non-treponemal test (excluding VDRL) and the BioPlex SyphilisTotal; but not TPPA. For the 65 samples reactive with manual RPR, BioPlex RPR, or both, we determined titers with non-treponemal assays (VDRL, manual RPR, and BioPlex RPR). BioPlex RPR data have positive and negative agreement of 92% and 95%, respectively, with our manual RPR data. BioPlex Syphilis Total data have positive and negative agreement of 99% and 100%, respectively, with our manual TPPA data. Compared to our current algorithm, the algorithm that screens with the BioPlex RPR has a sensitivity of 92% and specificity of 95%. Alternatively, the reverse algorithm screening with the BioPlex Syphilis Total had a sensitivity of 80% and specificity of 88%. In the latter approach, specimens reactive by BioPlex Syphilis Total reflexed to RPR and we resolved discrepant results by manual TPPA. Our study demonstrates a need for population-based validation prior to implementing a new infectious disease methodology. In general, selecting a robust testing algorithm that contains a high-sensitivity screening method and a high-specificity confirmatory method will ensure that as many instances of low-level antibodies or antigen are detected, but only those who are truly infected with the disease are treated.

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Pseudomonas aeruginosa Alters Staphylococcus aureus Sensitivity to Antibiotics
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Cystic fibrosis (CF) patients have impaired mucociliary clearance and thick mucus, which promote respiratory infections. Pseudomonas aeruginosa and Staphylococcus aureus are two of the most prevalent respiratory pathogens in CF infections. Both organisms are associated with poor lung function and patient outcomes. In addition, P. aeruginosa and S. aureus form biofilms in the airway, which cause chronic infections that are recalcitrant to antibiotic treatment. In this study, we found that P. aeruginosa broadly alters the antibiotic sensitivity profile of S. aureus biofilms. P. aeruginosa supernatant can lead to increased tolerance of S. aureus biofilms to certain classes of antibiotics, and conversely, can cause increased sensitivity of S. aureus biofilms to other compounds. We observed that P. aeruginosa supernatant significantly increased the antibiotic tolerance of S. aureus biofilms to protein synthesis inhibitors and cell wall-active antibiotics, including vancomycin. The small molecule 2-heptyl-4-hydroxyquinoline N-oxide (HQNO) and the siderophores pyoverdine and pyocheline contribute to the ability of P. aeruginosa to protect S. aureus from vancomycin. Additionally, we found that P. aeruginosa supernatant increased the sensitivity of S. aureus biofilms to 60 antibiotics, including chloroxylenol. Treatment of S. aureus with chloroxylenol alone did not decrease biofilm cell viability; however, the combination of chloroxylenol and P. aeruginosa supernatant significantly reduced S. aureus biofilm viability compared to exposure to chloroxylenol alone. We observed that exogenous HQNO can sensitize S. aureus biofilms to chloroxylenol in a dose-dependent manner. In this study, we have shown that polymicrobial interactions can have dramatic and unexpected impacts on antibiotic sensitivity.

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A Multiplexed Chemiluminescent Screening Assay for Determination of IgG Antibodies to Measles, Mumps, Rubella and Varicella Zoster virus (VZV)
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Background: Routine detection of Measles, Mumps, Rubella and Varicella Zoster (MMRV) IgG is used to determine antibody status where infection history or previous immunisation is unknown.
Materials/Methods: This MMRV assay was developed using the Dynex Technologies Multiplier system and coated bead technology. Antigen coated beads representing each MMRV specificity were embedded into the base of carrier 96 well assay plate. Each assay well contains the 4 MMRV targets for the test sample IgG detection. The final chemiluminescent reaction is imaged with the on-board camera and results output as index values referenced against the assay specific calibrator. Precision was measured by assaying a range of 14 samples 3 times across an assay plate on three instruments over

three days. A ROC analysis was run in order to set the cut-off for each of MMV and confirm it for Rubella where the cut-off was ultimately defined by the International reference RUBI-1-94. Based on the resulting cut-off values, concordance was assessed on up to 929 samples collected for MMRV screening; results were compared to 510k cleared ELISA assays.
Results: Percentage coefficient of variation (%CV) for each MMRV specificity was calculated and is summarized below:

Precision test	Measles (%CV)	Mumps (%CV)	Rubella (%CV)	VZV (%CV)
Within run	4.54	5.35	3.69	4.08
Between run	4.51	5.66	4.64	4.06
Between day	3.56	4.01	4.76	3.15
Between instrument	1.41	3.19	2.24	1.37

ROC analysis:
Area under the curve (AUC) and 95% confidence interval (CI) results were:
For Measles 0.995 AUC (0.991-0.998 CI), Mumps 0.987 AUC (0.977-0.997CI), Rubella 0.998 (0.997-0.999 CI) and VZV 0.999 (0.997-1.000 CI).
Percent positive agreement (PPA) and percent negative agreement (PNA) with 95% confidence intervals (CI) were calculated in two ways:
Equivocal samples scored as positive PPA: Measles - 95.3% (93.5-96.6%), Mumps: 90.2 (87.8-92.2%), Rubella: 93.9 (91.9-95.4%), VZV: 98.1 (96.8-98.8%). PNA: Measles – 94.2 (90.7-97.0%), Mumps: 93.3 (88.5-96.2%), Rubella 99.5% (97.4-99.9%), VZV 97.5 (96.3-99.2%).
Equivocal samples scored as negative PPA: Measles – 93.3% (91.2-95.0%) Mumps: 93.3 (91.1-95.0%), Rubella: 93.0 (90.9-94.7%), VZV: 97.7 (96.3-98.5%). PNA: Measles – 95.4 (92.0-97.4%), Mumps: 94.6 (90.8-96.9%), Rubella: 100.0 (98.4-100.00%), VZV: 99.2 (95.6-99.9%).
Conclusion: This multiplexed fully automated assay gives reproducible semi-quantitative results for MMRV IgG. It is ideal for batch testing as can handle up to ninety two test samples in a single plate to produce 368 results in <3 hours. When two plates are run together 736 results are generated in 5 hours.

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Novel ELISA Based on Antigens from Strongyloides papillosus Instead of Strongyloides ratti Exhibits Increased Serological Specificity

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Background: Strongyloidiasis is an infectious disease caused by the nematode Strongyloides. Human infection by Strongyloides stercoralis can manifest with dermatological, intestinal and pulmonal symptoms frequently passing into a chronic disease. Low parasitic loads and discontinuous larvae excretion may hamper diagnosis by coproscopy. Serological test systems are more sensitive to detect the infection. Available serological tests are commonly based on native antigens from S. ratti larvae and lack specificity. We developed and evaluated the first ELISA based on S. papillosus to increase specificity.
Methods: Evaluation of the ELISA based on S. papillosus was performed using the following three

approaches:[1] Participation in an external quality assessment scheme (NEQAS, UK) encompassing six positive and five negative samples[2] A correlation study with the commercial Bordier ELISA (Strongyloides ELISA kit based on S. ratti antigens; Bordier Affinity Products, Switzerland) including 89 sera pre-characterized as either positive (n = 59) or negative (n = 30) by means of Bordier ELISA[3] Comparison with an in house ELISA based on S. ratti by determining specificity with respect to a cross-reactivity panel (n = 193, samples from patients with other parasitic or bacterial infections) and a control panel (n = 688, samples from 500 healthy blood donors, 100 pregnant women and 88 children).
Results: [1] Results obtained with the Anti-Strongyloides ELISA were 100 % in agreement with NEQAS target values.[2] In 74 of 89 samples (83.1%), the result of the novel ELISA correlated with the Bordier ELISA. Seven discrepant cases, which were positive in Bordier ELISA but negative in the novel ELISA, were further examined. Serological analyses indicated the presence of antibodies against other parasites (Plasmodium spp., Schistosoma spp. and Echinococcus spp.) in six of these cases.[3] The S. ratti based ELISA was reactive in 13.9% of the sera in the cross-reactivity panel and in 10.6% of the samples from healthy individuals, yielding a combined specificity of 88.6 %. In comparison, reactivities of 6.2% (cross-reactivity panel) and 3.5% (healthy individuals) were detected with the novel Anti-Strongyloides ELISA, resulting in a combined specificity of 95.9%.
Discussion: The novel Anti-Strongyloides ELISA reveals a high diagnostic accuracy in the serological diagnosis of Strongyloidiasis. The use of native antigens from S. papillosus instead of S. ratti increases assay specificity by 7.3%.

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Development of a Novel NS1-based ELISA for Detection of Specific IgG Antibodies Against West-Nile Virus

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Background: West-Nile virus (WNV) is a flavivirus that causes flu-like symptoms in about 20% of infected humans. Cases have been reported in all of the continental United States. In < 1% of infections, neurological complications, e.g. meningitis, occur. Laboratory diagnosis of WNV infection predominantly relies on the detection of antibodies directed against the glycoprotein E. ELISA based on this highly conserved antigen are very sensitive but also cross-reactive with antibodies against other flaviviruses produced after infection or vaccination.In this study, we validated the sensitivity and specificity of a newly developed Anti-WNV ELISA based on the non-structural protein 1 (NS1) which is less conserved within the family of flaviviridae.
Methods: For this study the following human sera collectives were used: 1) Paired samples from nine meningitis patients with suspected WNV infection from Algeria. Samples were consecutively collected early after symptom onset at an interval of 4-8 days. WNV infections were confirmed by either detection of viral RNA or IgG seroconversion. The presence of antibodies against WNV was additionally confirmed by a Flavivirus IFA mosaic (EUROIMMUN AG, Germany).2) Samples from 500 healthy blood donors. 3) 90 patients tested positive for antibodies against Dengue (DENV, n=27), Hepatitis C (HCV, n=6), Zika (ZIKV, n=20), Tick borne encephalitis (TBEV, n=25) or Yellow fever virus (YFV, n=12) with ELISA or neutralization test. Samples were analyzed with the Anti-WNV NS1 ELISA IgG and a commercial Anti-WNV ELISA IgG

based on glycoprotein E (Euroimmun AG, Germany). A 2x titer increase of IgG level in two consecutive samples was defined as significant.
Results: WNV-specific IgG seroconversion and/or a = 2x increase of IgG level between the two consecutive blood samplings was determined with both ELISA in all patients from collective 1 (sensitivity 100%).1.8% of healthy blood donors were reactive in the Anti-WNV NS1 ELISA compared to 2.2% in the Anti-WNV ELISA (specificity 98.2% vs. 97.8%).In collective 3 the NS1- and the glycoprotein E-based ELISA showed identical or similar reactivity with patient sera positive for antibodies against HCV (0.0%), ZIKV (90.0% vs. 95.0%) and YFV (0.0%). Major differences in cross-reactivity were observed in samples positive for anti-DENV (11.1% vs. 77.8%) and anti-TBEV (4.0% vs. 20.8%) IgG.
Discussion: Both ELISA showed a high sensitivity in clinically characterized samples from WNV patients. Assay specificity was higher using NS1 as target antigen, particularly with respect to patient sera positive for antibodies against DENV and TBEV. The diagnostic strategy of measuring an acute and a follow up sample ensured detection of the infection in all WNV cases.

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Random Sampling Versus Blending: Improving Pathogen Detection in Food Samples

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Introduction: Improving food sampling techniques continues to be one of the biggest priorities in the food safety industry. To ensure the most sensitive and accurate pathogen detection analyses are performed on food commodities, homogenization of samples is critical. Microbial contamination of food can be localized in “hot spots”, creating the potential for pathogens to go undetected through traditional sampling techniques.
Purpose: The purpose of this study was to compare random sampling vs sample blending for improved pathogen detection.
Methods: The Florida Department of Agriculture and Consumer Services Bureau of Food Laboratories investigated a best sampling practices comparison; the commonly used random sampling technique versus blending the remaining sample. The study’s targeted pathogenic analyses (Listeria monocytogenes, Escherichia coli, and Staphylococcal aureus) and food commodities surveyed (ice cream, frozen vegetables and fruits, prepared salads, deli meats, smoked fish, sandwiches and cheeses) comprise the lab’s routine food testing program as well as high-risk samples.
Results: Results demonstrate that improving sampling practices by using blenders and other homogenization tools to test an entire sample enhances pathogen detection in food especially in commodities such as frozen vegetables and deli meat.

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Public Health Laboratory Internship with the United States Naval Academy: Experiences of the Inaugural Year

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During the spring of 2017, the Bureau of Public Health Laboratories (BPHL)-Miami and the United States Naval Academy (USNA), Annapolis, MD, established a Public Health Laboratory internship for USNA midshipmen with the goals of exposing the students to the roles and responsibilities of the public health laboratory. Following several months of program and curriculum development by BPHL-Miami staff, three midshipmen spent approximately three weeks at BPHL-Miami learning and training alongside experienced laboratorians, partner epidemiologists, and county environmental health staff. The USNA interns gained hands-on experience at the bench level as well as participated in guest lectures presented by State and Federal subject matter experts, national webinars and trainings, a tabletop case study exercise, and field excursions to witness public health in action. In addition, the interns selected a project and made presentations on their last day at the laboratory. To determine the effectiveness of the new USNA intern program, pre- and post-internship knowledge assessments were performed. An opportunity for final evaluations, including suggestions for improvements, was provided for the interns. The internship was well-received by both the midshipmen and the USNA and plans are underway to host the program in 2018; applications for the internship have increased 167% for the upcoming summer program.

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A Simple Analysis of 4-Methylimidizole using Automated Solid Phase Extraction and High Performance Liquid Chromatography with MS/UV Detection

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The compound 4-Methylimidizole (4-MEI) is formed as a byproduct in some foods and beverages (1). Caramel coloring type III and Type IV in beverages is one of the ingredients which may contain 4-MEI. There has been an increase in concern lately about 4-MEI being a suspected carcinogen. The state of California has added 4-MEI to its proposition 65 list of known carcinogens (2). California now requires products with an exposure potential of >29 µg/day to carry warning labels. The trend shows potential expansion as this compound is receiving a lot of public attention and is the subject of ongoing studies. Most of the current methodology to analyze 4-MEI in beverages uses tandem mass spectrometry. Mass spectrometry is becoming more available to a wider segment of laboratories in routine environmental and food analysis and analysis of the benefits and constraints has not been clearly compared. HPLC/MS will be compared with UV detection and sample preparation alternatives to demonstrate the utility of different choices. Mass spectrometry detection provides many benefits, however smaller labs may not have the resources to adopt mass spectrometry into the lab. Also, specially trained operators may be required for these methods. Often times the process operators are beverage and bottling companies are performing the QC checks and may not have a strong background in analytical instrumentation. This

poster will discuss a method developed for 4-MEI contamination in a variety of beverages. The approaches to sample preparation and detection will be examined for cost and analytical capability.
1 - US FDA Website:
http://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm364184.htm
2 - California Office of Health Hazard Assessment website:
http://oehha.ca.gov/prop65/prop65_list/010711list.html"

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Decreasing Specimen Cancellation Rates through Submitter Education

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Background: Proper labeling of specimens and patient identification are critical steps in the testing process and required by regulatory agencies. To ensure quality testing, accuracy, and report accountability, it is imperative that specimens be submitted using suitable and accurate identifiers and that appropriate shipping and handling of the specimen to testing laboratories occurs. Labeling errors and specimens shipped under suboptimal conditions lead to cancellation of specimens. This impacts patient care as treatment is postponed due to delay in results, lost analyst productivity, and higher testing fees due to repeat collection.
Method: To investigate specimen rejections at Indiana State Department of Health Laboratories (ISDHL) resulting from improper labeling and/or shipping conditions, data was gathered from ISDHL Information Management System, STARLIMS. Data was collected on submitters, reasons for cancellation, test requests, and specimen submission dates. This information was then examined to categorize the most common reason for specimen cancellations and identify submitting facilities. An instructional specimen submission training presentation was created and dispersed via an electronic mailing list.
Results: Data showed that specimen cancellations were most frequently due to incorrect patient identification issues or labeling. The training presentation was based on this data to highlight areas where errors were being made and then to present information on how to correctly submit specimens. Previously, the average cancellation was 5.17%. Following dissemination of this training tool, initial data indicated a decrease in the number of canceled specimens for the first month following the release of the presentation; however, the subsequent two months revealed a steady increase in cancellations. Specimen cancellation was at 3.14% in the month immediately following the training but then rose to 4.59% and 5.70% during the next two months.
Discussion: The initial decrease in specimen cancellation following the training tool dissemination does not appear to be long-lasting. This may be attributed to the fact that submitters have not fully incorporated the presentation into their specimen submission process, complete training using this tool has not been widespread, or staffing turnover. By continuing to track this data on a monthly basis, ISDH will be able to observe whether this increase is a trend and possibly identify ways to mitigate it. With an average of 19,000 HIV specimens submitted yearly, it is important to continue communication and education with submitters to decrease cancellations.

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Walking In Each Other's Shoes: The Importance of Building Relationships between Epi and Lab

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Background: Laboratorians and Epidemiologists must work closely together in public health. Their jobs are interdependent, and a strong relationship makes everyone's job easier. This can be difficult, especially if the two groups are not in the same location. ISDH recognized that the silo approach resulted in communication issues and poor relationship. For the laboratory, this included a lack of inclusion in outbreak discussions and receiving timely notification to expect specimens. For epidemiology, this included lab results reported that were confusing and not knowing the turnaround time needed for laboratory testing. Communications need to be improved and a positive relationship fostered.
Methods: The Enteric laboratory approached the epidemiologists about a job shadowing day. The epidemiologists spent half of a day in the laboratory to see an overview of the enteric lab, including both traditional bacteriology and molecular methods plus PulseNet methods. Time was also spent on the cluster detection, reporting, and interacting with submitters. The laboratory supervisor then spent half a day at the Epidemiology Resource Center (ERC) to learn about ERC programs, case investigation, reporting, and other aspects of the ERC team's job roles. In addition to this shadowing, a biweekly meeting was created to discuss ongoing cases, outbreaks, changing needs, etc. This meeting is held using the help of technology, such as teleconference or webinar platforms, that allow parties to see each other or share computer screens, which facilitates a better understanding of the discussions.
Results: The time spent shadowing has increased the level of understanding and appreciation by both the laboratory and epidemiology. This has allowed for discussions to be more productive and to dig into the details further when discussing outbreaks and sampling. Holding regularly scheduled meetings has allowed for in-depth discussions about what is going on within the State of Indiana when it comes to foodborne outbreaks. By using programs that allow us to either visually see each other or to share screens, we also are able to reduce misunderstandings and communication gaps.
Conclusions: The implementation of these practices between the laboratorians and epidemiologists in the Enteric division has allowed for an improved relationship. There is a deeper level of understanding on both sides, which has built trust and promoted collaborations. In addition, discussions about specimen collection and testing algorithms have helped to improve outbreak response and detection.

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Rapid Concentration of Biological Particles from Environmental Samples

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InnovaPrep has developed a suite of systems for concentration of bacteria and other biological particles from liquid samples. Volumes of water from a few milliliters to tens of liters of water are processed through flat or hollow fiber membrane filters to capture any biological particles that are present. The biological particles are then efficiently recovered from the membrane surface with a tangential flush

using carbonated "wet foam". The wet foam is expanded up to six times the original liquid volume and becomes highly viscous, allowing it to act at the membrane surface and recover the particles into volumes significantly smaller than can be attained with traditional liquid elutions. The process is scalable, efficient, and typically results in concentration factors of approximately 1000X per concentration stage. The CP Select, launched in September 2017, is the second generation of InnovaPrep's Concentrating Pipette (CP) instrument. The CP Select uses Concentrating Pipette Tips (CPT) to aspirate and concentrate bacteria from a large input sample, and then dispense a final concentrated sample. CPTs are disposed of after each sample, enabling the CP to be utilized for concentration of pathogens and indicator organisms from a variety of aqueous samples without cross contamination. Two types of flat membrane filter CPTs and four types of hollow fiber membrane filter CPTs, allow the system to be used for a variety of sample types and a variety of organisms, including viruses, bacteria, and parasites. Concentration of 100 mL water sample and 1 L water sample, experimentally spiked with 100 CFU Escherichia coli were performed using InnovaPrep's CP Select liquid concentrator using 0.2 µm hollow fiber Concentrating Pipette Tips (hf-CPTs) and 0.075% Tween 20/PBS elution fluid. Concentration of 100 ml spiked PBS resulted in an average recovery efficiency of 78.8% in the first elution, with an average elution volume of 337 µL, and an average processing time taking 0.8 minutes. Recovery efficiencies for 1 L spiked PBS were similar to data from 100 mL runs, with 75.3% recovery in an average of 362 µL elution volume. Overall recovery increased to 85.19% when combined with a second elution. Overall time to concentrate 1 L of spiked fluid took 7.22 minutes.

