

Indiana State Department of Health Laboratories



ANNUAL REPORT 2018

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Indiana State
Department of Health



Indiana
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TABLE OF CONTENTS

From the Director _____	3
Staffing _____	4
Welcome New Staff! _____	4
Farewell to Nearly 150 Years of Excellence and Service _____	6
Year at-a-Glance _____	8
Quarter 1 _____	8
Quarter 2 _____	8
Quarter 3 _____	9
Quarter 4 _____	9
Laboratory Advancements _____	10
Validations/Verifications _____	10
New Methods _____	11
Tales from the field _____	12
Safe Well Water for Maternal & Child Health _____	12
The ABCs of Outreach and Training _____	14
Advanced Molecular Detection and Cross-Collaboration _____	16
Chasing Antibiotic Resistance Through Whole Genome Sequencing _____	19
Fiscal Fitness _____	21
Protecting the Health of Hoosiers _____	22

FROM THE DIRECTOR

Dear Public Health Partners:

Every year in public health is an adventure with unforeseen twists and turns. We prepare for these challenges by expanding Indiana's public health laboratory system testing capacity. In 2018, we dealt with new environmental challenges, such as the opioid epidemic. We acquired new technology and started developing new methods to detect and measure the wide variety of illicit substances in both clinical and environmental samples. This expansion was made more challenging by staff shortages in our Chemistry Lab due to retirements; recruitment difficulties; and aging, unreliable testing equipment for routine work.

Responding to the governor's and agency's objective of reducing infant mortality, our environmental lab staff obtained a grant to present a conference on the Importance of Safe Well Water to Maternal and Child Health, which was held at Ivy Tech Conference Center. Participants included WIC and public health nurses, environmental health and laboratory staff, as well as CDC environmental staff. Four speakers covered the possible hazards of untested well water to children and expectant mothers.



"It continues to be my honor and pleasure to lead this outstanding group of laboratory scientists."

Indiana's attack on multi-drug resistant microorganisms (super-bugs in common parlance) accelerated with new training workshops for clinical laboratorians. Additional support for our sentinel laboratories was provided as our QA Director, Clinical Microbiology Division Director, and

Assay Development Supervisor hosted the first ever Validations Workshop. This workshop combined didactic lecture and hands-on exercises to help minimize what has been identified as a significant barrier in the implementation of new tests in clinical microbiology laboratories state-wide. Responding to sentinel laboratory requests, we also offered our clinical partners a parasitology workshop.

Regionally, our leadership joined neighboring public health laboratory representatives in Iowa to plan a regional Midwest Public Health Laboratory Consortium, with both environmental and clinical components. The past year was marked by technological growth and strengthening of our Quality Systems as evidenced by excellent reports from regulatory auditors. It continues to be my honor and pleasure to lead this outstanding group of laboratory scientists.

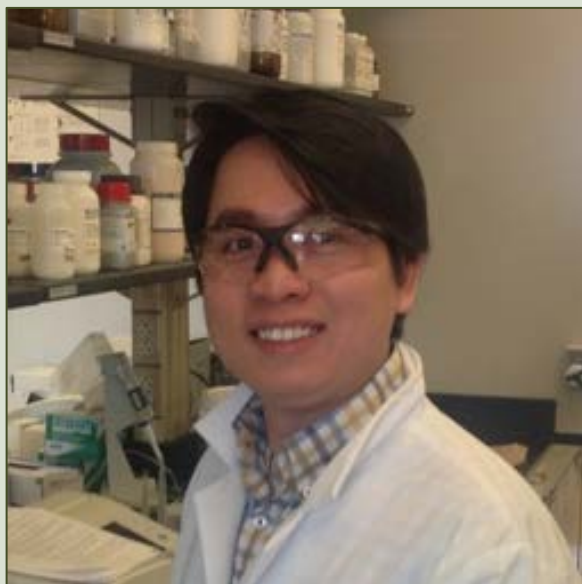
Sincerely,

Judith C. Lovchik

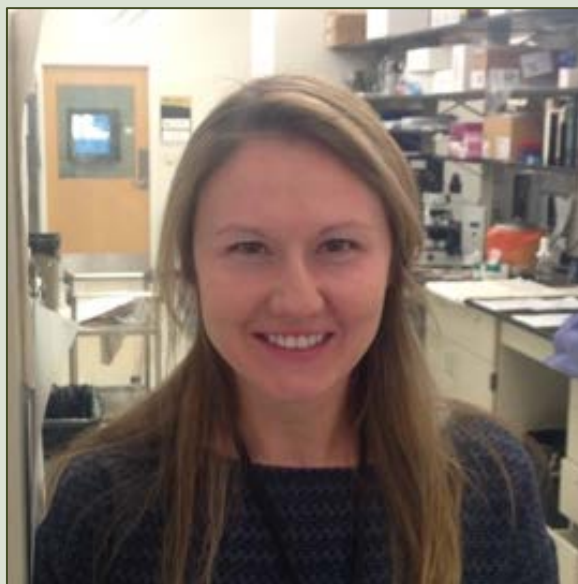
Judith C. Lovchik, PhD, D(ABMM)

