Poster Abstracts

P-001

New Mexico Scientific Laboratory Division Response to the Gold King Mine Spill, August 2015
R. Fuentes, C. Markham, A. Sanchez and F. See, Scientific Laboratory Division, Albuquerque, NM

The breach of an adit inside the disused Gold King Mine near Silverton, Colorado, on August 5th 2015, caused about 3 million gallons of highly contaminated waste water to flow down the side of a mountain and eventually into the Animas and then the San Juan Rivers, which flow through southern Colorado, northern New Mexico, and eventually into Lake Powell in Southern Utah. The waste water contained high levels of toxic metals associated with mining activities such as Lead and Arsenic. Samplers from the New Mexico Environment Department's Surface Water Quality Bureau (SWQB) collected surface water samples from both rivers before and after the contaminant plume passed through northern New Mexico, and subsequently onto Navajo Nation land that covers northwest New Mexico, southeast Utah, and northeast Arizona in the Four Corners area. The samples were delivered to the State Public Health Laboratory in Albuquerque over the following week for the analysis of various inorganic contaminants, with a request for the results to be reported out at the highest priority. This poster summarizes the samples delivered to the laboratory, the analyses requested, the results, and the turnaround times for final results. In all, 301 samples were collected for analysis, 1,009 tests were run, and 3,746 individual results were reported out. A calculation for the approximate amount of Total Lead in the contaminant plume was made.

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P-002

Laboratory and Biosafety Overview of Ebola Preparedness in the State of New Mexico
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Ebola virus is the cause of a rare but highly infectious disease, Ebola virus disease (EVD). In 2014, the largest EVD epidemic started in West Africa, with more than 28,000 confirmed or suspected cases of Ebola and over 11,000 deaths, resulting in ~40 % mortality for EVD patients. In January of 2016 the epidemic was finally declared over. As a result of the 2014 outbreak, several cases of Ebola occurred in the U.S. for the first time. The Centers of Disease Control and Prevention (CDC), in partnership with state public health departments, initiated the process of identifying and assessing possible Ebola assessment or treatment hospitals. New funding allowed laboratories to hire a biosafety officer to perform risk assessments of sentinel laboratories, among other functions. In New Mexico, we have identified several EVD assessment hospitals and have been working to better prepare them to care for an EVD person under investigation (PUI). Additionally, the Scientific Laboratory Division (SLD) has developed protocols and a plan to receive and test blood samples for Ebola virus from a PUI. Currently, New Mexico does not have a designated Ebola treatment center; however, it remains imperative that the New Mexico

Department of Health (NMDOH) along with SLD be prepared for a possible or suspected EVD case. Having such plans in place also helps the state be better prepared to handle other highly-pathogenic, emerging infectious diseases.

Here we will provide an overview of the SLD Ebola preparedness plan along with preliminary results from the assessment hospital site visits conducted. We will discuss strengths and weaknesses observed and provide guidance for best practices.

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P-003

The Importance of Chromogenic Agar and a Dilution Series for the Recovery and Isolation of STEC in Broth

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The Scientific Laboratory Division (SLD) receives MacConkey broth or GN broth for the isolation of STEC from patient who have screened positive for the Shiga toxin. The broths received are plated to a MacConkey Plate, MacConkey Sorbitol, and a MacConkey Sorbitol with Cefixime and Telluride as per lab SOP. We discovered that isolation of Shiga toxin producers is difficult from "loaded" broths (with high levels of background organisms). Though these plates are excellent for the recovery of E. coli 0157:H7 they do not help with the isolation of E. coli fermenters, due to their similar morphology on Mac plates.

We found that chromogenic agar, specifically CHROMagarTM 0157, greatly aids in the isolation of Shiga toxin producing E. coli other than E. coli 0157. The differentiation of organisms by color helps in deciphering other E. coli from one another, and has vastly improved our turnaround times.

Here we present data to demonstrate that the isolation of STEC organism from broth having high levels of background flora is possible using chromogenic agar along with a dilution series. These techniques, used on "loaded" broths can simplify and enhance recovery of the relevant organisms.

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P-004

Francisella tularensis Isolated from the Liver of Guam Kingfisher

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The purpose of this case study of *Francisella tularensis* is to highlight the public health laboratory's role in confirmation of an unexpected result from an unusual source. In November 2015, the General Microbiology section of the Scientific Laboratory Division received a request for confirmation of an isolate with an unexpected result of *Francisella tularensis* from a Guam Kingfisher liver; a source not usually associated with this pathogen.

The isolate submitted for confirmation had a high confidence rating for Francisella tularensis obtained from a molecular analysis. Utilizing established Laboratory Response Network procedures the suspect isolate was successfully confirmed as Francisella tularensis.

The ability to confirm an isolate suspected of being Francisella tularensis is a position the public health laboratory is uniquely qualified to perform.

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P-005

Project Collaboration with the Office of Medical Investigator to Improve Culture Methods to Aid in Cause of Death Investigation

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The Scientific Laboratory Division receives autopsy specimens from the Office of Medical Investigator for cases suspected of harboring infectious disease. The types of specimens that we get for routine bacterial culture includes a blood culture bottle and swab material from the right and left lung collected from the decedent. Often the lung swabs grow bacterial organisms typically seen in the oropharynx as normal respiratory flora. Significant pathogens may be masked by overgrowth of normal respiratory flora.

This poster will highlight a collaborative project between the SLD and the OMI where tissue specimens that are collected in conjunction with the routine specimens (mentioned earlier) are compared in order to evaluate whether tissue specimens would yield better recovery of pathogens.

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P-006

A Case of Active Pulmonary TB Treatment Failure: How Public Health, Reference and Clinical Laboratories Contributed to the Investigation

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Patients whose TB cultures are still positive after 4 months of treatment are considered to have failed treatment.

There can be a variety of reasons treatment fails and it can be a complex problem to solve. For example, the patient may not comply with the drug regimen or have an adverse reaction to the treatment. Other conditions may be present such as HIV, liver or renal disease which influence how therapeutic drugs are absorbed & metabolized. Or, the TB bacterium itself may be resistant to some or all of the drugs administered.

This poster will highlight how public health, reference and clinical labs contributed to the investigation of the cause of active pulmonary TB treatment failure in this case and aided the NM Dept. of Health TB Control Program with the aims of curing the patient, preventing the development of drug-resistant TB, and breaking the chain of TB transmission.

Presenters: Pam Morden, Greg Szklarz and Rey Griego, New Mexico Dept. of Health, Scientific Laboratory Division, Albuquerque, NM, Phone: 505.383.9126, Email: pam.morden@state.nm.us

P-007

Laboratory Developed Real Time PCR Assays for the Rapid Identification of MTBC and NTM Species

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Mycobacterium tuberculosis, the causative agent of tuberculosis (TB), is a highly infectious, pandemic pathogen credited as a significant cause of disability and death in many parts of the world. Rapid detection of this pathogen is crucial in preventing dissemination of the pathogen and ultimately disease fatality. While traditional methods might remain confirmatory they do not differentiate between mycobacterial species and may take several weeks to obtain a result, forcing laboratories to include nucleic acid amplification tests (NAATs) as part of their testing algorithm. The New Mexico Scientific Laboratory Division (SLD) has developed highly sensitive molecular techniques for identification of *Mycobacterium tuberculosis* complex (MTBC) and Non-tuberculosis mycobacterium (NTM) in patient samples, as well as species specific identification of NTMs.

By combining and modifying two previously published assays, with an in-house internal positive control assay, SLD has validated a highly sensitive and specific real time multiplex PCR assay for the same-day identification of MTBC and NTM in patient samples and cultures. We also validated a secondary multiplex real time PCR assay which is capable of identifying the more clinically significant NTM species as a reflex test when the primary PCR is negative for TB but positive for NTM. This assay was modified from an oligonucleotide array assay that can identify up to eighteen different NTMs.

We present the data from these validations, discuss the current algorithm for use of PCR at SLD, and how PCR compares to culture results.

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P-008

Rapid Identification of Bacteria by MALDI-TOF in the Land of the Flea, Home of the Plague

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Rapid identification of pathogens is crucial for the prevention of outbreaks, timely treatment or food safety. One such technology that has recently exploded in the public health scene is the matrix-assisted

laser desorption/ionization time of flight (MALDI-TOF) mass spectrometry. MALDI-TOF is useful for the rapid and inexpensive identification of bacteria and fungi through the detection of common macromolecular spectral patterns.

At the New Mexico PHL, prior to validation, an expanded prokaryote library was created to include representatives of the more commonly identified bacteria at our laboratory which included several select agents, endemic species of public health significance in New Mexico, along with control organisms (ATCC strains). We validated by comparing more than 600 bacterial isolates obtained from patient specimens, representing over 100 distinct species, to the results obtained with sequencing and the "gold standard" of culture and biochemical methods. Although the 16S ribosomal protein was the most commonly used target, other targets were used that allowed for higher resolution of some groups of organisms. Furthermore, to improve the identification of difficult genera, such as Nocardia, Actinomyces, Mycobacteria, and some Bacillus species, alternative methods to extract proteins were compared. Currently, the SLD algorithm is to run all isolates by MALDI-TOF. If only the genus is identified, or the organism is not identified, sequencing will be performed. The choice of target will be guided by microbiologists.

The results of the validation and the lists of organisms added to the database will be presented. The risk assessment phase included a biosafety experiment in which several select agents, which are endemic to NM, were tested to eliminate the concerns for accidental release or exposure. The processing methods and results of the experiment will also be shared.

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P-009

Next Generation Sequencing of RNA for Infectious Disease Diagnosis: SPIDR-WEB implementation for Clinical Samples

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SPIDR-WEB (Sample Prep for Infectious Disease Recognition With EDGE Bioinformatics) is a sample-to-result biotechnology platform, developed at Los Alamos National Labs, that enables efficient use of next generation sequencing (NGS) for pathogen detection in clinical samples. NGS has become a powerful tool for detection and characterization of both known and emerging pathogens. The main advantage of NGS is its non-biased approach that identifies all organisms in a sample, in contrast to traditional molecular assays that force us to look for a set of specific pathogens.

In most clinical samples, the relative abundance of pathogen nucleic acids (DNA or RNA) is vanishingly small, such that vast amounts of sequence data must be generated and analyzed to identify rare pathogen sequences. Clinical samples mostly comprise non-informative host RNAs or abundant housekeeping gene transcripts. Removal of non-informative RNAs (RNR), thereby enriching all other RNAs, including those from pathogens, can enhance the detection of pathogens, increasing sensitivity and specificity and/or allowing less expensive and faster sequencing.

EDGE bioinformatics data analysis platform provides rapid read classification at all taxonomic levels, and can detect all organisms present in a sample. EDGE is an efficient process, as it uses databases with pre-computed signatures, instead of aligning sequencing reads to the entire Genbank. In addition to RNR and EDGE, SPIDR-WEB includes robust, inexpensive and rapid sample lysis, RNA extraction, and library preparation steps.

We will describe SPIDR-WEB technology and show clinically-relevant results obtained from human stool and respiratory samples. Additionally, we'll discuss the implementation of this technology in a state public health lab and describe how to integrate SPIDR-WEB into existing workflows. This approach could potentially cut costs and allow more information to be obtained from a single sample, which might normally have to be split for viral and bacterial culture. SPIDR-WEB could be especially useful for samples where the etiologic agent is elusive.

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P-010

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. On April 20, 2015 a woman was bitten by a wild gray fox in Lincoln County, New Mexico. The animal was captured and euthanized, testing positive for rabies virus, and the patient received timely post exposure prophylaxis. Sequence analysis of the nucleoprotein gene revealed a novel RABV variant not previously detected in the USA. Phylogenetic analysis showed the RABV found in the gray fox is a new variant which is closely related to those circulating in *Lasionycteris noctivagans, Lasiurus cinereus* and *Lasiurus borealis*. Furthermore, another unique RABV variant was previously identified in a New Mexico dog in 2013 as a RABV variant associated with *Nyctinomops nigricans.*In 2004, a similar variant was also identified in a New Mexico skunk.

We present results from retrospective sequencing of nucleoprotein genes from RABV positive samples, along with cytochrome oxidase sequencing to identify host species. Phylogenetic analysis of RABV variants is combined with geographic distribution 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-011

The Art and Science of Effective Communication
S. Nicoletto, K. Gill and S. Master, New Mexico Department of Health, Albuquerque, NM

Public health laboratorians are constantly communicating among themselves and the outside world. Effective communication is crucial to the proper functioning of a public health laboratory whether it be for advocating, training, evaluating employees, speaking to the public, or interacting with peers. This depends, to a large part, in getting your point across through verbal, audio, or visual methods. Oftentimes communications break down, or become murky and mundane, because the appropriate tools or concepts have not been utilized.

Have you ever yearned to present with panache, tried to understand what makes your co-worker tick, or persevered to train engagingly? In this fun, interactive poster some of the tools to achieve this will be illustrated, and a few tricks presented, to assist you in communicating pointedly and with flair.

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P-012

***Listeria monocytogenes* in Raw Pet Food Results in an FDA Recall**
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The Scientific Laboratory Division, the only public health laboratory in New Mexico, is also responsible for testing food during suspected outbreaks. In March 2014, the lab was involved in a multijurisdictional investigation revolving around a sick dog with gastrointestinal distress. The lab received the suspect raw meat pet food, from the veterinary clinic, which was tested for the usual culprit enteric pathogens, but also for *Listeria monocytogenes*. An in-depth investigation resulted in the collection and testing of additional samples of that brand and an FDA recall. Here we present the particulars of the investigation, including methodologies used, agencies involved, and include a discussion on the ramifications of feeding raw pet food to animals.

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P-013

Performance of the Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test in the Miami Health Department STD Clinic: A Review of the First 11 Months of Use
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Project: To pilot the implementation of the first FDA approved rapid point-of-care (POC) 4th generation HIV-1/2 Ag/Ab Combo (Determine Combo) test into the practice of STD clinics in the state of Florida. Miami-Dade County ranks first in the number of diagnosed HIV and AIDS cases in Florida. FDOH Miami-Dade County Laboratory is AHCA/CLIA-certified for moderate complex and waived testing, performing approximately 5000 rapid HIV-1/2 tests annually in its high HIV-1 seroprevalence public health population.
Implementation: The Determine Combo detects and distinguishes HIV-1 p24 Antigen (Ag) from HIV-1 and HIV-2 Antibodies (Ab) and thus has the potential to improve diagnosis of acute HIV-1 infection. The transition from CLIA-waived Clearview Complete HIV-1/2 to Determine Combo involved laboratory staff training, test performance verification, PT (AAB) enrollment, CLIA and AHCA license upgrade and test performance monitoring. Per the established testing algorithm, POC reactive serum specimens were sent to the FBPHL-Miami for confirmation by Abbott Combo IA, Multispot HIV-1/HIV-2 differentiation and HIV-1 NAT for any discordant results. Determine Combo nonreactive results were reported as HIV-1/2 negative. In September 2015 testing algorithm was modified to test nonreactive specimens for acute infection by Abbott Combo IA.
Results: A total of 4,032 Determine tests were performed from 12/2/2014 to 11/30/2015, 2.7% (109/4032) were preliminary HIV-1 Ab positive, 77.98% (85/109) were confirmed by the laboratory-based algorithm. 742 nonreactive Determine specimens were sent for confirmation to the BPHL-Miami, 99.73% (740/742) were confirmed as negative. 2 false-negative were detected as acute cases. The observed specificity of 99.4% (3945/3969) is within the Determine 95% CI (97.7-99.5%). The observed sensitivity of 90% (18/20) on limited number of samples with confirmation of both reactive and non-reactive Determine results is below the Determine Combo 95% CI (99.4-100%). In addition, 50 Determine reactive specimens were also tested by Clearview Complete. More false-positive HIV-1 Ab results were observed with Determine and there was an absence of p24 Ag detection in the first 11 months of use.
Lessons Learned: Determine Combo was successfully implemented. HIV-1 antibody specificity was comparable to package insert specifications for high risk population, but more data is needed to verify Ag sensitivity and specificity. Testing algorithm was modified after first 9 months to test Determine nonreactive specimens for acute infections by the Abbott Combo IA. The clinic linkage-to-care process was modified due to the Determine Combo HIV-1 Ab false positive frequency. Alere Determine is a higher cost to the clinic due to PT enrollment and additional license fee. Use of Determine with serum/plasma requires more specimen preparation and licensed technical staff to perform the test.

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P-014

The Northern Plains Consortium Emerging Leaders Program

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The Northern Plains Consortium (NPC), comprised of state public health agencies from Idaho, Montana, North Dakota, South Dakota, and Wyoming, implemented an Emerging Leaders Program (ELP) modeled

after the Association of Public Health Laboratories' ELP. For its inaugural year, the NPC ELP followed a set curriculum based on training in key aspects of being a successful public health leader, with focus in the state public health laboratory. There were eight participants from all five states, with backgrounds in epidemiology, laboratory bench work, and management. Program activities included:
• Webinars given by NPC state public health lab directors and managers on topics such as fiscal management, strategic planning, and legislative processes and regulations
• In-person meetings involving exercises such as developing management character profiles, creating and writing a grant in one hour, and participating in mock media interviews on public health issues
• Visits to NPC state public health laboratories to study their organization and role in providing quality public health services

ELP members also participated in a group project on the impact of culture-independent diagnostic testing (CIDT) on public health surveillance, with outputs including:
• Results of a hospital survey on CIDT versus culture testing and sample submission to the state lab
• An analysis of state reported diseases over a six year period on pathogens that can be tested by CIDT

Finally, participants gave perspectives on the strengths and suggested improvements to the NPC ELP. The NPC plans to continue the development of qualified leaders to work effectively in the niche of the public health laboratory and related agencies by facilitating a second cohort of this program.

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P-015

Lean in the Chemistry Laboratory? Yes You Can!