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Colorectal Cancer Incidence and the Occurrence of Radium in Public Drinking Water Supplies in Iowa

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Cancers of the colon and rectum represent the third most diagnosed cancers in Iowa. There is also a substantial correlation to age, with a national incidence rate of 211.4 per 100,000 for persons over 65 versus 42.4 per 100,000 for persons under 65. Additionally, colorectal cancer affects both men and women, but men are impacted at a higher rate. Due to the high incidence of cancers of colon and rectum, it is important that potential environmental risk factors be evaluated. Few studies have examined the potential link between environmental exposure to Naturally Occurring Radioactive Materials (NORM), a common group of carcinogens in drinking water, and cancer incidence. Even fewer of these types of studies have focused on Iowa, with most studies in the past focusing on occupational exposure to uranium workers. With direct applicability to colorectal cancer, radium, the most common cause of Safe Drinking Water Act (SDWA) safety violations, represents a serious potential risk to the colon and rectum. While some radium is absorbed through the gut and retained for long periods of time by bone tissue, the vast majority of radium, 80%, is eliminated rapidly in fecal material. This route of excretion could lead to higher levels of exposure to the endothelial lining of the colon and rectum from radium isotopes, as well as their daughter products (many of which are short lived) during decay within fecal material. The results of an ecologic study of colorectal cancer incidence in Iowa, evaluating its potential correlation with radium in drinking water supplies will be presented. Age-adjusted, standardized incidence ratios for colorectal cancer in each Iowa county are compared with average radium-226 and radium-228 concentrations in community water systems in each county. A Poisson regression analysis is conducted independently for radium-226 and radium-228 to estimate a risk ratio

for varying levels of exposure. Covariate adjustment for poverty, smoking, obesity, and heavy alcohol use rates are included in this regression model.

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Teaching Public Health Laboratory Informatics

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Introduction: A public health laboratory has a unique set of informatics needs. To make the entire laboratory enterprise work smoothly and to fulfill the critical role of public health laboratories, the informatics team needs a clear understanding of the entire ecosystem of public health data exchange and dependencies. This system includes laboratory information management and disease surveillance systems, immunization registries, electronic laboratory reporting, and case notification messages, among others. An appropriate public health informatics curriculum must address system requirements; the goals of public health surveillance and emergency response; partnerships with private entities; a complicated jurisdictional landscape of local, state, and federal agencies; and the limitations of resource-constrained agencies.
Methods: J Michael Consulting is developing targeted informatics courses for those working in the public health laboratory space: bench scientists that need to be "trained-up" as informaticians, IT staff who need a crash course in public health and laboratory science, and laboratory leaders who require a high-level understanding of data management and system integration.
Results: Developing relevant, meaningful informatics courses for public health laboratory staff requires a diverse assembly of educators with experience in business, project management, laboratory science, and informatics. Our approach endeavors to make the complex subject matter of informatics more accessible by tying it to familiar laboratory use cases. Educators with sufficient laboratory backgrounds can speak the language of laboratorians and draw on real-world laboratory examples. Discussion: It is important for all biomedical informaticians to appreciate the unique needs of public health informatics. It is to everyone's advantage for private healthcare systems to share data and integrate with public health systems. By building up the informatics competencies within public health laboratories and agencies, we ensure that public health is ready to partner with EHRs and clinical laboratories.
Conclusion: The goals of this educational program are to equip public health laboratories and agencies with the knowledge and skillsets necessary to integrate and leverage existing systems; implement data exchange with varied messaging partners; and ultimately improve surveillance and coordinated response to public health emergencies.

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Playing with Building Blocks: The Newborn Screening Health IT Implementation Guide and Toolkit
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Background: Health information technology (HIT) continues to play a crucial role in improving newborn screening (NBS) processes. A key component of HIT is utilizing Health Level 7 (HL7) to send laboratory orders and test results between providers and the NBS laboratory. Several NBS programs have implemented, or are in the process of implementing, HL7 messaging using program-specific methodologies with varying levels of success. This disparate nature of implementation has produced inconsistent results and served as the impetus for the development of a NBS HIT resource guide and toolkit to provide guidance for programs implementing electronic messaging. Objective: To introduce the NBS HIT Resource Guide and Toolkit to the NBS community, educate them on the value of the guide, and facilitate an interactive discussion of it. Next steps for expanding the guide to other areas of HIT beyond electronic messaging will also be discussed.
Methods: The NewSTEPs 360 project, funded by the Health Resources and Services Administration (HRSA), works with NBS programs to improve timeliness of NBS from birth to results reporting. This includes activities to implement HIT solutions including electronic messaging. NewSTEPs 360 partnered with the Virginia Division of Consolidated Laboratory Services (DCLS) and J Michael Consulting (JMC) to bring together NBS programs, at various stages of electronic messaging implementation, and several national partners to author a NBS HIT Resource Guide and Toolkit.
Results: Representatives met for an in-person meeting in February 2017, which resulted in a detailed outline of NBS electronic messaging processes based on their diverse experiences. This outline will be developed into a resource guide planned for release by the end of August 2017. This first version will lead a NBS program through the steps needed to plan, implement, and maintain an electronic messaging project including details on such activities as establishing partnerships, workflow mapping, and message validation among others. The modular nature of the guide will allow the reader to utilize the sections that are important for their project status while setting aside the sections that are not relevant. The guide will also provide descriptions of the tasks needed to meet milestones, tools for accomplishing those tasks, and case studies from programs that have completed milestones highlighting lessons learned.
Conclusion: This poster will introduce participants to the NBS HIT Resource Guide and Toolkit, walk them through the layout and explain its utility.

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Designing Reusable and Scalable Options for Public Health Data Exchange
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The NNDSS Modernization Initiative (NMI) Technical Assistance (TA) Team developed a configurable Rhapsody route template to facilitate Public Health Agencies' (PHAs) implementation of HL7 case

notification messages to the CDC. Mapping jurisdiction-specific data codes and formats to national standards is a challenge common to any data exchange implementation. Integration engines, such as Rhapsody and Mirth, provide a technical solution to this challenge, but require time and expertise to configure. The Rhapsody template, which supports Generic v2.0 based Message Mapping Guides (MMGs) and the Arboviral v1.3 MMG, enables agencies to implement standard mapping by entering jurisdiction-specific information into a configuration table rather than writing code to map every data element. This approach reduces the need for custom code and development resources. PHAs can use the table-driven code, instructions, and existing structure to develop routes that will support future HL7 message development. PHAs can extend the functionality of the routes independently by updating the custom code section of the Rhapsody template. The table-driven route presents a scalable and configurable option for implementing HL7 case notification messages with limited customization. This approach can be adapted for other public health data exchange needs.

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Advantages of Self-Directed Regional Public Health Laboratory Networks

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Implementing rapidly expanding technologies and maintaining a well-trained competent workforce while ensuring quality and safety present continuous challenges for public health laboratories in an era of tight budgets. One of the innovative strategies that PHL directors and senior leadership have developed is the establishment of regional PHL networks that are driven by state and local laboratories and are not mandated by funding sources. There are many advantages to participation in these regional networks including building relationships and collaborations, increasing workforce development, and sharing services, resources and best practices. Already there are success stories from existing state- and local-directed PHL networks. The Northeast Environmental and Public Health Laboratory Directors (NEEPHLD) consortium identified a need for rabies laboratory assessments in their participating states, and undertook a project under which inter-laboratory audits were conducted to ensure quality rabies testing. The Northern Plains Consortium (NPC) conducted two regional emerging leader programs in the past three years. This program, designed after the APHL Emerging Leaders Program, strove to increase

the leadership skills of promising public health professionals. Both consortiums also support regular conferencing of their PHL biosafety officers to share best practices and approaches for clinical laboratory safety outreach. The Southeast Consortium (ColLABorators) (SEC) have identified numerous opportunities for sharing documents and best practices. The newly formed Mid-Atlantic Consortium (MAC) has started to develop policies and procedures for sharing best practices, test services, and samples and isolates for validation studies. Also, with the acquisition of whole genome sequencing capabilities and other emerging technologies, workforce development has benefited from PHL networks through regional trainings that include webinars and hands-on workshops. Finally, through regular conference calls or in-person meetings, regional PHL networks benefit from building professional relationships among their peers and establishing lasting friendships. Through the formation of state and local-directed regional public health laboratory networks, with or without formal Memorandums of Understanding (MOU), member laboratories can continue to provide needed services while enhancing workforce development and quality assessment. Using these self-directed networks, PHLs are able to leverage resources to better address PHL challenges as a result of technology and priority changes, while maintaining, and even increasing, laboratory capabilities and capacities.

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Carriage of *Neisseria meningitidis* Among Men Who Have Sex with Men in Los Angeles County

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Background: An ongoing outbreak of invasive meningococcal disease (IMD) has been occurring among men who have sex with men (MSM) in Southern California since 2016. The outbreak strain, *Neisseria meningitidis* serogroup C (NmC), has been responsible for numerous global outbreaks in this population. In order to better understand background carriage and associated risk behaviors, the Los Angeles County Department of Public Health began a study to describe IMD carriage in three anatomical sites as well as risk behaviors among MSM during the outbreak.

Methods: After eligibility screening and informed consent, participants completed a 20 minute online behavioral questionnaire followed by swabbing of the urethra, throat, and rectum. Swabs were plated on InTray GC selective media and all plates were incubated for 24 hours at 37°C at the clinic. Specimens were then submitted to the Los Angeles County Public Health Laboratories (LACPHL) via courier for isolation and characterization of meningococci and gonococci. Suspicious colonies were isolated on Chocolate Agar and characterized by gram stain, oxidase, and API NH rapid biochemical tests. *N. gonorrhoeae* isolates were confirmed by the Gonogen II rapid test. All *N. meningitidis* isolates were grouped based on reaction to serogroup-specific antisera.

Results and Conclusion: From April 2017 - January 2018, 201 culture submissions were received, 8 were rejected, and 192 were used in analysis. These cultures were submitted by 3 clinics and were collected from 67 participants. Of these, 3 different participants had a single positive *N. gonorrhoeae* at each anatomical site (1.5%). Of the 67 oropharyngeal samples received, 13.4% (N = 9) were positive for *N. meningitidis* in this single site. The *N. meningitidis* isolates were sub-typed as serogroup A (N = 2), serogroup X (N = 1), serogroup Y (N = 2), serogroup Z (N = 1), serogroup Z'/29E (N = 2), and ungroupable (N = 1). *N. meningitidis* was not found in any rectal or urethral sites. Interestingly, of the carriage we have isolated to date, none have been the outbreak strain from this population.

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Economic Impact of the 2014-2015 Multi-state Measles Outbreak on the Local and State Public Health Sector in California

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Background: Measles outbreaks are a recurring economic issue for public health infrastructure. In December 2014, several individuals were exposed visiting the Disney theme park area in California resulting in 131 confirmed measles cases throughout California, with additional cases in other US states, Canada and Mexico. An understanding of the economic impact of this outbreak on the California public health system is needed to evaluate response costs to local and state communicable disease control programs (CDCPs) and public health laboratories (PHLs).
Methods: Surveys were sent to local and state CDCPs and PHLs representing all California counties and health jurisdictions. Survey data was used to model the outbreak using confirmed measles cases in each county (x1) and spatial variables associated with measles transmission: county distance from epicenter (x2) and population density per county (x3). Using Poisson regression, we estimate the expected number of epidemiological measles contacts in California counties. To estimate local response costs, observed Los Angeles County data was used as a proxy and adjusted to account for variations in CDCP and PHL response by county. Sensitivity analyses were performed to validate our model.
Results: Forty-five of 132 (34%) local and state CDCPs and PHLs responded to the surveys. The model predicted 10,591 epidemiologically-linked measles contacts throughout the state including contacts investigated in California counties without confirmed measles cases. The total local and state public health epidemiologic and laboratory cost in California was $3.36 to $3.70 million. Local costs are estimated to be $2.75 million ($2.36-$3.27 million): CDCPs, $2.64 million ($2.27 to $3.13 million) and $108,000 ($90,300-$131,000) for local PHLs. State costs for both laboratory and epidemiological response are estimated to be $276,528-$619,145.
Conclusions: California public health response to measles outbreaks require significant financial resources. However, our overall economic assessment is comparable to previous studies. During the 2014-15 US multi-state measles outbreak, expenditures for contact investigations and local response costs contributed most of the public health expenses across all California counties. Our modeling revealed that population density was a primary driver in determining the epidemiological linked measles contacts. Additionally, our model provides a method that could be used in evaluating cost for future measles outbreaks.

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Laboratory Response Network – Chemical (LRN-C) Level 3 Resource Handbook

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The APHL Chemical Threat Collaborative Workgroup (CT-CWG) developed the Laboratory Response Network-Chemical (LRN-C) Level 3 Resource Handbook. The guide was designed to be used by LRN-C member partners and coordinators who provide Level 3 outreach to healthcare facilities, first responders, and any other agency expected to respond to a chemical release resulting in human exposure. The first version was released in November 2014 and was placed on the LRN-C Toolkit APHL SharePoint site. Specific funded benchmark Level 3 capabilities, as defined by the Centers for Disease Control and Prevention (CDC), should be sustained, including the provision of preparedness measures for healthcare partner response to public health emergencies, such as chemical threats. Robust Level 3 programs, developed by state member laboratories, include healthcare partner training, exercises, and outreach. Whether a state, territorial, or metropolitan area, each LRN-C laboratory is unique with regard to demographics, size, and hospital system. To aid Level 3 Coordinators to fill any gaps in their programs, a resource guidance document was proposed by CT-CWG members. This document would include practical information that could be used to develop a robust Level 3 program with consideration for each jurisdiction's specific needs. APHLs Environmental Health Committee (EHC) and eleven volunteers from the CT-CWG provided subject matter expertise for development of a universal guidance document for the Level 3 Coordinators. Meetings, hosted by APHL members, were held utilizing an APHL SharePoint site for efficient coordination of conference calls and email. The group established experience based recommendations that would be most helpful for Level 3 activities. The group also solicited ideas from the entire APHL CT-CWG. The workgroup met frequently to discuss progress and suggest edits for improvements to the Level 3 Resource Handbook. Since the first version release, minor revisions were made to the document in March 2015. December 2016, the EHC proposed a refresh of the Level 3 Resource Handbook. Short term goals included addition of an acronym list, repairs to URLs, and Emergency Response Laboratory Network (ERLN) information. Long term goals were identified for the training section of the guidebook that would include enhancement of training program practices and an exercise experience library as portrayed by the different member states. Short term revisions were completed in September 2017 by a smaller group of CT-CWG members using similar communication paths developed during the making of initial version. Our poster will announce and share the remake of the (LRN-C) Level 3 Resource Handbook.

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Creating a Knowledge Sharing Hub for Biosecurity Using an Online Collaborative Tool

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An array of biosecurity threats both known and unknown exists today. With technological advances such as the de novo synthesis of horsepox virus, biosecurity professionals need to be well informed, trained and equipped to recognize these risks. Although there is an abundance of technical references available, there is no single roadmap to follow or a central location for individuals to access them and otherwise promote an interactive engagement. Our team proposed to develop a novel engagement tool using web-based software for networking across sectors and regions. This work was part of a Global Health Security (GHSA) related proposal competition, which our submission was awarded first place. Using online collaboration tools can be used to reinforce existing biosecurity best practices, standards, and policies that are important for achieving GHSA and Joint External Evaluations (JEE) biosecurity objectives. Related information, research and learning is also used to inform national policy development. In order to effectively implement the GHSA, one must recognize that there are clear biosecurity gaps in both the GHSA and JEE. Our goal is to create a low-cost repeatable model for next generation biosecurity professionals to engage with experts in the field by means of a question and answer forum by creating an online portal of biosecurity resources and tools to assist users in achieving the biosecurity targets within the GHSA and JEE. By collaborating with partners, experts, and using software and apps, this model serves as a useful forum to discuss biosecurity and also related issues among working groups and peer institutes such as state and local public health laboratories.

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Rapid Mycobacterial Identification using Real Time PCR and MALDI-TOF Testing

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Objective: The primary goal for a Mycobacteriology laboratory in the public health setting is to rule in/out the presence of Mycobacterium tuberculosis complex (MTBC) in clinical specimens and cultures positive for acid-fast bacilli. The Michigan Department of Health and Human Services (MDHHS) goal was to create an algorithm using real time PCR and MALDI-TOF testing platforms that would maintain the turnaround time of the Hologic Mycobacterium Direct (MTD) amplification and HPLC tests.
Study Design: MDHHS began this task by validating a real time PCR test for clinical specimens, both respiratory and non-respiratory sources, and broth cultures. Within 24 hours of receipt in the laboratory, a physician will have a result of MTBC DNA Detected or not Detected. Broth cultures are the majority of culture types received at MDHHS for identification, but they have a poor success rate when directly tested with MALDI-TOF. Our algorithm validated testing of these broth cultures with the real time PCR assay to rule in/out MTBC and then utilize the MALDI-TOF platform for final identification. The MALDI-TOF validation for Mycobacterium sp. cultures included cultures grown on solid media and 7H9 broth subcultures of the original culture. The subcultures are tested using MALDI-TOF when they reach

an approximate turbidity of a 3.0 McFarland standard, usually 1-4 days after incubation. Acid-fast bacilli positive cultures on solid medium are tested directly with MALDI-TOF. All clinical specimens and culture aliquots are heat killed before real time PCR or MALDI-TOF testing is performed. MALDI-TOF testing is performed as per the manufacturer instructions for Mycobacterium sp. from Bruker Daltonics. The real time PCR test is a laboratory developed test, originally designed by the Wadsworth Center, involving a simple extraction procedure followed by DNA detection.
Results: MDHHS has been able to transition from using MTD and HPLC testing without compromising turnaround time or cost.
Conclusions: The current MDHHS algorithm provides the laboratory with cost effective testing, while providing the physician with the most rapid identification possible to aid in patient treatment.

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Identification of Carbapenem Resistant Enterobacteriaceae from Rectal Swabs using the ABI 7500

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The emergence of Carbapenem-resistant Enterobacteriaceae (CRE) has become a serious concern for both clinicians and public health officials. These organisms confer antibiotic resistance through several mechanisms that often require advanced molecular methods to identify. The most common mechanism that is used to confer immunity is through the creation of extended-spectrum ß-lactamases (ESBLs). Common ESBLs that confer resistance of Carbapenems in the United States are Klebsiella pneumoniae carbapenemase (KPC), New Delhi metallo-beta-lactamase 1 (NDM-1), oxacillinase carbapenemase (Oxa) and Verona integron-encoded metallo-ß-lactamase (VIM). State public health laboratories, in correlation with the Centers for Disease Control and Prevention (CDC) have develop molecular methods that can be used to identify these enzymes. The issue of broad spectrum drug resistance in CRE organisms is especially concerning from a public health standpoint because, typically, healthy people do not acquire these infections. Most commonly the infections are spread in hospitals and long term care facilities. The close proximity of patients in these facilities creates massive issues in terms of infection control. Additionally, rapid identification of these organisms is difficult in clinical laboratories due to lack of automated equipment and the use of phenotypic testing yielding low specificity of results. In order to combat this issue state public health laboratories were looked at to develop methods to transport, receive, test, and report specimens from clinical sites to control the spread of these organisms. Molecular testing can be utilized to identify antimicrobial resistance genes and provide accurate and timely results for use by clinicians and infection control teams. The State of Michigan has developed methods to identify organisms containing resistance genes both from culture specimens submitted by clinical laboratories and clinical specimens in the form of rectal swabs submitted from patient care facilities. The State of Michigan, Bureau of Laboratories molecular method is based off of the use of the ABI 7500 real time PCR instrument with primers, probes and controls provided by the CDC. The validation of this method for identifying gene resistance using rectal swabs examined specimen conditions and types of swabs that could be used effectively for testing. The conditions were tested to examine acceptable specimen criteria for testing of real time clinical specimens. The Bureau of Laboratories provides collection materials to care centers and understanding which conditions affect the results of testing results is vital to ensure optimal testing. Resulting data demonstrated the

effectiveness of the method at isolating DNA for multiple mechanisms of CRE under various conditions without sacrificing result quality.