STAFFING

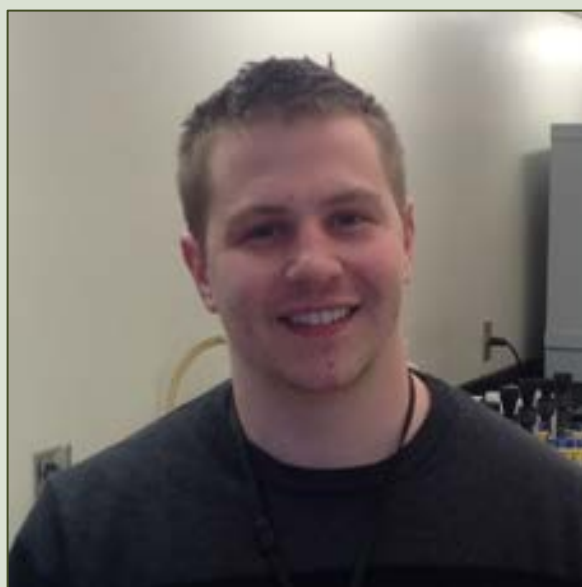
Welcome New Staff!



Tung Ho, Inorganic Chemistry
Laboratory



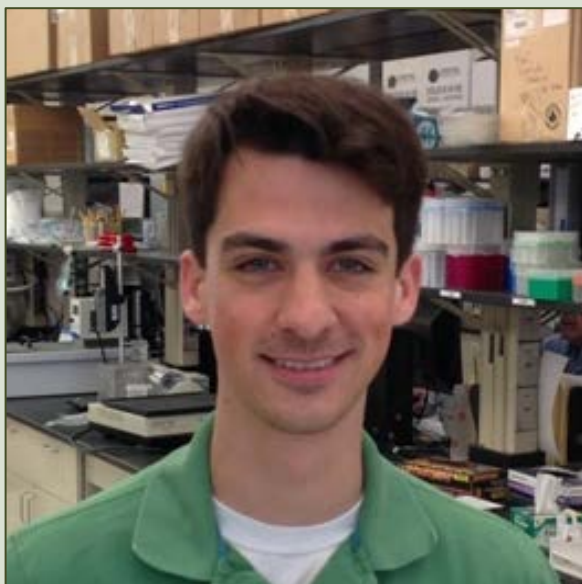
Elizabeth Rempala, Supervisor,
Bacteriology/Mycology/CT/GC
Laboratories



Michael Kohlmann, Inorganic Chemistry
Laboratory



Prathyusha Kolconda, Clinical
Microbiology Laboratory



Luke Ryle, Enterics/PFGE Laboratory



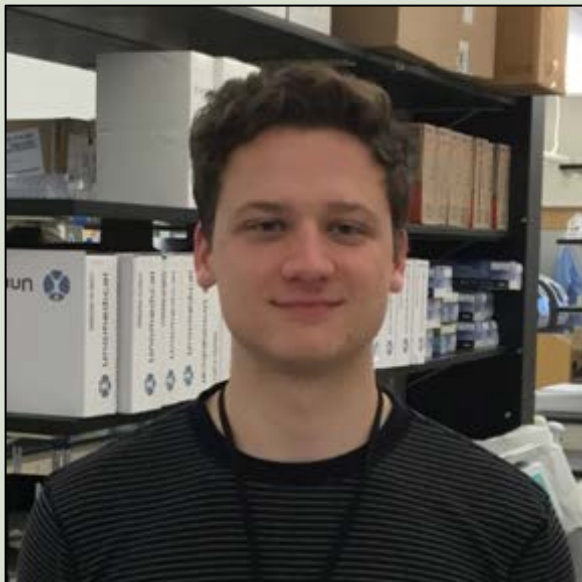
Alisha Aschenbrenner, Quality Assurance Specialist



Laura Banter, Inorganic Chemistry/Metals Laboratories



Smitha Thomas, Reference Microbiology Laboratory



Nathan Ray, BioWatch Laboratory



Anna Lay, Serology Laboratory

Farewell to Nearly 150 Years of Excellence and Service

Jyl Madlem, MS, MT(AMT)



Jon Radosevic,
Supervisor, Reference
Microbiology Laboratory



Brent Barrett,
Enterics/PFGE Laboratory



Deepak Patel, Inorganic
Chemistry Laboratory

The winter months brought about fond farewells to long-standing employees of our laboratory. Kiran Khurana (not pictured per her request) and Jon Radosevic, both from Reference Microbiology, retired on the same day in January after 40 and 38 years, respectively. These two are responsible for much of the initial pilot testing that brought the *Carbapenem* resistance testing into the ISDH Laboratories.