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In 2012, the Indiana State Department of Health (ISDH) embarked on a new initiative to improve efficiencies throughout the agency. Several program areas participated in sessions for Yellow and Green Belt Lean Training. The Laboratories selected a team and project which involved reducing the number of Indiana Department of Environmental Management (IDEM) Sample Delivery Group (SDG) water samples reported beyond the 30-day turnaround time (TAT). These water samples are environmental monitoring samples from rivers and streams throughout the state.

The Laboratories' Lean team used the DMAIC (Define, Measure, Analyze, Improve and Control) Model to assess the TAT issues for these particular samples. The team discovered a significant number of unnecessary steps in the process map. Causes for delays in reporting were revealed in a fishbone diagram, and the root cause analysis revealed additional causes for delays in reporting. Ultimately, our Impact/Effort Matrix suggested several improvement activities which would allow for improvement in TAT, thereby decreasing the number of SDGs reported beyond the 30-day expected time. Since this project, the number of SDGs reported beyond the expected TAT has been improved by as much as 64%. Lean concepts can easily be applied to the chemistry laboratory. Using the DMAIC Model and lean tools, inefficiencies are revealed and improvements are highlighted. Our lean team used several of the DMAIC and lean tools, including root cause analysis, fishbone diagram, Pareto charts, questionnaires for staff

and supervisors, impact/effort matrices, and value stream mapping, to successfully reduce the number of SDGs reported beyond the stated 30-day TAT.

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P-016

The Indiana Laboratory System: Outreach and Training for Environmental Partners

S. Matheson, J. Madlem and M. Glazier, Indiana State Department of Health Laboratories, Indianapolis, IN

The Indiana State Department of Health (ISDH) Laboratories Outreach and Training Team conducted a Laboratory System Improvement Program (L-SIP) Assessment in 2009. A baseline was necessary to determine how to improve and enhance the Indiana Laboratory System (ILS). Although a strong relationship was already established with Indiana clinical laboratories, it was determined ISDH needed to also work with its environmental partners. Through surveys, database creation, and avid networking, nearly 100 Indiana environmental laboratories (water, food, and veterinary) were identified. Many of these laboratories were unaware there was a system, that they were a part of the system, or that they could contribute to the system.

Reaching out to those environmental laboratories, the ISDH Laboratories Outreach and Training Team developed a robust environmental outreach and training program. Since 2009, the number of environmental trainings provided and vendor booths hosted increased by 1600% and 600%, respectively. Currently, the team conducts seven types of environmental trainings and hosts vendor booths at seven environmental conferences each year. One team member currently serves on the Association of Public Health Laboratories (APHL) Environmental Laboratory Sciences Committee. The environmental ILS has grown significantly since 2009. Not only has the team developed more trainings, but they have increased the number of partnerships exponentially. Looking forward, the ISDH Laboratories Outreach and Training Team is partnering with the Indiana Environmental Health Association and APHL to expand this part of the ILS even further. Additionally, the team plans to continue to provide the current menu of trainings, perform an ILS reassessment, and partner with the Indiana Environmental Chapter of the American Society for Microbiology (ASM) to further enhance the environmental component of the ILS.

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P-017

Increase in Listeria Isolates in Indiana

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Background: The Indiana State Department of Health (ISDH) Laboratory identified an increase in *Listeria monocytogenes* isolates received for PFGE testing during 2015. Listeriosis is a required reportable

disease and *Listeria monocytogenes* is a required isolate submission in Indiana according to Indiana's Communicable Disease Rule 410 IAC 1-2.5.
Methods: A total of 23 Listeria isolates were received in the ISDH Laboratory from 20 patients. Upon receipt of the isolates, the Bacteriology lab performed testing to confirm *Listeria monocytogenes*. The PFGE lab received one isolate per patient from the Bacteriology lab for further characterization. Once PFGE was completed, cluster detection and analysis was performed using BioNumerics 6.6. Analysis results were uploaded to the CDC's PulseNet site. Isolates were also sent to CDC for whole genome sequencing (WGS) and antimicrobial susceptibility testing (AST) characterization. An additional isolate from an Indiana resident was tested in Virginia.
Results: The ISDH PFGE Laboratory received a total of 20 isolates for testing. The patient's ages ranged from less than one year to 93 years. Of the 20 isolates tested by PFGE, 18 AscI-patterns and 18 ApaI-patterns were observed with a total of 20 pattern combinations, meaning that all specimens were unique by PFGE. Seventeen of the patients tested were immunocompromised, elderly, or pregnant women. Five patients died from various complications while ill with Listeriosis and one fetal loss. All patients were hospitalized and most visited the Emergency Room prior to hospitalization.
An additional case was reported to ISDH, but not tested at the ISDH Laboratory. The patient was an Indiana resident who was ill while traveling. Specimen was confirmed *Listeria monocytogenes* and PFGE was completed by the Virginia Department of Health. AscI-pattern and ApaI-patter were different than those observed in Indiana.
Common food sources were investigated; however, no epidemiological link for the increase in *Listeria monocytogenes* was discovered. All isolates were unique by PFGE and WGS.
Conclusions: The average number of *Listeria monocytogenes* isolates received by ISDH PFGE lab is 11 isolates per year. An increase of almost twice that number was seen in 2015. Despite the increase in submission of isolates for PFGE testing a common PFGE pattern combination was not found in the submission, and only two samples matched a national outbreak. No common source of infection could be found by epidemiological investigation. Continued surveillance of *Listeria monocytogenes* is important to public health in Indiana.

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P-018

Visualize Your Informatics Roadmap - Using the Informatics Self-Assessment Tool
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The web-based Public Health Informatics Self-Assessment Tool is an interactive, role-based application adapted from the paper-based assessment tool developed through the CDC/APHL Laboratory Efficiencies Initiative. This automated tool makes it easy to conduct an assessment of the 19 distinct but equally-critical areas of capability needed to insure a comprehensive and sustainable informatics infrastructure exists within a public health laboratory (PHL). The data generated through the assessment tool will identify areas of maturity as well as gaps in the PHL's Informatics-related processes. The many visualization options available within this web-based tool provide PHL leadership a quick way to pinpoint areas of weakness and identify where their focus and/or resources are needed.

The self-assessment application can be used internal to your organization to assess the laboratory

globally or to focus on specific areas of interest. All the PHL's assessments are stored electronically for easy on demand retrieval and analysis. This feature allows an organization to compare their results against previous assessments, and to track their progress from year to year. Even more beneficial, when a PHL is willing to share their assessment results, that laboratory is able to compare their PHL's informatics capabilities with other PHL's across the nation. Using the visualization tools provided, a PHL can quickly and easily compare their strengths and weaknesses to one or more PHLs looking at any or all capability areas. The information gained through these comparisons allows PHL's with common concerns to join together and reach out to those PHL's that demonstrate strengths in those particular areas; in order to seek advice, assistance and learn from their successes.

As an added benefit, the ability to compare informatics capabilities across multiple PHL's not only becomes a valuable tool for an individual PHL but for APHL as an organization. The information that would be available in the Self-Assessment Tool if all PHL's shared their assessments would provide a national scorecard of the state of public health laboratory informatics. This data could then be used by the APHL Informatics Committee and program staff to prioritize projects and provide more targeted support to APHL membership. Shared with the APHL Board members and CDC leadership, this information could be used to demonstrate the need for assistance and to seek funding to build and maintain the informatics infrastructure necessary to meet the needs of the PHL today - and into the future.

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P-019

Wadsworth Center Master's Degree in Laboratory Science: 4 Years Strong

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The New York State Department of Health's Wadsworth Center Master of Science in Laboratory Sciences (MLS) Program is designed to train the next generation of public health laboratory (PHL) scientists and supervisors. The program provides a comprehensive overview of PHL fundamentals and allows development of advanced technical and analytical skills, combining didactic lecture-based coursework with lab training. Students gain hands-on practical experience and training in the major areas of a PHL, including infectious disease, environmental health, genetics, clinical biochemistry, clinical/diagnostic immunology, biodefense/emergency preparedness, translational medicine and lab quality certification. The two-year, six-semester (60-credit) curriculum includes nine core courses, four special topics courses, lab rotations, and culminates with a capstone project. By addressing a practical challenge in the PHL, the capstone project provides essential lab training and strengthens analytic, interpretive and writing skills. Unique aspects of the program include extensive development of communication skills; exposure to lab operations and management, including best practices, financial operations, and human resource management; hands-on experience with outbreak investigations and new assay development and validation; and access to core facilities using state-of-the-art instrumentation and technology, including next-generation sequencing. The MLS program is in its fourth year with five current matriculated students. Six graduates have worked in grant-funded positions at Wadsworth Center's newborn screening, biodefense, bacteriology/mycobacteriology, virology and bloodborne viruses labs. Several have earned competitive Emerging Infectious Diseases (EID), Oak Ridge Institute for Science and

Education (ORISE) and Advanced Molecular Diagnostics Emerging Infections Program (AMD-EIP) fellowships sponsored by the Centers for Disease Control and Prevention (CDC) and Association of Public Health Laboratories (APHL). Graduates of the MLS program are well-equipped to conduct lab analysis with cutting-edge tools and technology, investigate complex public health questions and respond to everyday challenges in public health.

Presenter: Denise Kay, Wadsworth Center, New York State Department of Health, Albany, NY, Phone: 518.474.7610, Email: denise.kay@health.ny.gov

P-020

A Comprehensive Testing Approach to Detect and Characterize *Legionella pneumophila* serogroup 1 in Autopsy Specimens During a Large New York City Outbreak

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The largest outbreak of Legionnaires' disease to occur in New York City began in July 2015. This outbreak ultimately claimed the lives of 16 of the 138 confirmed cases. The Wadsworth Center, NYSDOH's public health laboratory, received a total of 62 specimens from 13 cases collected during autopsies as part of this investigation. Some cases were considered unexplained deaths. Between 1 and 6 specimens were received from each case representing fresh and formalin-fixed tissues from the right and left lungs, vitreous humor, and urine. Specimens underwent DNA extraction and real-time PCR to detect *Legionella* spp., *Legionella pneumophila* (serogroups 1-15) and specifically *Legionella pneumophila* serogroup 1 (LPSG1) DNA. Of the specimens tested, 10 of 13 cases tested positive in at least one specimen by real-time PCR for LPSG1 DNA. All 10 cases had positive fresh and formalin-fixed lung tissue but real-time PCR cycle threshold (CT) values indicated different levels of LPSG1 DNA in these different specimens and differences between right and left lung specimens were observed. Vitreous fluid specimens were submitted for 6 of the 10 cases, and 3 of these 6 were positive for LPSG1 DNA. Urine specimens were submitted for 4 of the 10 cases, and 1 of these 4 was positive for LPSG1 DNA. All fresh lung tissues were cultured utilizing various methods to suppress the growth of competing organisms including acid washing, heat treatment and ethanol treatment. Of the 17 fresh lung tissue specimens that were cultured from the 10 positive cases, 4 specimens from 3 cases were culture positive for LPSG1. Although the utilization of both acid washing and heat treatment suppressed the growth of competing organisms to some degree, there was no effect on the recovery of *Legionella* from these specimens. Ethanol-treatment had no impact on suppression of competing organisms or recovery of Legionella. All 3 culture-positive cases, including 1 case for which no respiratory isolate was available, were also tested by Pulsed-Field Gel Electrophoresis and Whole Genome Sequencing (WGS) and determined to be part of the outbreak; contributing to the epidemiological and laboratory data in this investigation. A novel amplicon-based WGS approach was developed and utilized in an effort to compare the *Legionella* DNA from PCR-positive, culture-negative specimens to the outbreak strain by WGS. While fresh and formalin-fixed lung tissues are optimal for detection of *Legionella* DNA, specimens such as vitreous humor and urine may also provide positive test results in some cases. The use of a rapid real-time PCR test to detect LPSG1 DNA and culture methods provided valuable information, resulting in the inclusion or exclusion of unexplained deaths in the investigation.

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P-021

The Northern Plains Laboratory Consortium and Emerging Leader Programs Address Regional Needs

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Background: The Public Health Laboratories (PHLs) in Idaho, Montana, North Dakota, South Dakota and Wyoming share demographic characteristics that lead to common challenges. In 2006 the PHLs in these states formed the Northern Plains Consortium (NPC) in order to foster collaboration and coordinate system improvement activities. The NPC has actively worked to identify, prioritize and address areas of need. Most recently the NPC has focused on coordination and training of biosafety outreach officers, in addition to consistently fostering resource sharing and leadership development within member laboratories. Here we highlight key activities of the NPC with an emphasis on shared testing services and succession planning via the regional Emerging Leaders Program (ELP).
Methods: A shared testing services spreadsheet was developed and populated by NPC laboratories. The spreadsheet was similar to the PHL System Database and captured each NPC member laboratory's testing capability and willingness to share services. From there, various shared service arrangements were made between states on an as needed basis. In addition, the NPC worked to share training resources. A regional Eagleson Institute biosafety training is currently being planned in SD to assist with development of biosafety expertise within the NPC. A regional ELP was also developed to provide leadership training to staff in NPC laboratories. The NPC ELP is modeled after APHL's national ELP and the ASCLS leadership program. Eight future leaders were enrolled from staff in each PHL. NPC ELP members participated in monthly webinars, face-to-face meetings, and a team project. The faculty included current PHL leadership and 2 graduates from the national ELP. APHL provided training materials in addition to faculty, and CDC has supported funding for travel.
Results: NPC members have successfully shared low volume testing services, thereby increasing capability and decreasing costs. Shared testing services have included: Hantavirus serology, *M. tuberculosis* nucleic acid testing, 16s rDNA sequencing, Lyme Western blots, Hepatitis C RNA testing and HepC genotyping. Resources continue to be effectively shared for the development of biosafety expertise and leadership development, with the first regional ELP cohort graduating in early 2016.
Conclusion: The NPC represents a regional, grassroots effort to improve PHL systems and increase efficiencies through need-based collaboration. Activities have included: development of a shared services menu, sharing of resources to meet grant deliverables, and the first regional effort to improve management skills in rising PHL staff who might not otherwise have access to leadership training. The NPC serves as a successful model for regional networks to expand access to leadership training, increase efficiency and enhance capability.

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P-022

An Approach to Implementing Culture-Independent Testing of Nationally Reportable Bacterial Causes of Gastroenteritis

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Introduction: Culture-independent testing (CIDT) (e.g. Biofire FilmArray GI Panel [FGIP]) is easy to perform, provides improved sensitivity and turnaround time, and could improve estimates of infectious causes of gastroenteritis. However, clinical and public health laboratorians are faced with challenges to monitor microbiological and molecular trends when using CIDT. The purpose of this study was to develop an approach to preserve epidemiological and surveillance practices for bacterial pathogens detected by the FGIP in the clinical and public health laboratory.
Methods: All stool specimens submitted to the laboratory between January and December in 2015 with an order for the FGIP were evaluated. Stools were collected in or transferred to Cary Blair or Enteric Plus transport media (ratio of stool to medium at 2:15). Bacterial pathogens known to cause nationally reportable gastroenteritis included in this evaluation were *Salmonella* serotypes, *Campylobacter* spp, *Vibrio* spp, *Yersinia enterocolitica*, Shiga-like toxin-producing *E. coli* (STEC), and *Shigella*/Enteroinvasive *Escherichia coli*. Bacterial pathogens detected by the FGIP were reflexed to traditional stool culture for organism recovery. Antibiotic susceptibility testing was performed for all *Salmonella* serotypes, *Campylobacter* spp, and *Shigella* spp for patient management or EPI surveillance. Guidelines for interpreting results from the FGIP and recommendations for empiric therapy of gastroenteritis were established based on the published literature.
Results: A total of 2255 stools were received for FGIP testing (703 inpatient, 877 outpatient, 636 reference clients, and 39 public health samples). Of the stools tested by the FGIP, 141 (6%) had one or more notifiable pathogens to include 51 *Campylobacter* spp, 30 *Salmonella*, 22 STEC, 15 *Shigella,* 10 *Y. enterocolitica*, 5 STEC O157, and 3 *Vibrio* spp. Coinfections were detected in 5 stools each with STEC in combination with *Campylobacter* spp (3 samples), *Shigella* spp (1 stool) and *Salmonella* (1 stool). Of the positive FGIP, culture was successful in recovering 23 *Salmonella* spp (77%), 35 *Campylobacter* spp (69%), 9 *Shigella* (67%), 2 *Vibrio* spp (67%), 3 STEC O157 (60%), 9 STEC (41%), and 3 *Y. enterocolitica* (30%).
Conclusions: CIDT and culture is needed to detect, monitor, and characterize bacterial causes of nationally reportable disease. The reduced recovery of bacterial pathogens by culture is likely due to the enhanced sensitivity of the CIDT. These data suggest that the CIDT can guide laboratorians to select appropriate media for stool culture, and that CIDT can be used to monitor trends in disease incidence and clinical decision-making. Future studies will be done to assess whether CIDT alone can be used to predict disease burden for bacterial, viral, and parasitic causes of gastroenteritis.

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P-023

Diagnosis and Surveillance of Hepatitis C Virus Infection Using Next-generation Sequencing

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Hepatitis C virus is a bloodborne virus that can cause serious liver disease from which approximately 500,000 people die each year worldwide. Diagnosing hepatitis C infection and monitoring the effects of treatment requires three primary laboratory tests: 1) targeting antibodies to hepatitis C virus, and 2) determining the concentration of virus in the blood stream, or viral load (IU/mL), and 3) targeting the single-stranded RNA genome itself to determine genotype. In order to reduce the cost of performing HCV diagnostics in terms of the number appointments and blood draws a patient is required to undergo, our laboratory designed a testing algorithm that is capable of determining all three important parameters from a single blood draw. Serum is initially screened using the Ortho v.3 HCV antibody ELISA. Positive sera, those that demonstrate the presence of HCV antibodies, are reflexed to a qPCR test to determine the presence of RNA. Those that are positive for hepatitis C RNA then undergo library preparation for next-generation sequencing. Sequencing results are capable of determining genotype as well as quantity. For validation, our experiment compares the genotype results obtained by next-generation sequencing to results obtained by the Roche Linear Array. The quantity determined by next-generation sequencing is expressed as a ratio of HCV RNA reads to common housekeeping genes, and these values are correlated to copies/uL as determined by qPCR and IU/mL as determined by the Roche COBAS. Next-generation sequencing is shown to definitively diagnose and characterize hepatitis C infections and can be considered a critical tool in providing genome-level surveillance in this age of successful antiviral therapies.