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Measles and Mumps and Chickenpox, Oh My! Minnesota's Response to Three Overlapping Outbreaks

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Background: Between April - August 2017, the Minnesota Department of Health (MDH) responded to three concurrent vaccine preventable disease (VPD) outbreaks. We experienced the largest in-state outbreak of measles in 30 years, a large mumps outbreak on college campuses, and several small outbreaks of chickenpox (VZV). As a VPD Reference Center (VPD-RC), we also provided testing support for a nationwide mumps outbreak. Due to the generally low demand for VPD testing, lab staff fit these assays into routine testing responsibilities. This low demand is reflected in the equipment platforms, which are optimized for rapid testing of small batches of specimens. These factors became major limitations when faced with a need for large volume testing on small volume platforms during the peak of these three outbreaks.
Response: MDH-PHL, Infectious Disease Epidemiology, Prevention and Control (IDEPC) and local public health partners met daily during the measles outbreak to optimize response efforts. Additional testing staff were trained and staff work schedules adjusted to increase the length of the testing day. Equipment was reserved for outbreak response use, with flexible priority scheduling on additional instruments. Multiple batches were scheduled throughout the day. Measles specimens were prioritized over mumps and VZV. VPD-RC turn-around times were not affected. A Saturday testing schedule was temporarily implemented to address the increased demand and maintain rapid turn-around. The Operations (Ops) unit was delegated to handle communication with submitters. The Ops unit was provided with answers to frequently asked questions to assist with communications.
Results: The MN outbreaks began within three weeks of each other, requiring a rapid expansion of the MN response. MDH-PHL tested 1033 measles specimens, 523 mumps specimens, and 176 VZV specimens April through August 2017. Average diagnostic turn-around times were 8 hours, 1.5 days, and 2.5 days for measles, mumps and VZV, respectively. One additional staff member was fully trained on measles and mumps testing, resulting in five staff members able to work a rotating testing schedule. The Operations staff were able to respond immediately to submitter questions, reducing the burden on testing personnel.
Conclusions: Rapid response times are key to minimizing the spread of human illness. Measles, mumps, and chickenpox are highly contagious, with limited treatment options, and can become resource-intensive for public health, and for individual families. Working closely with IDEPC to match response needs with testing capacity allowed us to focus efforts appropriately and minimize turnaround times during overlapping outbreaks. The ability to adjust quickly to changing testing needs allowed rapid follow-up with clinicians and patients, a more efficient public health response, thereby reducing the spread of outbreaks in the community.

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Reliable Identification Methods for Carbapenem-resistant Carbapenemase-producing Acinetobacter (CP-CRA)

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Antibiotic resistance is a worldwide concern impacting the healthcare system with difficult to treat infections. An emerging threat is resistance to the carbapenem class of antibiotics, which has resulted in surveillance efforts to understand the prevalence and epidemiology of carbapenem resistant organisms. Acinetobacter baumannii is a hospital-associated, opportunistic pathogen with both intrinsic and acquired antibiotic resistance mechanisms. Carbapenemase-producing carbapenem-resistant Acinetobacter spp. (CP-CRA) often harbor carbapenemase genes on a plasmid that has the potential to transfer between bacterial species and genera. The prevalence of CP-CRA containing plasmid-encoded carbapenemases is poorly understood and the clinical significance is unclear. Therefore, it is imperative that efforts are taken to detect the carbapenem resistance mechanisms of CP-CRA to aid in infection control measures. Fundamental to treatment and control of CP-CRA are phenotypic and nucleic acid-based methods for carbapenemase detection. Here we used established phenotypic methods for carbapenemase detection, in conjunction with real-time PCR (RT-PCR) for Acinetobacter blaOXA ß-lactamase genes, to identify correlations between phenotype and genotype and provide insight into the clinical significance of CP-CRA. The carbapenem inactivation method (CIM) and modified CIM (mCIM) are phenotypic tests performed routinely for the detection of carbapenemase production in Enterobacteriaceae; however, these methods are unreliable for use with Acinetobacter spp. Therefore, we opted to re-examine the interpretive guidelines for carbapenemase production of CRA by comparing CIM and mCIM results with data obtained from RT-PCR detecting the presence of Acinetobacter plasmid-associated blaOXA genes (OXA-23, -24/40, -58) and the intrinsic blaOXA gene (OXA-51). We concur with the literature that the mCIM is not reliable for detecting CP-CRA. However, our data demonstrates that the interpretive criteria for CIM positive Acinetobacter spp. should include any zone size with colonies spread throughout the zone of inhibition. Use of the new interpretation strongly correlates with the identification of an Acinetobacter blaOXA gene. There are some isolates that harbor a blaOXA gene, but are CIM negative, requiring further molecular testing to determine gene expression levels that could explain the negative phenotype. In addition, the chromosomal or plasmid location of each blaOXA gene needs to be determined along with its capability for horizontal gene transfer (HGT). Overall, our data provide strong evidence that CIM results are a reliable indicator for CP-CRA and accurately predict the presence of a blaOXA gene. The identification of a CP-CRA isolate harboring a blaOXA gene, which may be plasmid-associated, is highly important considering the possibility of HGT to other pathogens.

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Evaluation of Laboratory Procedures for Detection of Mycobacterium tuberculosis in Gastric Fluid

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The global Tuberculosis (TB) epidemic is well documented with additional attention being given to the specific challenges of TB diagnosis in children. Culture for Mycobacterium tuberculosis is important to confirm the diagnosis and determine antibiotic response. Because infants and young children do not expectorate sputum, aspiration or lavage of gastric fluid is the usual procedure for obtaining a pediatric specimen to test for M tuberculosis. Currently, there is no standard laboratory procedure available in the literature for culture of pediatric gastric fluid specimens. In fact, there is conflicting information presented on the value of neutralizing the acidic fluid prior to culture and/ or analysis on the Cepheid GeneXpert Mtb/Rif assay, the two primary detection methods in many countries. The primary goal of this study, funded by the NIH NIAID contract number HHSN272201700001C for Mycobacterium Tuberculosis (Mtb) Quality Assessment Program (TBQA), was to determine the effect of sample neutralization on organism detection and recovery under various conditions, in order to determine the best laboratory procedure for processing gastric fluid. Limit of detection in gastric fluid was also evaluated by live culture. Commercially available simulated gastric fluid was inoculated with M tuberculosis H37Ra at different concentrations. Samples were either neutralized or not with 8% sodium bicarbonate and processed that day or held under varying environmental conditions before processing following the Association of Public Health Laboratories (APHL) sample processing method. Sample sediments were inoculated in duplicate onto Lowenstein Jensen agar slants and incubated for 6 weeks, checking periodically for growth to compare neutralized vs not neutralized samples under the same conditions. Samples were also analyzed on the Cepheid GeneXpert Mtb/Rif assay. Results will be presented to the NIAID-funded AIDS Clinical Trials group (ACTG) and International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT) who are coordinating a large scale clinical trial on household contacts, particularly children, of patients with multi-drug resistant TB.

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Detection and Characterization of Salmonella in Environmental Samples

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Field-ready methods for rapid detection and characterization of Salmonella directly from food and/or environmental samples could have a significant influence on the economic impact of foodborne illnesses and reduce the sample-to-answer turn-around times typical for current surveillance efforts. To address this challenge, we demonstrated the use of field-based protocols and systems such as the Biomeme two3 qPCR system and Oxford Nanopore Technologies MinION sequencing platform for on-site detection and sequence-based characterization of Salmonella in water and sediment samples. The objective of this study was to assess the ability to rapidly detect Salmonella in field samples from 24 h pre-enrichments. Twenty-four samples originating from the Virginia Tech Eastern Shore Agriculture Research and Extension Center (AREC) and surrounding areas were analyzed for the presence of

Salmonella by modified BAM methods and a FDA developed real-time qPCR assay on the portable Biomeme two3 system, with isolate confirmation by the VITEK MS. Of the samples tested, 10 detected positive for Salmonella, with the first detection occurring within 30 hours of collection. Select qPCR positive samples were also subjected to metagenomic shotgun sequencing on the portable MinION sequencing platform for sample characterization. The successful demonstration of these methods is an important step towards developing and validating field-ready methods aimed at shortening the sample to answer timelines for routine foodborne pathogen surveillance and outbreak investigations.

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A Quality-Integrated and Leadership-Focused Approach to Biorisk Management Training In West Africa

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The high rate of Ebolavirus infection among West African laboratory workers during the 2014-2016 epidemic demonstrated a need to strengthen biorisk management (BRM) in local, national-staffed laboratories. A systems approach for integrating biosafety and biosecurity within an institute or facility, BRM is typically taught as a set of policies and procedures distinct from other clinical laboratory training. A common underlying assumption is that, once trained, participants will develop BRM programs for their institutions with minimal guidance and harmonize them with their existing laboratory quality management systems (LQMS). This assumption is problematic in West African laboratories. Many labs currently lack fully developed LQMS. The labs also typically lack strong leadership and support required for successful implementation and sustainment. With these deficiencies in mind, a unique curriculum was created integrating LQMS training into a standard BRM training curriculum and specifically targeting institute directors, deputy directors, stakeholder ministry representatives, and laboratory management personnel. The training curriculum was implemented in three countries; Liberia, Sierra Leone, and Guinea. Case studies for each are presented along with their individual challenges and strengths. It is important to remember that while our models are state and local health departments in the USA, the structures that allow for efficient operations at these facilities are not always available, or differ in West African countries.

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Building Social Networks for Sustainable Local Outbreak Response Capabilities

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Outbreaks of high consequence and emerging pathogens, such as Brucella and MERS, do not stop at national borders and require international cooperation and aid to those countries with limited agricultural and human health resources. For many years such cooperation has facilitated efforts to contain outbreaks that may impact public health and security. We have, in a number of instances, been

engaged to implement USG-funded science that includes cooperative biological research, activities in biosafety and security, and the development and implementation of multi-faceted training strategies in Kazakhstan and West Africa. Such training programs facilitate the ability of host countries to prepare and respond to the next disease outbreak. There are, however, limitations to the existing comprehensive programs. They are not always customized to address the specific circumstances of individual host country laboratories and resource-limited countries are unable to sustain some detection and diagnostic technologies, such as multiplex RT-PCR and Next-Generation Sequencing. Our team has developed a Capacity Building Pathway aimed at cost effective training and knowledge acquisition. The system of blended learning, documentation, and quality processes that can be co-developed with the host nation culminates in a knowledge transfer process that is adopted, maintained, and sustained by the host nation to train future generations. The approach utilizes a web-based platform that will provide a forum for continued communication between the partner country and international contract participants. Ideally, this web-platform will continue to remain active after the ongoing contract period of performance and be monitored and supported by US scientific and project management experts. As capacities grow, the program will work towards supporting a regional network of "communities of practice" whereby in-country partner laboratories can effectively share information and coordinate their efforts. The proposed workflow is adaptable to various types of training including: biosafety, biosecurity, sample management, research projects, standard operating procedure development, and proficiency testing. Moreover, critical components can be migrated to other users that may need the knowledge generated. As one moves through the Capacity Building Pathway, ownership of the process increases for the host nation until they have the ability to own and manage it.
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Triple Quadrupole ICP-MS for Biomonitoring Applications

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Triple quadrupole inductively coupled plasma mass spectrometry (ICP-QqQ-MS) offers many advantages over traditional single quadrupole ICP-Q-MS, including enhanced analyte selectivity, sensitivity, and matrix tolerance, making it a useful tool for performing highly sensitive trace elemental measurements in a variety of clinical matrices for biomonitoring public health studies. The Biomonitoring Program at the New Hampshire Public Health Laboratories (NH PHL) employs triple quadrupole ICP-MS to assess exposures to trace metals in communities around the state. The NH PHL has developed several analytical methods on a triple quadrupole ICP-MS to conduct two ongoing public health studies: a targeted investigation that assesses exposure to arsenic and uranium from private well water in high-risk communities around the state, and a surveillance study that monitors for toxic metals exposures in urine and blood from the state population. The two quadrupoles (Q1 and Q2) are separated by a collision/reaction cell, which allows for effective removal of interfering polyatomic ions when operated in tandem MS/MS mode. The instrument may also be operated in traditional or single quadrupole mode, with Q1 acting as an ion guide for enhanced signal-to-noise when measuring analytes that have very low abundances, such as uranium. By coupling a high-performance liquid chromatograph (HPLC) to the ICP-MS, the NH PHL has also developed a method for measuring six arsenic species in urine with limits of quantitation as low as 0.5 ppb, which allows for very low-level background exposures to be determined for surveillance study applications. The analytical flexibility and advanced performance of

triple quadrupole ICP-MS methods are suitable for determining a wide array of analytes of interest for biomonitoring public health studies, and may be particularly useful for studies that investigate changes in toxic metals exposures as the result of industrial practices or natural disasters, as well as studies that track the effectiveness of remediation techniques on reducing human exposures.

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Validation of a High Throughput Method for Measuring Exposure to Perfluoroalkyl Substances (PFAS) in a Statewide Biomonitoring Study

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Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs) are a group of man-made chemicals that are widely used in consumer products. PFAS compounds can remain inside the body for an extended period of time and their health effects are still unknown. The Biomonitoring Program at the New Hampshire Public Health Laboratories (NH PHL) plans to implement a statewide surveillance study to assess exposure of New Hampshire residents to a variety of chemicals that may be present in the environment, including perfluoroalkyl substances. The NH PHL has validated a method for the analysis of 12 PFAS (6 perfluorocarboxylates, 3 perfluorosulfonates, and 3 perfluorosulfonamides) in serum for this study. The method uses high-performance liquid chromatography – tandem mass spectrometry (LC-MS/MS) and sample preparation is simple, rapid, and semi-automated. A 96 well plate utilizing protein precipitation and phospholipid removal is able to quickly prepare large batches of samples for analysis. In addition, an on-line solid phase extraction (SPE) method with reusable SPE cartridges has been developed to supplement sample preparation capacity. The method validation demonstrated accuracy, precision, and linearity from 0.1 – 50 ng/mL over twenty independent analytical runs. Matrix-matched quality control materials were prepared in-house and characterized during the validation. NIST standard reference materials (SRM 1957 and 1958) were also analyzed throughout the validation to verify method accuracy. The method requires only a small sample volume (50 µL) and is highly sensitive, with limits of detection ranging from 0.03 to 0.09 ng/mL, making it suitable for large-scale biomonitoring studies. An important goal of the statewide surveillance study is to improve the health and wellness of New Hampshire's citizens with robust PFAS exposure data.

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Serum Concentration of Polychlorinated Biphenyls (PCBs) in New Jersey Residence

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Polychlorinated biphenyls (PCBs) are persistent pollutants and detectable amounts are constantly found in blood of most populations that have been examined. As part of efforts of New Jersey Department of Health State Biomonitoring program, forty ortho-substituted PCBs are measured in 300 serum samples

collected from New Jersey residence using high-resolution gas chromatography/isotope-dilution high-resolution mass spectrometry (HRGC/ID-HRMS). The objectives of this study are to characterize the concentration level and pattern of PCBs in New Jersey residence by age, gender and ethnicity and identify major exposure factors. Based on the completed analysis of 150 samples so far, the median concentration of the sum of 40 PCB congeners (SPCBs) was 110 ng/g lipid, with a 90th percentile of 255 ng/g lipid, minimum of 13 ng/g lipid, and maximum of 819 ng/g lipid. As the sample analysis continue going, the reported numbers will be subject to change later. With the completion of more samples in the subsequent months, we will compare the SPCB concentrations in New Jersey Residence to the NHANES 2003-2004 results stratified on age and race. In addition, the relative contribution of individual congeners to SPCBs will be examined and their variation among different age and race group will be elucidated. Furthermore, factor analysis modeling will be applied to identify the co-varying congener patterns to reveal the contributing exposure factors for the observed variation of measured PCB congeners in collected samples.

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Public Health Laboratory Internship & Employee Engagement - What the Student Leaves Behind
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Overview - The value of a public health laboratory internship program is demonstrated through the benefits derived by students, the laboratory and the Department. In tangible terms, this can be measured as return on investment (ROI) of financial input versus outcome. Though, the intangible side of the transaction is where true value can be articulated and appreciated, if not always readily measured. PHEL is presenting its internship program and highlighting the value the laboratory derives through the internship by improved employee engagement; by "telling a story" from the viewpoint of a QAO's experience as an intern mentor. In the process of developing the New Jersey PHEL's internship program, four overarching goals were identified: 1. to serve student needs for real world experience, 2. the laboratory's need for visibility, 3. pursuit of operational and scientific "back burner" projects and 4. the employee mentor's need for professional development. All four goals are met in part through each internship to varying extents. This story highlights the impact of an internship on the mentor.
Project – Approached by NJDOH Outreach manager, laboratory personnel were asked to work with college interns to provide exposure to work experiences in a public health environmental laboratory. The initial introduction to QA began with providing the intern a copy of the laboratory's Quality Assurance Manual. Next the intern shadowed analysts performing various analytical methods. This exposure to laboratory operations led to interactive discussions between the QA officer and intern on how and why each activity in the QA Manual and test performance relate to regulatory requirements. The first consideration for a project was to create a power point presentation correlating to the eleven chapters of the QA manual. It was later changed to a poster depicting universal QA practices in the laboratory representing the three stages: pre-analytical, analytical and post analytical. New employee in-service training was then added to emphasize the importance of introducing all employees to QA and Safety protocols at the onset of laboratory employment.
Outcome – An educational QA poster entitled "Quality Assurance Yields Quality Data" was created to highlight and bring attention to QA practices and protocols. In addition to the poster and the students newly found knowledge and skills, the mentor gains much from the experience as well. Having to explain

the benefits of QA makes one more familiar and fluent in the description of their craft. It is gratifying to know that the information being passed on will help develop future laboratory personnel. The field of Quality Assurance can be very fulfilling particularly when employee engagement with interns and co-workers provide positive outcomes, lending a greater appreciation of their work. This is "what the student leaves behind".

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Workflow Analysis of the New Jersey Public Health Mycobacteriology Laboratory

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Background: For Mycobacterium tuberculosis (TB) infections, timely identification and rapid detection of drug resistance is critical to ensure proper treatment and infection control measures. Culture is still required for the gold-standard of TB identification, and as a slow-growing organism cultures need to be monitored for up to 6 weeks. Additionally, repeated specimens need to be tested over a period of days or weeks for monitoring of disease progression. With multiple specimens needing to be monitored for such a prolonged time, efficient management of laboratory processes to streamline testing is essential for the timely and accurate identification of TB.
Objectives: A workflow analysis of the Mycobacteriology lab in the NJ Public Health and Environmental Laboratory (PHEL) was undertaken to increase timeliness of reporting and decrease testing burden on staff.
Methods: A process map of all TB lab workflow was drawn to diagram and clarify the algorithm by which specimens are processed, identified and reported. This process map was used to identify key gaps in current practices and areas that could be improved. Key indicators, such as turnaround time data, was retrospectively queried to identify areas that were not meeting our benchmark goals.
Results: Four key areas were identified that hold the potential for improvement: Initial identification of specimens, antimycobacterial susceptibility testing (AST), recording and reporting of results, and media contamination. In order to improve these key areas, between three and five actionable recommendations were made for each. Key indicators were assigned to monitor each of these metrics quantitatively, including monitoring of turnaround time for individual steps in the process map, overall turnaround times, rates of reporting error, and contamination rates. As individual changes are implemented on an ongoing basis, continued monitoring of these indicators will be compared to baseline to see which changes are useful in improving laboratory processes and efficiency.

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A Community Biomonitoring Study to Assess PFASs Body Burdens from PFNA-Contaminated Drinking Water in New Jersey

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In 2012, elevated perfluorononanoic acid (PFNA), a man-made chemical composed of per- and poly-fluoroalkyl substances (PFASs), was detected in public water systems and private wells in Paulsboro and West Deptford communities in New Jersey (NJ). PFNA is very stable in the environment and can be bioaccumulated in the human body once absorbed through ingestion. Beginning in 2014, interventions were intermittently carried out by the NJ Department of Environmental Protection (NJDEP) in these communities, and granular activated charcoal (GAC) filters were installed in public water systems and private wells. However, the communities expressed serious concerns about their exposure to PFNA and effectiveness of interventions. To respond to these concerns, the Public Health and Environmental Laboratories (PHEL), New Jersey Department of Health (NJDOH), partnered with Environmental and Occupational Health and Sciences Institute (EOHSI) from Rutgers University and New Jersey Department of Environmental Protection (NJDEP), initiated an exposure study to monitor the change of PFNA in blood serum of local residents after interventions. This study, using a convenience sampling approach, aims to measure PFNA and additional 11 PFASs (listed in CDC Method 6304.04) in serum for three consecutive years, once per year, for a total of 100-200 volunteers, between the ages of 20-74, from the residents who have lived in the affected communities during past three years. Drinking water and house dust are also measured for 14 PFASs listed in EPA water testing method (Method 537) in first year. Questionnaires are administered to collect information on demographics and potential PFNA sources. The subject recruitment was begun in summer of 2017. To date, 85 subjects were recruited and home visits were made, including questionnaire survey, blood draw, and water/dust collection. Among the collected samples, 65 sera, 46 tap waters, and 36 house dust samples were analyzed at PHEL in NJDOH. The results showed serum PFNA ((GM [95% CIs]; 4.10 [3.09-5.44] ng/mL, n=65) were higher than a national average (0.68 [0.61-0.74], n=2168) from the latest National Health and Nutrition Examination Survey (NHANES). For drinking water, all samples were lower than reporting limits (5 ng/L). Some PFASs were detected (>10 ng/g) in house dust. We will complete the first-year recruitment and sample analyses by the summer of 2018, and repeat serum analyses for the same subjects at year 2 and 3. The obtained data will be used to evaluate whether the intervention is effective and to identify significant sources of PFNA exposure. This study will demonstrate a biomonitoring study is a useful tool to assess effectiveness of intervention on community exposure to PFAS-contaminated drinking water. In addition, this study approach will provide a foundation for future researches in other PFAS-affected communities across the US.