Next came the retirement of Brent Barrett from our Enterics Laboratory after 37 years in February. Brent served on the board of directors for the South Central Association for Clinical Microbiology (SCACM) and is still active on the American Society for Microbiology's (ASM's) Division C listserv, which allows members to communicate about microbiology-related topics. Brent also was the 2006 recipient of the SCACM Significant Contributor Award and the 2012 recipient of the Scherago-Rubin Award for his outstanding bench work.

In March we said good-bye to 33-year veteran Deepak Patel from our Inorganic Chemistry Laboratory. Deepak was the go-to guy for troubleshooting. His mechanical skills kept the chemistry lab running on several occasions. ISDH Laboratories would like to thank each of these employees for their combined 148 years of service to the laboratories and dedication to the mission of public health.

YEAR AT-A-GLANCE

Quarter 1

- The Environmental and Food Chemistry Laboratories successfully completed its ANAB audit to maintain ISO/IEC 17025:2005 accreditation.
- The ISDHL hosted Dr. Tommy Cullen, an IU Health CPEP fellow.
- The TB Lab Supervisor Jessica Gentry, presented a talk on “Deciphering TB Lab Results” for World TB Day.
- The Clinical Microbiology Division Director Dr. Sara Blosser participated in a panel discussion on “Lab-Epi Communication” at the National ELC HAI/AR Meeting in Atlanta, GA.
- Several staff members completed the ISDH Leadership at All Levels Advanced course.



Quarter 2

- The ISDH Laboratories successfully completed its CLIA audit with minimal findings.
- The Food Microbiology and Media Laboratories successfully completed ANAB and FSIS/USDA audits to maintain ISO/IEC17025:2005 accreditation.
- Sherry Adams and Jyl Madlem assisted with the Howard County annual Head Start screening for lead exposure, where approximately 100 filter paper blood-spot specimens were collected from preschoolers for testing at the ISDH Laboratories.
- Stephanie Dalenberg and Jamie Yeadon-Fagbohun presented posters at the APHL National Meeting in Pasadena, CA.



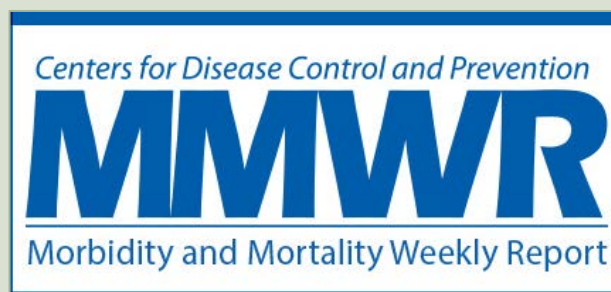
Quarter 3

- The Chemistry Division and Water Microbiology Laboratories were awarded full EPA Safe Drinking Water Certification.
- Sampling videos for water microbiology, fluoride, and nitrates/nitrites were completed, placed online for our external customers, and may be found at <https://www.in.gov/isdh/24550.htm>.
- Chemistry Division Director, Mary Hagerman, MS, presented Indiana's response to brodifacoum poisoning on synthetic cannabinoid products at the LRN National Meeting in Atlanta, GA. This work was also published; Bolner, A. et. al. (Summer 2018, Issue 3) *"Indiana and Wisconsin Respond to Synthetic Cannabinoid Contamination"*, Lab Matters, 16.
- Virology Supervisor Brian Pope, in conjunction with the ISDH ERC, published an article in the CDC MMWR on July 26, 2018, regarding the mumps outbreak in Indiana during 2016.
- The lab hosted ASM/CDC Fellows from Ghana and Tanzania for 3 weeks.



Quarter 4

- The ISDHL QA Director, Clinical Microbiology Division Director, and Assay Development Supervisor hosted the first ever "Validations Workshop" on October 5. For clinical laboratorians, this workshop combined didactic lecture and hands-on exercises to help minimize what has been identified as a significant barrier in the implementation of new tests in clinical microbiology laboratories state-wide.
- Enteric Laboratory Supervisor Jamie Yeadon-Fagbohun, contributed to an MMWR article collaborating with our Food Protection Division and others; Sundararajan M, Enane LA, Kidwell LA, et al. *Cronobacter sakazakii*



Meningitis in a Full-Term Neonate Fed Exclusively with Breast Milk – Indiana, 2018.