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P-024

Quantitative Determination of Cannabinoids in Cannabis Plant Material Using High Performance Liquid Chromatography - Diode Array UV - Mass Spectrometry (Trap) Detector

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As of June 2015, twenty three states in the United States of America and Washington D.C. have legalized the use of *Cannabis* for medical purposes. The New Jersey Medical Marijuana Program (NJMMP) was established in 2011. One of the objectives of the NJMMP was to provide high quality safe *Cannabis* plant material to qualified patients.

An efficient, cost effective, and defensible test method for the analysis of cannabinoids with a short sample testing turnaround time was needed to ensure compliance to the NJ Medical Marijuana regulation that any finished medical *Cannabis* dispensed product would have no more than 10% THC. A rapid, high resolution, reversed phase high performance liquid chromatography (HPLC) method using a core shell column was developed to determine the potency and profile of cannabinoids in *Cannabis* plant material.

The *Cannabis* plant material was ground and then extracted with a methanol:chloroform mixture. An aliquot of the extract was injected into a HPLC and the cannabinoids were separated by a reversed-phase core shell C18 column with mobile phase of methanol and 25 mM aqueous ammonium acetate using a gradient program. A diode array UV detector was used for presumptive identification and quantitation of cannabinoids. Confirmatory identification of the different cannabinoids was performed using a mass spectrometry (MS) detector (Trap). Validation data for both external and internal standard

methods and the summary of the results of approximately fifty cultivars of *Cannabis* plant material submitted by the New Jersey Alternative Treatment Centers are presented.

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P-025

The Relationship Between Newborn Screening Unsatisfactory Specimens and Unsatisfactory Results

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Background: The Clinical and Laboratory Standards Institute (CLSI) has published guidelines explaining appropriate DBS collection techniques and standards for specimen acceptability. In New Jersey, newborn screening (NBS) dried blood spots (DBS) are collected from newborns 24-48 hours after birth. Specimens that are considered invalid or unsatisfactory according to the CLSI guidelines are not tested and a repeat specimen is requested. These invalid specimens could potentially cause harm to affected newborns due to delays in screening for time critical disorders.
Current Approach: When a DBS specimen is deemed invalid, NJ NBS laboratory personnel immediately call the facility that submitted the specimen to inform them that the specimen was invalid and to request a new specimen. In addition, unsatisfactory results reports are mailed to the hospital and physician of record requesting submission of a repeat specimen within two days.
Problem: Delays in testing for time critical newborn screening disorders can have adverse effects on the newborns. In addition, for some newborns, no repeat specimen is ever received, indicating that there are newborns that remain unscreened.
Quality Improvement Opportunity: A systematic analysis of unsatisfactory specimens to determine which categories described by the CLSI guidelines will, in fact, result in inaccurate results is necessary. If some categories currently considered invalid provide routinely accurate results, future specimens could be tested and abnormal results reported in a more timely fashion without the need to wait for a repeat specimen.
Action: A pilot study comparing results of matched initial unsatisfactory specimens with acceptable repeat specimens was conducted. Special attention was paid to time critical disorders, as defined by the Secretary's Advisory Committee for Heritable Disorders in Newborns and Children. Results were compared to evaluate trends and differences in interpretations based on unsatisfactory category.
Results: A summary of unsatisfactory specimens received by the NJ NBS Laboratory will be presented. This summary will include a temporal distribution to evaluate trends associated with weather and facility staffing. In addition, analyte specific comparisons distributed by unsatisfactory category will be presented to identify those categories that warrant consideration for future routine testing. Several months of data will be presented.

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P-026

The ELC Risk Assessment Experience

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Background: The performance of a risk assessment is an essential component and initial step in mitigating any potential hazards in the work environment. As part of the Enhanced Laboratory Capacity agreement, Public Health Laboratories are to review the safety processes in place at Public Health Laboratories, implement changes in the risk assessment protocols and perform the risk assessment for high pathogen testing. The performance of the risk assessment, also called job hazard analysis, is a regulatory requirement anytime that personal protective equipment is issued. This is a review of our experience in updating the Public Health Laboratories risk assessment mitigation steps. The next phase will be to reach out to the Ebola assessment and treatment center laboratories in Washington to assist in their risk assessment process, if needed.
Conclusions: The risk assessment process is evolving and changes to meet the laboratories' needs. Diagnostic laboratories often handle specimens with known infectious agents but an unknown infectious agent or hazard could pose a significant risk. There is often the assumption that a given specimen contains no infectious agents and this leads to reduced risk perception. There is a need for implementing a risk assessment template that is user friendly which would help alleviate inappropriate risk perceptions. A risk assessment template has been updated at the Washington Public Health Laboratories and performed for high pathogen testing. The risk assessment is incorporated into the Public Health Laboratories safety program to include lab personnel, facilities, maintenance, epidemiology, etc. A table summary is utilized as a quick guide on the findings and recommendations for laboratory staff. This Risk Assessment summary guide is included in the Supplemental section of the laboratory protocols to enable easy review by the laboratory staff. Key additions to the risk assessment are the incorporation of evaluation for chemical, radiological, physical as well as biological hazards in the workplace. Most laboratories have some combination of these hazards that they encounter and need to mitigate. The effort into performing a meaningful risk assessment will help to ensure a safe and effective workplace and prevent future incidents or accidents.

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P-027

Development of Real-Time PCR Methods for Surveillance of Cryptosporidium and Cyclospora in Fresh Produce in Iowa

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Introduction: *Cryptosporidium* and *Cyclospora cayetanensis* are parasitic protozoans that cause gastrointestinal illness in humans. The parasites can be transmitted by food that has fecal contamination from an infected host. In 2013, there was a large outbreak of cyclosporiasis in Iowa (and other states) that was traced to lettuce. There was also a large increase in *Cryptosporidium* positive stool samples during this same time frame.
Purpose: In response, a food safety surveillance program was initiated by State Hygienic Laboratory and Iowa Department of Inspection and Appeals to test fresh produce from retail and farmers markets for both parasites.

Methods: Two real-time polymerase chain reaction (qPCR) assays were developed for the rapid and sensitive detection of *Cryptosporidium parvum/hominis* and *Cyclospora cayetanensis* in leafy green produce. The *Cyclospora cayetanensis* PCR targets the 18S rRNA gene. The *C. parvum/hominis* assay is a multiplex PCR assay that amplifies a *Cryptosporidium* specific gene and contains two probes that are species specific and labeled with distinct fluorophores. The performance of the PCR assays on leafy green produce was evaluated by inoculation with oocysts and processed/washed according to the protocol described by Orgeta *et al* (J Food Protection, 2014). Nucleic acid was isolated by bead beating followed by the easyMAG. The methods are sensitive and able to detect *C. cayentanenis* and *C. parvum/hominis* parasites in leafy green products inoculated with 60 and 40 oocysts, respectively, 100% of the time.
Results: Surveillance testing for *C. cayetanensis* was conducted for 105 packaged leafy green products from 15 different manufactures that were obtained from 13 Iowa grocery stores. *C. parvum/hominis* was tested for in 98 locally grown leafy green products from 37 different vendors/farms obtained from five different farmers markets. No parasites were detected in the 203 samples.
Significance: The 2013 *Cyclospora* outbreak suggested that the incidence of these parasites in produce may be of greater significance than previously recognized and sensitive real-time assays were developed to initiate a testing program. Surveillance testing will continue in 2016.

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P-028

A Survey of Heavy Metal Exposure in High-Risk Childhood Lead Program Populations in Iowa
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The State Hygienic Laboratory at the University of Iowa (SHL) has been the central laboratory for determining blood lead concentrations on behalf of the Iowa Department of Public Health Childhood Lead Poisoning Prevention Program since the early nineties. The Iowa State Public Health Department reports about 1-2 % of children ages 1-6 are confirmed to have blood lead levels > 10 µg/dL[1]. The primary source of exposure is attributed to lead-based paint from pre-1950 housing stock. Since May 2012, the Centers for Disease Control Prevention has recommended that blood lead levels at or above the most recent reference range of 5.0 µg/dL be used to determine lead poisoning[2]. Assessing Blood Lead data analyzed by Graphite Furnace Atomic Absorption Spectrophotometry (GFAAS) for March 2015 through December 2015 shows 7.7% (565/7376) of children screened are at levels at or above the 5.0 µg/dL reference range for the general population of children ages 1 – 6. In the data set surveyed, 7376 total specimens were analyzed for ether capillary screening (6586) or venous confirmatory testing (790) of blood lead. The percentage of total tests that were venous confirmatory specimens was 10.7% (790/7376). The prevalence of confirmed venous positive specimens ≥ 5.0 µg/dL was 2.2% (165/7376). Although GFAAS is an excellent techniques for analyzing lead in blood, one of the limitations of the instrumentation used blood lead screening programs is only one element can be analyzed at a time. Instrumentation is available to perform multiple elements simultaneously or in rapid sequence so as to appear as if simultaneous. However, the most versatile and sensitive of these is the inductively-coupled plasma mass spectrometer (ICPMS). In this study, we used ICPMS to survey 196 randomly chosen anonymous venous specimens for lead, cadmium, mercury, selenium and manganese.

Geometric means along with 50 and 95 percentiles were calculated for lead, cadmium, mercury,

selenium and manganese. The results suggest that children exposed to high levels of lead can have significant exposures to other heavy metals such as cadmium and mercury. The data also supports the use of ICPMS as a valuable tool in assessing heavy metal exposures in children exposed to lead.

- https://idph.iowa.gov/lpp
- http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6120a6.htm

Presenter: Donald Simmons, State Hygienic Laboratory at the University of Iowa, Ankeny, IA, Phone: 319.335.4500, Email: donald-simmons@uiowa.edu

P-029

Antimicrobial Susceptibility Profiles of *Shigella sonnei* Isolates Circulating in Colorado in 2015

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The rise of antimicrobial resistance in *Shigella sonnei* is a growing problem in the United States. This study evaluated the antimicrobial susceptibility of isolates of *Shigella sonnei* submitted to the Colorado Department of Public Health and Environment (CDPHE) Laboratory in 2015. During 2015, the CDPHE laboratory confirmed 78 *Shigella sonnei* isolates and performed pulse field electrophoresis (PFGE) typing. In this study, these isolates were examined for susceptibility to ampicillin, trimethoprim/sulfamethoxazole (TMP/SMX), ciprofloxacin, azithromycin and ceftriaxone. Antimicrobial resistance profiles were then compared to PFGE patterns and epidemiological data to develop profiles of circulating *Shigella sonnei* among particular groups in Colorado. The results of this study will be used to develop prevention strategies targeting specific patient populations.

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P-030

Multi-State Investigation of Antimicrobial Resistance Genes in U.S. Drinking Water

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Background: The recent increase in community-acquired antimicrobial-resistant infections is a significant public health concern. The rise in multidrug-resistant infections is especially alarming, particularly those caused by bacteria resistant to cephalosporin and carbapenem antibiotics. Environmental sources of these resistant enteric bacteria have been confirmed; however, community drinking water is rarely considered as a source of antimicrobial-resistant organisms, especially in the United States. Although most U.S. water distribution systems adhere to strict water quality regulations, there are occasions when enteric bacterial intrusions occur. The purpose of this study was to investigate whether tap water samples containing coliform (enteric) bacteria are also positive for genes encoding cephalosporin and carbapenem antibiotic resistance.
Methods: To increase the efficiency of coliform-positive water sample acquisition, state public health laboratories were recruited through APHL outreach efforts to participate in the study. Participating state public health laboratories in New York, Illinois, Pennsylvania, Wisconsin, and Utah preserved coliform-

positive water samples from routine and investigative water testing. Samples were shipped to Salt Lake City for testing and were screened by PCR for extended spectrum beta-lactamase (ESBL) genes encoding cephalosporin resistance and carbapenemase genes encoding carbapenem resistance. PCR products from positive samples were sequenced to confirm the specific genes present. The ESBL and carbapenemase-producing bacteria were subsequently isolated from positive samples and identified and tested for susceptibility to various antibiotics.
Results: Of 150 coliform-positive samples tested to date, more than 20 tested positive for ESBL genes by PCR. Sequencing results of PCR products produced multiple DNA sequence matches with ESBL and non-ESBL resistance genes. The most predominant ESBL genes belonged to the species *Serratia fonticola* and *Klebsiella oxytoca*; however, these were primarily chromosomally-encoded (intrinsic) ESBL genes. ESBL genes encoded by mobile DNA were also identified. Two samples tested positive by PCR for carbapenemase genes and were confirmed by PCR product sequencing.
Discussion: While *Enterobacteriaceae* detection in treated U.S. tap water is uncommon, these bacteria can harbor multidrug resistance genes encoding resistance to potent, and sometimes last resort antibiotics. The presence of multidrug-resistant bacteria in U.S. tap water indicates a potential for widespread distribution of these organisms in the community. More research is needed to further determine the public health implications of these resistant bacteria in community drinking water.

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P-031

Local Laboratory Committee - Who We Are and What We Do
D. Gaskins, Association of Public Health Laboratories, Silver Spring, MD

The Local Laboratory Committee would like to present a poster promoting the relatively new committee along with Local Lab membership. Please see below for a short summary of what we'd like to provide to the viewer - this list will likely grow during design/production:

- Definition of a Local PHL
- LLC goals/objectives/current and future projects/contact information
- How to become a local lab member and who to contact for more information
- APHL Public Health Institutional - Local Member list
- Local Lab Luncheon information
- Highlight the posters at the Annual Meeting being presented by local lab members
- Highlight projects/publications done by local labs

Presenter: Akin Babatola, MS, Santa Cruz Environmental Health Laboratory, Santa Cruz, CA, Phone: 831.420.6045, Email: ababatola@cityofsantacruz.com

P-032

A Collaborative Laboratory Response to Legionnaires' Disease in New York City
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In the summer and fall of 2015, New York City experienced two separate outbreaks of Legionnaires' disease that were among the largest ever observed in the United States. Separate sources for both outbreaks were ultimately linked to cooling tower water contaminated with *Legionella pneumophila* serogroup 1 (Lp1). Prior to these outbreaks, the New York City DOHMH Public Health Laboratory (NYC PHL) had limited experience with Legionnaires' Disease-associated surge testing. The ability of the NYC PHL to handle this dramatic increase in testing was made possible by close collaborations with the Wadsworth Center (WC), New York State DOH's public health laboratory, and the Centers for Disease Control and Prevention (CDC). Environmental water and swab samples from cooling towers identified in the outbreak zones were sent to the WC for screening using an in-house developed real-time PCR assay. Culture-based testing at NYC PHL was performed only for those environmental samples in which *Legionella pneumophila* (serogroups 1-15) DNA was detected. Because cooling tower water is generally more contaminated with a higher quantity and more diverse group of organisms than potable water, it was necessary to process water samples for culture using varied conditions including undiluted and concentrated, with and without acid treatment. Processed samples were then plated on multiple types of growth media and suspected *Legionella* colonies were selected for follow-up testing based on colony morphology. Due to the slow growing nature of *Legionella* and background contamination by other organisms, it could take up to 2 weeks to identify suitable isolated colonies for further testing. To confirm Lp1 isolated from environmental samples, either direct Fluorescent Antibody (DFA) or a real-time PCR assay developed by the CDC were utilized. Isolates identified as Lp1 were then analyzed by pulsed-field gel electrophoresis (PFGE) at NYC PHL. Concurrent to the environmental testing occurring during the outbreaks, NYC PHL also was testing clinical specimens associated with the outbreaks. Based on PFGE patterns it was possible to link clinical cases with specific cooling towers in both outbreaks. Additional analysis to corroborate the PFGE results included Whole Genome Sequencing (WGS) at WC and Sequence Based Typing (SBT) at the CDC.

To adequately respond to these nearly overlapping outbreaks required NYC PHL and WC staff to maintain a schedule of afterhours and weekend testing for weeks at a time. Furthermore, effective and timely response to both outbreaks was made possible through the efforts of state and local partners and the utilization of molecular techniques to rapidly screen water samples and confirm Lp1 isolates.

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P-033

Impact of a Local Public Health Laboratory as a First Responder in Vaccine Preventable Disease Investigations: Milwaukee – 2015

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Behind the scenes, the public health laboratory is an essential team member in identifying, confirming and mitigating some of the most critical vaccine preventable diseases (VPDs) in the community, including mumps, measles, rubella and pertussis. As one illustration of this point the Milwaukee Health

Department Laboratory (MHDL) in November and December of 2015 alone performed real-time testing for 12 such cases in a matter of hours.

By utilizing the capabilities of molecular detection, serology and viral culture for VPDs, a public health laboratory can prioritize testing same day or within 24 hours, for the purpose of ensuring the safety of the local community. While the primary mission of other local clinical, reference or state public health laboratories may differ, local public health agencies can prioritize work and engender a feeling of urgency and community ownership that might be different from a more removed public health jurisdiction.

Laboratories are key for VPD determinations and investigations (ref. CDC):

- Virus isolation is considered among the best methods for confirming mumps infection
- Laboratory confirmation is essential for all sporadic measles cases and all outbreaks
- Clinical diagnosis of rubella is unreliable, therefore, cases must be laboratory confirmed

A recent example is the college student who was confirmed "PCR mumps positive" by MHDL in real time late in the day before a four-day holiday weekend. This rapid response (in a matter of hours) allowed MHD epidemiologists, public health nurses and physicians to respond immediately with contact tracing and other control measures to forestall a community outbreak. Sending out such a test to a distant or non-public health reference lab would have resulted in delayed response in this critical public health intervention process.