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Comparison of ETEST® and Broth Microdilution Methods for Antimicrobial Susceptibility Testing of Shigella sp. Isolates in New York City

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The New York City Department of Health and Mental Hygiene (DOHMH) Public Health Laboratory (PHL) performs antimicrobial susceptibility testing (AST) on all Shigella isolates submitted by clinical laboratories (submission is required by the NYC Health Code). PHL performs antimicrobial susceptibility testing (AST) using ETEST® (bioMeriéux) and forwards a sample of the isolates to the National Antimicrobial Resistance Monitoring System (NARMS) at the Centers for Disease Control and Prevention (CDC) for AST by Sensitire® broth microdilution using dried panels. PHL uses the Clinical & Laboratory Standards Institute (CLSI) guidelines for interpretation, while CDC uses NARMS established breakpoints for susceptibility interpretation (this includes CLSI breakpoints and proposed Epidemiological Cutoff Values (ECV) if no CLSI breakpoint is established). In this study, we evaluated the ETEST® method versus the broth microdilution method to inform the establishment and assessment of clinical breakpoints for Shigella. We analyzed data from 104 Shigella spp. isolates with collection dates of April, 2013 through December, 2016. Antibiotics tested using both methods were azithromycin (AZM), ciprofloxacin (CIP), ampicillin (AMP), and trimethoprim/sulfamethoxazole (SXT). Any ETEST MIC values that fell between standard two-fold dilutions were rounded up to the next two-fold value for data analysis. CLSI breakpoints were used for all drugs except AZM; CLSI epidemiological cutoff values for S. flexneri and S. sonnei were used for AZM, which lacks clinical breakpoints. Resistance rates, error rates, and descriptive statistics for both methods were determined and categorical and essential agreements were calculated by methods described in CLSI M23, 4thed.CIP results had the best categorical agreement (100%) with no errors, while SXT and AMP results did not meet the required acceptability of 90% or higher (82.7% and 87.5%). AZM results had categorical agreements of 89.8% for S. sonnei with 4 major errors, and 100% for S. flexneri with no errors. SXT results had the most major (13) and very major errors (5). AMP results showed eight major errors and one minor error. The highest essential agreement (+/- 1 doubling dilution) results were observed in AZM for S. sonnei (89.8%), CIP (87.5%) for all species, and AZM for S. flexneri (82.8%). Both SXT and AMP results (81.7%) for all Shigella spp. had the lowest essential agreement. Results showed that overall, ETEST® resulted in higher rates of resistance interpretation for several of the antibiotics compared to broth microdilution. Although shigellosis is not routinely treated with an antibiotic regimen, treatment should be considered for persistently symptomatic cases. MIC interpretations, in conjunction with treatment and outcome data representative of all four species of Shigella, will be used to establish clinical breakpoint recommendations.

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Laboratory Testing for HIV on OCME Specimens at the New York City Public Health Laboratory: History and Opportunity

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At the start of the AIDS epidemic in the 1980s, the New York City Department of Health and Mental Hygiene (DOHMH) Public Health Laboratory (PHL) began HIV testing of all cases of suspicious death brought to the NYC Office of the Chief Medical Examiner (OCME) for fear of missing AIDS cases. Currently, the Bureau of HIV/AIDS Prevention and Control (BHIV) maintains NYC's HIV Registry, a population-based registry of all diagnosed cases of AIDS and HIV infection in NYC[1]. The goal of this study was to retrospectively determine the number of cases from OCME that had been previously diagnosed with HIV and therefore were already present within the HIV Registry prior to death, and use this information to inform the future direction of HIV testing of these cases at PHL. Using data retrieved from the PHL laboratory information system, StarLIMS, all reactive and indeterminate results from specimens received from the NYC OCME for HIV testing between October, 2013 and November, 2017 were analyzed. PHL data was matched against the HIV Registry using a deterministic matching algorithm. Descriptive statistics were gathered using Microsoft Excel and PowerPivot. This retrospective analysis included data from October 15, 2013 (the earliest data available in StarLIMS) through November 21, 2017. During this period, PHL conducted 30,529 HIV tests on 19,920 unique specimens received from the NYC OCME. Of these, 1,101 (5.5%) specimens from unique cases were reactive for HIV. Forty-eight (0.24%) specimens from unique cases had indeterminate results. After matching against the HIV Registry, 1,060 (92.25%) cases were found to already be known HIV-positive patients. HIV-positive OCME cases were overwhelmingly male (852 male and 272 female), and had a median age of 53 years at the time of death. Sixty-nine and 21 patients had no record of date of birth or sex at birth, respectively. Fifty-nine (5.13%) patients were diagnosed by post mortem testing performed at PHL (i.e., were not in the HIV Registry at the time of death). Results for 30 patients were unable to be matched to the registry. This was due to a number of reasons including: indeterminate status, lag time between testing and entry into the registry, pediatric exposures, missing lab results and missing name and/or DOB in the PHL dataset. Because so few new HIV cases were found through post-mortem testing, this data strongly suggests that DOHMH testing, outreach, and surveillance is reaching at-risk populations. Future efforts include modifying OCME specimen testing algorithms so PHL staff are able to search the name of the decedent in the HIV Registry prior to testing, reducing unnecessary testing. Overall, this study provided a new lens into New York City's evolving approach to HIV testing and revealed an opportunity for saving precious laboratory resources.

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Arbovirus Molecular Testing at New York City Public Health Laboratory during the Zika Outbreak

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After the first confirmed case of Zika virus (ZIKV) infection in Brazil in May 2015, ZIKV spread rapidly throughout South and Central America. On February 1, 2016, the WHO declared ZIKV a Public Health Emergency of International Concern. Soon after the New York City Public Health Laboratory (NYC PHL) started to receive requests for clinical ZIKV testing. This emergency resulted in NYC PHL rapidly expanding its current arboviral molecular testing of dengue and chikungunya viruses to include ZIKV. Specimens in this report were tested by rRT-PCR for ZIKV at PHL between February 17, 2016 and October 31, 2016. From February 17, 2016 through July 2016, serum specimens were tested by rRT-PCR for ZIKV, dengue virus, and chikungunya virus. Urine specimens were tested only for ZIKV. After July 2016, dengue and chikungunya rRT-PCR testing on outbreak specimens was discontinued, and only ZIKV rRT-PCR was performed. From October 31, 2016, the majority of ZIKV molecular testing was performed using the Hologic Panther system, except for specimens with inadequate volume for the Panther platform which were tested using ZIKV rRT-PCR. In 2016, NYC PHL performed approximately 15,589 arbovirus rRT-PCR tests on 6,176 urine and 6,597 serum specimens from patients suspected to have ZIKV infection and a travel history from a ZIKV affected area. Of the 12,773 specimens tested by ZIKV rRT-PCR, a total of 525 (4.1%) were positive for ZIKV. Among these, 319 (2.5%) were positive in urine only, 72 (0.56%) were positive in serum only and 67 (0.52%) were positive for both urine and serum. These findings are in accordance with published results noting higher ZIKV viral loads and prolonged viral shedding in urine compared to serum. Seventy-two of the 525 positive specimens (13.7%) were from pregnant women, with the largest proportion showing a positive result in the serum specimen only (34/72, 47.2%). We tested 937 specimens on the Panther system. From these specimens, 15 (1.6%) patients were positive. Among these patients, 13 were positive in serum only, and 2 were positive in serum and urine. None were positive in urine only. Twelve of the 13 (92 %) positive serum specimens were from pregnant women. This is consistent with published reports of an increased detection window for ZIKV RNA in the serum of pregnant women. Of the 1,408 serum specimens tested by dengue virus and chikungunya virus rRT-PCR, three were positive for dengue type 1 virus (0.21%) and one was positive for chikungunya virus (0.07%). NYC PHL's rapid response and testing flexibility enabled NYC to better monitor and manage the ZIKV outbreak.

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Zika Virus Antibody Testing using the DiaSorin LIAISON XL Zika Capture IgM Assay

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Zika virus has spread through the Americas and the outbreak has been declared a public health emergency by the WHO. Because of the risk of harm to the fetus, rapid and accurate diagnosis of Zika virus infection is critical. Definitive diagnosis can be made by detection of Zika virus-specific RNA,

however the viremic period is short and may be missed. Serology is a critical diagnostic and commonly includes a screening test for Zika IgM followed by PRNT. This study compared two methods used to screen for Zika IgM: a high-throughput DiaSorin LIAISON XL Zika Capture IgM and the CDC MAC-ELISA using 583 specimens. The CDC MAC-ELISA assay uses a pan-flavivirus antibody, 6b6c-1, and Zika virus E glycoprotein, which likely results in a high level of cross-reactivity with other flaviviruses. The LIAISON XL Zika Capture IgM uses a Zika NS1 peptide antigen that is more specific to Zika virus and less subject to the effects of non-specific binding by antibodies against other related flaviviruses. This first comprehensive analysis provides evidence for reproducible results and improved clinical testing sensitivity. Compared to the CDC MAC-ELISA, the LIAISON XL Zika Capture IgM Assay has a 95.2% negative agreement, a 69.1% positive agreement, and an overall agreement of 78.0%. The 69.1% positive agreement is likely due to differences in testing methodology resulting in non-specific flavivirus IgM cross-reactivity in the CDC MAC-ELISA. About 80% of the discrepant specimens were PRNT positive for Zika and dengue. This difference was further investigated by testing the discrepant specimens with the EuroImmun Zika IgM assay which also uses Zika NS1 protein and PRNT. The overall agreement between the LIAISON XL Zika Capture IgM and the EuroImmun Zika IgM was 97.8% supporting the accuracy of the LIAISON XL Zika Capture IgM assay testing results. All of the specimens with inconclusive results from the CDC MAC-ELISA test had negative results on the LIAISON XL Zika Capture IgM assay, indicating that CDC MAC-ELISA specimens with inconclusive results likely represent true Zika IgM negatives with nonspecific interference causing a non-negative result on the CDC MAC-ELISA. Additionally, our data show that 50 out of 132 total equivocal CDC MAC-ELISA specimens were positive for Zika virus IgM when tested using the LIAISON XL Zika Capture IgM, suggesting an improved clinical testing sensitivity for the LIAISON XL Zika Capture IgM assay, allowing for a definitive result with a decreased turnaround time. Finally, the LIAISON XL Zika Capture IgM Assay has a Zika IgM intra-run precision of 2.4% of 66578.9 RLU and an inter-run precision of 4.1% of 66117.2 RLU. The LIAISON XL Zika Capture IgM will be a useful tool for laboratories to differentiate Zika virus infections from infections with other flaviviruses and will enable more rapid serological testing of potential Zika virus infected patients.

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Routine Utilization of CIDT, FilmArray Gastrointestinal Panel, with Simultaneous Stool Culture Leads to Increased Isolate Recovery

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The wide acceptance and adaptation of culture-independent diagnostic tests (CIDT) for enteric pathogens, while providing many improvements for clinicians, has introduced challenges to public health laboratories directly related to recovery of isolates. For enteric pathogens like Salmonella, culture-based strain characterization has been the gold standard for decades, and outbreak investigations rely on either pulse-field gel electrophoresis (PFGE) and/or whole genome sequence (WGS) analysis, both of which require an isolated organism. However, very little data exists to examine the impact that CIDT has had on isolate recovery in clinical laboratories. In our clinical laboratory, which maintains stool culture in conjunction with the FilmArray Gastrointestinal (GI) Panel, we have seen an increase in isolate recovery when using the FilmArray as a screening test. We performed a retrospective

analysis from 2016-2017 of all specimens for which pathogen DNA was detected by the FilmArray GI Panel, and found that, of the 22 targets included in the panel, we detected 18 (not detected were Rotavirus A, Sapovirus, Entamoeba histolytica, and Giardia lamblia). Ninety-six patient specimens were included in the analysis, age ranged from 1 month to 103 years, with an average collection to receipt time of 2 hours 46 minutes. Of the 13 bacterial targets included in the panel, 5 are Escherichia coli species, which are difficult to differentiate in culture, and were not included in the analysis. Of the remaining 8 targets, Campylobacter, Salmonella, and Shigella were recovered in greater than 10 specimens each and considered for further analysis. The time to recover and identify the pathogen was determined with each correlating FilmArray result. The average time from culture-based identification was 65 hrs 25 mins, 58 hrs 39 mins, 83 hrs 58 mins, respectively, all of which exceeded the standard 48 hour incubation for stool cultures. Prior to the implementation of the CIDT, these stool culture plates would have been discarded before the pathogen was recognized. From the detection and later isolation of these three organisms, our results also indicate that 28 isolates would have been missed and not submitted to the NYC Public Health Laboratory for PulseNet analysis and 34 isolates wound not have been included in the DOHMH NYC Molecular Typing surveillance project. We have found that when used in combination with culture, CIDT methods lead to increased sensitivity of culture. Prior knowledge of the pathogen result in increased efforts by technologists to recover the organism, including longer hold times or specialized growth conditions. Increased recovery of isolates, in turn, leads to the improvement of public health surveillance.

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New York City Public Health Laboratory Ordering and Reporting Portal

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The New York City Department of Health (DOHMH) Public Health Laboratory (PHL) receives more than 200,000 specimens annually from hospitals, private practitioners, law enforcement, and other organizations for clinical, environmental, and bioterrorism testing. Submitters are required to complete and attach a paper requisition specifying patient, submitter, and test request information, with the specimen. Once the specimen arrives, laboratory staff must manually input the data into the laboratory information and management system (LIMS). Many specimens come to PHL with incomplete or incorrect paper requisitions. These problematic specimens require personnel time and constant communication with submitters to complete the data entry into the LIMS system. Ongoing issues with paper requisitions motivated DOHMH to develop a system that can decrease problematic cases and increase the efficiency of test ordering and reporting. In February 2016, PHL received more than 4,000 specimens for Zika testing. Due to the high specimen volume, many with problem requisitions, the IT team at DOHMH quickly developed a web-based application which allowed NYC DOHMH Zika Testing Call Center staff to submit Zika test orders electronically in a system interfaced with the PHL LIMS. This significantly reduced workload for data entry staff at PHL. It also reduced tedious back and forth communication between submitters and data entry staff to correct or complete requisitions. From June 2016 to January 2018, PHL has received 16,308 Zika test orders through this application. This success motivated PHL and IT teams to enhance the application to include all other PHL tests and to allow all NYC healthcare providers the ability to order tests and retrieve reports through the system. The

application, named eOrder, makes it easier for both PHL and submitters to order PHL performed laboratory tests. The team had to provide all submitters, including clinical labs, private providers, and others, access to the application while maintaining security. In addition, the system needed to be flexible, not too complicated for users, and readily accessible 24/7. Using different approaches including retrospective data analysis, the team was able to create a system that has been flexible yet straightforward and well received. As a result, PHL received fewer problem specimens and was able to allocate fewer staff to resolving these time consuming issues. Submitters are able to retrieve reports as soon as they are released, further reducing calls to PHL. In the future, PHL aims to refine eOrder further and to collaborate with submitters to interface with their own patient and/or laboratory information systems. An easy-to-use and accessible ordering system improves both PHL and submitter's experience. By developing a web-based ordering and reporting system, PHL is able to provide better service to NYC and is better prepared for future outbreaks.

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Impact of Rapid Mycobacterium tuberculosis Complex Identification on Turnaround Time and Drug Resistance Predictions at the New York City Public Health Laboratory

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New York City encounters an above average rate of tuberculosis cases, 6.9 per 100,000 people in 2016[1]; most cases are in foreign born individuals. The NYC Public Health Laboratory (PHL) serves as the primary diagnostic testing laboratory for Health Department Chest Center clinics and tests approximately 5000 primary specimens per year. PHL also performs testing on ~600 referral isolates per year. The development of rapid molecular testing options for the diagnosis of Mycobacterium tuberculosis complex (MTBC) from primary patient specimens has presented an exciting opportunity to decrease diagnostic turnaround time (TAT), which has long been a challenge in the field. In this study, we evaluated the impact of implementing the Cepheid GeneXpert MTB/RIF assay in place of the HAIN GenoType MTBDR Line Probe Assay for molecular detection of MTBC. Molecular testing is routinely performed on smear positive primary specimens only. We retrospectively analyzed results from HAIN Line Probe assays performed in 2016. This set included data from 315 specimens from 290 patients, of which 110 were positive for MTBC by the HAIN Line Probe assay. One advantage of the HAIN Line Probe Assay is its ability to detect mutations associated with resistance to both rifampin (RIF) and isoniazid (INH). In contrast, the Xpert MTB/RIF assay detects mutations only associated with RIF resistance. Therefore, we analyzed the 110 MTBC positive specimens to determine the percentage of INH mono-resistance detected by the Hain Line Probe Assay and found that for one year of testing, only 5 patients (4.5%) had INH mono-resistance which would have been missed by the Xpert MTB/RIF Assay. We also evaluated the impact of switching assays on TAT for reporting molecular results. The HAIN Line Probe Assay required 7 hours of personnel time, which was typically completed the day after reporting a positive microscopy result. Implementation of the Xpert MTB/RIF Assay would decrease personnel time from 7 hours to <1 hour, affording the opportunity for molecular testing to be completed on the same day as microscopy. This would allow for the release of a preliminary report a full working day earlier than the current algorithm allows. We determined that by performing an IQCP we would be able to meet regulatory requirements and discontinue the practice of performing daily quality control. This allowed the change of testing assays to have a minimal impact on cost despite the difference in cost

between the two test kits. Our analysis demonstrates that implementation of a new molecular testing stratagem can result in minimal impact on drug resistance predictions, reduce TAT for results reporting, while maintaining overall testing costs and providing a viable solution for the future of MTBC molecular diagnostic testing in New York City.

1. New York City Department of Health and Mental Hygiene. Bureau of Tuberculosis Control Annual Summary, 2016.

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An Assessment of Serum for Six Perfluoroalkyl Substances from a Small Human Population

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Six perfluoroalkyl substances (PFAS) used by the U.S. EPA to assess drinking water under the Third Unregulated Contaminant Monitoring Rule (UCMR3) were tested in 151 randomly selected de-identified serum samples. PFASs are a group of chemicals used in a variety of industries and consumer products. As a result of their use, these persistent chemicals can be found in drinking water. The six PFAS contaminants tested in drinking water by the U.S. EPA under UCMR3 include perfluorobutanesulfonic acid (PFBS), perfluoroheptanoic acid (PFHpA), perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), perfluorooctanoic acid (PFOA), and perfluorooctancsulfonic acid (PFOS). The serum samples selected for testing had unknown exposures to these six PFASs. Sixty-four (64) of the samples tested were from females and 87 from males. The samples were from individuals ranging in age from 1 to 90 years (average = 40.7 ± 20.7 years; median = 41.5 years) and were submitted from 24 different U.S. states. The quantitative assay used to test for the six PFASs in these serum specimens consisted of HPLC separation with negative-ion electrospray tandem mass spectrometry (LC-MS/MS). The samples were prepared for analysis by adding analyte specific 13Carbon isotopes as internal standards with subsequent protein precipitation. The analytical measurement ranges (AMR) were 0.05 to 10 ng/mL for PFBS, PFHpA, PFHxS, and PFNA; and 0.5 to 100 ng/mL for PFOA and PFOS. This population of specimens (n=151) with unknown exposures to these substances showed the following respective median and 97.5th percentile values as measured for the linear components of PFBS (<0.05, 0.06 ng/mL); PFHpA (<0.05, 0.47 ng/mL); PFHxS (0.99, 5.75 ng/mL); PFNA (0.42, 1.44 ng/mL); PFOA (1.12, 4.13 ng/mL); and PFOS (1.77, 11.5 ng/mL). The values determined in this investigation were similar to other studies that measured these substances in the general population. This assay can be used in biological monitoring of serum for the six PFASs tested in drinking water under EPA UCMR3.