MMWR Morb Mortal Wkly Rep 2018; 67:1248-49

https://www.cdc.gov/mmwr/volumes/67/wr/mm6744a7.htm?s_cid=mm6744a7_w

LABORATORY ADVANCEMENTS

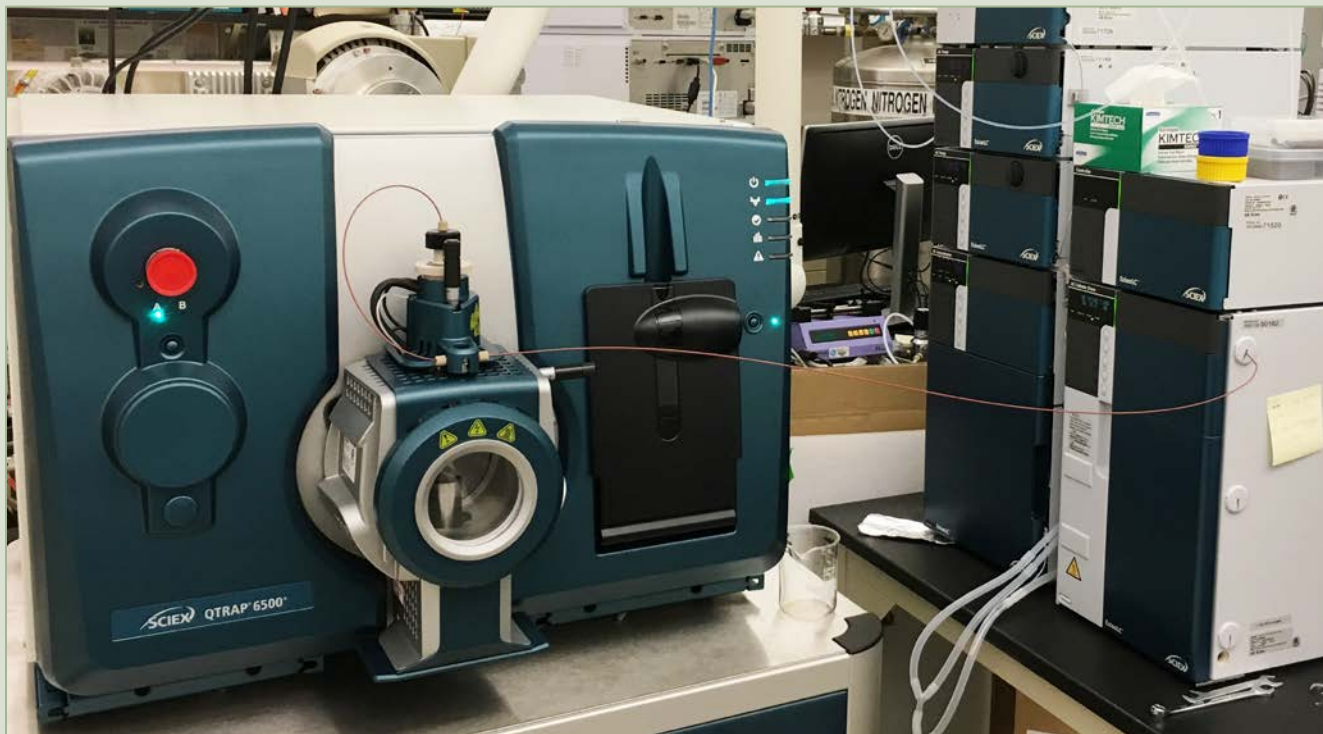


Figure 1. The Sciex QTRAP 6500+ Liquid Chromatograph/Tandem Mass Spectrometer (LCMSMS) was purchased through an opioid crisis grant and installed in the Chemistry Laboratory.

New Instruments

- A UV-6300 Spectrophotometer was received in the Chemistry Laboratory.
- High Performance Liquid Chromatograph (HPLC) for Glyphosate analysis.
- Gas Chromatograph-Electron Capture Detector (GC/ECD) for water disinfection by-products and pesticide analyses.
- Liquid Chromatograph with tandem Mass Spectrometer and Linear Ion Trap (LCMSMS) for Chemical Threat and opioid analyses.

Validations/Verifications

- *Mycobacterium abscessus/Mycobacterium chelonae* MALDI Complex validation was completed in January, which allows for identification of non-tuberculous *Mycobacterium* species.
- QIAcube Viral RNA validation was completed and signed in February allowing for more efficient RNA extraction for outbreak testing of specimens for norovirus, measles, mumps, enterovirus, and influenza.

- Hepatitis A IgM verification was approved for in-house testing amid a hepatitis A outbreak in southern Indiana.
- La Crosse Virus (LACV) PCR validation is complete and allows for the detection of LACV from mosquito pools using RT-qPCR.
- TB/MAC PCR went live as of June this year providing alternative diagnoses for those AFB smear-positive/TB PCR-negative patients.
- The Enteric Laboratory completed the Shiga-Toxin Producing *E. coli* (STEC) PCR validation in July reducing the cost from the previous assay and adding the ability to detect Stx2f variant.
- BIOMIC method was validated allowing for automated antibiotic susceptibilities.