Another example was an imported suspect case of measles with over 100 exposures extending to a variety of at-risk populations in our community.

While other laboratory facilities may have these testing capabilities, in 2015, three large local health care institutions, two university health centers and MHD epidemiologists chose to utilize the local PHL service to optimize VPD testing interventions in *real-time* in the context of a team response of public health investigators.

By maintaining laboratory proficiency in VPD testing, MHDL continues to contribute to both small, local investigations and surge capacity for larger statewide outbreaks.

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P-034

Screening a High Risk Population for *Trichomonas vaginalis* at a Local Public Health Laboratory Using a NAAT Assay to Improve Sexually Transmitted Infection Case Management Practices

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Background: *Trichomonas vaginalis* (TV) is one of the most common sexually transmitted infectious agents in the U.S. Symptomatic women with trichomoniasis often develop vaginal discharge,

vulvovaginal soreness, and/or genital area irritation. About 10 to 50% of infected females remain asymptomatic, and even higher proportions in males. Detection of *T. vaginalis* using culture method is technically challenging, and time consuming. Culture sensitivity is 38% to 82% when compared to molecular methods. "Wet-prep" microscopy for *T. vaginalis* is 35% to 80% sensitive compared to culture, depends on microscopy experience, and is sensitive to time of specimen transport to the lab. CDC recommends screening for women who receive care in high-prevalence settings (e.g., STD clinics, correctional facilities), demonstrate high risk for infection (e.g., multiple sex partners, prostitution, illicit drug use, history of STD), and HIV positive at entry to care and annually thereafter.
Methods: An FDA-cleared, APTIMA *Trichomonas vaginalis* (ATV) nucleic acid amplification test (NAAT) was used on the Panther platform for screening *T. vaginalis* to diagnose trichomoniasis in symptomatic and asymptomatic cases. Specimens included unisex swabs (vaginal, endocervical and male urethral) and urines (male and female). The verification results were assessed by percent agreement to the expected results, repeat rate, and inter-run reproducibility following laboratory-defined acceptance criteria. Clinical case management was performed at the STD clinic based on results from TV screening.
Results: A total of 259 clinical specimens were analyzed during the verification study. Percentage agreement was 99.4% (168**/**169), 92.7% (38/41) and 97.9% (48/49) when compared with other NAAT testing platform, culture and wet prep respectively. During routine screening, 421 females (average age 29 years) were tested for TV by wet-prep microscopy, NAAT-vaginal swab and NAAT-urine, 9.5 %, 18 % and 15 % respectively were found positive for TV. Our results indicate TV NAAT vaginal swab is almost twice as sensitive as wet-prep from vaginal source and 3% more sensitive when vaginal swab was compared to urine. A total of 863 male urines were tested for TV and 6 % were found positive by NAAT. The results indicate TV infection is more common in women than in men. In this population, the women over 30 and men over 40 years old have the highest rates of trichomoniasis.
Conclusions: APTIMA TV NAAT assay has allowed simultaneous detection of trichomonas, chlamydia, and gonorrhea from high-prevalence population. TV NAAT is twice as sensitive as wet prep and results are available within 24 hours. Inclusion of TV with CT/NG can improve screening asymptomatic patients, prevent preterm delivery in pregnant women and minimize risk of HIV transmission, thus significantly improve STI surveillance and case management practices in public health agencies.

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P-035

Evaluation of HIV 4th Generation Reflex Testing After Rapid Oral Fluid HIV 1/2 Testing for a Local Health Department

L. Wolf, Louisville Metro Health Department Laboratory, Louisville, KY

Background: In order to improve the health of the local community, a road map entitled "Healthy Louisville 2020" (HL2020) was developed. Related to **HIV Prevention and Screening,** the HL2020 goal is to increase the percentage of people who know their status from 87.2% to 90%. Beginning July 1, 2014, the Louisville Metro Department of Public Health and Wellness (LMPHW) offered OraQuick HIV 1/2 rapid oral fluid tests to clients at no cost. LMPHW Laboratory, LMPHW Specialty Clinic (primary clinic for sexually transmitted diseases) and the Kentucky Division of Laboratory Services (KY DLS) collaborated on a pilot project in order to determine the number of additional HIV cases that could be detected by use of a 4th generation HIV antigen/antibody serum test.
Methods: A consent form was developed with approval from the LMPHW Medical Director and the

Jefferson County Attorney. Clients of the Specialty Clinic having a non-reactive result from the rapid HIV oral fluid test, who had signed the consent form and had blood drawn for syphilis screening were included in the study.
KY DLS began offering a 4th generation HIV test on September 1, 2015. KY DLS uses the BioRad GS HIV Combo Ag/Ab EIA. For the months of October and November 2015, clients of the LMPHW Specialty Clinic who met all three criteria had serum forwarded to the KY DLS in Frankfort. Patient information collected included the following: zip code, date of birth, gender, race, ethnicity, HIV and syphilis test results. The date of collection, date of receipt by KY DLS, and date of final report from KY DLS were collected to track turnaround time (TAT).
Results: Of the clients with a non-reactive rapid test result, 77.5% agreed to the additional testing process, and one of the 395 was reactive by the 4th generation HIV test (0.25%). The age range of clients was 15-70 years old, with an average of 31.6 years old. Of the 395 clients, 62% were male and 38% were female. The racial breakdown was 46.8% white, 48.4% black and 2.02% Asian, while the ethnicity was largely non-Hispanic (93.4%). The total TAT from date of collection to date of report was an average of 5.6 days, with a range of 3-10 days. Maps showing frequency of distribution of clients seeking HIV tests at Specialty Clinic indicate that clients will travel some distance for STD services and imply a high level of trust in the services provided.
Conclusions: One client of Specialty Clinic with a non-reactive rapid HIV oral fluid test was reactive by the 4th generation HIV test, and notified within 7 days of rapid test result. Based on this two-month pilot project, LMPHW and KY DLS will implement this tiered approach to HIV screening and diagnostic testing as standard practice in January 2016 to find additional HIV positive clients. This approach provides clients with the benefits of both high quality rapid testing and 4th generation HIV testing through a successful collaboration of state and local public health agencies.

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P-036

Review of Clinical and Non-clinical Features of Active TB Cases 2012-2014, Jefferson County, KY
L. Wolf, Louisville Metro Health Department Laboratory, Louisville, KY

Background: In 2012, Han, *et. al.* published an article entitled "Nonclinical Selection Criteria for Maximizing Yield of Nucleic Acid Amplification Tests in Tuberculosis Diagnosis" [*J. Clin. Micro*. 50 (8):2592]. We reviewed confirmed TB cases from 2012 to 2014 to describe those served by the LMPHW TB Clinic, and characterized the following for clients diagnosed with active TB: (1) nonclinical risk factors (2) clinical risk factors and (3) comparison to state and national data. These data will inform the best use of laboratory tests to aid in rapid diagnosis of TB.
Methods: A spreadsheet was developed to collect data from the TB case reports completed 2012-2014 from Jefferson County, KY. This included both clinical (medical history, laboratory findings) and non-clinical (country of origin, time in US, occupation, zip code, and living situation, *e.g.*). SAS 9.4 analytical software was used to perform data analysis.
Results: The demographic data for the 68 cases 2012-2014 show 70.6% males; 39.7% white, 36.8% black and 23.5% Asian, and 88.2% non-Hispanic. The average age is 46 years. Almost half of the TB cases lived in five zip code areas, and 55.9% were foreign born. The average time spent in the US before TB diagnosis was seven years. Other common non-clinical risk factors among TB cases included being homeless, in a long-term care facility, in a correctional facility, or a health care worker. The most

common clinical risk factors included the following: tobacco use; incomplete treatment for latent TB infection; diabetes; drug/alcohol abuse; HIV infection; contact to a TB patient; and pulmonary disease. Culture results were available for 60 patients, with 56.7% having positive results. Of these, 83.3% had first line drug susceptibility testing performed, with 14% resistant to INH and 8.5% resistant to STM; of note, 4.3% were resistant to INH and STM. AFB smear results were available for 60 patients, with 41.7% positive. During this time period, PCR was performed on 39 patients, with 74.4% of this subset positive. When both AFB smear and PCR were performed for 37 patients, the results agreed 83.8% of the time. Interferon gamma release assay (IGRA) results were available for 38 patients with 81.6% having positive results. Tuberculin Skin Test (TST) results were available for 33 patients with 60.6% having positive results.
Conclusions: The analysis of the TB cases in Jefferson County, KY provides key information about local risk factors. When compared to available state and national averages for similar time periods, the local TB case rate was higher than the regional or state average all three years, and was higher than the national average in 2014. In Jefferson County, more TB cases were homeless than the national rate, but the number in correctional facilities was similar to the national rate. Based on local data, future policies and laboratory procedures can be tailored to better diagnose TB disease in Jefferson County.

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P-037

Urban Garden Soil Testing

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Background: Urban agriculture including community gardens and school gardening are rising trends within Marion County; however, urban soils have the potential for heavy metals contamination, specifically in Marion County of lead (Pb). In the spring of 2013, the Marion County Public Health Department (MCPHD) Laboratory researched options to validate urban soil testing including preanalytical guidance, test method, and post analytical support for the public environmental laboratory test panel. Other areas in MCPHD including Water Quality Hazardous Material Management and the Lead Program also received inquiries about urban soil garden testing for private residents in the county. The laboratory reached out to local organizations including Keep Indianapolis Beautiful and the Department of Earth Sciences within IUPUI, to survey community gardens and brochure guides. The guides were helpful as companion pieces for testing by providing information to clients on how to test soil, how to interpret results and heavy metal alert levels, and how to create a garden.
Methods: Our lab began exploratory/fit-for-purpose testing in March of 2013. With increased urban garden soil test requests, we continued developments for method validation. We became proficient for lead, cadmium, chromium, and arsenic using EPA method 3051A for acid digestion of soil samples and analyzed the samples on an ICP-MS using EPA method 1060A. We subscribed to ERA PT testing. We requested and the MCPHD Board approved a $30 fee for service charge per soil sample submission.
Results: The lab passed external method assessment by achieving 100% on ERA round SOIL 91.The lab tested 147, 55 and 35 garden soils in 2013, 2014 and 2015 respectively. These results affected elementary school playgrounds, community gardens, neighborhood gardens, and residential gardens. The lab also tested soils for a church garden in Hendricks County that supplies produce for an estimated 5,000 individuals within that neighboring county. Garden soil testing was also used at no-cost for employees within the health department.

Conclusion: The MCPHD Public Health Lab effectively validated garden soil heavy metal testing in-house, and made that testing available at a reasonable price with relevant guidance and interpretation for the public. Until recently, there has been a limited amount of information regarding heavy metals in urban soil for Marion County, IN. This project was an effective partnership between the several departments within MCPHD and community partners to address a topical area of public health.

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P-038

Standardization of Gram Stain Method across Laboratory Areas

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Purpose: As a quality and efficiency improvement project, we evaluated the Gram Stain procedure variations in use between three laboratories in order to standardize using one procedure.
Method: The experiment was undertaken by 13 competent testing personnel evaluating four technique variations, encompassing variables in fixation method, staining and decolorizing reagents and processing times. Held constant were physical techniques for organism preparation, rinsing, and decolorizing. Five routinely encountered organisms, three gram negative and two gram positive and two organism mixtures from this group were stained and read microscopically at 100X magnification using immersion oil. Technical bias was eliminated by one person preparing all organisms suspensions at a 2.0 McFarland and applying to the slides prior to dissemination to the labs. Blinding of the gram stain method was accomplished by assigning numbers to the slides in a random order while maintaining a key to the method identity. Conclusions were based on basic statistical analysis performed on graded scores from 1-3, one being “poor”, 2 being “mediocre”, 3 being “good”.
Results: The overall quality score for the method performed by our STD clinical laboratory was the highest (12.10 out of possible 15), while the method in the Environmental Microbiology lab had a very close overall score (11.92). Further evaluation of parameter values across organisms, method simplicity, and reagent costs between these two methods were then utilized to make a final choice of method across laboratories.
Conclusions: Gram Stain techniques that have been optimized by reagent manufacturers or microbiology laboratories can produce results of equivalent quality.

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P-039

Surveillance of Carbapenem-resistant Enterobacteriaceae in Los Angeles County

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Background: The emergence and spread of carbapenem-resistant Enterobacteriaceae (CRE) is a significant public health concern. The Los Angeles County Department of Public Health initiated

enhanced CRE surveillance in January 2015. Community hospitals, skilled nursing facilities, and reference labs were requested to submit CRE Klebsiella pneumoniae, E. coli, and Enterobacter sp. CRE organisms were defined as resistant to imipenem, meropenem, doripenem, or ertapenem OR possession of a carbapenemase. Information gained from this surveillance project will be used to define the extent of antibiotic resistant Enterobacteriaceae in our jurisdiction and target prevention efforts.
Methods: A survey was sent to hospital epidemiologists and lab directors in Los Angeles County to request enrollment. Submitters provided information on patient history, age, specimen source, organism identification, antibiotic susceptibility testing methods, and susceptibility results. Bacteria were streaked for isolation on TSA-blood agar and MALDI-TOF MS was used to confirm submitter identification. An isolate suspension was made using TSB and used as input material for the Nanosphere Verigene Gram Negative Blood Culture (BC-GN) assay. This rapid molecular test was used to compare organism identification with MALDI-TOF MS and identify molecular markers associated with beta-lactam and carbapenem resistance. Antibiotic resistance genes detected by this commercial assay include CTX-M, IMP, KPC, NDM, OXA, and VIM.
Results and Conclusion: A total of 283 carbapenem resistant enteric isolates were received between January - December 2015 from 31 enrolled sites. The majority of submitted isolates were from patients' age 51 or older. Eighty-two percent of CRE isolates were identified as Klebsiella pneumoniae with urine as the predominant source. Six sites submitted more than 15 CRE isolates during the year-long surveillance period (range = 0-64 isolates; average = 9). The majority of isolates had a single resistance marker detected with KPC as the most common carbapenemase gene. There were 14 K. pneumoniae isolates with more than one resistance gene detected (CTX-M + KPC, CTX-M + NDM, CTX-M + OXA). One E. coli strain had both CTX-M + NDM detected. Twenty-seven bacterial isolates (9.5%) did not have any antibiotic resistance marker detected, and the majority were Enterobacter sp. Confirmation of carbapenem resistance by broth MIC and additional molecular testing including whole-genome sequencing is in progress for a subset of these isolates. In conclusion, the Nanosphere Verigene BC-GN assay was used as a rapid screening method for resistance to beta-lactams including carbapenems in enteric bacteria and was 100% accurate for organism identification. KPC-producing Klebsiella pneumoniae are the predominant carbapenem-resistant enteric organism in Los Angeles County.

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P-040

A Comparison of Three Treponemal Assays

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Laboratory diagnosis of syphilis can be time consuming and methods used are often subjective (RPR and TP-PA). We compared the performance, cost, and ease of use for three high-throughput treponemal assays: Phoenix Biotech Trep-Sure Syphilis Total Antibody EIA, Siemens Advia Centaur Syphilis, and DiaSorin Treponema assay. All methods detect total treponemal antibody. The Siemens treponemal assay was performed using the Siemens Advia Centaur XP and the DiaSorin treponema assay was performed using the DiaSorin Liaison XL platform. One thousand serum samples submitted to the Los Angeles County Public Health Laboratories for routine syphilis screening according to conventional CDC syphilis algorithm were used in this study. Results of the EIA and two chemiluminescent treponemal

assays were compared to the performance of the Fujirebio Serodia TP-PA. Fluorescent treponemal antibody absorption (Zeus Scientific Inc. FTA-Abs) was performed as needed to resolve discordant results. The automated chemiluminescent assay instruments, DiaSorin Liaison XL and Siemens Advia Centaur XP, were able to process more specimens per batch with faster time to results compared to the Trep-Sure EIA method. All three assays had comparable sensitivity and specificity (98-100%) and provided equivalent results compared to TP-PA. No false reactive samples were identified. Results from TP-PA that were indeterminate/invalid were positive using treponemal total antibody immunoassays and confirmed by FTA-Abs. The number of tests able to be processed per batch ranged by method (24-120 samples/batch). Hands-on technologist time was significantly greater using the manual EIA method compared to the two automated chemiluminescent platforms (80 minutes vs. 30 minutes). The EIA method required more wells to be used for controls/calibrators than TP-PA or automated chemiluminescent methods. Reagent cost was comparable at approximately $5 per test. For laboratories with a high syphilis serology workload, the use of automated treponemal assays or EIA format is an acceptable alternative and less subjective compared to TP-PA for syphilis confirmation.

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P-041

"Riddle Me This Batman! Who Identifies Unsafe and Misrepresented Food/Feed Products Every Day?" – Riddler "That's an Easy One, Riddler!! The Public Health Laboratorian!" - Batman

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Many states and some local jurisdictions have laboratories that perform testing for food and feed. The capabilities vary, but some basic capabilities include testing for food or feed safety concerns such as microbiological contamination, unapproved food components, filth, chemical and heavy metal contaminants, new food and food packaging technology, nutrition and other label claims, natural toxicants, and other health/safety issues. Some laboratories perform analysis for economic fraud as well, such as fraudulent labeling, misrepresentation of fish species, authentication of honey, fruit juices and olive oil, among other things.

As governmental food/feed safety partners move towards more preventive-based approaches to food safety with the implementation of the Food Safety Modernization Act of 2011, including widespread surveillance efforts, the demand for laboratories that meet recognized best practices of analytical competency has risen dramatically. These best practices are demonstrated by adherence to ISO/IEC 17025 accreditation requirements, as well as other practices described by the Partnership for Food Protection (PFP). The PFP is the structure used to meld and coordinate representatives with expertise in food, feed, epidemiology, laboratory, animal health, environment, and public health to develop and implement an Integrated Food Safety System-the PFP Food/Feed Testing Laboratory Draft Best Practices Manual is currently being updated by the Laboratory Sciences Workgroup.