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Health Concerns Addressed in North Carolina through Public Health Laboratory Practices

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In the United States, both federal and state government scientists share a responsibility to address public health concerns to preserve the health and safety of their citizens. The Association of Public Health Laboratories (APHL), in collaboration with the Centers for Disease Control and Prevention (CDC), sponsored the Infectious Diseases Laboratory Fellowship (ID) in 2017-2018 to allow scientists to explore public health initiatives related to infectious diseases. Two ID fellows assigned to the North Carolina State Laboratory of Public Health (NCSLPH) worked to fulfill this commitment. Under the supervision of mentors and trained specialists, fellows assisted in the development and implementation of strategies to improve public health laboratory services impacting the health and well-being of North Carolina citizens. Through a collection of workshops, trainings, and applied laboratory techniques, fellows worked to reduce laboratory acquired infections, highlight biosafety and biosecurity, improve laboratory-based arboviral disease surveillance, integrate MALDI-TOF technologies for bacterial identification, and support influenza virus subtyping to enhance laboratory services to lessen the morbidity and mortality of communicable diseases in North Carolina. By utilizing an approach that encouraged the sharing of information and ideas gathered from their personalized fellowship experiences, the fellows acquired the appropriate knowledge and skills needed to better address areas of concern that may arise during careers in public health. The fellows plan to showcase public health issues encountered within the state of North Carolina, as well as problem-solving strategies applied throughout their ID fellowship experiences, to emphasize the way in which a state government addresses public health concerns affecting its citizens.

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Advancing Public Health Laboratory Websites: Northern Plains Consortium - Emerging Leaders Program

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Background: The Northern Plains Consortium (NPC), consisting of Montana, North Dakota, South Dakota Wyoming, and later Idaho, was formed in 2006. The intent was to develop a regional public health laboratory system where collaboration and laboratory system improvement activities could be established across the region. In 2014 a consortium-wide need for succession planning was recognized and our regional Emerging Leaders Program (ELP) was born. Cohort 1 of the regional ELP occurred in 2015 and our current ELP, Cohort 2, commenced in 2017. Each state selected an individual to participate in the program that highlighted leadership, communication, behavior style and grant knowledge in a public health setting.
Methods: The participants of each cohort identified and worked on a group project. Cohort 2 chose to advance each of their own state's public health laboratory websites to provide the most user-friendly

access as well as disseminating the most up-to-date and pertinent information to the residents of their states. A review was conducted where the participants compared the websites and created a spreadsheet for identifying the types of changes to be completed. This spreadsheet was shared on an APHL SharePoint site that was accessible to all members. Among the considerations was working towards updating the websites to meet the Americans with Disability Act (ADA) compliance. Also identified was a need to create a common page describing the NPC for each state website. Once a plan was in place, each participant was responsible for updating their respective state's website.
Results: A webpage was created and hosted on Idaho's website to discuss the various aspects of the NPC. Included are a description of the NPC, the consortium's mission, recent publications, and links to each states' websites. In turn, each state has a link to the NPC site on their webpage. In addition, some states updated their websites to meet ADA regulations, using computer programs such as Microsoft Word, Microsoft Power Point and Adobe Pro to conform non-compliant electronic documents. A major goal of the states for ADA compliance is ensuring that the content is available to everyone, including the disabled.
Conclusion: The NPC continues to represent a regional effort to improve PHL systems and increase efficiencies. The activities through the ELP has enabled each state to advance their own state public health websites to increase efficiency and enhance public knowledge of our capabilities. Each PHL is working within its own state to roll out the finalized website updates in 2018. Since technology is ever evolving, each state will continue to monitor and update information as needed.

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Performance Evaluation and Clinical Application of the GeneXpert MTB/RIF Assay in a Local Public Health Laboratory

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Background: 1. The objective of this study was to analyze the performance of the Cepheid GeneXpert® MTB/RIF Assay in comparison to culture results and patient diagnostic and treatment information to establish effective protocols to maximize efficiency of performing a Nucleic Acid Amplification Test (NAAT) for appropriate Tuberculosis (TB) suspects. 2. This research was funded through a grant from the CDC through the Association of Public Health Laboratories (APHL) to evaluate the performance of molecular diagnostic tests for TB and increase evidence-based knowledge regarding the most appropriate use of these assays.
Methods: 1. NAAT was performed on at least one respiratory specimen from each patient, along with conventional culture and broth-based antimicrobial susceptibility testing (AST). 2. Six-hundred seventy specimens from 632 patients were tested. 3. GeneXpert results were compared to culture results and patient diagnostic and treatment information.
Results/Key Findings: 1. Of the 670 specimens evaluated, GeneXpert had an overall sensitivity, specificity, positive and negative predictive values of 82.8%, 97.9%, 80.3% and 98.2%, respectively. The sensitivity was higher (97.7 %) in acid fast bacilli (AFB) smear positive specimens. 2. GeneXpert had better correlation (sensitivity) (85.7%) with culture results if Mycobacterium tuberculosis complex (MTB) detected in any culture from that patient was considered. 3. For the detection of Rifampin (RIF) resistance, the GeneXpert had sensitivity, specificity, positive and negative predictive values of 100%. 4.

The average TAT for GeneXpert to detect MTB and RIF-resistance was 2 days. 5. The average TAT by culture was 22 days for identification of MTB, and an additional 15 days for RIF-resistance results.
Conclusions: 1. For smear-positive specimens, a negative NAAT result yielded a shorter period of patient isolation (average 17 days) than a positive NAAT result (average 63 days). 2. In 19 cases, negative NAAT results were used to remove patients from isolation by the TB control program. 3. There were 103 pulmonary TB cases and 81 contact investigations. Twenty-nine of the 81 contact investigations were initiated based on the NAAT results. 4. Overall, GeneXpert showed good correlation with culture results for detection of MTB and RIF-resistance. Performance was better in specimens with a positive AFB smear.

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P-101

Whole Genome Sequence Analysis of Salmonella Montevideo Isolates from Multiple Outbreaks at a Restaurant between 1997 and 2012
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Background: Multiple outbreaks of Salmonella montevideo associated with a single restaurant located in Orange County, CA occurred from 1997 to 2012. A total of 48 cases were identified, including 30 patrons and 18 staff. Intense environmental investigation in 2012 identified multiple sites at the facility with S. montevideo contamination. Pulsed-field gel electrophoresis (PFGE) was performed on 30 patient and 10 environmental isolates. Eight PFGE patterns with less than four band differences between them were identified.
Methods: OCPHL performed retrospective WGS and bioinformatics analysis on 30 isolates. DNA libraries prepared with the Nextera XT Library Prep Kit PulseNet (Illumina Inc.) and were sequenced on the MiSeq (Illumina Inc.). Bioinformatics analysis was performed using a combination of non-reference and reference based analysis including the lyve-SET pipeline from CDC PulseNet. All analysis was performed using the Google Cloud Platform for less than $10.
Results: The phylogenetic tree from lyve-SET hqSNP analysis identified 4 clades, with none of the isolates differing from any other by more than by 96 single-nucleotide polymorphisms (SNP). One clade contained isolates from 2000, the other three clades were from 2012 isolates. SNP differences between clades ranged from 13 to 68 SNPs.
Conclusions: The three clades from 2012 all contained case, employee, and environmental isolates, demonstrating that the restaurant contained at least three separate strains. The 2000 clade contained isolates which differed from 2012 isolates by as few as 13 SNPs, strongly suggesting that these Salmonella strains were residing in the restaurant and caused outbreaks for over 15 years. Molecular analysis of the case isolates alone may have suggested that the 2012 clades were unrelated, but careful epidemiological investigation clearly tied these clades together through employee and environmental isolates.

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P-102

An International Collaboration to Develop Laboratory Leadership Competencies to Strengthen Laboratory Workforce Development in Support of Global Health Security

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In 2014 the Global Health Security Agenda (GHSA) was launched to accelerate progress towards global health preparedness and to support capacity-building efforts. The GHSA Workforce Development Action Package emphasizes the need for rigorous and sustainable training programs including practical hands-on experience for public health professionals. Currently, laboratory science training programs vary widely across the globe; however, a component consistently absent in these curricula is leadership training. In low- and middle-income countries there are limited stand-alone opportunities for laboratory-specific leadership training. Thus a majority of laboratory managers learn on-the-job through experience and if available, mentorship rather than formal training. Core competencies for laboratory leadership are critically important to improve training opportunities by informing curriculum development and guiding professional development. The need for a comprehensive global framework including competency-based and laboratory-specific leadership training and mentorship will allow countries to move forward towards meeting the GHSA workforce development goals. Global consensus and publication of laboratory leadership competencies will encourage standardization of laboratory leadership learning approaches and encourage their use by national and international implementing agencies. To this end the Association of Public Health Laboratories (APHL), the U.S. Centers for Disease Control and Prevention (CDC), the European Centre for Disease Prevention and Control (ECDC), the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (OIE) and the World Health Organization (WHO) have partnered to develop a Laboratory Leadership Competency Framework and training package for a Global Laboratory Leadership Program (GLLP). The goal of this partnership is to ensure a One Health approach to laboratory leadership training and to promote coordination and cooperation between all components of a country's health laboratory system. The Competency Framework provides a comprehensive standardized outline of the knowledge, skills and abilities needed to manage and lead a national laboratory system (or one of its major components) and the training package includes core course materials for inclusion in a curriculum designed for specific country needs. By developing strong laboratory professionals to lead their laboratories or laboratory systems to the next level, this international partnership encompassing all One Health disciplines is committed to support countries' laboratory systems to meet the critical Global Health Security demands.

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P-103

Transition of a Manually-Performed Laboratory-Developed Test (LDT) to the Fully Automated cobas® 6800/8800 Systems Using the cobas® omni Utility Channel

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Introduction: Laboratory-developed tests (LDTs) remain an integral component of patient management within US clinical laboratories, most commonly for infectious disease testing when an FDA-approved IVD option is unavailable. Additionally, LDTs often afford rapid responses to outbreaks and emerging threats, and therefore are important elements of laboratory medicine and public health. Unfortunately, LDTs are often labor intensive and typically require several instruments to complete the testing workflow. As diagnostic testing menus expand and complexity of laboratory workflow increases, the need for LDT automation is unequivocal. The cobas® 6800/8800 Systems are fully automated, sample-to-result platforms for routine or high-volume molecular testing that relies on TaqMan®-based PCR detection. The cobas® omni Utility Channel facilitates the automation of user-defined PCR tests, including sample pipetting from primary/secondary tubes, nucleic acid extraction, reaction setup and amplification, and result reporting. Here, we demonstrate the transition process for converting a labor-intensive manual LDT onto the cobas® 6800/8800 Systems.
Methods: The cobas® omni Optimization kit, which contains the universal cobas® omni master mix reagents, was used for off-board optimization of a LDT following a stepwise process. After optimizing the reaction conditions, assay performance was verified on the cobas® 6800 System; all tests runs incorporated AmpErase as an effective contamination prevention measure, as well as an optional universal internal control. Importantly, the only manual step was pipetting the cobas® omni Utility Channel Master Mix Reagents into a cobas omni Utility Channel reagent cassette, which is loaded onto the cobas® 6800 System alongside clinical specimens.
Results: Use of the cobas® omni Optimization kit facilitated the transition onto the cobas® 6800 System. The stepwise workflow demonstrated the optimization of an established TaqMan®-based Trichomonas vaginalis LDT prior to transitioning onto the cobas® 6800 System using the omni Utility Channel. Evaluation of the amplification curves and Ct values demonstrated that the enzyme included in the Opt kit is compatible with the unmodified primers and probes.
Conclusions: This study demonstrates the transition of a manually-performed LDT to the fully automated cobas® 6800 System. The cobas® omni Utility Channel enables automation of LDT testing by utilizing the same platform, consumables, and reagents as the FDA-approved IVD assays also performed on these systems.

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P-104

Comparison of Water Quality Indicator Methods for Recreational Water in San Diego County

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Background: There are three accepted and widely utilized EPA approved bacterial water quality methods to monitor recreational beach water quality. These methods include multiple tube fermentation (MTF), membrane filtration (MF), and the defined-substrate method. Each method has

benefits and drawbacks. The purpose of this study is to identify the best water quality analysis method for the San Diego County shoreline based on quality, cost effectiveness, and timeliness. Objective: San Diego County has an abundance of natural bathing beaches and ocean coastline to enjoy. In order to assure the public's health, the Department of Environmental Health (DEH) and Public Health Services set standards for bacterial contamination and engage in sampling, testing and reporting to the public the ongoing status of area beaches. The 1997 Beach Water Act (CA AB411) established the requirement for jurisdictions to monitor the quantity of the indicator bacteria known as total coliforms, fecal coliforms and enterococci. In 2004, the Federal Beach Water Act was passed, which required the monitoring of two bacterial indicators: Escherichia coli and enterococci. MTF is the current coliform method being used to assess water quality of San Diego County beaches and will be the benchmark against which the other methods are compared. MTF is labor-intensive and takes a long time to yield results. The San Diego Public Health Laboratory (SDPHL) hypothesized that equivalent results could be obtained in a shorter time frame with other methods.
Method: More than 2,000 samples from approximately 48 locations are to be collected and analyzed between April 2017 and April 2018. The EPA Site-Specific Alternative Recreational Criteria Technical Support Materials for Alternative Indicators and Methods will be used, along with the recommended index of agreement (IA) statistical calculation, to assess the agreement among methods and determine which methods can be used for each beach location.
Results: Method comparison results will be available at the conclusion of the study in April 2018. SDPHL will show the IA for paired samples that meet the detection criteria for each collection site. The study will demonstrate which method provides the best data based on accuracy, time to report and expense for each site.

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P-105

Next Generation Sequencing of the Hepatitis A Virus Outbreak in San Diego County

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In San Diego County, California, a Hepatitis A Virus (HAV) outbreak developed, with the first case identified in November of 2016 and affecting over 575 people since then. Unlike other HAV outbreaks, the nature and size of this particular outbreak was unique as it has circulated in the homeless and illicit drug user population. The County of San Diego declared a local public health emergency from September 1, 2017 to January 23, 2018. The declaration significantly increased the involvement of the San Diego Public Health Laboratory (SDPHL) for diagnostic testing. Collaborating with public health partners, such as the California Department of Public Health Viral and Rickettsial Disease Laboratory (VRDL) and the Centers for Disease Control and Prevention (CDC), allowed SDPHL to implement both PCR screening and sequencing to increase the testing capacity, improve detection, and focus on prevention efforts for HAV in San Diego County. SDPHL created a testing workflow that first screens suspect patient specimens with a laboratory developed TaqMan assay to determine if the HAV RNA is present. If detected, the virus is sequenced using Sanger sequencing of the VP1/P2B region of the HAV genome, which demonstrates high sequence variability compared to other regions in the genome. Genotyping and cluster identification showed that the outbreak was caused by HAV genotype IB, with the majority in one main cluster and 16 other additional sub-clusters identified. Sequencing the VP1/2PB region has been performed on all specimens during the outbreak by either VRDL or the CDC using

Sanger sequencing technology. SDPHL will use the GHOST next generation sequencing (NGS) protocol and compare the NGS data to the Sanger sequence data to determine if there is a better picture of the transmission in the community during the outbreak.

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P-106

Molecular Epidemiology of Rabies Virus in New Mexico: Identification of Novel Variants and Their Associated Hosts

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Rabies is a fatal viral disease enzootic to the United States, with serious public health implications. Currently, different rabies virus (RABV) variants circulate in New Mexico, associated with different mammalian species. Recent and historic evidence suggest that RABV is capable of jumping from one host to another and can successfully establish emerging enzootics in novel reservoir hosts. We present results from sequencing of nucleoprotein genes from RABV positive samples, along with cytochrome oxidase sequencing to identify host species. We have sequenced many of the host species submitted for RABV testing in New Mexico over the past 10 years, and have identified 11 different bat species, 2 different skunk species, and 27 unique species total among the animals tested for RABV. Eight unique strains of RABV were identified in the state over the past ten years, with Arizona gray fox and south-central skunk as the most commonly identified strains. Phylogenetic analysis of RABV variants is combined with geographic distribution of both host species and RABV variants from New Mexico and surrounding states, to better understand RABV circulation and emergence of new RABV variants. Understanding how these events occur can lead to better rabies control and prevention of human exposure.

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P-107

Single-Injection Screening of 664 Forensic Toxicology Compounds using an Innovative Benchtop High Resolution Mass Spectrometer

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Quadrupole Time-of-flight mass spectrometry (QTOF-MS) provides high-resolution, accurate-mass data for full-scan information of both precursor ion and all product ions. This is an ideal approach for forensic toxicology screening where unknown compounds in complex biological samples must be identified from information-rich data sets. Herein, we present a single-injection method for screening 664 most up-to-date forensic compounds using an innovative benchtop QTOF mass spectrometer. The obtained data provided both structural information and retention times to enhance identification accuracy, especially for structurally similar isomers. Sample preparation procedures for urine and whole blood samples and

library-search settings are described for confident unknown substance identification within an efficient, all-in-one workflow. Urine and whole blood samples were spiked with stock standard mixtures and used to determine the retention time of the 664 compounds. Urine samples were diluted with mobile phase and analyzed; whole blood samples, were extracted by using protein precipitation and centrifugation; supernatant was evaporated and reconstituted in mobile phase for analysis. Analytes were chromatographically separated using a Phenomenex Kinetex phenyl-hexyl column. Mobile Phase was ammonium formate in water and formic acid in methanol, 600 µL/min flow rate. The QTOF-MS was operated in positive electrospray mode with information dependent acquisition MS/MS methods. Samples were evaluated against a list of parameters containing the names, molecular formulas and retention times for all compounds. Compound retention time (RT) was a critical element for accurate identification of each forensic analyte using this screening method, the following RT reproducibility tests were conducted for each compound to evaluate the robustness of the LC condition in this method: (1) reproducibility on 3 separate columns; (2) the inter-day (n=3) reproducibility; (3) the reproducibility in neat versus matrix samples. The reproducibility tests indicated that the RTs generated from the optimized LC conditions are consistent and reproducible. RTs measured on three separated analytical columns all have %CVs of less than 5% for each of the 664 compounds. RT inter-day reproducibility (tested on 80 compounds) resulted in %CVs less than 5% over 3 days. Lastly, RT variability in human whole blood and urine samples (tested on 80 compounds) indicated that the %CV for 3 individual lots is less than 5%. The retention time determined by the optimized LC condition combined with high-resolution mass spectrometry and MS/MS spectra, enabled accurate compound identification across the workflow. Retrospective analysis was also performed on the acquired data sets to screen for new compounds without having to re-inject samples, allowing data sets to be re-processed as new forensic targets were discovered.

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P-108

Quantitative Analysis of Dicamba and Related Acid Herbicides and Metabolites

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With the EPA ruling to continue to allow the application of Dicamba to important agricultural crops, interest in this and related herbicide compounds and their degradation products has increased in the US. Dicamba, 2,4-D, and other herbicides comprise a large portion of the widely applied chemical herbicide compounds. Quantitative determination of these and other related acid herbicides and metabolites to low levels in relevant environmental matrices represents a crucial analytical need in the environmental and agricultural testing spaces. The ability to effectively and reliably perform quantitative analysis in complex extracts of soil and plant tissues by LC-MS/MS without the need for chemical derivatization is demonstrated. A SCIEX QTRAP 6500+ system is employed for its sensitivity and robustness. Isotopically labelled version of a subset of the target analytes are employed as internal standards for achieving the highest quality quantitation data in complex soil and plant extracts. Quantitative method performance and recovery values were investigated and reported. Chromatographic separation of these highly polar, low molecular species was achieved using a Phenomenex Kinetex F5 column. Excellent analyte retention and peak quality is demonstrated using this relatively novel stationary phase. Preliminary sensitivity data for the acid herbicides suite using the

QTRAP 6500+ system demonstrates that achievement of limits of quantitation (LOQs) in the parts per trillion range is possible. Reproducibility and robustness over multiple injections is reported.