New Methods

- The Water Microbiology and Containers STARLIMS module went live in January.
- The Food Micro Laboratory, along with the LIMS team, made it possible to directly submit results to the FDA electronic Laboratory Exchange Network (eLEXNET) surveillance system from STARLIMS.
- The Media Laboratory integrated several new processes from its Lean Rapid Improvement Event (RIE) in 2017, including a new media-prep recording system, ordering tickets, competencies, SOPs, and document consolidation—all of which improved internal customer satisfaction by 23.4% since Quarter 2 of 2017.

TALES FROM THE FIELD

Safe Well Water for Maternal & Child Health

Mary Hagerman, MS

The Indiana State Department of Health (ISDH) along with the Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health Hazards and Health Effects Division hosted a one-day meeting with our Indiana environmental health system partners. The Safe Well Water for Maternal & Child Health Conference was held in Indianapolis in October 2018. Invitees included both clinicians and environmental health specialists.



Importance of Safe Well Water for Maternal & Child Health

Friday, October 5, 2018
9 a.m. - 5 p.m.

Ivy Tech Culinary & Conference Center
2820 N. Meridian St.
Indianapolis, IN 46208

No registration fee, lunch provided.

Speakers

Dr. Susan Buchanan
Director
Great Lakes Center for Children's Environmental Health

Steve Wilson
Groundwater Hydrologist
30-year veteran of Illinois State Water Survey


Indiana State Department of Health

For additional information, contact Mary Hagerman at 317-921-5553.

REGISTRATION: https://www.surveymonkey.com/r/safe_well_water

This meeting was supported through an Association of Public Health Laboratories Cooperative Agreement and 45U560603-03 grant funded by the Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the Department of Health and Human Services.

This activity has been submitted to the Ohio Nurses Association for approval toward four contact hours. The Ohio Nurses Association is accredited as an approved continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation, 0269 001 91.

Primary objectives were to raise awareness of the hazards of unsafe well water for providers, clinicians (particularly targeting public health nurses) and environmental health specialists; to increase testing of private well waters to ensure safe water supplies to our most vulnerable populations, primarily encouraging annual testing for bacteria, nitrates, and arsenic; and to encourage communications between our clinical and environmental partners on the importance of safe well water for expecting parents and young children.

Speakers included experts in the field such as Dr. Susan Buchanan, who discussed the physiological effects of

toxicants on the body; Steve Wilson who discussed well types and challenges of getting well owners to test, Andrew Pappas who discussed the particular dangers of arsenic in wells and who may be at higher risk based on location within Indiana, and Mark Basch who discussed private well construction challenges. Presentations may be viewed here:

<http://videocenter.isdh.in.gov/videos/channel/135/>.

Approximately 45% of Indiana's wells will have some detectable levels of arsenic, and of those, approximately 11% will have greater than the maximum contaminant level of 10 ppb (parts per billion), potentially affecting as many as 725,000 Hoosiers. Post-meeting activities included leveraging lessons learned to provide mothers with information on well water testing at the time of immunization schedules for young children and during obstetricians' checklist for safe pregnancy.

The ISDH Laboratory continues to work with the Indiana Health Commissioner exploring new ways to encourage obstetricians and pediatricians to promote well water testing, thereby becoming a model for other states. Additionally, ISDH has plans to update Indiana's pregnancy mobile phone app (LIV-Pregnancy) to enable users to find recommended well water tests, certified laboratories and treatment information for unsafe well water.

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PARENTING?
PLANNING TO BE?**

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- Easily locate doctors, hospitals and other services near you.
- Keep a journal.
- Set alerts in real time.
- Get messages tailored for you.
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- Use interactive features like the calendar, due date calculator and baby weight calculator.

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Download on the **App Store** | GET IT ON **Google Play**

Indiana State Department of Health | Labor of Love *Helping Women Protect Against Death*

The ABCs of Outreach and Training

Jyl Madlem, MS, MT(AMT)

Outreach and training—those three little words can mean a lot to so many people. The ISDH Outreach and Training Team has made significant strides over the last 8 years. Shelley Matheson and Jyl Madlem have increased the number and frequency of their participation in events, trainings, presentations and publications by approximately 750% since 2011.

During 2018, training offerings to external Indiana Laboratory System (ILS) partners included the likes of the following:



Figure 2. Training materials for various 2018 events, used to promote future events.

- Chemical Threat (CT) workshops
 - Phlebotomy Refresher trainings
 - Blood Lead Collection and Case Management trainings
 - Biothreats (BT) 101 workshops
 - Packaging and Shipping (P/S) of Division 6.2 Category A Infectious Substances trainings
 - Multi-Drug Resistant Organisms (MDRO) workshops
- And new additions to the portfolio:
- Validation/Verification (V/V) workshops
 - A two-day Parasitology workshop

This team also developed new training videos, which can be viewed on the ISDH YouTube website (<https://www.youtube.com/user/INStateHealthDept/videos>) for venipuncture and capillary puncture blood collections, handwashing and the CDCs Flu-Near-You participation.