Regulatory agencies have to quickly utilize laboratory data to identify, prevent and remove unsafe food/feed products from the marketplace, leading to a coordinated, faster and more effective response to food safety events such as outbreaks. Examples of laboratory success can be exemplified with a review of recalls of food or feed due to laboratory findings. Often these are paired with findings from

the field, with the laboratory providing the so called “nail in the coffin”. Each day, these test results, along with outbreak data from PulseNet, provide powerful tools to remove unsafe and misrepresented products from the market and help to ensure the public health is protected. Daily, just as super heroes do, the public health food and feed testing laboratory and its analysts just do what they do best-working hard every day to make sure our food is safe.

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P-042

Development of a Career-spanning Competency-based Training Curriculum Framework for Governmental Food and Feed Laboratories

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The Association of Food and Drug Officials (AFDO), Association of Public Health Laboratories (APHL), Association of American Feed Control Officials (AAFCO) Food and Drug Administration (FDA) have been collaborating since 2013 with the International Food Protection Institute (IFPTI) to develop a career-spanning competency-based training Curriculum Framework for Governmental Food and Feed Laboratories (Laboratories).

The Curriculum Framework is intended to assist Laboratories in training staff to perform analytical services that will facilitate sharing of quality data and mutual reliance among local, state, federal, territorial and tribal food and feed regulatory partners.

The Curriculum Framework is being developed by a group of Subject Matter Experts (SMEs) comprised of laboratory professionals with State Food and Feed Laboratories, FDA, U.S. Department of Agriculture, Canadian Food Inspection Agency, APHL and AFDO staff. The draft Curriculum Framework, which includes training content areas and definitions for Entry-Level, Mid-Level, Expert-Level, Supervisor/Manager Level and Senior Administration Level staff was completed in 2013 -2014. Level 1-5 competencies developed for 16 Entry Level Foundation content areas were completed in 2015. The work was guided by information from a survey on the proposed content areas which received 49 responses from governmental laboratory professionals. The SMEs are completing Level 1 – 5 competencies for the chemistry, microbiology, and radiological competencies in 2016, with a goal of completing competencies for all entry level content areas this year. Results can be used to identify training gaps, needs, and serve as a blueprint for developing entry level training to help achieve consistent performance outcomes from entry level professionals.

The poster presents the basic curriculum framework and results to date.

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P-043

Laboratory Accreditation is a Key Building Block of an Integrated Food/Feed Safety System

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Laboratory accreditation attests to the competency and technical capability of a laboratory, leading to results which are defensible to a recognized standard. Additionally, it supports the traceability and accountability of results generated by a laboratory that may be made available for consideration by federal agencies for enforcement actions. ISO/IEC 17025 is an accreditation standard utilized by laboratories throughout the world. Decision makers can take regulatory action with confidence when using data from accredited laboratories.

The Food Safety Modernization Act of 2011 stresses the importance of quality testing standards and directs FDA to establish a program for laboratory accreditation. In 2012, FDA entered into five-year cooperative agreements with 31 state food-testing laboratories to either attain ISO/IEC 17025:2005 accreditation (23 laboratories/$300,000/year) or expand and maintain existing accreditation (8 laboratories/$150,000/year). In 2015, an additional cohort of 6 food and 20 feed testing laboratories was awarded funding to obtain accreditation.

FDA's mandate to establish a program for laboratory accreditation is also being strengthened in collaboration with three national associations and their member governmental laboratories. In 2012, FDA awarded a five-year cooperative agreement to APHL to support accreditation in collaboration with the AFDO and the AAFCO. APHL, AFDO and AAFCO are providing several resources to laboratories seeking accreditation including a Discussion Board, >200 documents posted to a resource website, >15 training webinars that have already been delivered to >800 participants, targeted assistance to 16 laboratories not covered under FDA's ISO Cooperative Agreement, a Laboratory Curriculum Framework for Governmental Food and Feed Testing Laboratories, and *GOODSamples* (Guidance for Obtaining Defensible Samples) publication.

With all of the efforts above, the number of accredited laboratories performing regulatory testing will be significantly increased by fall 2017. Investment in governmental laboratory accreditation for the nation's regulatory food and feed testing laboratories provides added value towards the mission of protecting the public health. Accreditation leads to greater laboratory capacity, improved quality of data submitted to regulatory food agencies leading to a coordinated, faster and more effective response to food safety events such as outbreaks.

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P-044

Test Characteristics of Xpert HPV and OncoE6 for Point-of-care Cervical Cancer Screening among HIV-infected Women in Zambia

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Invasive cervical cancer (ICC) is the most common cause of cancer death in women in sub-Saharan Africa, and Zambia has the second-highest ICC incidence rate worldwide. HIV is also prevalent in sub-Saharan African countries, and is associated with a higher incidence of precancerous cervical lesions and faster progression of these lesions to ICC. Thus, cervical cancer prevention programs should include, if not target, HIV-infected women.

In response to a high burden of cervical pre-cancer and ICC in HIV-infected women in Lusaka, Zambia, the Cervical Cancer Prevention Program in Zambia (CCPPZ) was established in 2006. CCPPZ is integrated into the nationwide HIV/AIDS care and treatment infrastructure and offers visual inspection with acetic acid (VIA) screening, with same-day cryotherapy treatment for eligible precancerous lesions or referral for ineligible lesions. CCPPZ has screened more than 200,000 women and provides nationwide coverage. VIA is cost-effective and fast, but it has moderate sensitivity and specificity. Newer tests that detect human papillomavirus (HPV) could be more accurate. Some newer tests have short turn-around-times (TAT), can be used at the point-of-care, and may be useful for national cervical cancer screening programs like CCPPZ. We determined the test characteristics of two new tests: Xpert HPV and OncoE6. Xpert HPV is a DNA test with a TAT of ~60 min, while OncoE6 has a TAT of ~90 min and detects the HPV E6 oncoprotein. Histology was the gold standard, with cervical intra-epithelial neoplasia grade 2 or worse (CIN2+) and CIN3+ thresholds.

Of the 200 HIV-infected women enrolled, 47% were positive by Xpert HPV and 6% were positive by OncoE6. The sensitivity and specificity for CIN2+ were 88% (95% CI: 71–97%) and 60% (95% CI: 52–68%) for Xpert HPV, and 31% (95% CI: 16–50%) and 99% (95% CI: 97–100%) for OncoE6. Similar patterns were seen with the CIN3+ threshold.

Cervical cancer screening programs in areas with a high HIV burden should strongly consider Xpert HPV, due to its high sensitivity. The low sensitivity of OncoE6 prevents its use in primary screening, but it may be useful as a triage test.

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P-045

Evaluation of MALDI-TOF MS for the Identification of Isolates of *Vibrio* Species from Clinical and Environmental Sources

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Objective: Public health laboratories serve as an essential resource for accurate identification of both clinical and environmental isolates of *Vibrio* species for public health surveillance. To date, large-scale evaluations of MALDI-TOF MS performance for *Vibrio* identification are lacking. We evaluated the performance of the Bruker MALDI Biotyper CA system for the identification of a large collection of clinical and environmental isolates of *Vibrio*.
Study Design: A total of 206 isolates, representing 27 species of *Vibrio,* were analyzed by MALDI-TOF MS using the Bruker Biotyper CA system (Bruker Daltonics, Billerica, MA) with RUO software version DB-

5989. DB-5989 contains spectra for 54 *Vibrio* species. *Vibrio* isolates tested included a diverse representative taxonomic set of strains from the Centers for Disease Control and Prevention and strains from the Washington State Public Health Laboratories. All isolates were identified using standard biochemical methods (SBM) or by DNA sequencing of the *rpoB* gene. Score values (SV) >2.0 were considered reliable species-level identifications; SV between 1.7 and 2.0 were considered reliable genus-level identifications. Isolates were tested using the direct spot method. Isolates yielding SVs <2.0 or that gave incorrect identifications with a SV >2.0 underwent extraction and were reanalyzed. Concordance was defined as matching results between MALDI-TOF MS and SBM or DNA sequencing.
Results: MALDI-TOF MS correctly identified 128/206 (62%) of the isolates from 13 species to the species-level (SV >2.0). The remaining 78 (38%) *Vibrio* isolates from 14 species were not identified to the species-level (SV <2.0). Full protein extraction improved identification by 7%. All *V. parahaemolyticus* and *V. vulnificus* and 95% of the *V. alginolyticus* isolates tested were correctly identified to the species-level. Discordant identifications between SBM and MALDI-TOF MS were observed for 7 strains from 6 species. Discrepancies are being resolved by sequencing of the *rpoB* gene. Despite spectral representation in the database, 12 *Vibrio species* were not identified to the species-level. Additionally, as spectra for *V. cholerae* and *V. metoecus* are not contained in the database, these 2 species were not correctly identified. Importantly, 16/28 (57%) of the *V. cholerae* isolates tested were misidentified as *V. albensis* with a SV >2.0. Spectra from these 14 species are candidates for inclusion in a custom *Vibrio* database. The custom database will be evaluated using a second test collection of clinical and environmental *Vibrio* isolates.
Conclusions: MALDI-TOF MS has the potential to correctly identify a wide-range of *Vibrio* species. Development of a custom *Vibrio* database with additional spectra may increase the utility of MALDI-TOF MS for the identification of a diverse range of *Vibrio* isolates in both clinical and public health laboratories.

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P-046

Sampling and Characterizing Airborne Pollen over Barbados

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Barbados is a tropical Caribbean island, covered with lush natural vegetation, agricultural crops and grasses. In response to public health concerns, especially asthma, we initiated a program to measure daily pollen concentrations and to provide this information to the public media for dissemination. Airborne pollen was monitored during May 2000 to July 2005 using a Rotorod® Sampler. The most abundant pollen was grass pollen, comprising 75% of total the airborne pollen for which we found a clear seasonal cycle with low concentrations of pollen grains (2–5 grains/m^3) in the dry season (December to April) and higher concentrations (6-18 grains/m^3) in the rainy season (May to November). Low (1-5 grains/m^3), medium (6-9 grains/m^3) high (10-62 grains/m^3) and very high > 62 grains/m^3 values were established for the island based on the 50^{th}, 75^{th} and 99^{th} percentiles. The start of the grass pollen season was established to be between July and September each year, in response to the rainfall pattern. Our studies show that rainfall is the dominant meteorological variable that controlled the production of grass pollen. Tree pollen counts are much lower and constitute 25% of airborne pollen. Airborne weed

pollen is almost non-existent.

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P-047

4th Generation Rapid HIV Testing Can Expedite Linkage to Care: A New Efficient Diagnostic Model

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Objective: In 2010, the CDC and the Association of Public Health Laboratories (APHL) proposed a new algorithm for HIV testing. The algorithm consists of first performing a rapid HIV-1/2 immunoassay that can detect HIV-1/2 Ab and p24 Ag. If this initial test is positive then the performance of an immunoassay that can differentiate between HIV-1 and HIV-2 Ab is performed. If the follow up test is negative or indeterminate, then a qualitative Nucleic Acid Test (NAT) is performed. The goal of this study was to compare the performance of two non-automated rapid tests, the Determine (Alere) HIV-1/2 Ab/Ag and the INSTI HIV-1/HIV-2 Ab (bioLytical), and to evaluate their utility as part of an improved diagnostic testing algorithm that could eliminate the need for the HIV qualitative NAT assay.
Study Design: 94 samples of patient plasma that were positive on the HIV Combo (ABBOTT LABORATORIES), but indeterminate/negative on the Multispot (BIORAD) were collected, along with one negative control and five positive controls (SeraCare Panel). All samples were tested by the Determine and INSTI assays. All results were then compared to the NAT results.
Results: Of the 94 Combo positive patient samples, 9/94 were positive by NAT. 5/94 samples were subsequently excluded; NAT was not run. The Determine Assay was able to detect all 9 cases that were positive by NAT, sensitivity of 100%, and differentiate between Ag and Ab positivity, but could not differentiate between HIV-1 and HIV-2 Ab. However, 16 cases were found to be false positive by the Determine based on NAT testing, while 64 cases were true negatives; specificity of 80%. In contrast, the INSTI only identified 5/9 NAT positive samples, sensitivity of 55.5%, but it is unable to detect HIV Ag. The INSTI assay misidentified 9 NAT negative samples as positive while correctly identifying 71 NAT negative samples; specificity of 88.7%.
Conclusion: The Determine assay's ability to detect Ag during an acute retroviral infection, when it is crucial to link patients to early care and prevent transmission during these states of hyperinfectivity, makes it a valuable tool for early detection and rapid diagnosis. We propose a new algorithm utilizing a 5^{th} generation initial assay which can be confirmed with the Determine and the Genius (BIORAD) assays. These assays, in combination, can adequately detect and differentiate HIV 1/2 Ab and Ag. This would eliminate the need for qualitative NAT, which extends the time to diagnosis. Ideally patients should be tested with a quantitative HIV viral load, which will confirm primary HIV infection and establish a clinical baseline.

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P-048

Detecting Oseltamivir-resistant Influenza Viruses in Respiratory Specimens using iART: An Ongoing Collaborative Project

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Oseltamivir is the most commonly prescribed drug for treating influenza A and B infections. It acts by inhibiting the neuraminidase (NA) enzymatic activity of the virus. Presently, laboratories participating in U.S. national influenza virological surveillance utilize the NA inhibition (NI) assay and/or pyrosequencing to detect oseltamivir-resistant viruses. Both assays are cumbersome, and require highly-trained laboratory personnel and sophisticated equipment. Moreover, only propagated virus isolates can be characterized using currently available NI assays. This requirement not only delays testing, but can also lead to false positive results due to selection of NA mutants during virus culturing. Using the new iART research assay, it is possible to measure NA activity directly in respiratory specimens. Notably, similar to current NI assays, it is necessary to determine antigenic type of the virus (A or B) prior to testing with iART. The new test consists of a kit for sample processing and a small benchtop luminometer.

Approximately 0.1-0.5ml of nasal wash/swab in VTM is needed to measure NA activity in the presence and absence of oseltamivir. Based on predetermined criteria built into the device software, the test result is displayed as 'nonresistant' or 'resistant.' It takes 45 minutes to test one sample in iART, and, if staggered, 15-20 samples can be tested in 1.5 hours by one laboratorian. In this study, the prototype of the iART device and kit were first used to test reference oseltamivir-sensitive and resistant viruses from the CDC NI Susceptibility Reference Virus Panel. These cell-grown viruses were diluted (1:256-1:1024) and then tested according to the developer's protocol. All oseltamivir-resistant reference viruses exhibiting highly reduced inhibition in NI assays were identified as oseltamivir-resistant by iART. Next, a set of 46 respiratory specimens was assembled. This set contained A(H1N1), A(H1N1)pdm09 and A(H3N2) subtypes and type B viruses with Ct values ranging from 17.8 to 29.3. Viruses in specimens were screened for markers of oseltamivir-resistance (e.g. H275Y) using the CDC pyrosequencing assay; their respective isolates were tested by NI assay using commercially available kits. All respiratory specimens, containing oseltamivir-resistant viruses (n=19), were correctly identified as such with iART. Similarly, all oseltamivir-sensitive viruses were accurately identified as "nonresistant." One respiratory specimen, containing type B virus, had to be diluted to reduce high signal; it is known that influenza type B viruses typically exhibit higher NA activity than type A viruses. To overcome the need to dilute type B samples, the iART device used in this study has been modified and will be evaluated by several influenza surveillance laboratories in the near future.

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P-049

Strategies to Support Post-market Evaluation of Commercial Diagnostic Tests for Influenza – CDC/FDA Collaboration

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Background: Rapid influenza diagnostic tests (RIDTs) are widely used by clinicians and hospitals to aid in the diagnosis of influenza infections and determine patient management. The Food and Drug Administration (FDA) has proposed to reclassify antigen based rapid influenza virus antigen detection test systems intended to detect influenza virus directly from clinical specimens from class I to class II. The reclassification of RIDTs, if finalized, would enable the FDA to enforce higher performance criteria and monitoring of annual reactivity testing and analytical performance validation by the manufacturers of influenza virus antigen detection systems. In order to support performance monitoring, Centers for Disease Control and Prevention (CDC) will provide *in vitro* diagnostic test manufacturers with characterized influenza viruses to be used by manufacturers who have voluntarily chosen to conduct the annual reactivity testing or analytical performance validation as described in the proposed order issued by FDA.
Materials and Methods: CDC developed panels of influenza viruses containing characterized reference viruses for the evaluation of influenza diagnostic assays. The CDC Human Influenza Virus Panel includes recently circulating seasonal influenza viruses (influenza A(H1N1), A(H1N1)pdm09, A(H3N2), B (Yamagata Lineage), B (Victoria Lineage). These viruses are antigenically/genetically similar to those found in circulation or anticipated to be circulating in the United States, including those wild-type viruses chosen by the World Health Organization for subsequent Northern Hemisphere influenza vaccines. The CDC Non-Human Influenza Virus Panel will contain a selection of variant animal-origin influenza viruses that have caused infections in humans and have potential to become transmissible from human to human. In Fall 2015, in response to the emergence of avian A/H5Nx influenza viruses in the United States, the CDC H5Nx Influenza Virus Panel was made available to diagnostic test manufacturers that included inactivated domestic avian A/H5N2 and A/H5N8 influenza isolates.
Results/Discussion:
In December 2015, manufacturers were able to voluntarily request CDC reference virus panels for testing. Fourteen panels were provided to eight manufacturers that included the CDC Human Influenza Virus Panel and the CDC H5Nx Influenza Virus Panel. Companies were provided with instructions for testing and sharing of test results. In order to manage requests, CDC established a website where manufacturers can submit their requests and information, including the FDA submission number, after referral from FDA. Although, testing and sharing of analytical performance data is currently voluntary, FDA is accepting such information from manufacturers that choose to share their information with FDA.