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P-109

Microcystins in Drinking Water Utilizing High Resolution Mass Spectrometry

K. Hyland, SCIEX, Redwood City, CA

High resolution-accurate mass (HRAM) mass spectrometric analyses allow environmental screening and quantitation methods to be extremely confident in the identification of residues and contaminants. Quantitative workflows typically involving a targeted list of MRM transitions for acquisition can be expanded to include suspect and nontarget screening, and utilization of both accurate mass and spectral database searching to achieve the most useful information. Paramount to the success of these types of applications is the ability to identify residues in environmental samples, confirm such identification using multiple attributes, and to quantify an identified target. Workflows are presented which demonstrate multiple approaches for using MRMHR to achieve quantitative and qualitative analyses of microcystins in drinking water. Additional workflow showing the parallel application of SWATH data independent MSMS acquisition is also outlined, and the advantages and challenges of these approaches are directly compared. The capacity to achieve high resolution mass spectral data for environmental screening, monitoring, and measurement of trace level organic contaminants combined with seamless data processing for multiple workflows on a single platform is presented as an advantage to the environmental analyst interested in multiple facets of sample analysis.

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P-110

Using Process Mapping to Actively Improve Laboratory Processing in TB Contact Investigations

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The South Carolina Public Health Laboratory (PHL) validated and implemented the quanitFERON-TB Gold (QFT) test to be utilized in TB contact investigations in place of the TB skin test in July of 2015. The QFT test offers advantages over the TB skin test including removing the need for a return visit to have the test results read, reducing the patient contact time and removes the risk of losing a patient to follow-up for the reading of the TB skin test. The performance of QFT test requires three tubes of blood to be drawn in specialized tubes with strict requirements for sample volume. The three tubes need to be grouped and sample volumes checked before testing can be performed. Patient identifiers need to be placed correctly on the tubes to not block the fill line. In a large contact investigation this can be time consuming and the need to recollect due to incorrect sample volume can potentially lead to delayed results. In the spring of 2017 a large school contact investigation was being planned, and the PHL wanted to ensure rapid sample turnaround time. To do this the PHL process mapped the steps involved in the testing of a large amount of samples in order to identify steps in the process that could lead to more streamlined testing. The PHL identified three areas that if improved would save time and allow for streamlined processing of samples. They were: ensuring samples arrived at the laboratory drawn

correctly, sample labeling and matching of the three tubes for each patient. In order to manage all three of these processes the PHL sent a laboratory technologist into the field to monitor collection volumes, organize samples, and perform sample accessioning as samples were drawn. This poster will highlight the benefits of this approach to handling TB contact investigations and next steps to continuous process improvement.

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P-111

Validation of Instrumentation and Methodologies for CLIA Certified Laboratories

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Public health and clinical diagnostic laboratories are responsible for providing detailed and accurate testing results to healthcare providers to screen and diagnose patients. Current and emerging technologies are implemented in public health laboratories to serve the community testing needs. The breadth of testing in a public health laboratory is across multiple disciplines. For example, congenital disorders and metabolic conditions screening, infectious disease testing, foodborne pathogens and contaminants, among other biomonitoring testing activities. This poster abstract will focus on the Clinical Laboratory Improvement Amendments (CLIA) requirements for clinical screening and diagnostic tests. While the CLIA regulations require four elements of validation for FDA approved tests to be verified, there are often different approaches to meet the requirements. For non-FDA approved tests, there are additional requirements for limit of detection, interferences and sample stability for example. To this end, at the South Carolina DHEC Public Health Laboratory, we have established a validation protocol to guide method validations. In this poster, we will outline the key requirements and provide examples of how to meet the requirements. The backbone of our validation protocol is to establish a validation plan. Many times, a plan is already developed in the mind of the laboratory supervisor. By documenting the elements of the validation testing, it allows for a complete validation to be performed without having to "start over". The key elements to address are 1. Accuracy, 2. Precision, 3. Reportable Range, 4. Reference Range/Interval, 5. Sensitivity, and 6. Specificity. The overall process may be more streamlined by having a concise validation plan agreed upon by the laboratory director, division director, QA office, laboratory supervisor and testing personnel. Establishing the validation plan up front allows for the validation studies to be conducted more efficiently in terms of instrumentation, time, assay reagents, and personnel resources. In addition, we have revised our validation summary format to be more prescriptive and descriptive of the validation study. The standard operating procedure and competency assessment are elements we capture on a validation checklist. A final validation checklist helps to ensure all items have been completed and documented prior to patient testing. Our going forward approach is training of the updated validation SOP. We will integrate feedback from our staff on the validation process in continuous quality improvement. As we move forward, we will evaluate the efficiency and robustness of the process.

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P-112

Method Evaluation and Qualification for an ABSciex 5500 Triple Quadrupole Mass Spectrometer

J. LaPalme, Y. Wang, O. Adair and R. Dixon, South Carolina Public Health Laboratory, Columbia, SC

The timely and accurate testing for exposure to toxic substances is a critical component of the Public Health Laboratory's mission. The Centers for Disease Control and Prevention Laboratory Response Network for Chemical Threats (LRN-C) leadws the effort in ensuring emergency response capabilities. In this poster we will highlight the method performance of an organophosphate nerve agent metabolites in urine assay by ultra-performance liquid chromatography tandem mass spectrometry (LC-MS/MS).Due to South Carolina DHEC Public Health Laboratory's chemistry division instrumentation reaching the end of its life cycle and vendor support, the previous ABSciex 4000 triple quadrupole mass spectrometers were updated to the SCIEX 5500 model with support from the LRN-C program. In order to maintain testing capabilities, the analytical methods were transferred and rigorously evaluated with a thorough CLIA validation protocol.The LC-MS/MS assay for organophosphate nerve agent metabolites in urine was one of the first methods to be transferred from the ABSciex 4000 MS/MS to the SCIEX 5500 MS/MS. The analytical Chemistry Supervisor and the Chemistry Division Director agreed upon the method validation protocol to be implemented. The following method characteristics were examined: accuracy, precision, method comparison, reportable range, analytical sensitivity, analytical specificity, carryover, matrix effects and reference range. Acceptance criteria were established to ensure method robustness and accuracy. The validation study was carried out over a three week period. Six different laboratory chemists participated in the performance evaluation producing 20 calibration curves. There are 8 calibration levels plus 4 quality control levels including a matrix blank. Analytical accuracy was determined by comparing the calculated mean value with the true target value. Precision was determined by calculating the percent coefficient of variation (%CV) of the quality control sample measurements at three different levels across the analytical measurement range. Both intra-day and inter-day precision demonstrated less than 6.25 %CV. Method comparison involved previously assayed samples for each analyte. The data was plotted by analyte for each regression analysis. Matrix effects were evaluated using three concentration levels across 4 amounts of sample matrix. The reference range was evaluated using 20 genuine blinded human urine samples. This multi-analyte assay validation met the acceptance criteria established, enabling the laboratory to continue providing accurate testing to the community of South Carolina. Laboratories need to continually update assays, instrumentation and processes. In order to successfully transition between techniques, method evaluation allows for staff training and performance validation in a compliant fashion to ensure high quality test reporting.

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P-113

Method Validation for Testing of Trichomonas from Urine Samples

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Introduction: South Carolina regional public health laboratories use wet mount microscopy, which is simple, rapid, and inexpensive. However, this technique is less sensitive than the Nucleic Acid Amplification Testing (NAAT) technique. South Carolina Department of Health and Environmental

Control (DHEC) Public Health Laboratory intends to include the Trichomonas vaginalis assay by sharing urine specimens with GC/CT testing. This abstract highlights our validation study using the Aptima Trichomonas vaginalis (ATV) assay data for the detection of Trichomonas vaginalis in multiple specimen types including male urines in compliance with CLIA regulations.
Method: A total of eighty male urine samples were used in conducting studies for determining precision, specificity, and accuracy using two different GEN-PROBE Tigris instruments. Additional study samples included Aptima panels and previously tested samples, provided by the Alabama Public Health Laboratory. The clinical specificity, sensitivity, and accuracy was evaluated using those eighty male urine samples. Interfering substances may influence the detection of Trichomonas vaginalis from the Aptima Trichomonas vaginalis (ATV) assay. To verify this, a total of seven interfering substances, including acetaminophen, ibuprofen, spermicide, Astroglide, Vagisil, KY liquid, and Lotrimin were used in this validation according to manufacturer guidance. The interfering substance(s) was spiked into unique sample(s) and panels to ensure robust assay performance for patient testing. Preliminary
Result: Reproducibility and Intra-run reproducibility were 100%. The invalid rate was 0.625% which was calculated by the total number of invalid results divided by the total number of results. The acceptance criteria for the invalid results was less than 5%. Clinical specificity and sensitivity from the Tigris 1942 was 92.5% and 100% and from the Tigris 1944 are 90.0% and 100%, respectively. The positive agreement between the Tigris 1942 and the Tigris 1944 was 100%. The correlation between the two instruments was 97.5 %.The results of the interference study resulted in no observed effect of spiking 5% of an interfering substance into the control sample(s) and negative urine specimens. All sixteen controls A and B achieved the expected result and no false positive for Trichomonas vaginalis was identified from the archived negative urine samples. It was demonstrated that spiking 5% (V/V) of interfering substance did not result in changing the result of ATV assay. The interference effect was calculated by the number of discrepant results from the control samples divided by the total number of control samples.
Novel Aspect: South Carolina DHEC PHL has validated and will offer an expanded test menu for NAAT based sexually transmitted infections consisting of Chlamydia, Gonorrhea and Trichomonas, including male urine samples.

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P-114

Using Podcasts to tell Public Health Stories

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As a part of the Emerging Leaders Program (ELP), Cohort 10 is producing a series of podcasts as a method of communicating the importance of the work done in Public Health Laboratories. ELP, sponsored by the Association of Public Health Laboratories (APHL) National Center for Public Health Laboratory Leadership, is a 12-month leadership development program designed to strengthen the leadership capabilities of mid-level laboratory professionals. Cohort 10, one of the largest thus far, is comprised of 16 professionals from Public Health and Agricultural Laboratories from across the United States and Canada with a broad range of technical and managerial expertise. The process used to develop the idea of using podcasts to tell Public Health Laboratory stories was an exercise in team-building. Over several weeks, the cohort progressed from a brainstorming session which produced over

100 ideas on the most relevant topics in public health to a consensus of 3 topics for presentation by podcasts. Each podcast intends to tell Public Health Laboratory stories, but each podcast presents different aspects viewed from very different lenses. Buy-in was assured by exploring all expressed opinions and allowing Cohort members to volunteer to work on the podcast that most closely aligned with their passions. As subgroups worked on the 3 podcasts, the Cohort as a whole reviewed the progress of each podcast to ensure the series continued to align with the original goals of the project. Studies have shown that people listening to podcasts has tripled over the last ten years, regardless of age and education. People today multi-task and podcasts are a great way to educate the public in a passive way while they continue to do other activities. As part of this project, the Cohort also identified the resources needed to produce the podcasts. The Cohort created and utilized a project plan to define the purpose, deliverables, in scope/out of scope items, risks/challenges, resources/estimated cost, and assumptions. In this project, the major challenges were managing resources such as time, cost and technical expertise. The challenges of securing and operating equipment/software for recording, editing and tracking views were minimized due to support from APHL. The 3 episodes in the podcast series are:- Public Health Labs in Everyday Life - shares how countless aspects of an individual's daily life connects back to Public Health Laboratories;- A World without Public Health Laboratories – scenarios of what would happen with/without Public Health Laboratories;- Careers in Public Health Laboratories – highlights a broad range and diversity of Public Health Laboratory careers with personal stories of the paths taken. This poster covers the experience of ELP Cohort 10 in the planning, creating, and distribution/marketing of 3 podcasts as a way of communicating important aspects of Public Health Laboratories.

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Reducing Time to Treatment by Tracking Specimens
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Specimens that are transported to the laboratory by courier occasionally get delayed or lost. This delays testing, diagnosis and treatment, not to mention the inconvenience and possible pain and anxiety for a patient – as well as cost to the medical system – if a replacement specimen must be collected. The ability to track samples from the time they are collected through transport, delivery and storage produces a complete audit trail for a public health program. It alerts the laboratory and submitters of delays so that action, such as locating the specimen or recollecting, can be taken sooner. It documents the performance of submitters for greater transparency, accountability and the identification of improvement measures. Documenting that specimens were received at the lab meets submitter regulatory requirements. The laboratory gets a global view of all specimens that are in transit to the lab; this allows lab staff to anticipate workloads and capture performance metrics. In addition, tracking storage assists laboratories to retrieve specimens. Finally, everyone benefits from smoother audits. Here are two examples where specimen tracking is making an impact: Newborn screening (NBS): Specimens must be tested within 48 hours of collection to identify babies who are at risk of serious disease. Delays in diagnosis and treatment can result in delay in development, lifelong serious disease or premature death. Yet samples do go astray. Track-Kit specimen tracking is used by Newborn Screening Ontario. When fully implemented, Track-Kit will track 150,000 NBS specimens a year, submitted from 200 hospitals and midwives across Ontario and sent by courier to their laboratory in Ottawa, Ontario. Sexual

assault kits (SAK): Many states now have laws specifying that rape kits must be sent to the lab and processed within a certain timeframe; some enforce that survivors must be able to access their testing results. Track-Kit is being implemented in Washington State, Arizona and Michigan to track SAKs from the time they are collected at the hospital, in the custody of law enforcement, and delivered to the DNA lab. Survivors can access the location and status of their SAK and the testing results via a confidential survivor portal. States are able to maintain a global view of all SAKs to meet their legislative and reporting requirements.

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Clinical Laboratory Tests of Public Health Significance: What is Really Necessary?

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One of the core functions of public health laboratories is disease prevention, control and surveillance. Each state laboratory performs mandated disease testing (tests of public health significance) according to their respective state requirements. In Iowa, these are found in the Iowa Administrative Code 641 (Public Health) Chapter 1.18. While no state lab is alike, there are certain core tests offered by all labs. A thorough review of all state laboratory clinical test menus shows a broad range of tests offered. Many are provided due to geographical endemicity of disease within their respective state and are often associated with specific testing or surveillance programs. Over time, state menus added some new tests as recommended by the CDC (Ebola, Zika), but overall many laboratories dropped numerous tests or service testing areas due to funding limitations. Of note, many tests offered by state labs can be performed in most hospital laboratories due to affordable technological advances and requirements. This decreases test volumes which will conversely affect lab testing costs. This trend is expected to continue and will impact all state's abilities to provide appropriate testing per individual state requirements.

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Genomic Similarity of *Legionella pneumophila* Isolated from Routine Monitoring of Hospital Premise Plumbing Systems

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Whole genome sequencing (WGS) was performed on *Legionella pneumophilia* (Lp) strains isolated from routine monitoring of hospital premise plumbing systems in order to better understand strain diversity over time. 46 Lp isolates from various locations in two facilities were analyzed; Facility A predominately isolated Lp serogroup (sg) 1 (sampled 2012-2016) and Facility B had predominately Lp sg 4 (sampled 2013-2016). The selection of Lp isolates to sequence represented different collection dates to determine if a dominant lineage was observed over time and location. wgMLST analysis of Illumina MiSeq Next

Generation Sequence data showed that there were two commonly found sequence type (ST) populations in Facility A. Cluster ST36 is known to be associated with various outbreaks in the U.S. There was a separate cluster of ST1, which is the most common ST among sporadic disease and environmental Lp globally. Resfinder identified a beta-lactam resistance gene, blaOXA-29, in the ST1 genomes. A BLASTn analysis indicated that this sequence is associated with the Paris strain plasmid (pLPP). Facility B isolates belonged to ST378. The international SBT database showed detection of this ST in Canada and Europe but not yet reported in the US. The strain populations from both facilities appeared to be persistent using wgMLST analysis. A SNP-based typing scheme revealed that although these strains were all closely related, some facility locations had sub-clusters that persisted over time. This work better characterizes Legionella species that colonize hospital plumbing systems and may help inform what actions are needed when Legionella is isolated.

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An Alternative to Liquid Handling Robots in Next-Generation Sequencing: Streamlined Semi-Automated DNA Library Preparation Incorporating Electronically Adjustable Tip Spacing Pipettes

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Manual library preparation in next-generation sequencing (NGS) is a time-consuming and labor-intensive process. Commercial automated library preparation platforms are available, but may not be practical for many public health laboratories given the high cost, particularly for a lower throughput laboratory. Additionally, both library preparation and automated liquid handling technologies are rapidly changing, and the instrumentation could become outdated relatively quickly. As an alternative, we developed a semi-automated library preparation protocol utilizing programmable, adjustable manifold pipettes (Integra Voyager II). Compared to automated library preparation this procedure requires very little investment in equipment or validation with existing library preparation kits. Our laboratory uses the Illumina Nextera XT DNA Library Preparation kit for all CDC PulseNet and FDA GenomeTrakr sequencing. The protocol we developed incorporates the Integra Voyager II series of electronically adjustable tip spacing pipettes to automate many of the DNA library preparation steps. At their widest setting these pipettes are capable of transferring DNA extracts from racked microcentrifuge tubes into either narrower PCR strip tubes or 96-well PCR plates. We have created multi-stage programs that incorporate aspiration, dispensing and mixing steps. This allows for automated up-front multiple step DNA dilution starting from DNA extracts in individual tubes and ending with diluted DNA in a 96-well plate that is ready for tagmentation, without the need to change pipettes or tips throughout the dilution steps. We have also created programs that automate mixing reaction components in the tagmentation and PCR stages in the pre-amplification portion of library preparation, as well as automate Agencourt AMPure XP bead mixing, washing and DNA elution in the post-amplification stages of library preparation. This method saves significant technician time and allows for DNA library preparation of 16 isolates, from the initial quantification of DNA extracts through the final elution of the DNA libraries, to be completed in as little as three hours. The automated mixing steps require only a single button press that eliminates physical stress resulting from repeated manual pipetting and mixing. Performing the library preparation in a 96-well plate format using a multichannel pipette reduces the chance of pipetting errors that could result from using a single channel pipette to prepare multiple libraries on the

same plate. Our library preparation protocol provides many benefits over a traditional fully manual library preparation without the high cost of automated library preparation.

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P-119

Implementing a Real-time Method for Aedes aegypti Surveillance for the Tennessee Department of Health

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In the wake of Zika virus spread, state health departments have sought to understand the mosquito distribution and potential presence of the primary Zika virus vector, Aedes aegypti. Historically, Ae. aegypti has been found through the Southeastern United States; however it is unknown whether this geographical distribution is current. The Tennessee Department of Health (TDH) Vector-borne Diseases Program has been actively engaged in determining the presence of Ae. aegypti through statewide mosquito surveillance in collaboration with county and metro health departments. The current methodology requires the identification of field captured adult mosquitoes and the rearing and identification of laid mosquito eggs in oviposition cups collected from the environment. The challenge faced by the TDH Vector-borne disease program is the time required for rearing of mosquito eggs to adulthood and the poor condition of field captured mosquitoes for identification. To overcome these challenges, the TDH Vector-borne Diseases Program is implementing a mosquito rearing and processing protocol combined with a real-time molecular assay to efficiently identify and confirm the potential presence of Ae. aegypti in the state of Tennessee for this upcoming mosquito trapping season. The new protocol will reduce the rearing and identification process from approximately 3 weeks down to only a few days. This would ultimately alleviate the work load of a vector surveillance program and allow personnel to increase the amount of oviposition cups collected from the environment, thus maximizing the coverage of surveillance. Additionally, this real-time method can decrease the time-lapse between capture and identification, allowing health departments to more efficiently direct the control of Ae. aegypti in the environment.

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Laboratory Surveillance of Enterobacteriaceae Isolated from Patients in Tennessee

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Background: Enterobacteriaceae are a common cause of hospital-acquired infections. Laboratory-based surveillance on both a national and local level is critical for monitoring the spread. The objective of this study was to create a state-wide surveillance profile by analyzing the distribution and antimicrobial susceptibility patterns of Enterobacteriaceae throughout Tennessee.