While the ISDH Outreach and Training Team generally jumps in and takes the reins for many of our trainings, they also offer logistical support for other subject matter experts to take the front of the room. For example, Mary Hagerman, Chemistry Division Director, and Billy Brewer, Emergency Preparedness Division Director, both lecture during the CT workshop, which is attended by emergency department personnel across the state. Biological Preparedness, Laboratory Outreach and Logistics Director Mark Glazier takes the lead role for the BT 101 workshop, with Jyl and Shelley providing ancillary lectures and laboratory support for this workshop designed to teach bench level microbiologists how to rule out biothreat organisms in their own laboratories. Sara Blosser, PhD, D(ABMM), Clinical Microbiology Division Director, along with Elizabeth Rampala, Reference Microbiology

Supervisor, teach the MDRO course intended for bench-level hospital microbiologists who would be identifying resistant organisms in patient cultures. Chris Grimes, Quality Assurance Director, pitched in to assist Dr. Blosser with the V/V workshop, which was another huge success, likely due to the request for attendees to bring a live project on which to focus during the training.

While many of these workshops are hosted at our laboratory located in Indianapolis, there are circumstances that necessitate taking the show on the road. Phlebotomy, BT 101 and P/S all are frequently held at offsite locations throughout Indiana at facilities generous enough to host these trainings.

We wrapped up the year with “Those Pesky Parasites: A Hands-on Workshop in Medical Parasitology,” taught by Ryan Relich, PhD, D(ABMM), MLS(ASCP)CMSMCM, Associate Professor at the Indiana University School of Medicine, and co-sponsored by South Central Association for Clinical Microbiology (SCACM), to provide nine hours of P.A.C.E.® continuing education credits.



Figure 3. Dr. Relich discussing recovery techniques with attendees during the "Pesky Parasites" workshop.



Figure 4. Jennine Griffith-Vandi viewing a prepared slide during the "Pesky Parasites" workshop.

The Kirkpatrick method is used to assess trainings, and the data clearly indicate significant learning by the attendees. Post-test scores increased by a range of 23.5-117% with a mean of 45%. Our most popular and most requested trainings tend to be Phlebotomy and BT 101, respectively, although the recently added MDRO and first-time V/V and Parasitology workshops were very well attended and received.

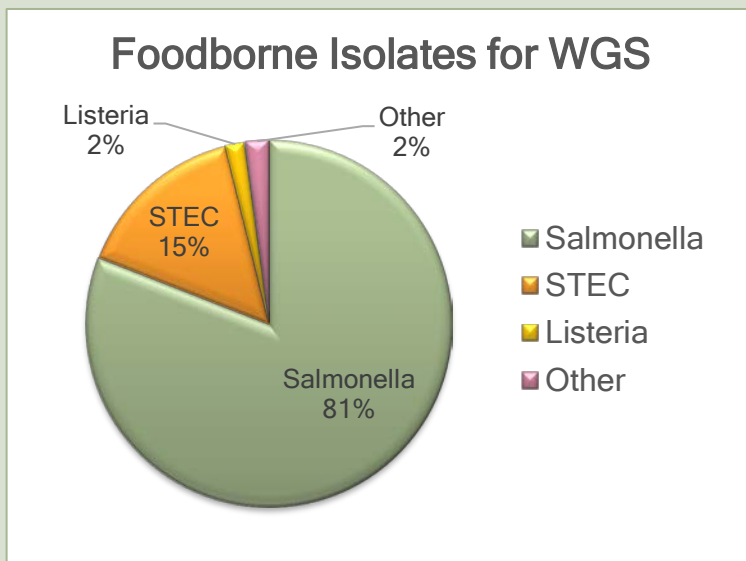
For more information about our training offerings, please email isdh-lab-info@isdh.in.gov.

Advanced Molecular Detection and Cross-Collaboration

PulseNet Whole Genome Sequencing of Foodborne Pathogens

Jamie Yeadon-Fagbohun

Whole genome sequencing (WGS) has become fundamental in the detection of foodborne outbreaks. This year, our Enterics Laboratory completed 50 MiSeq runs. A total of 937 isolates were run through WGS for PulseNet. The ISDHL had a median turn-around-time of 7 days to upload the isolate information into the national database once the identification had been confirmed.