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P-050

Building a National Biomonitoring Network

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Biomonitoring provides unique and valuable information on human exposure to environmental compounds by measuring chemicals or their breakdown products in people's blood or urine. The Centers for Disease Control and Prevention (CDC) uses biomonitoring to conduct an ongoing assessment of the U.S. population's exposure to environmental chemicals; however, CDC's biomonitoring data do not provide exposure information by specific state or locality. Recognizing the need for biomonitoring capability at the state and local level, CDC and the Association of Public Health Laboratories (APHL) are working to establish and expand national capacity to conduct high-quality biomonitoring laboratory

sciences through 1) CDC's State Biomonitoring Cooperative Agreement, 2) development of technical and administrative resources for all state and local biomonitoring programs, and 3) a formalized National Biomonitoring Network. Since 2003, CDC has provided competitive funding awards to help selected states use biomonitoring to assess chemical exposures of concern in their communities. States use funding to purchase laboratory equipment and supplies; hire and train specialized staff; and conduct fieldwork and data analysis, while CDC provides training and technology transfer, quality assessment services, and technical assistance to awardees. CDC and APHL work together to promote system-wide networking and collaboration and to provide critical non-financial resources for all state and local programs interested in conducting biomonitoring. APHL developed consecutive five-year National Biomonitoring Plans to guide a nation-wide, state-based system approach for biomonitoring, resulting in the APHL Biomonitoring Guidance Document, Toolkit, Discussion Board, Laboratory Capabilities List, and other resources promoting high-quality biomonitoring science. In 2012 and 2015, CDC and APHL convened stakeholders from across the environmental public health system to promote national scientific and programmatic engagement on biomonitoring issues including laboratory methods, proficiency testing and quality assurance, study design, and data analysis and communication. Leveraging these efforts and existing laboratory infrastructure, APHL and CDC are now formalizing a national network of regional, state and local laboratories to promote use of high-quality biomonitoring science in routine public health practice. The goal of the National Biomonitoring Network is to ensure the quality and consistency of national biomonitoring measurements, ultimately enabling public health practitioners to better address community exposures. Through these efforts, chemical exposures will be better identified through standardized, high-quality biomonitoring programs across the country.

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P-051

Implementation of the Competency Guidelines for Public Health Laboratory Professionals: Moving Forward

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Background: The *Competency Guidelines for Public Health Laboratory Professionals* were published in the *Morbidity and Mortality Weekly Report* (MMWR) in May 2015, the result of a 2.5-year collaboration between CDC and APHL. The guidelines are intended to form the basis of competency-based approaches to improve organizational and system-wide PHL workforce development efforts. Early implementation successes include development of an example Biosafety Officer/Official position description, and use of recommended competencies as the foundation for the new Laboratory Leadership Service (LLS) Fellowship program and for CDC's revamped biosafety training program. APHL and CDC aim to facilitate widespread adoption of the guidelines across the public health laboratory (PHL) system, which will require thoughtful planning, ongoing strategic guidance, and the availability of resources to aid implementation.
Methods: Two groups, consisting of PHL representatives and staff from APHL and CDC, were formed: 1) a Steering Committee that would focus on aiding PHLs with integration of the competencies into their HR management system processes (e.g., job description development, performance management); and, 2) an Advisory Group that would focus specifically on the APHL/CDC Public Health Laboratory Fellowship

programs. Each group met in person in January 2016 for critical discussion and to make recommendations about their respective topic areas. Subsequent work will involve refining recommendations and providing ongoing guidance to APHL, CDC, and state/local PHL leaders regarding these efforts.
Results: The Steering Committee is developing a strategy to aid implementation in state/local PHLs that builds upon early activities, a strategy that includes: more extensive communication and outreach about the competencies; and prioritization of tools and resources (to be developed by separate work teams) to assist PHL leaders, other PHL professionals, and HR staff in applying the competency guidelines to HR systems and processes. The Advisory Group is providing guidance to APHL on the structure and evaluation of its fellowship programs, on better integration of its various fellowships, and on the development of a competency-based framework for the fellowships.
Conclusions: Enhanced communication about the competency guidelines and the availability of valuable tools and resources should bolster the integration of the guidelines by PHLs into their own organizations. Keen guidance is helping APHL create a stronger, integrated fellowship program that is well structured to address workforce needs at the national level. The resulting outreach, products, and programs from these efforts are expected to significantly enhance adoption of the competency guidelines throughout the PHL community, which will strengthen multiple workforce development efforts such as recruitment, staff training and development, and succession planning.

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P-052

The Influenza Partner Portal – A Microsoft Dynamics-based Tool for Centralized Information Management at CDC

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The CDC Influenza Division (ID) has developed a software solution called the Influenza Partner Portal (IPP) to integrate management and tracking of services provided to its external partners in support of diagnostics, surveillance, pandemic preparedness, and global health securities objectives. Through management of its laboratory relationships, including inventory of specimens received for testing and distribution of reagents, IPP simplifies routine manual functions such as tracking email conversations, follow-up requests for support and custom reports. Future IPP modules will also support internal processes including ID's Quality Management System and development and deployment of proficiency panels.

IPP utilizes Microsoft Dynamics Customer Relationship Management (CRM) System software that is integrated with Outlook and SharePoint. MS Dynamics views and workflows have been configured to suit ID's specific needs so that it can operate seamlessly with existing processes. IPP takes information management out of email, file shares and siloed databases and integrates it into a centralized collection point where related datastreams can be linked. For example, an email notification from a regional lab about a local influenza outbreak could be linked to fast-tracked shipping of diagnostic reagents from CDC's Influenza Reagent Resource (IRR) program. Situation-specific dashboards facilitate further coordinated responses and can be configured to display any information tracked within IPP.

Each component of the IPP platform is developed as an independent module that will build on others. The first module to launch during the 2015-2016 flu season supports requests for reagents, including diagnostics and other reagents that ship from the IRR program. CDC receives over 13,000 requests for influenza reagents each year. Within IPP's customized dashboard, these orders can now be sorted, reviewed and acted on more quickly than before.The IPP dashboard automatically vets requests based on reagent type, inventory quantity, and requesting lab. Requests that require additional guidance are flagged for expert consideration and follow-up communications are captured in the requestor's profile, allowing ID to maintain a historical repository of reagent support. Ultimately, IPP's repository of information will facilitate the standardization of laboratory support globally and rapid emergency responses.

Like many organizations today, the growing complexity of ID's operations and institutional knowledge requires development of smarter solutions for managing its data. In the coming years, IPP will be an integrated communication and information hub for many ID processes. The vision includes development of a web portal to allow external partners direct interface with IPP to access epidemiological and laboratory resources in support of their own influenza-related activities.

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P-053

CDC's National Report on Human Exposure to Environmental Chemicals: An Update

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Objective: CDC's National Biomonitoring Program uses unique and high-quality measurements in blood and urine (biomonitoring) to measure more than 300 environmental chemicals or their metabolites in participants of the National Health and Nutrition Examination Survey (NHANES). CDC publishes findings in the *National Report on Human Exposure to Environmental Chemicals (Exposure Report)* and in *Updated Tables* that include newly available biomonitoring results. Together, the *Exposure Report* and *Updated Tables* provide an ongoing assessment of the U.S. population's exposure to environmental chemicals, presented by age, sex, and race/ethnicity.

Results: CDC's *Exposure Report* and *Updated Tables* include results from NHANES survey periods from 1999 to 2014 and now include data for 305 environmental chemicals. Biomonitoring measurements show continuously declining blood lead levels in children and widespread exposure in the U.S. population to certain industrial chemicals including perfluorochemicals, polybrominated diphenyl ethers, bisphenol A and perchlorate. In the most recent *Updated Tables February 2015,* new chemicals measured for the first time include copper, zinc, and selenium in serum; manganese, strontium, and tin in urine; cyclohexane-1,2-dicarboxylic acid mono(hydroxy-isononyl) ester (MHNCH) a urinary metabolite of the plasticizer 1,2- cyclohexane dicarboxylic acid, diisononyl ester (DINCH; and 28 urinary metabolites of several volatile organic compounds. The *Updated Tables 2015* also presents data from a special sample of adult cigarette smokers and nonsmokers for selected chemical groups that are associated with tobacco smoke exposure.

Conclusions: CDC's *Exposure Report* and *Updated Tables* provide the most comprehensive assessment of American's exposure to environmental chemicals. By measuring and tracking the presence and amount of environmental chemicals in a nationally representative sample of the U.S. population over

multiple NHANES survey periods, CDC can identify trends in exposure and help identify at-risk population groups and assess the effectiveness of interventions to reduce harmful environmental exposures. Recent oversampling and special samples also provide additional information on particular exposures to population subgroups and adult cigarette smokers.

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P-054

Development of the CDC Laboratory Leadership Service Program (LLS)

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Background: CDC established the Laboratory Leadership Service (LLS) fellowship program to create tomorrow's leaders in public health laboratory science and safety, and as one of the critical components to make CDC laboratories the model for scientific excellence and safety. LLS aligns with the Epidemic Intelligence Service (EIS) to promote interdisciplinary training, applied learning, and networking, thereby strengthening bonds between the laboratory and epidemiology disciplines. The goal of the LLS program is to produce graduates that will maintain the highest standard of public health laboratory (PHL) science by applying principles of safety and quality management systems as the cornerstones of their work.
Program Development: Under the guidance of an advisory committee, program competencies were derived from the 2015 CDC-APHL Competency Guidelines for Public Health Laboratory Professionals. The LLS training curriculum was developed to address those competencies with a focus on biosafety, quality management systems, and management and leadership. It comprises didactic portions and applied on-the-job training that includes 11 core activities of learning (CALs) to measure the progress each fellow makes during the two years of training and evaluate their competency achievements upon completion. Fellows are matched with host laboratory supervisors for mentorship and guidance and for the service learning portion of the fellowship. Eligibility criteria for upcoming classes were refined in 2015: LLS fellows must be scientists who hold a doctoral-level degree in a laboratory-related discipline and have a minimum of two years of post-graduate laboratory experience.
Program Implementation: The inaugural LLS Class of 2015 (7 fellows) started July 2015, and the LLS Class of 2016 (8 fellows) will start July 2016; all are assigned to CDC laboratories. In the first 6-months, the inaugural class completed an intensive, one-month classroom training, conducted laboratory risk assessments, participated in field activities (e.g., outbreak response, applied research, and technical assistance), and assessed safety and quality protocols.
Future Directions: LLS will continue to evolve to develop future PHL leaders who integrate laboratory safety and quality as a principal standard of practice in every facet of their work. Field assignments at state or local public health laboratories will be implemented in 2017 in collaboration with APHL. Lab-Aids, which are a mechanism for public health authorities to request the short-term public health laboratory assistance, will be incorporated into the program. The LLS fellowship structure and competency framework can serve as a model for additional PHL fellowships. Program evaluation and the assessment of the achievement of program goals and the impact of the fellowship will be conducted. Recruitment for Class of 2017 will begin in May 2016.

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P-055

Influenza Molecular Diagnostic Performance Evaluation of International Laboratories: Assessing and Identifying Training Needs

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Background: The Influenza Division (ID) of the Centers for Disease Control and Prevention (CDC) provides support globally to help countries' national influenza laboratories attain or maintain World Health Organization (WHO) National Influenza Center (NIC) status and standards of practice. Support is provided in the form of funding and technical assistance to National Ministries of Health through bilateral cooperative agreements (CoAgs). In order to effectively provide support and determine training needs for CoAg funded laboratories, capacities to perform laboratory testing for influenza are evaluated by 1) performing laboratory assessments with a standardized tool, 2) review of laboratory's test results with the WHO External Quality Assessment Project (EQAP), and 3) review of laboratory's test results with the CDC Influenza Molecular Diagnostic Performance Evaluation (IMDPE).
Method: In the fall of 2014 CDC's ID offered the IMDPE panel to 54 partner and CoAg funded countries in order to assess their molecular testing capacity for influenza. The panels included 10 simulated human specimens that contained inactivated influenza viruses and/or cultured human cells, including 6 influenza A samples (A(H3N2), A(H3N2)v, A(H1N1)pdm09, A(H5N1), and A(H7N9)), 2 influenza B samples (Yamagata and Victoria lineages), and 1 negative sample. The performance of individual laboratories was assessed based on the laboratory's ability to correctly detect and characterize the included viruses though no grades or rankings were assigned. Additional information regarding laboratory methods and equipment were collected. Test results from the 2014 exercise were compared against those collected from a pilot exercise conducted in 2011.
Results and Conclusion: A total of 51 laboratories enrolled through a CDC webpage to request panels by submitting their laboratory information. Results from the 2014 exercise showed 44 of 51 (86%) of CoAg funded laboratories correctly identified 9/10 samples, and 49 of 51 laboratories (96%) achieved a pass rate of 80%. Only two laboratories missed 3 or more evaluation samples. These results showed an overall improvement from the 2011 pilot exercise when 20 of 26 (77%) of laboratories correctly identified 9/10 samples, 22 of 26 laboratories (85%) achieved a pass rate of 80%, and four laboratories missed 3 or more evaluation samples. Overall, CoAg funded laboratories demonstrated high performance and implementation of updates to CDC testing procedures, although in 2014, only 28 participants (55%) correctly identified a sample containing A(H3N2)v variant virus. With support of the Association of Public Health Laboratories, two training courses for advanced rRT-PCR influenza testing were held that focused on technical areas identified in the 2014 evaluation. A subsequent IMDPE will be offered to evaluate laboratories and measure improvement following training.

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P-056

Developing a Legionnaires' Disease Outbreak Laboratory Response Plan: Are You Ready?

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Incidence of Legionnaires' disease (LD) increased 217% in the first decade of the new millennium and annual reported cases are still on the rise. *Legionella*, the causative agent of LD and the leading cause of waterborne pneumonia outbreaks in the United States, is not spread person to person but primarily via inhalation of aerosols from improperly maintained man-made water systems. Currently, positive identification of the source of an LD outbreak currently requires isolation of *Legionella* bacteria from both clinical and environmental samples for comparison by typing. Obtaining these isolates is often challenging and requires specialized media and processing techniques. The Centers for Disease Control and Prevention (CDC) assists state and local public health departments with dozens of outbreaks each year. To complement the multiple LD environmental and epidemiologic investigation instruments that CDC has developed to assist with outbreak response, the new tools presented here are intended to aid state and local public health laboratories in developing a Legionnaires' Disease Outbreak Laboratory Response Plan. During an outbreak, state and local public health laboratories may suddenly be faced with the prospect of processing hundreds of samples. Preparing a Response Plan can help every state and local public health laboratory develop a strategy before such an incident occurs, regardless of a laboratory's current *Legionella* testing capacity. Response Plans may be as simple as vetting and establishing a point of contact with an outside certified laboratory for handling of potential outbreak samples or as complex as complete workflow algorithms for processing clinical specimens or environmental outbreak samples including the different testing, typing, and reporting of the corresponding isolates. The Response Plan development tools presented here include: 1) a *Legionella* testing capacity self-assessment flowchart, 2) resources for identifying qualified external laboratories for outbreak support, 3) essential media, reagent, and equipment checklists, 4) example clinical and environmental sample and isolate workflow processes (with and without use of PCR), 5) example documents for managing large numbers of samples and isolates, and 6) suggestions for development of *Legionella* testing capacity and proficiency. Establishing a Legionnaires' Disease Outbreak Laboratory Response Plan will help state and local laboratories strengthen their LD response capabilities and prepare for potential outbreaks with confidence.
The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the the Centers for Disease Control and Prevention.

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P-057

Enhancing Analytical Preparedness and Response to Water Contamination Incidents
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Charged by Homeland Security Presidential Directive 9 to develop a national laboratory network for water quality, the Environmental Protection Agency (EPA) established the Water Laboratory Alliance (WLA). The WLA is a nationally integrated network of public health, environmental, and commercial laboratories capable of analyzing samples in the event of a water contamination incident involving chemical, biological or radiochemical agents. To bolster the Water Sector's preparedness, coordination and response to contamination incidents, the WLA develops and provides a variety of tools, training resources and exercises. The foundation of the WLA is the WLA Response Plan (WLA-RP), which focuses on incidents that may require more analytical support than what a typical utility, state or federal

laboratory can provide alone. To help implement the WLA-RP, the EPA has conducted numerous laboratory response full-scale exercises (FSEs) that provide Water Sector stakeholders with the opportunity to practice coordinated laboratory response to a drinking water contamination event including communication, sample shipping and analyses, and data review and reporting. The EPA is currently piloting a FSE Toolkit which will provide the necessary information and guidance for organizations to plan and conduct their own contamination emergency response exercises, thereby increasing the outreach impact and sustainability of the full-scale exercises. The WLA recognizes that the process for improving preparedness and response to contamination incidents can be overwhelming. Water Sector stakeholders may not know where to begin and time and resource constraints may limit stakeholder involvement in preparedness efforts. This poster highlights key tools and resources offered by the WLA Program that enhance Water Sector preparedness to water contamination incidents.

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P-058

Informatics Technical Assistance

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APHL developed the Technical Assistance (TA) Team approach to guide and support public health laboratories, public health agencies, and other partners and meet their needs for interoperable data exchange. Our team helps national and international partners with improving public health systems, establishing enhanced surveillance, infrastructure improvements, and successful project delivery. We offer assistance in a variety of areas, from project management and business analysis to data standards, terminology, technical architecture design and assessment, as well as workflow analysis. TA is available for implementations for long-term for maintenance issues.

In collaboration with the Centers for Disease Control and Prevention (CDC), the Technical Assistance Team supports implementations of the following data exchanges:

- Electronic Laboratory Reporting (ELR) to Public Health, with help available for the laboratory, the agency or both
- Implementation of the Public Health Laboratory Interoperability Project (PHLIP) Electronic Laboratory Surveillance Message (ELSM) for Influenza and other respiratory viruses from testing laboratories to CDC
- ELSM for Vaccine Preventable Disease testing results from Reference Center Laboratories to CDC
- ELR for Animal Rabies from testing laboratories to CDC
- Case notification messages from Public Health Departments to CDC under the NNDSS Modernization Initiative (NMI)
- Pilot web portal to support Electronic Test Order and Result (ETOR) of TB testing between submitters and laboratories

The APHL Informatics Messaging Services (AIMS) platform supports all of these data exchanges, and works with the TA team to onboard new messaging partners and data streams. Jurisdictions can leverage AIMS to limit the burden of point-to-point communications, and once on the hub can quickly implement exchanges with other AIMS partners.