Methods: Isolates were submitted from hospitals and reference laboratories across the state. Antibiotic susceptibility was determined at the TN Department of Health (TDH) Laboratory by Kirby-Bauer disk diffusion. Microbiological data from June to November 2017 were collected from the TDH laboratory information management system and analyzed through WHONET 2017 using current CLSI breakpoints. CRE was defined as an isolate that was resistant to at least one of the carbapenems tested; carbapenemase producing-CRE (CP-CRE) was determined through the modified carbapenem inhibition method (mCIM), followed by resistance mechanism testing using PCR. County of residence was used to determine State regions.
Results: A total of 402 isolates were submitted to the TDH. Enterobacter cloacae, Klebsiella pneumoniae, and Escherichia coli were the three most common species. A moderate majority (39%) of all isolates came from Middle TN. E. cloacae and K. pneumoniae isolates were more commonly resistant to the antibiotics tested compared to E. coli. There were variations in the frequency of resistance across state regions for some of the antibiotics (imipenem resistance was identified in 20%, 58.5% and 80% of K. pneumoniae isolates from West, Middle and East TN, respectively). A total of 203 isolates were confirmed to be CRE. CP-CRE made up 55% of the CRE isolates, with the majority (45%) coming from East Tennessee. CP-CRE were resistant to more antibiotics compared to non-CP-CRE. For carbapenemase producers, resistance to all of the 7 drugs (aztreonam, cefepime, ceftazidime, ceftriaxone, ertapenem, imipenem and meropenem) was identified among E. cloacae (95.6%), K. pneumoniae (90.7%), and E. coli (100%). In contrast, for non-carbapenemase producers, only 15.8% of E. cloacae, 5.6% of K. pneumoniae, and 22% of E. coli were resistant to all 7 drugs.
Conclusion: There were some variations in the distribution and antimicrobial susceptibility of Enterobacteriaceae across the state. Resistance to the drugs above appeared to be strongly associated with carbapenemase production. These findings suggest creating a regional antibiotic profile may be beneficial for surveillance and infection control guidelines.

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The EPA's Water Contaminant Information Tool (WCIT): A Look at Three New Contaminant Profiles; Perfluoroctane sulfonate (PFOS), Perfluorooctanoic acid (PFOA) and Legionella

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In the event of a natural, intentional, or unintentional water contamination incident a quick and effective response is crucial to limiting the impact on water systems and public health. Responding to a contamination event requires accurate information on the nature of the contaminant and how to properly treat it. The Water Contaminant Information Tool (WCIT) is a dynamic and valuable resource designed to provide this information to responders, and address new risks and issues as they arise. WCIT is a secure, online database that contains vital information, such as analytical methods, drinking water and wastewater treatment processes, and medical information, on priority contaminants of concern for drinking water and wastewater systems. As such, this tool facilitates the dissemination of vital information that can be used to help communities prepare for, respond to, and recover from an incident. Here we provide an overview of the tool, highlighting some of its unique features and uses and report recent updates to the database. WCIT is constantly being updated with information on priority contaminants to help utilities and other users respond effectively and efficiently to drinking water and wastewater contamination incidents. The most recent updates to the tool have focused on adding new

profiles on emerging contaminants of the greatest concern. For example, perfluorooctane sulfonate (PFOS) and perfluorooctonanoic acid (PFOA) have gained a lot attention recently due to their persistent nature in the human body and environment and their potential adverse health effects in people. The EPA released a new health advisory in 2016, lowering the recommended levels in drinking water (from 400 ppt for PFOA and 200 ppt for PFOS to 70 ppt combined PFOA and PFOS). Following the release of this updated health advisory, WCIT profiles have been developed for these contaminants and will be discussed here. Additionally, another contaminant that has garnered a lot of attention in recent years and is a major concern for water systems is Legionella pneumophila. Legionella is a bacterium that thrives in warm water and can cause a severe pneumonia-type lung infection that has a high mortality rate (up to 30%), especially in immunocompromised people. To help utilities and responders address this contaminant a WCIT profile was created and is also discussed.

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Increasing Preparedness through Laboratory Full-Scale Exercises

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Drinking water and wastewater systems face a number of challenges when confronting a contamination incident. Whether the contamination happened because of a natural disaster or due to an accidental or intentional release, several key decisions need to be made. These include how best to access the analytical laboratory support that will be necessary to respond to the incident and return the water system to service. The decisions made and actions taken during the response, remediation and recovery processes will depend on the circumstances of each incident. Therefore, responders and water utility personnel can benefit from tools that help utilities practice and update their response plans and decontamination strategies. During a water contamination incident, laboratories and utilities will need to reach out to the appropriate analytical partners to help confirm the identity of the contaminant, characterize the extent of contamination, and verify that cleanup efforts have been successful. The Water Laboratory Alliance (WLA) provides a nationwide network of analytical laboratories that are available to provide water and wastewater utilities with the analytical capabilities and capacity to assist with the response to a contamination incident. Practicing the coordination between the utility and laboratory communities in advance of an incident is important for ensuring an efficient and appropriate response during an emergency. The Water Laboratory Alliance program in EPA's Water Security Division has developed tools and resources to aid the water sector in preparing for and responding to chemical, biological or radiochemical contamination incidents. One such resource is the Analytical Preparedness Full-Scale Exercise (AP-FSE) Toolkit. This toolkit provides water utilities with the necessary information to plan and conduct a laboratory full-scale exercise. The toolkit outlines a step-by step process for how to design, initiate and implement an exercise involving coordination between the water utility and laboratory sectors. The toolkit includes a chemical and a biological scenario, as well as relevant templates and forms for developing the necessary exercise documentation and training, and for collecting evaluations and feedback to assist the implementation of an exercise improvement program. The toolkit has been piloted with five utilities and is scheduled to be released in early 2018.Another useful resource that the Water Laboratory Alliance Team has developed is an interactive resource for Accessing Laboratory Support. This interactive training resource will provide users with information on how to receive analytical support when it is needed. The resource guides users through the available

access routes beginning at the local level, and progressing, based on the scale of the need, to the state and federal levels. Accessing Laboratory Support was published in July 2017.

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A Closer Look at U.S Environmental Protection Agency Facilities

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From the earliest days of public health, environmental protection has been fundamental to preventing disease and ensuring a healthy population. From John Snow and the Broad Street Pump to chlorinated drinking water in Jersey City, NJ, protecting the environment has been a core public health function. The same is true today. While the public health community in the U.S. no longer faces large-scale cholera outbreaks, environmental protection remains crucial to ensuring healthy communities and a clean environment. A critical component of protecting the environment is a strong scientific understanding of the underlying information and technology measuring exposure, assessing impacts, and mitigating risk. U.S. Environmental Protection Agency's (EPA) Office of Research and Development (ORD) provides scientific research and technology that is the foundation of decisions to better protect public health and the environment. ORD focuses on topics such as safe and sustainable water; air, and energy; chemical safety evaluation and risk assessment; homeland security; and sustainable and healthy communities. ORD works closely with groups to identify the most important environmental health challenges facing the nation and discuss how research could be used to address these challenges. ORD is comprised of national laboratories and centers located in 14 facilities across the country. ORD facilities are world-class scientific organizations, providing research used at the local, regional, national and international levels. These facilities play a major role in engaging local communities in science. The poster will present an overview of ORD's technical capabilities by summarizing scientific research and providing examples of capabilities from a sample of six out of the 14 facilities across the country. The six ORD research facilities are briefly described below. • Narragansett, Rhode Island - Focuses on the health of ecosystems located along the Atlantic Coast. • Gulf Breeze, Florida - Focuses on the impact of human-made stressors on public health and the ecosystems of the Gulf Coast. • Research Triangle Park, North Carolina - Focuses on decontamination technology research for homeland security, computational toxicology research, and research on the health effects of air pollution. • Cincinnati, Ohio - Conducts a variety of research to manage chemical risks, clean up hazardous sites and protect water quality. • Duluth, Minnesota - Focuses on predicting and assessing stressors such as pesticides, bacteria, and changes in land use affect human health and the water resources of the Great Lakes and United States. • Ada, OK – Features several unique research capabilities, including laboratories, field equipment, and test wells to perform specialized subsurface investigations on groundwater contaminant transport, and develop and assess technologies for remediating groundwater contamination.

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Laboratory Biosafety and Biosecurity Partners Forum, Looking into the Future

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In May 2015, APHL was awarded a three year, $2.2 million Cooperative Agreement, for Domestic Laboratory Biosafety for Ebola and Other Highly Infectious Diseases, by the US Centers for Disease Control and Prevention (CDC), with one of the many objectives being to facilitate state, local and territorial public health laboratories (PHLs) with outreach efforts to their clinical laboratory partners, with the goal of enhancing biosafety and biosecurity within these facilities. APHL's member PHLs reach out to clinical laboratories via a number of activities such as training courses, information sharing during emergencies, assistance with risk assessments and routine communications. APHL engages diverse stakeholders, including non-governmental organizations and federal agencies that do everything from laboratory testing to accreditation. In 2016, APHL 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 includes over 14 different partners, comprising 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 Laboratory Management Association (CLMA), American Association for Clinical Chemistry (AACC), to name a few. This Forum enables 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. Over the course of the past two years, the Forum has met in person to discuss these clinical outreach issues and have assisted with the development of tools that are freely available on APHL's publicly accessible biosafety and biosecurity website www.aphl.org/biosafety. The website houses resources developed by the Partners Forum such as the Clinical Laboratory Biosafety Risk Management Program Assessment Checklist; a guide for biosafety officers to complete with their clinical laboratory partners and online trainings developed by the partners that can be used by PHLs for outreach programs, as well as directly by the clinical laboratories themselves. Aside from the website, APHL is also developing a new online discussion board, generated by the group to include both PHL biosafety professionals and clinical laboratory staff to share ideas and build on the current APHL Biosafety Community of Practice along with assistance from the Partners Forum; creating a survey to be sent out to the clinical laboratories across the US. to ascertain their level of biosafety and biosecurity programs.

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Gastrointestinal Yersiniosis in Nebraska: A Laboratory and Epidemiological Analysis Following the Introduction of the BioFire FilmArray® Gastrointestinal Panel

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Background: Yersinia enterocolitica (YE), an important but often overlooked food-borne pathogen, can be difficult to detect in stool by routine culture, likely resulting in under reporting. Since the introduction of the BioFire FilmArray Gastrointestinal (GI) panel in 2015 to multiple laboratories in Nebraska, a >4-fold increase in yersiniosis has been reported in the state when compared to prior years, with 16 cases reported in 2015, 47 cases in 2016 and 17 cases in 2017. This study was done to evaluate culture methods for recovery of YE from stools positive by the GI panel and subsequently to evaluate these isolates further using laboratory epidemiological methods for outbreak investigating.
Methods: Stools preserved in maintenance media that had YE detected by the GI panel were either directly cultured to CIN agar plates incubated at room temperature (RT) for up to 5 days or 500 µl placed into sterile PBS (10 ml) and incubated at 4°C (cold enrichment) for up to 2 weeks with incremental subcultures to CIN agar. Isolates detected from these stools were subsequently tested by pulsed-field gel electrophoresis (PFGE) using XbaI restriction enzyme and whole genome sequencing (WGS) (Illumina MiSeq). Cluster analysis of PFGE profiles and WGS single nucleotide polymorphism (SNP) analysis were performed using BioNumerics 7.6.
Results: 26 stools positive by the GI panel were cultured for YE. YE was recovered from 14 stools (53.8%) following RT incubation and a total of 21 stools (80.1%) following cold enrichment. 18 of these isolates were further evaluated using PFGE and WGS. Cluster analysis of PFGE patterns revealed high diversity among isolates; however, four clusters (2-4 isolates in each) of indistinguishable PFGE patterns, were observed. SNP analysis of the WGS of these 20 isolates also demonstrated similar results when compared to the PFGE patterns with most isolates found to be unrelated with >200 SNPs among the isolates. Two of the 4 potential clusters from PFGE had WGS with ~180 SNPs identified between isolates in each cluster, suggesting that the isolates within these two clusters were not outbreak related. However, the isolates within the other 2 clusters showed no SNPs between them, suggesting that the isolates within each cluster were clonal.
Conclusion: This study showed that the addition of the cold enrichment method to routine culture improved recovery of YE. Results also showed the enhanced discriminatory processes of WGS when compared to PFGE for the assessment of YE strains. The enhanced discriminatory power of WGS did show that 2 clusters of yersiniosis may have occurred in 2016 although a majority of the isolates were unrelated. Additional epidemiological studies and further bioinformatic analysis of these YE cases are ongoing.

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Application of Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) Mass Spectrometry for Identification of Campylobacter jejuni in the Public Health Laboratory

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Introduction: Campylobacteriosis is a leading cause of diarrheal illness in the United States, with an estimated 1.3 million infections each year (1). Rapid identification of Campylobacter is critical to both public health outbreak investigation and surveillance as well as clinically, as it guides antimicrobial therapy and resistance testing. Matrix-Assisted Laser Desorption Ionization-Time of Flight (MALDI-TOF) Mass Spectrometry (MS) offers a time and cost-saving alternative to traditional culture methods that use selective media and biochemicals for organism identification. This study describes the verification of the Bruker® MS for the identification of Camplylobacter jejuni and incorporation of MALDI-TOF mass spectrometry into the microbiology workflow in the public health laboratory.
Methods: C. jejuni was included in the Bruker® FDA-cleared (CA system) reference database validation, thus the purpose of this study was to verify the Bruker® MS for species-level organism identification of C. jejuni at the North Carolina State Laboratory of Public Health. Eight patient samples previously identified as C. jejuni via routine methods including Gram stain, microaerophilic culture on selective media, and biochemicals including hippurate were used in the verification. Campylobacter coli was used as a Campylobacter spp. (non-jejuni) control and Escherichia coli was used as a non-Campylobacter control. Isolates were spotted in quadruplicate by two technologists and from two validated media types to assess accuracy and precision of the MS organism identification. All isolates included in this study had species identification confirmed by 16S rRNA gene sequencing (reference method).
Results: Among the isolates tested, 10/10 isolates were in agreement between 16S rRNA gene sequencing and the Bruker® MS to the genus and species level. Among all spots tested on the Bruker® MS, the mean log(score) value was 2.22, correlating with a high confidence identification. We found that isolates were identified with a higher log(score) value when incubated for >36hrs. 16S rRNA gene sequencing identified each isolate to the species level with ≥99% sequence identity. The accuracy of analyzable results was 100% (10/10).
Conclusion: Results from this verification support the use of Bruker® MS in routine testing, as it correctly identified all C. jejuni isolates and was in 100% agreement with the reference method (16S rRNA gene sequencing). MALDI-TOF MS technology provides a rapid and accurate means of organism identification that once integrated in the public health laboratory, can substantially decrease turnaround time, labor, and overall cost.

References: 1. Centers for Disease Control and Prevention. Campylobacter: Information for Health Professionals. https://www.cdc.gov/campylobacter/technical.html

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Genomic Investigation of a Protracted Carbapenem Resistant Enterobacter aerogenes Outbreak in a Cardiac ICU at a Tertiary Care Center in Rochester, New York

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Background: Enterobacter spp. are significant nosocomial pathogens associated with outbreaks in intensive care units (ICUs). Between Jun-Oct 2017, carbapenem-resistant Enterobacter aerogenes (CR-EA) strains were isolated from patients in our cardiac ICU (CICU). Whole genome sequencing (WGS) of CR-EA isolates was undertaken to investigate patient-to-patient transmission, assess phylogeny relative to global strains, and characterize molecular determinants of resistance and virulence.
Methods: 22 CR-EA strains (12 outbreak, 10 other wards) were sequenced (Illumina Miseq) and investigated for phylogenetic relatedness by whole genome multi-locus sequence typing (wgMLST) using Ridom® Seqsphere+ and the CFSAN SNP pipeline. To establish phylogeny with global E. aerogenes strains, 113 publically available sequences were used for comparison using HARVEST genomics suite. Markers for antibiotic resistance and virulence factors were identified using curated databases.
Results: WgMLST and core-SNP analyses revealed every CICU CR-EA isolate to be part of a single clonal cluster, grouping distantly from strains isolated from other wards and previous years. Barring a single 2015 strain, harboring an nmcAR locus, none of the CR-EA strains isolated from our hospital harbored genes encoding carbapenemases. Some CICU strains harbored mutations resulting in premature stop codons in outer membrane porin genes (omp36), likely contributing to the carbapenem resistant phenotype. Virulome analysis revealed the CICU strains to harbor genes encoding yersiniabactin and colibactin systems on the ICEKp10 pathogenicity island.
Conclusions: Carbapenem resistant Enterobacteriaceae are a major public health concern, with rapid spread attributed to the production of mobilizable carbapenemases. Here, we describe a hospital ward outbreak involving a clonal group of E. aerogenes carbapenemase non-producing strains. Virulence and resistance determinants underlying infections by Enterobacter spp. are poorly understood and the latter may involve mechanisms such as porin disruption and/or AmpC cephalosporinase overproduction, which present complex diagnostic and management challenges. Yersiniabactin and colibactin systems have been implicated in the invasiveness of hyper-virulent Klebsiella pneumoniae. Intact clusters of these components in the CICU outbreak strains may indicate a role for these loci in enhanced survival and effective transmission in a subset of E. aerogenes lineages. Prospective WGS presents a powerful resource to complement traditional epidemiology in helping hospitals and public health institutions track transmission events and assess the effectiveness of control measures in real-time.

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Strengthening Clinical and Veterinary Laboratory Systems and Capacity in Cambodia through Mentoring and Training

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Background: In resource-limited countries, poor laboratory quality has been documented to have a negative impact on health care systems. I-TECH with financial support from DTRA implemented a mentored laboratory quality stepwise implementation (LQSI) and training program to strengthen the quality and capacity of infectious disease diagnosis and surveillance in 12 national and provincial clinical laboratories across Cambodia in August 2014 – March 2016. All 12 laboratories established the foundational practices of a quality management system and improved their operations. In September 2017, after an 18- month hiatus, I-TECH resumed the mentoring program to continue implementation of quality management system (QMS) at the 12 previously supported laboratories.
Methods: In collaboration with the Ministry of Health, I-TECH trained select laboratory mentors to be quality auditors. Prior to the start of QMS activities, the auditors conducted baseline assessments of the program laboratories using the SLIPTA checklist from December 2017 – Jan 2018. A national dissemination meeting was held to share the audit results and communicate the national vision and goals for laboratory services and quality.
Findings: Overall, the average audit score was 38%, with scores ranging from 23 % to 65%. The laboratories performed strongest in information management and facilities and maintenance sections where the average scores were 67% and 53% respectively. The weakest performance was registered for corrective actions where the average score was 7%, followed by occurrence management where the average scored was 9%. Half of the laboratories scored 0% in these sections. The average score for management review was 11% followed by evaluations and audits with an average score of 12%. Lessons learned: Evidence from the baseline audits suggest that when the LQSI program stopped in 2016, most of the quality improvement efforts in the laboratories stalled as evidenced by the lack of documented corrective actions, internal audit reports and laboratory meeting minutes in 83% of the laboratories. Regular on-site mentoring allowed staff to learn concepts of quality management; however, building a culture of quality in the early stages of QMS implementation requires continuous support for effective adoption and implementation of proposed recommendations effectively.
Next steps: Results from the assessments will inform strategies that I-TECH mentors use to customize corrective action plans for each laboratory. Mentors will use the LQSI tool to routinely monitor progress for quality improvement initiatives in 12 laboratories. Quarterly dissemination meetings will be held to strengthen accountability and engagement. The laboratories will have follow up assessments in a year.

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P-129

Development of a National Strategic Plan 2017-2020 for the Laboratory System in Côte D'Ivoire

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Strong laboratory system governance requires committed leaders, and clear guidelines and strategic plans to guide national priorities and processes for implementation. Funded by the Center for Disease Control (CDC)-PEPFAR, the International Training and Education center in Health (I-TECH) supported the government of Côte d'Ivoire to develop a current National Strategic Plan for their Laboratory network (NSPL). From November 2016 to November 2018, I-TECH used a rigorous participatory approach to develop the country new NSPL 2017-2020. Throughout the process, I-TECH engaged high-level representatives of the Ministry of Health as well as other key stakeholders who were convened in a series of meetings and workshops over a period of 9 months. During the initial meetings, stakeholders define the mission and visions as well as the priority areas to address in the NSPL. Small technical working groups (TWG) were then formed to define objectives to achieve the strategic goals. During this period a new national laboratory strategic plan was developed and validated over a total of 8 key stakeholders work meetings, consisting of 2 to 5 meetings for each of the 5 TWG and 2 major workshops. Stakeholders achieved consensus on 5 priority goals to improve the laboratory system over a 4-year timeframe. These areas included the legal regulatory and institutional framework, access to quality laboratory services nationwide, quality management systems, information systems, and biosafety and biosecurity. Each TWG defined 4 to 10 objectives that were further elaborated into activities with performance indicators, stakeholders' responsibilities, and implementation timelines. All relevant activities were budgeted and an operation plan developed. A total of 37 organizations including the public and private sectors, the military and CDC-PEPFAR implementing partners participated to generate this NSPL. At the validation workshop held in September 2017, stakeholders agreed to the implementation and monitoring strategies for the NSPL 2017-2020. The NSPL 2017-20 now provides a road map to improve the laboratory system in the next 4 years for the country. The NSPL 2017-2020 was used to generate the 2018 operational plan for the laboratory network. We attribute the success in developing this NSPL to the active involvement of high-level MOH representatives, as well as the clear goals and timelines for work achieved by each technical group. Collaborative efforts of all laboratory network stakeholders (public, private, military, Universities, implementing partners) will ensure ownership of the work featured in the document.