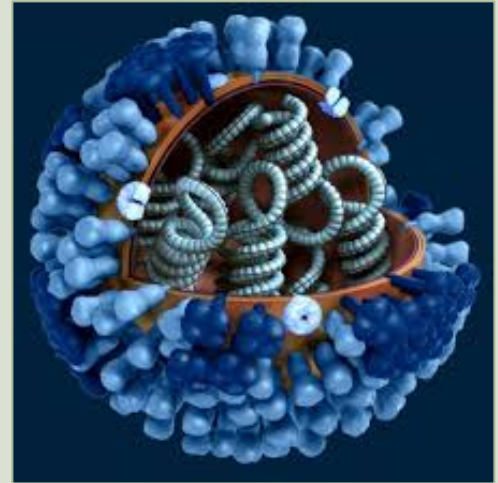
Approximately 80% of our sequenced isolates were *Salmonella*. All positive shiga-toxin producing *Escherichia coli* and *Listeria monocytogenes* isolates were also sequenced. ISDHL currently has five analysts certified for PulseNet WGS wet lab procedures. Two of those analysts were certified in 2018, and we plan to certify an additional two in 2019. As we look to the future, the lab

is working to complete analysis and cluster detection in-house.

Global Hepatitis Outreach and Surveillance Technology (GHOST) Project

Nick Epie, PhD, TS (ABB); MT (ASCP)

The ISDH Laboratories completed an evaluation of a CDC-developed Next-Generation Sequencing (NGS) method complemented with a powerful bioinformatics analysis pipeline for the Global Hepatitis Outreach and Surveillance Technology (GHOST) project. ISDHL received funding from the CDC and the Association of Public Health Laboratories (APHL) in 2017 to evaluate the GHOST method for genotyping and phylogenetic analysis of hepatitis C virus during surveillance and/or outbreak investigations, which provides Indiana public health epidemiologists the ability to identify genotypes including multiple hepatitis C genotypes present in an infected patient using NGS. At the end of this GHOST project, Indiana state public health lab genotyped two panels of unknown samples provided by the CDC and patient hepatitis C positive specimens from Indiana.



This project allowed the ISDHL to train one microbiologist in NGS sequencing using the Illumina® MiSeq platform and provided the opportunity to work with the CDC and the APHL in resolving laboratory technical issues encountered by state public health laboratories. The project also demonstrated great collaborative spirit amongst the ISDH Laboratory Divisions of Clinical Microbiology, Virology/Serology and Environmental/Enteric Microbiology.

Illumina® MiSeq and CLC Bio Genomics Workbench Validation

Cassie Campion, MS

The ISDHL validated the Illumina® MiSeq and CLC Bio Genomics Workbench for use in outbreak analysis, the detection of antibiotic resistance and the identification of bacterial isolates. This validation established performance metrics for the workflow typically seen in the microbiological public health laboratory under CLIA guidelines for laboratory-developed tests.

This validation determined the platform accuracy of our two MiSeq analyzers; assay accuracy for four applications within CLC Bio Genomics Workbench; 16S identification, resistance typing, in silico Multi-Locus Sequence Typing (MLST) and genotyping; and CLC Bio Genomics Workbench pipeline accuracy. Our staff traditionally named the instruments in their areas; the Sheldon and the Leonard share a room in our assay development laboratory.

Additionally, platform repeatability/reproducibility, application repeatability and reproducibility for 16S identification, resistance determination and in silico MLST were assessed and showed 99.9% and 100%, respectively.

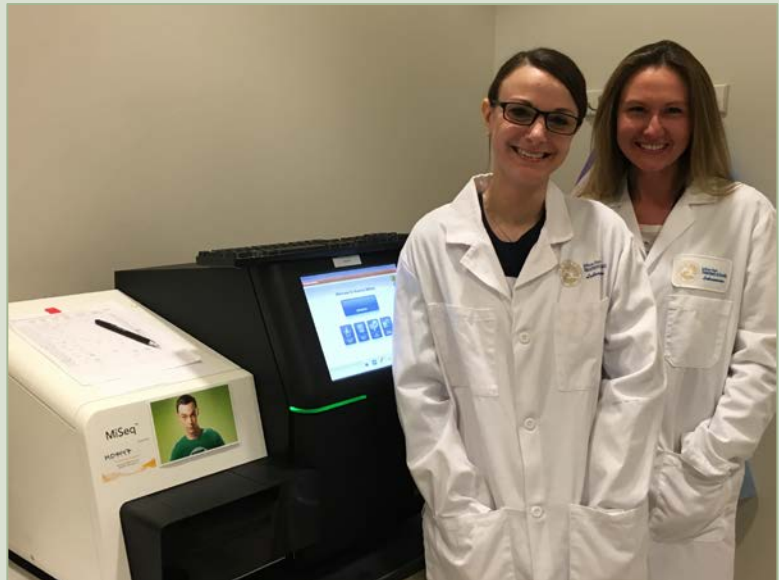


Figure 5. Cassie Campion and Elizabeth Rampala with "Sheldon", one of our two MiSeq analyzers. His roommate is "Leonard".