APHL Informatics and CDC continue to refine the TA Team approach, and have recently established internal coordination among the various implementation projects in order to offer a broader range of services to public health laboratories and agencies. The TA Team will evaluate the needs of any laboratory that requests technical assistance and offer all applicable support.

This poster describes the technical assistance model, including the focus on developing re-usable components and the transfer of specialized knowledge to jurisdictions. It reviews the evolution of the TA approach and discusses how the consolidation of services will ensure a more efficient delivery of technical assistance for all relevant interoperability projects.

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P-059

2015 Landscape of State Public Health Laboratories

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Objective: Using data obtained from a variety the 2015 APHL surveys, the Institutional Research (IR) will showcase the state public health laboratories (SPHLs) capacities and capabilities in several areas.
Project Design: The Institutional Research (IR) program provides accurate and timely information on the public health laboratory system on a diverse range of topics. One tool used to collect and disseminate information to members is via surveys. In 2015 the IR program fielded 10 surveys to SPHLs with response rates ranging from 45% to 100%. Utilizing data from several of the 2015 surveys: Comprehensive Laboratory Systems Survey (CLSS), All Hazards, Workforce, and Next Generation Sequencing (NGS), the IR program analyzed the data to paint a picture of the status of SPHLs. Data points extracted from several surveys such as funding, laboratory capabilities, and workforce information on a state level are presented.
Results: The CLSS was fielded to the 50 SPHLs and the District of Columbia yielding a response rate of 96.1% (49 laboratories). Data from the CLSS pointed out that 100% of the participating SPHLs had met the Emergency Response sub-objective with 100% reporting that they provide or assure testing on clinical specimens in the event of suspected chemical terrorism. The Policy Development sub-objective was met by 76% which exceeded its Healthy People 2020 target of 74% and revealed that 92% of the directors from the participating SPHLs regularly participate in developing state-specific standards for health-related laboratories. The All Hazards survey was fielded to the 50 SPHLs, the District of Columbia, Los Angeles, New York City, and Puerto Rico yielding a response rate of 100%. Data from the All Hazards survey reveals that CDC PHEP funding for the participating laboratories has decreased by 64% since 2002. The Next Generation Sequencing Survey was fielded to the 50 SPHLs and the District of Columbia yielding a response rate of 98%. Data from the NGS survey reveals that 60% of the participating SPHLs had sequencing instrumentation at the end of 2015.
Conclusions: This poster provides a landscape of the SPHLs capacities and capabilities. While they still face challenges with regards to funding as the All Hazards survey results show it should be noted that they are still meeting the targets set out by the Healthy People 2020 objectives. Alongside this the NGS survey reveals that a majority of SPHLs are currently utilizing innovative technologies.

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P-060

Creating the Conditions in which Public Health Laboratories Can Better Engage in Research

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Objective: To highlight research accomplishments from within the public health laboratory community at the local level and reaffirming the engagement in research as a core function of public health laboratories. This poster will help identify where the barriers are that prevent the public health laboratory community from being more engaged in public health related research and showcase research objectives at the local level.
Project Design: As a part of the focus of the Knowledge Management initiatives within APHL, it has been recognized that APHL must identify better ways to document the value of research within public health laboratory systems and practice. In the most recent Public Health Laboratory Systems Survey (PHLSS) findings, it is evident that engagement in research needs strengthening. PHLs have indicated that they often do not engage in research because of competing priorities and funding. Research may not be seen as part of the individual public health laboratories' mandate. There are various types of research performed in public health labs that this poster can capture. Some of the types of research being conducted at the local level are applied, clinical, systems and services and translational.
Results: Previous research sessions at APHL meetings have highlighted the research performed at state PHLs. In order to demonstrate the broad application and contributions of research to public health laboratory practice this project shares the representative research accomplishments of local PHLs. These examples can serve to educate and promote the importance of conducting public-health related research more widely. Showcasing the many types of research performed at the local level will enlighten members on the value of research by sharing new knowledge, introducing new technology, improving practices, fostering scientific innovation and establishing new partnerships.
Conclusion: This poster is designed to broaden the scope and understanding of what constitutes research by exposing the participants to practical examples of successful research initiatives. The information shared will give PHLs insight as to what other laboratories have been able to accomplish across the research spectrum.

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P-061

Showcasing APHL Tools

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Objective: To showcase the various toolkits APHL offers to its members. All of these support the members in different areas and aspects. This poster will demonstrate some of the tools and the many benefits they offer.
Project Design: APHL committees and programs have developed a variety of tools for laboratories to help manage their workload more efficiently, identify gaps, and collect organizational information. A large number of APHL members are either not aware of the tools or have not seen the benefits of using them. The APHL Knowledge Management Committee (KMC) and APHL staff collaborated in marketing and promoting the usage of these toolkits to its members through e-blasts, Lab Matter articles and at various APHL committee meetings.
Results: This poster will showcase the different tools available, their application and implementation, as well as provide examples and tips on how to get the most out of the toolkits. Some of the toolkits available are: the *Knowledge Retention Toolkit* which provides a comprehensive resource to capture critical and essential knowledge in sustaining key organizational operations that help support public health research efforts. *A Practical Guide to Moving to a New Site for Public Health Laboratories: Additional Tips* and *A Practical Guide to Dealing with Laboratory Floods*, both provide best practices and key considerations when planning to relocate and when responding to a flood emergency. The Biomonitoring Toolkit, serves as a one stop shop for public health professionals to access resources, ask questions and view biomonitoring related announcements.
Conclusion: KMC is promoting a variety of APHL toolkits that provide readily available information within single resource documents. The toolkits specifically capture best practices and tips that target key operations that are vital to running public health laboratories more efficiently.

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P-062

New and Improved Member Resource Center

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Objective: To promote and display the improved APHL Member Resource Center (MRC) and encourage staff, members and committees to take a more active role submitting documents and using the MRC.
Project Design: The MRC is a web-based tool developed by APHL that offers resources to help strengthen the operation of all types of health laboratories. APHL programs including Institutional Research, Communications, Information systems, Quality Systems, Informatics, and Membership have been updating and improving the MRC, specifically by making the submission process easier and the search functionality more user friendly. APHL staff plan to field a survey in January regarding the MRC. The survey, posted on the QA Listserv will ask members questions on their experiences using the site.
Results: Currently the MRC houses over 600 useful documents. The MRC provides users with access to documents and procedures specifically related to public health laboratory operations and practice. Attendees will also hear success stories entailing how the MRC was beneficial to public health labs along with suggestions from APHL staff on how to improve the MRC. The newly improved website includes enhanced searching capabilities along with easier filtering mechanisms to make the process more user friendly. The poster presenters will seek input from the attendees regarding the new and improved MRC sites functionality.

Conclusion: This poster is designed to demonstrate recent improvements to the MRC, and explain the numerous benefits it has to offer. In addition, tips and tricks on utilization of the site will be shared with the attendees along with input from members and APHL staff. Using the feedback from internal discussions inside APHL regarding the MRC, we plan to use these improvements and incorporate them to the site and highlight them in the poster. The APHL Knowledge Management Committee will continue to showcase the MRC to members and encourage them to submit useful documents to share with other APHL members.

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P-063

The Public Health Laboratory System Database (PHLSD): A New Approach to Information Sharing

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Objective: The objective of this poster is to provide members with information on progress, design and utilization of the PHLSD that has been designed for PHL information management and as a foundation for a national PHL test directory. The poster will demonstrate how the PHLs can benefit by improving recordkeeping for regulatory inspections, personnel vacancies, tests, and equipment inventory.
Project Design: The PHLSD is a web-based tool developed by APHL with support from CDC, which enables PHLs to access information on their regulatory and testing capabilities. The PHLSD provides "one-stop shopping" for querying testing services across PHLs. The Microsoft Access version of the database was piloted with review and input from states and subsequently converted to a SharePoint-based application for increased and user-friendly functionality. The database provides the laboratories with an updated list of tests conducted and access to an equipment inventory to prepare for inspections by accrediting agencies. There is continuing work to ensure that reporting features align with PHL needs for CLIA inspections and search functions to identify PHLs with related testing services.
Results: This new database provides a central repository for both external and internal information sharing, real-time and comprehensive information on the capabilities of PHLs, and improved reporting capabilities including recordkeeping for CLIA audits. Additional features, functionality and the ability to review aggregate test data are available in the new application. By developing and administering the PHLSD, APHL is hoping to decrease the number of surveys fielded and their length and is providing access for PHLs to a national test directory to inform local decisions.
Conclusion: The database and resulting national PHL test directory offers a strategic approach for organizing, reporting, and sharing information, as well as increasing the efficiency of PHL information management. This will allow for greater transparency, enhance opportunities for collaboration, inform interoperability efforts, and provide a resource in times of emergency or surge.

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P-064

The Future of Select Agent Research and Emerging Threat Testing in the US

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Recent lapses in biosafety practices involving federal government laboratories has provoked a heightened awareness of select agent and toxin research in the United States (US). In addition, the 2014 outbreak of Ebola in West Africa and subsequent imported cases in the US have identified more gaps in biosafety practices at public health and clinical diagnostic laboratories. These events also highlighted the lack of biosafety programs and oversight around the country, most notably in clinical laboratories. The Department of Defense (DoD), the Centers for Disease Control and Prevention (CDC), and the Association of Public Health Laboratories (APHL), have embraced these challenges, aiming to transition laboratories to a culture of responsibility and safety by providing the resources and tools to improve biosafety and biosecurity and shape new policies involving select agents and toxins and emerging infectious diseases like Ebola. As a measure toward preventing future lapses, enhancing biosafety and laboratory biosecurity, as well as promoting life sciences research, the CDC and DoD took immediate action by partnering to develop recommendations to enhance the current system of biosafety and biosecurity oversight and practice. Moreover, CDC, in accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, recently completed their biennial review of the current list of biological threat agents and toxins and proposed amendments for republication. These rule changes aim to improve policies surrounding biological select agent and toxin research and testing, especially as it pertains to public health laboratories who are members of the Laboratory Response Network for Biological Threats Preparedness (LRN-B). The guidance and policies provided by these partner organization will improve biosafety and biosecurity across the country.

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P-065

Emerging Technologies: Assuring Safety and Accuracy of MALDI-TOF Technologies

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This poster will address some of the challenges associated with adopting new technologies such as MALDI-TOF, a mass spectrometry based analysis to identify bacteria and toxin activity. It will also reflect the work of APHL to evaluate the safety and accuracy of this technology. Many clinical laboratories and public health laboratories are in the process of adopting MALDI-TOF. These technologies provide significant benefits by promptly diagnosing patients and limiting reliance on time-consuming conventional methods. However, these efficiencies must be balanced with safety and accuracy. Some technologies may accurately identify routine clinically relevant microorganisms but not exhibit an expected level of sensitivity and specificity when “unusual organisms” are present in samples. Prior to implementing MALDI-TOF, there are several considerations including training of staff, biosafety, sample preparation techniques and the accuracy of the technology. As new technologies emerge, without assuring that biosafety and accuracy has been evaluated, this could increase lab exposures. This poster will focus an overview and considerations of APHL's activities to evaluate sample preparation techniques and performance of MALDI-TOF platforms, as they relate to safety and accuracy as well as share the findings from these studies.

The poster will demonstrate new information which may impact the use of MALDI-TOF technology in private clinical and state and local public health laboratories. Specifically, so attendees can learn more about the results of APHL scientific studies to evaluate extraction methods as well as the accuracy of MALDI-TOF and recommendations to shape the use of this technology in laboratories.

The poster will show the findings are relevant and timely: Given ongoing biosafety concerns and issues with sample referral to state and local public health laboratories, it will be important for APHL and its members to play a leadership role in evaluating new technologies and providing guidance to governmental and private laboratories. This poster is timely and addresses the activities within APHL to evaluate MALDI-TOF and to collaborate with partners to shape quality laboratory practices in laboratories and prevent laboratorian exposures.

Learning Objectives:
• Describe MALDI-TOF technology and its use in private clinical and public health laboratories.
• Provide the specific study findings on extraction methodologies for MALDI-TOF that ensure safe practice.
• Provide study findings of the safety and accuracy of MALDI-TOF to address what can be done to improve this technology as it relates to identification of potential high consequence organisms.
• Explain recommendations to sentinel clinical laboratories using this emerging technology to better manage expectations of the various users

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P-066

Enhancing Biosafety and Biosecurity in America's Public Health Laboratories
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The ability to work with high consequence and emerging pathogens is a necessity for public health laboratories, as recently demonstrated by the Middle Eastern Respiratory Syndrome corona virus (MERS CoV) and Ebola virus outbreak. However recent highly publicized lapses in biosafety involving select agents at multiple government institutions, has exposed gaps in the biosafety/biosecurity apparatus in place to protect both the laboratory worker and the general public. In order to close these gaps the Association of Public Health Laboratories (APHL) has partnered with the Centers for Disease Control (CDC) in a three year program to increase the capability of public health laboratories to work safely and securely with these pathogens. APHL will accomplish this objective by performing multiple functions in support of this program; such as providing subject matter expertise and biosafety/biosecurity tools, training and resources for our public health laboratory partners. In addition APHL will coordinate national efforts of communication between public health labs and clinical labs. The success of this program will be measured via calls and surveys with the participating laboratories.

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P-067

APHL and Abbott Laboratories Lean Workflow Studies in in the Tennessee Public Health Laboratory

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Objective: As public health laboratories continue to be challenged to do more with less, many have looked at using Lean principles to improve processes, eliminate waste, and increase efficiency. For the third year, Association of Public Health Laboratories' (APHL) Diamond level corporate members, Abbott Laboratories has offered to provide Lean workflow assessments in three member laboratories, with a follow-up session to recommend the potential improvements or changes that will improve workflow utilizing Lean concepts.
Project Design: Staff from interested public health laboratories (PHL) were required to complete an application that described specific goals and efficiency challenges for their laboratory. Applications were received and reviewed by APHL and Abbott staff, with selection based on the scope of the project and best matches for the skills and knowledge of the Abbott consultants. The Tennessee Public Health Laboratory, featured here requested a workflow analysis of General Bacteriology/Environmental Micro sections where a multitude of testing including traditional biochemical testing, PCR, and Gen-Probe testing is performed. Due to the many different types of specimens and samples received each day, the TN goal is to develop a more efficient way of completing high volume and/or time consuming testing with current staff levels.
Results: The consultants recommended that the laboratory better utilize available technologies like Maldi-TOF, better organize the layout of the laboratory, such as removing equipment not in use, set goals regarding turn-around time and then monitor which will help drive efficiency and performance, use IT to the laboratory's advantage and re-allocate some of the sample processing works so senior technologists spend less time on prep work.
Conclusions: It is expected that if the recommendations from the assessments are followed, a new level of efficiency will be obtained with a savings of time and or budget.

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P-068

Pilot Project on the Return on Investment Tool

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Objective: The objectives of this poster presentation are to 1) describe what the return on investment (ROI) tool is and what it means to public health laboratories, 2) present data from a pilot study of beta-test sites and demonstrate its application, and 3) share the benefits of using the tool.

Project Design: A workgroup was created with representatives from the Knowledge Management and Laboratory Systems and Standards committees with technical consultation from Dr. Paul Speaker at West Virginia University to develop a ROI tool for public health laboratories. The tool was modeled from Project FORESIGHT, the global standard for business metrics in forensic laboratories. The ROI model combines data from laboratory public health program testing, personnel, the 11 Core Functions and expenditures. Data was collected from seven pilot sites for FY14 that includes six state sites (Utah, Arizona, Minnesota, New York-Wadsworth, New Hampshire and Iowa) and one local laboratory (Tulare County, California) for influenza, tuberculosis, public health emergency preparedness, PulseNet, newborn screening and Safe Drinking Water Act programs. The data entry is designed for ease of use through an Excel tool.
Results: Results begin to demonstrate the contribution of the benefits for their jurisdictions and are presented in both traditionally dollars of investment and quality of adjusted life years (QALY). These findings offer a sense of the dramatic benefit that public health laboratories offer and can be utilized to support justification for increased funding in laboratory services. The Excel spreadsheet can also serve as an internal management tool for decision making and strategic planning.
Conclusion: The ROI tool provides immediate results and validation that support strategic management of the laboratory and can help with test and expenditure projections. Laboratories can also use the data to communicate to stakeholders and leadership their efficiency and cost effectiveness. Using their experience in developing and populating the tool, representatives from the seven pilot sites can serve as mentors to other public health laboratories as they learn how to use the tool.

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P-069

National PHL Drug Susceptibility Testing Reference Center for *Mycobacterium tuberculosis*

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A total of 9,421 tuberculosis (TB) cases were reported in the United States in 2014. It is imperative that laboratories provide results from drug susceptibility testing (DST) to aid in clinical decision making. Performing growth-based DST is technically demanding and because maintaining proficiency is critical to ensuring accuracy, it is recommended that laboratories perform DST for at least 50 Mycobacterium tuberculosis (MTB) isolates per year. However, data from a 2012 National TB Services Survey indicated that 42% of responding laboratories performed DST for five or fewer MTB isolates per month, below or near the recommended test volume for maintaining proficiency. To address the need for public health laboratories (PHL) with low volumes for DST, APHL and CDC worked collaboratively to establish the National DST Reference Center for Mycobacterium tuberculosis at the California Microbial Diseases Laboratory (MDL) in March 2015.