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P-130

Application of Whole Genome Sequencing to an Outbreak of E. Coli O157:H7 in a Rural Community in Utah and Arizona

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Shiga toxin producing Escherichia coli subtypes, including Escherichia coli O157:H7 are responsible for an estimated 265,000infections and 30 deaths annually in the United States according to the Centers for Disease Control and Prevention. In July of 2017, the Utah Department of Health and Utah Public Health

Laboratory (UPHL) identified a cluster of E. coli O157:H7. During the course of the investigation, UPHL applied whole genome sequencing and molecular phylogenetic analysis to patient and environmental samples to aid in the investigation, to help identify the source of the outbreak, and to help prevent further illness. In addition to routine whole genome sequencing (WGS) phylogeneticanalysis, metagenomic analyses were performed on a sub-set of samples, including samples that were positive of E. coli O157:H7 via culture independent testing (CIDT) but no E. coli O157:H7 was recovered via traditional culturing techniques. This subset of samples includes the reference (index) patient and an environmental sample of horse manure.

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Informatics Self Assessment Tool

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In 2017, nearly 30 laboratories used the Informatics Self Assessment Tool to evaluate their capabilities, and monitor their growth and needs over time. By using the data gleaned from participants, APHL has established a national aggregate and baseline for over nineteen specific and critical operational areas within the laboratory. Designed to be a collaborative exercise for laboratory personnel, SA Tool users gain broad insight and are provided a more comprehensive view of their own laboratory's functionality, and how they compare to others. The assessment also serves as a blueprint, showcasing areas of excellence to strive for. In this poster, we will share some of the national trends discovered from the last assessment, and issue a call for participation in 2018.

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Validation of a Six-Gene Next Generation Sequencing (NGS) Panel for Second-Tier Newborn Screening

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Background: The New York State (NYS) newborn screening (NBS) program has developed a six-gene next generation sequencing (NGS) panel to replace Sanger sequencing as a second-tier test for Pompe disease, Krabbe disease, mucopolysaccharidosis type I (MPS-I), X-linked adrenoleukodystrophy (X-ALD), very long-chain acyl-CoA dehydrogenase deficiency (VLCADD), and medium-chain acyl-CoA dehydrogenase deficiency (MCADD). These inherited metabolic disorders often result in death in infancy or childhood. With timely diagnosis, treatment may improve morbidity and/or mortality. In NYS, the current testing algorithm involves first-tier tandem mass spectrometry followed by second-tier Sanger sequencing. Sanger assays are expensive, labor intensive, and cannot detect large, heterozygous deletions and duplications (del/dup). Since these conditions are autosomal recessive (except for X-ALD),

all infants with a single mutation must be referred for diagnostic testing and clinical evaluation, as they may carry an undetected del/dup. Many infants who are carriers and will never develop disease are referred, leading to unnecessary follow-up testing and undue emotional stress for families. In 2016, 125 infants were referred for confirmatory testing for these six conditions, though only 21 infants were confirmed to have disease.

Objective: The aim of this project is to validate the six-gene panel, and to replace the individual Sanger sequencing assays that are currently in place for these six conditions. The validation will include testing to assess the analytical and clinical validity of the panel, including accuracy and reproducibility testing. Turnaround time and cost will also be assessed.

Methods: A TruSeq Custom Amplicon (TSCA) panel, which uses 178 amplicons to target regions of the GAA, IDUA, GALC, ABCD1, ACADVL, and ACADM genes was designed. DNA from a well-characterized genomic DNA (Coriell cell line NA12878) and 30 dried blood spot (DBS) samples previously screened by the NYS program will be run on the panel. DNA will be extracted from a single 3-mm punch DBS per sample and 10 ng will be used to prepare sequencing libraries, which will be run on an Illumina MiSeq using a version 2 flow cell with 300 cycles. A bioinformatics pipeline will be developed, and variant calling and analysis will allow for the identification of genetic variants, including the detection of del/dups with copy number algorithms. The panel will be assessed by comparison to Sanger results and evaluation of the Coriell DNA.

Conclusions: Implementation of this panel may improve the current algorithms used in NYS by decreasing false positive referral rates, if only infants with two mutations can be referred. It will also be possible to expand the panel to include additional conditions, allowing for additional cost-savings.

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Whole-Genome Sequencing of Carbapenemase-producing *Klebsiella pneumoniae* Isolates Recovered from a CRE Colonization Investigation

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In this study, whole-genome sequencing (WGS) was used to retrospectively analyze carbapenemase-producing carbapenem-resistant *Enterobacteriaceae* (CP-CRE) isolates. These isolates were recovered during a point prevalence survey at a 120-bed long term care facility (LTCF) in Pennsylvania, where 8 cases of CP-CRE were confirmed at the Centers for Disease Control as bla_{KPC}-positive *Klebsiella pneumoniae*. As the Northeast Regional Antimicrobial Resistance Laboratory Network (ARLN) laboratory, the Wadsworth Center is funded to perform CRE colonization testing in response to the detection of CP-CRE. Multiplex real-time PCR assays performed in our laboratory detected the bla_{KPC} gene in 13 of 77 dual rectal swab specimens collected from residents of the PA facility; 12 unique *K. pneumoniae* isolates were recovered using colonization culture methods from 10 of the original 13 specimens. The retrospective analysis of these isolates by WGS determined all isolates to be sequence type 258 (ST258) by multilocus sequence typing analysis. WGS analysis also determined that all isolates were positive for the bla_{KPC}-3 variant, which is associated with a plasmid that harbors other antimicrobial resistance determinants, including genes that confer aminoglycoside, sulfonamide, and trimethoprim resistance. Other beta-lactamase families identified during this analysis include OXA (83%), TEM (100%), and SHV

(100%). Antimicrobial susceptibility testing by broth microdilution indicated 11 of 12 isolates recovered were resistant to ertapenem, imipenem, and meropenem. These 11 isolates were also positive when tested for phenotypic carbapenemase production using the modified carbapenem inactivation method (mCIM). WGS investigations of the single mCIM negative, carbapenem-susceptible isolate revealed a nonsense mutation in the bla_{KPC} gene that introduced a premature stop codon. The majority of isolates in this study (10 of 12) were also resistant to trimethoprim/ sulfamethoxazole (TMP/SMX). In contrast, 2 of the 12 isolates were sensitive to all aminoglycoside antibiotics, along with TMP/SMX. The susceptibility profile differences of these two isolates correspond with the absence of 4 genes that confer aminoglycoside resistance and 3 genes known to be involved in trimethoprim and sulfonamide resistance; these genes are present in the WGS data of the other 10 isolates. PFGE analysis revealed 2 clusters formed by 9 isolates, with the remaining 3 of 12 isolates unrelated. Interestingly, WGS SNP analysis identified 1 unrelated isolate and characterized 11 isolates into 2 clusters; one cluster contained 8 isolates, while the other cluster is formed by 3 isolates. Continued work on this study and in similar studies will contribute to the understanding of the transmission of emerging CP-CRE strains and impact infection control activities.

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Expanding the Timeframe for Whole Genome Sequence Analysis of Listeria monocytogenes: New York State's Experience with an Outbreak Spanning Multiple Years

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The CDC PulseNet laboratory network has used pulsed-field gel electrophoresis (PFGE) as the primary method for cluster detection of Listeria monocytogenes for over 20 years. In January 2018, PulseNet transitioned from PFGE to whole-genome sequencing (WGS) analysis which provides a higher level of discrimination over PFGE. Using BioNumerics 7.6 whole-genome multilocus sequence typing (wgMLST) analysis, New York State Department of Health (NYSDOH) identified an outbreak of Listeria monocytogenes which continued intermittently during a period of just under 3 years. Between 2014 – 2017, 7 cases, which included 3 deaths, of Listeria monocytogenes were identified from the same county with PFGE patterns that were indistinguishable. NYSDOH Listeria monocytogenes PFGE clusters are detected by evaluating isolates collected within a 120-day timeframe. Therefore, 3 separate PFGE clusters were identified due to the length of time between cases [2014 (3 cases), 2016 (2 cases), 2017 (2 cases)]. One additional out-of-state PFGE match was also detected between 2014-2017. Prior discussions between NYSDOH epidemiologists and the Wadsworth Center Bacteriology Laboratory had established that WGS cluster analysis would include all Listeria monocytogenes isolates present in the NYS database instead of limiting analysis to the 120-day window as was the practice for PFGE. Analysis of the entire NYS database using wgMLST identified that the isolates from the 7 cases which occurred between 2014 – 2017 were highly related, differing by 0-3 alleles. Additionally, wgMLST analysis indicated that the recent out-of-state PFGE match was not related to the NYS cases. A common food

preparation and delivery establishment was identified for 6 of the 7 NYS clinical cases. Environmental sampling was performed at the facility and Listeria monocytogenes was recovered from 4 of the 40 samples collected. The environmental isolates had PFGE patterns which were indistinguishable from those of the clinical isolates. Furthermore, wgMLST analysis confirmed that the environmental isolates and clinical isolates were highly-related, differing by 1-6 alleles. Use of the expanded timeframe for WGS analysis was crucial in confirming the relatedness of these intermittent Listeria monocytogenes cases and in the determination of the source of this outbreak.

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Validation of a Real-time PCR Assay for Rapid Detection of Emerging Multidrug-resistant C. auris from Blood

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Candida auris is an emerging multidrug-resistant yeast, causing invasive healthcare-associated infections with high mortality in several countries including the United States of America. Mortality associated with C. auris infections are found to be common among the elderly, severely ill patients with indwelling catheters and hematological malignancies. Conventional blood culture considered as “gold standard” for candidemia identification, is time-consuming and takes at least 5-7 days. In certain instances, C. auris has been misidentified as C. haemulonii or C. sake by this method as well, thereby making it easy for the oblivious spread of this yeast. To overcome these problems, we utilized our recently developed real-time PCR assay in the laboratory for the validation of blood as a matrix for the detection of C. auris. The limit of detection of the assay was 5 C. auris CFU/PCR reaction with an efficiency rate of 87% to 91%. The assay was highly reproducible as it produced consistent results within and on different days of testing. Overall, our assay is rapid with a turn-around time of 6 h as compared to 5-7 days with blood culture, and present a better approach for managing patients with C. auris induced candidemia as well as the implementation of public health measures to control the spread of this emerging multidrug-resistant yeast pathogen.

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Public Health Role in Reducing Legionnaires’ Disease Risk

P. Root, IDEXX Laboratories, Inc., Westbrook, ME

Legionella pneumonphila is the number one waterborne pathogen and the causative agent of Legionnaires’ disease. The mortality rate for healthcare-acquired Legionnaires’ disease is 25%. Yet, as the US CDC published in 2017, 9 out of 10 cases of Legionnaires’ disease can be prevented with proper water system management. Several organizations have developed standards designed to address the prevention of Legionnaires’ disease. For healthcare facilities, water safety management requirements

are specified in the Centers of Medicare and Medicaid (CMS) rules published in June 2017. But many healthcare facilities are still unclear how to proceed and are contacting their local public health laboratories for assistance. The CMS rules and the roles public health laboratories play in reducing Legionnaires' disease risk in their communities will be outlined in this poster.

Effective Legionnaires' disease management can be accomplished through following one of several standards. The CMS Rule points to two documents: ASHRAE 188:2015 and the US CDC Tool Kit. This poster will outline the key objectives and activities of water management planning and oversight, including;

- Water Safety Management Plan Development: What are the key elements of a good plan? How do they fit together?
- Water Safety Management Program Team: What can public health professionals contribute to planning teams?
- Water Safety Management Program Verification and Validation: What controls should be considered? What is the value of microbiological testing? What roles can public and commercial laboratories play?

This poster will provide details on tools, resources and other support that public health professionals can provide to help healthcare facilities develop and implement water safety management programs that successfully reduce the incidence of Legionnaires' disease.

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Facilitating the Transition to Accurate Hormone Testing: Activities of the Partnership for the Accurate Testing of Hormones (PATH)

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Endocrine disruptors are chemicals that may interfere with the body's endocrine system and produce adverse developmental, reproductive, neurological, and immune effects. Measuring the effects of these compounds highly depends on accurate and reliable hormone tests. Many hormone tests were found to be inaccurate and unreliable, and efforts are under way to improve this situation. The Partnership for the Accurate Testing of Hormones (PATH) is working with key organizations - including APHL - to ensure that the analytical quality of hormone tests meets clinical and public health needs. Furthermore, it provides information to help those relying on accurate laboratory tests about the quality of hormone tests and approaches to assess analytical quality of these tests. This poster will summarize the state of hormone testing including analytical performance of hormone tests and its impact on research translation, patient care and public health; describe PATH's programs and activities to improve the quality of hormone tests; describe quality indicators for hormone tests and how to obtain information about test quality.

Note: This poster has been prepared in collaboration with the Partnership for the Accurate Testing of Hormones (PATH) and the APHL Environmental Health Committee.

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Suitability of Self-collected Swabs for Influenza and Respiratory Pathogen Detection

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Background: Surveillance for respiratory viruses in Wisconsin relies upon specimen collection performed in clinical or research settings, which may overly burden trained personnel. We examined the suitability of self-collected mid-turbinate nasal swabs for monitoring influenza activity.
Methods: The Oregon Child Absenteeism due to Respiratory Disease Study (ORCHARDS) is carried out in 6 schools within the Oregon School District in south-central Wisconsin. Anterior nares or oropharyngeal (OP) swab specimens were collected during the 2016-2017 school year from students (K-12) exhibiting respiratory illness by trained research staff using foam swabs (Pur-Wraps®) and flocked swabs (Remel®), respectively. Household members of ill students self-collected either a mid-turbinate specimen using flocked swabs (COPAN®) (2016-17 school year) or a nasal specimen using a foam swab (Quidel®) (2017-18 school year) to study household transmission dynamics. Household members received training. Staff did not observe specimen collection. All respiratory specimens were tested for influenza using PCR (CDC Human Influenza Virus RT-PCR Panel). Detection of the human RNAse P (RP) gene, an indicator of the presence of epithelial cells, was used to determine specimen acceptability. Failure to detect the RP gene (Ct>38) indicated that the specimen collected was suboptimal (inconclusive). Collected and self-collected swabs were compared.
Results: A total of 873 ORCHARDS study participants from the 2016-2017 school year (319 students and 554 household members [collected on day 0 and day 7]) submitted specimens. Of the 319 student OP swabs collected by trained staff, none were determined to be inconclusive. Forty-one of the 1,108 (3.7%) self-collected mid-turbinate nasal swabs were determined to be inconclusive. Of the specimens tested, the mean RP Ct value was 26.4 for the swabs collected by trained staff from students and 31.7 for the self-collected swabs (p<.00001). More of the self-collected specimens were acceptable after switching swab types (foam-tipped) and collection site (nasal) during the 2017-2018 school year.
Conclusions: A small percentage of the self-collected mid-turbinate nasal swabs were determined to be unsuitable for PCR testing. However, of the specimens tested, the mean RP Ct difference indicated fewer epithelial cells were present on the self-collected swabs, meaning the likelihood of detecting influenza in the self-collected specimen may be lower than in the staff-collected ones. Data indicated that switching from flocked swabs to foam-tipped swabs and changing the specimen collected from mid-turbinate to nasal improved the suitability of self-collected swabs for influenza detection. Reasons may be the larger surface area of the foam-tipped swab or better tolerance of nasal than of mid-turbinate collection.

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Comparison of Sequence-based Salmonella Serotyping Methods for Use in a State Public Health Laboratory

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Background: Public health surveillance and outbreak investigations of Salmonella are historically monitored through Salmonella serotyping. With the introduction of whole genome sequencing (WGS), public health laboratories are looking to sequencing to replace conventional testing by producing a highly accurate analysis of the genotype. However, in order to use WGS in a public health laboratory the approach must undergo a rigorous validation to meet Clinical & Laboratory Standards Institute (CLSI) standards.
Methods: As part of CLSI validation, we evaluated two sequence based Salmonella serotyping tools, the Salmonella in silico Typing Resource (SISTR) and SeqSero for use at the Wisconsin State Laboratory of Hygiene. We compared serotype identification of 255 Salmonella enterica isolates using conventional antisera, SISTR, and SeqSero.
Results: Agreement was highest between conventional serotyping and SISTR at 93%, which improved to 95% after repeating conventional serotyping on 5 discordant isolates. Agreement between SISTR and SeqSero was lower at 88%. Agreement was lowest between conventional serotyping and SeqSero at 85%, but improved to 87% after repeating conventional serotyping on 5 isolates as above. Between all 3 methods there was an overall agreement of 85%.
Conclusion: Both sequence based Salmonella serotyping methods provided results at a higher accuracy than conventional antisera. Agreement between the sequence methods led to the repeated analyses on 5 samples that had been incorrectly serotyped. SeqSero's difficulty in distinguishing closely related serotypes or subspecies accounted for most of the disagreements between the sequence based methods. SISTR's approach of using both O, H1, and H2 antigen gene detection alongside a core genome MLST analysis appears to allow the most accurate serotype determination.

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Reduced Viability of Candida auris and Other Candida Species from MALDI-TOF Extractions

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Candida auris is emerging as a health care associated and often multidrug-resistant, global public health threat. The ability of this yeast to persist in the environmental and colonize skin has made it challenging to eradicate and complicated efforts to prevent transmission in health care settings. C. auris is capable of causing invasive infections and is associated with increased mortality. There continue to be reports of laboratory misidentifications of this previously rare organism. Matrix-assisted, laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry is an accurate and relatively cost effective method for identifying this emerging species of Candida. However, there is a lack of data about C. auris viability after the various preparation protocols for MALDI-TOF testing. In an effort to evaluate and improve biosafety for laboratorians we investigated the viability of Candida after different MALDI-TOF extraction methods. We tested 10 isolates of C. auris and 15 isolates of other Candida species with

three different MALDI-TOF extraction methods: on-plate extraction with formic acid; 50% ethanol in a tube; and tube extraction with formic acid and acetonitrile. After spotting the Bruker MALDI-TOF target with each preparation, overlaying with matrix, and allowing to dry, a flocked swab dampened with RPMI broth was used to remove the dried preparation. Swabs were inoculated into RPMI broth and onto Sabouraud dextrose agar and observed for growth after 24 and 48 hours of incubation at 37 C. No growth was observed with any species after treatment with 50% ethanol or after any step in the tube extraction with formic acid and acetonitrile. On-plate extraction with formic acid greatly decreased the viability (average: 99% decrease in colony counts). And, colonies were only observed with C. albicans. These data indicate that the ethanol treatment and tube extraction methods are sufficient to kill C. auris and other Candida species prior to MALDI-TOF analysis.

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One of These Things is Not Like the Other…Or is it? Why Informatics Should Lean Heavily on Lessons Learned in Disparate Industries to Create Novel Solutions

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Background: Often when trying to solve a problem, we find ourselves looking in familiar places for the answer. But when it comes to data and Informatics surface similarities aren't enough. Familiar methods such as HL7 and other health informatics go-tos have drawbacks that confine data entry to certain formats and prevent access to important non-standardized data sets stored in different formats. This technological set of road blocks can keep data in silos and prevent complete and accurate reporting as well as hinder case management efforts.
Methods: A novel software framework built in C# with a WPS and React front end was modified from its original purpose to track trucking data to collect and store surveillance data from around the globe. This flexible software allowed for ingestion and normalization of various data types, creating a case management system that allow disparate data to be presented in normalized formats. In addition, because it was build for the trucking industry originally, the system was designed to adapt to large amounts of data that came from different locations, at different times, in different formats.
Results: The software solution was adapted from its original purpose in trucking to intake surveillance and healthcare data from disparate sources (CSV, REDCap, XML, PDF, .JPEG, .PNG, and others), extract the data for input into SQL tables, combine the data into a case management system, and display data in a unified report format. The collected reports were then used to determine the cause of death in infant mortality cases globally.
Conclusions: This project demonstrates how seemingly different problems -preventing childhood mortality and tracking trucks across the US - were solved using the same technical philosophy. We offer advice on how approaching technical puzzles from a different angle can lead to successful software projects as well as discuss the expertise, time, and budget needed to implement methods such as these.

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