The DST Reference Center serves as a resource for low-volume PHL to obtain growth-based DST for both first- and second-line antituberculosis drugs as well as molecular detection of drug resistance to isoniazid and rifampin by pyrosequencing. Current services offered include: first-line DST, second-line DST and molecular detection of drug resistance using pyrosequencing. First-line DST is performed using BACTECTM MGITTM 960 for rifampin, isoniazid, pyrazinamide, and ethambutol with a mean turnaround

time (TAT) of 18 days. Second-line DST includes ethionamide, capreomycin, amikacin, and moxifloxacin with a mean TAT of 14 days (excludes reflex testing), with kanamycin being added in 2016. Pyrosequencing is performed on specimens or isolates that meet pre-determined criteria for suspicion of drug resistance. Loci examined include rpoB, inhA, katG, and ahpC with a mean TAT of 2–3 days with fabG1 and rpoB-176 loci being added in February 2016.

As of December 31, 2015, the DST Reference Center has performed 216 tests on 150 specimens at no charge to the submitting PHL with the exception of shipping costs. Fifteen eligible laboratories have enrolled with 12 having submitted samples thus far. The DST Reference Center has detected 5 isoniazid, 4 pyrazinamide, and 1 ethionamide resistant isolate as well as 1 extensively drug-resistant isolate. The reference center has demonstrated the feasibility and successes of a shared service model for DST. It provides high quality testing services for PHLs with low testing volumes in an effort to improve DST in the United States and works closely with the CDC Division of TB Elimination Laboratory Branch.

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P-070

Nampula Central Hospital's LIMS Story: How Laboratory Information Management Systems Improve the Entire Hospital System

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In 2014, Nampula Central Hospital implemented a project to upgrade laboratory information management systems (LIMS) to improve testing efficiency, sample tracking, and test reporting to reduce delays in obtaining results for patients and increase access to treatment in a timely manner. The Association of Public Health Laboratories (APHL) was issued by the United States (US) Centers for Disease Control and Prevention (CDC) technical assistance funds to collaborate with the Mozambique Ministry of Health towards identifying and developing a workplan for implementation of a LIMS. Laboratory System Technologies (LST) Disa*Lab software was selected to implement at Nampula Central Hospital between August and September 2014. LIMS impact assessments are ongoing with preliminary evaluations indicating improvements from laboratory technicians to clinicians in the wards. This abstract will detail improvements in data capturing regarding service delivery, operational efficiencies, testing quality and timeliness, cost savings, and impact on patient care. Qualitative studies will be reported regarding impact on provincial health priorities as well as implementation of LIMS at other testing sites.

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P-071

State Legal Requirements for Submission of Enteric Isolates and Other Clinical Materials from Clinical Laboratories: A Review of State Approaches

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Background: Since 2013, FDA has approved several culture-independent syndrome-based, multi-analyte nucleic acid panels for enteric pathogens. These culture-independent diagnostic tests (CIDTs) allow a clinical laboratory to simultaneously and rapidly detect a wide range of enteric pathogens. CIDTs offer faster turnaround time in the clinical laboratory setting, among other benefits. Use of these tests has implications on isolate-based public health surveillance systems, such as PulseNet. The Association of Public Health Laboratories (APHL) commissioned an analysis of current state legal requirements for the submission of isolates or other clinical materials from clinical to public health laboratories in the United States. Additionally, a checklist was developed to assist public health departments in revising and strengthening their requirements for submission of isolates or other clinical material from clinical laboratories.
Methods: A review of state statutes and regulations among the 50 states and the District of Columbia was compiled from electronic research databases and state publications from June 9-26, 2015. A total of 8 enteric pathogens were included in the analysis: *Campylobacter* species, *Clostridium botulinum, Cryptosporidium, E. coli* (O157 and non-O157 STEC)/Shiga toxin producing *E. coli, Listeria monocytogenes, Salmonella* species (Typhi and non-Typhi), *Shigella* species and *Vibrio* species. A checklist was then developed citing examples of strong legal frameworks and language which supports mandatory submission of isolates or other clinical materials by clinical laboratories.
Results: Among the regulations and statutes analyzed, several approaches were used by states in mandating submission of isolates or other clinical materials from clinical laboratories. Forty-three state jurisdictions mandate submission of isolates or other clinical materials for at least three of the eight pathogens analyzed. Of the remaining jurisdictions, four do not require routine submission of isolates or other clinical materials and others only require submission under certain circumstances (upon request or suspicion of bioterrorism or outbreaks).
Conclusions: While some states have robust laws mandating isolate submission, a need still exists for improvement in many states, given the increasing challenges of CIDTs. States should consider using the checklist that was developed to strengthen their legal framework for mandatory isolate submission. Isolate submission is critical to maintaining the nation's foodborne disease surveillance and response system.

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P-072

Development of Interim Guidelines for the Submission of Enteric Pathogens from Positive Culture-Independent Diagnostic Test (CIDT) Specimens to Public Health

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Background: Since 2013, several companies have received FDA approval of culture-independent syndrome-based, multi-analyte nucleic acid panels for enteric pathogens. These culture-independent diagnostic tests (CIDTs) allow a clinical laboratory to simultaneously detect a wide range of enteric pathogens rapidly. Although CIDTs offer faster turnaround time in the clinical laboratory setting, use of these tests has implications on isolate-based public health surveillance systems, such as PulseNet. To address the emerging trends with implementation of CIDTs by clinical laboratories the APHL Culture Independent Diagnostics Subcommittee, in conjunction with American Society for Microbiology (ASM),

have developed interim guidelines for the submission of enteric pathogens from positive CIDT specimens to public health. These guidelines are intended to be used by clinical laboratories for the timely submission of enteric isolates or clinical materials to public health departments.
Methods: A workgroup was formed by members of the APHL Subcommittee which met monthly to develop a draft set of recommendations for review by the ASM Lab Practices Committee. A conference call was held among both groups to finalize the guidelines. This publication will be posted on the APHL website along with distribution via various ASM, CDC and APHL communication platforms.
Results: A key recommendation in the guidelines state that communication among clinical laboratories and public health is essential when considering adoption and implementation of a new CIDT assay. Clinical laboratories considering implementation of a CIDT assay should notify the public health laboratory within its jurisdiction for the specific guidance of pathogen submission requirements and specimen types preferred by their public health partner. Additionally, clinical laboratories should continue to obtain isolates and submit them to local or state public health laboratories for timely detection of outbreak clusters. If clinical laboratories are unable to provide isolates to public health laboratories, specific recommendations for specimen type and transport media are included in the guidelines.
Conclusions: As more clinical laboratories migrate towards implementing CIDTs, adoption of these guidelines is critical to ensure the timely transport of isolates or specimens to public health laboratories. Isolate-based surveillance systems are the cornerstone for the rapid detection of foodborne disease clusters and outbreak response activities in the United States. APHL and CDC plan to update these interim guidelines based on data from isolate recovery studies conducted in 2015 by CDC and local/state public health laboratories.

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P-073

Environmental Testing in State Laboratories: 2006-2015
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Last summer, APHL fielded the 2015 Environmental Health Laboratories Survey to assess laboratory capabilities, capacities, training and funding, and to gain a better understanding of environmental health laboratory needs. APHL administered the survey using *Qualtrics*, an online survey platform, and sent it to 125 APHL member and non-member public health, environmental and toxicology laboratory directors. The response rate was 42% (53/125), with 45 state public health laboratories and eight state environmental laboratories completing the survey. Data were analyzed and compared to results from the 2006, 2009 and 2012 APHL Environmental Health Laboratories Surveys. This quantitative data will be the only aggregated information on the current and past status of environmental testing at state public health and environmental laboratories across the US. Laboratories will be able to assess their individual capabilities in comparison to the nationwide results, and a strategy can be developed to determine how environmental health laboratories can better meet national public health needs in the future.

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P-074

A Brave New World II: Navigating the Digital Age

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A modern public health laboratory (PHL) is under a constantly increasing need to create, process and distribute more data. Indeed most PHLs consider their ultimate product to be the information that is generated by the testing, surveillance analytics, and research data.

With the growth of reliance on IT systems within the laboratory, many jurisdictions have found that they are expanding far beyond their organizations previous informatics realm to acquire and use the IT products and services they need to fulfill their mission. In 2015 the APHL Informatics committee published "Brave New World II: Navigating the Digital Age", a whitepaper that explores some of the information technology strategies used within public health laboratories and provides helpful guidance in successfully navigating the process of establishing a good IT foundation for public health laboratories. This poster gives an overview of the findings of that white paper and our conclusions as to how public health laboratories can best "navigate the digital age".

Today's laboratory stakeholders expect information to be more comprehensive and to flow faster and more securely than ever before, both to satisfy the needs of external clients and to improve internal operations. Well-implemented electronic information management helps laboratories reduce errors and creates a consistent multiplier when it is used to produce consistent data in a timely manner. In short, laboratory information technology (IT) services are now a mission-critical component of PHL operations. In the paper we highlighted how a new way of addressing IT services was critical in the timely delivery of newborn screening results in KY. We also explored how the Division of Environmental Protection in NJ used a messaging-based system to automate the delivery of environmental health data to federal partners.

In our exploration of this topic we concluded that a strong informatics capability must exist now more than ever to support and extend PHL practices. Furthermore processes on the horizon including Next Generation Sequencing will entail that laboratories be capable of processing such huge amounts of information with intricate software to translate complex mathematical models into functional algorithms. All this means that computing power and informatics knowledge will expand now more than ever. We concluded that laboratory leadership must focus on informatics as being a core capability required for our organizations to fulfil its public health mission and goals.

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P-075

How eLEXNET is Improving the Food Safety System

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The overarching goal of the Food Safety Management Act (FSMA) of 2011 is to shift the food safety system in the United States from a reactive to a proactive paradigm. Foodborne disease outbreaks frequently transcend State borders and require a coordinated response involving local, state and federal officials across multiple jurisdictions and various agencies. These blended response teams need tools and resources to facilitate collaboration and data sharing. FDA is working with laboratorians, epidemiologists and regulatory officials to develop the Electronic Laboratory Network (eLEXNET) as one of those tools.

FDA's eLEXNET provides access to an unparalleled trove of laboratory data that food safety officials can use to support outbreak response, surveillance and regulatory action. FDA has invested significant effort to modernize the eLEXNET system to meet the needs of end users. Last year, eLEXNET went live with a new user interface, quality controls and an interactive data analysis tool (iDAT). iDAT's visualization tools allow users to quickly view results by county, state, or lab, as well as by product or analyte.

FDA is reaching out to potential end users within FDA, as well as at the local and state level, to ensure that all stakeholders are aware of the system's feature set and understand the multifaceted role that eLEXNET has to play in the food safety system. FDA has been working with the National User Group, created as part of a Cooperative Agreement with APHL, to articulate how food safety programs can integrate eLEXNET queries into their process flows. Jurisdictions can use eLEXNET as a collaboration tool to share lab data and other resources internally between laboratorians, investigators, epidemiologists and food safety analysts. eLEXNET effectively creates a network of users, all with access to the same lab data. Laboratories can thus simultaneously share results with FDA, state-level departments of health and agriculture, local agencies, and other jurisdictions. In addition, epidemiologists can analyze data from local and state labs alongside data from FDA and USDA labs, and regulators can review recent trends in other states and prioritize their own testing schedule accordingly. The new features of eLEXNET demonstrate FDA's commitment to enhancing partnerships between FDA and local and state food safety programs, reducing data silos, and integrating the food safety system.

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P-076

Food Provenance Confirmation by Combined LCMS, GCMS and ICPMS and Statistical Analysis

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The verification of provenance is very important in establishing food authenticity. For high value foods, the country of origin has a dramatic effect on the price, as such; falsifying the provenance of foods is an attractive proposition to fraudsters. A prime example is olive oil, being marked incorrectly from desirable countries or regions. Whilst various techniques such as trace metal analysis or isotopic ratios have been shown to separate different geographical classes, other factors such as year on year crop variations and changing weather conditions have caused these separations to be less conclusive. As such, using more than one technique and/or chemometric analysis to differentiate can be more

conclusive. This work uses TIBCO Spotfire® advanced analytics and visualization software to separate the geographical origin of olive oil from GCMS data, Wine using ICPMS data and Whisky using ICPMS and LCMS data combined.

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P-077

Detecting Antimicrobial Resistance Genes Directly from Sequence Data in the BaseSpace® Cloud with SEAR: Antibiotic Resistance

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Antimicrobial resistance remains a growing and significant concern in human and veterinary medicine. Current laboratory methods for the detection and surveillance of antimicrobial resistant bacteria are limited in their effectiveness and scope. With the rapidly developing field of whole genome sequencing beginning to be utilized in clinical practice, the ability to interrogate sequencing data quickly and easily for the presence of antimicrobial resistance genes will become increasingly important and useful for informing clinical decisions. Additionally, use of such tools will provide insight into the dynamics of antimicrobial resistance genes in metagenomic samples such as those used in environmental monitoring.

The Search Engine for Microbial Resistance (SEAR) is a powerful, yet user-friendly tool, which allows researchers to construct full-length, horizontally acquired Antimicrobial Resistance Genes (ARGs) from sequencing data. SEAR has been designed with environmental metagenomics and microbiome studies in mind, where the diversity and relative abundance of ARGs need to be determined both quickly and easily. Originally developed as a command-line tool, SEAR has been developed and release for use in the Illumina BaseSpace cloud computing platform. In BaseSpace, the SEAR: Antibiotic Resistance application allows users to set up and perform analyses on sequenced microbial samples with a simple graphical input form and easy-to-understand output report. The app outputs a graphical overview of the ARGs identified in the dataset, a data table describing all ARGs, relative abundance of the gene, a copy of the consensus sequence for each ARG, and BLAST results associated with each ARG.

SEAR enables researchers to quickly and easily interrogate sequence data for the presence of ARGs, which can be useful for informing both clinical decisions and providing insights into the dynamics of ARGs in the environmental metagenome.

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P-078

Consistency and Access with an Electronic Quality Management System

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Public health laboratories are vital in our society and continue to protect our lives on a daily basis. In such an important environment, quality and accuracy are essential for success. Henry Leibovitz with the Rhode Island Public Health Laboratory knows the importance of a quality laboratory. At Rhode Island, they have implemented an electronic QMS in over a dozen labs. Henry will speak about the integration of an electronic QMS into his lab's processes, his experience moving to and utilizing an electronic system as well as their accreditation, audit and compliance results.

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P-079

Board Certification for Laboratory Directors and Supervisors

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Since the CLIA '88 regulations were amended in 2003, board certification for laboratory directors has been required. For non-physician laboratory directors, there are only a few options for board certification. One of the CLIA-approved board certifications is provided through the American Board of Bioanalysis (ABB). Doctoral-level scientists can qualify by passing ABB examinations in **Public Health Microbiology**, as well as Clinical Chemistry, Molecular Diagnostics, Microbiology, Hematology, Immunology, Andrology and Embryology. Currently, ABB certifies or re-certifies about 700 doctoral-level scientists per year.

For doctoral-level scientists in Public Health Microbiology, ABB offers a **Public Health Laboratory Director (PHLD)** certification that is CLIA-approved. Successful candidates must have four years of experience in Public Health Microbiology or Clinical Microbiology and at least two years supervising or directing. The technical examination focuses on Public Health Microbiology, instead of the Clinical Microbiology typically performed in the hospital setting. Candidates must also pass ABB's "General Knowledge" examination, which covers administrative, regulatory, and management responsibilities of a laboratory director. The **PHLD** certification is equivalent to ABB's **High Complexity Clinical Laboratory Director (HCLD)** certification.

For multi-disciplinary laboratorians, another option is to pass at least three technical examinations and the "General Knowledge" examination to receive the **Bioanalyst Clinical Laboratory Director (BCLD)** certification.

For non-doctoral scientists, ABB also offers a **Technical Supervisor (TS) certification in Public Health Microbiology** as well as the other disciplines listed above. TS certification requires passing one or more of the technical examinations listed above, but not the "General Knowledge" examination. CLIA requires a Technical Supervisor, as well as a Director, for all high complexity testing. The Technical Supervisor certification requires a minimum of a Bachelor's degree and four years of experience, or a Master's degree and two years of experience.

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P-080

Developing a Liquid Chromatography-Mass Spectrometry (LC-MS) Library: An Example for Drinking Water Screening

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This poster provides an overview of a liquid chromatography-mass spectrometry (LC-MS) approach to screening drinking water samples suspected to be contaminated.

LC-MS can rapidly detect a wide range of contaminants, potentially making it a valuable tool for drinking water laboratories. One challenge for laboratories is the lack of an LC-MS reference library of the same type available for GC/MS. With this in mind, an LC-MS library was developed, and a multi-laboratory study was conducted to evaluate the performance of the library. A total of 129 potential contaminants were randomly distributed among six volunteer laboratories as unknown solutions containing 9 to 11 chemicals. Each chemical was analyzed by three laboratories. Of the compounds analyzed in the study:

- 88 were tentatively identified by all three laboratories
- 19 were tentatively identified by two laboratories
- 16 were tentatively identified by one laboratory
- 6 were not successfully identified

The mixed success in the tentative identification of the compounds demonstrates that the library, which was developed by a single laboratory on a specific instrument, is not transferable for all compounds to other laboratories, even those using similar LC-MS instruments. The step-by-step procedures used to develop the library can serve as an example of resulting performance for other laboratories interested in developing their own instrument-specific library.

Because of the mixed performance of the library search for some compounds, further screening may be warranted to improve confidence in the presence and identity of a contaminant. This is particularly critical when the library used is constructed with a different instrument than the one used for analysis. For this reason, a semi-quantitative LC-MS screening procedure will also be described in this poster. To test the procedure, 13 of the contaminants from the library were investigated. The sensitivity of these compounds to LC-MS was determined by measuring each compound's limit of detection, which ranged from 50 to 1000 ppb. This LC-MS screening procedure was used to tentatively identify the contaminants by retention time match and characteristic ions in a variety of complex drinking water matrices, suggesting that this procedure may be widely applicable for comparatively rapid screening of samples in contamination incidents.

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