Chasing Antibiotic Resistance Through Whole Genome Sequencing

Elizabeth Rampala and Cassie Campion, MS

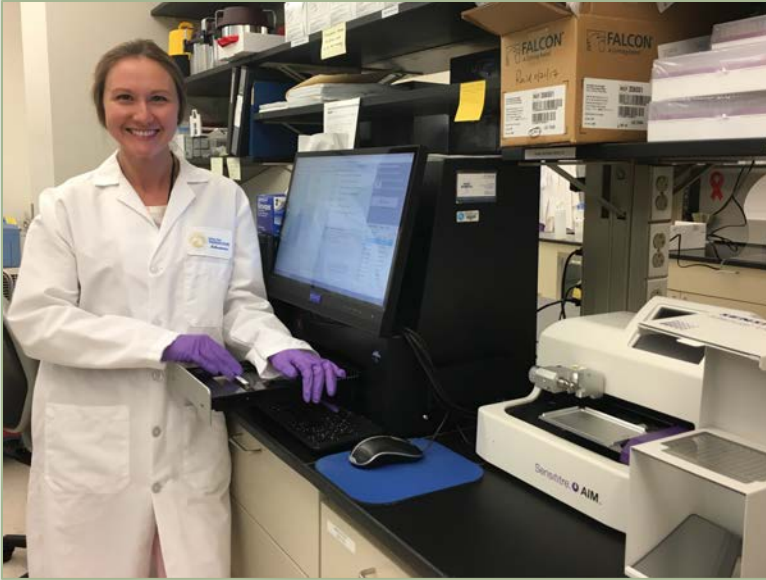


Figure 6. Elizabeth Rampala, Reference Microbiology Supervisor, demonstrates the Sensititre® GNX2F.

The year has brought about many adjustments in staffing and leadership in the Reference Microbiology section providing antibiotic susceptibility testing. Such drastic change has allowed the section to become more efficient and explore innovative means of improvement. To minimize reporting delays and unnecessary repeat testing of identifying antibiotic-resistant genetic markers, in August

we started incorporating results from clinical laboratories generated via Cepheid Xpert® Carba-R for carbapenem-resistant *Enterobacteriaceae* (CRE), *Pseudomonas aeruginosa* (CRPA) and *Acinetobacter* spp. (CRAB) into our testing algorithm. This decreased identification time for genes associated with carbapenem resistance by two days, thereby alerting the Antibiotic Resistance Laboratory Network (ARLN) and implementing comprehensive infection control measures more quickly.

Additionally, the broth microdilution susceptibility testing validated for Sensititre® GNX2F in 2017 was re-validated from a 10µL inoculation volume to a 50µL inoculation volume per plate. The validation was completed, and testing went live in November, increasing the number of antibiotics tested with each isolate from eight for *Enterobacteriaceae* and seven for *Pseudomonas* to 18 and 13, respectively, and 14 antibiotics for *Acinetobacter*. These 96-well micro-broth plates are read via the BIOMIC V3 automated system for consistency among analysts, and the acquisition and current validation of the Sensititre® AIM plate auto-inoculator will further streamline the testing process, constructing a more efficient and reproducible means of generating clinical susceptibility results.

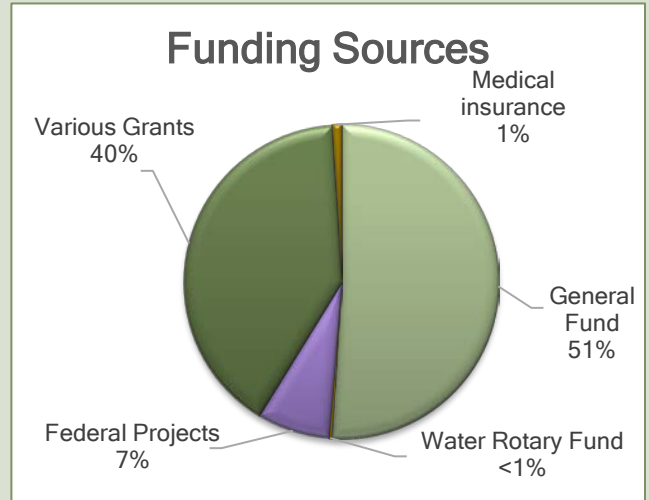
Furthermore, the newly validated BioMIC digital imaging system was updated for reading AST plates as opposed to reading the wells manually. This offers a uniformity to the minimal inhibitory concentration (MIC) interpretations, which is superior to readings with a mirrored

view box. Reference Bacteriology tested 679 isolates to detect carbapenemase producing-CRE/CRPA/CRAB from 44 Indiana counties; of these, 352 isolates were identified as carbapenemase producers. Among the carbapenemase producers, *bla*_{KPC} (244 isolates), *bla*_{NDM} (15 isolates), *bla*_{VIM} (10 isolates) *bla*_{OXA-48-like} (4 isolates) and *bla*_{IMP} (1 isolate) genes were detected. The validation of whole genome sequencing by Assay Development was completed in December and will aid in future outbreak investigations with the addition of variant specific resistance typing as well as phylogenetic analysis via single nucleotide variant typing.

FISCAL FITNESS

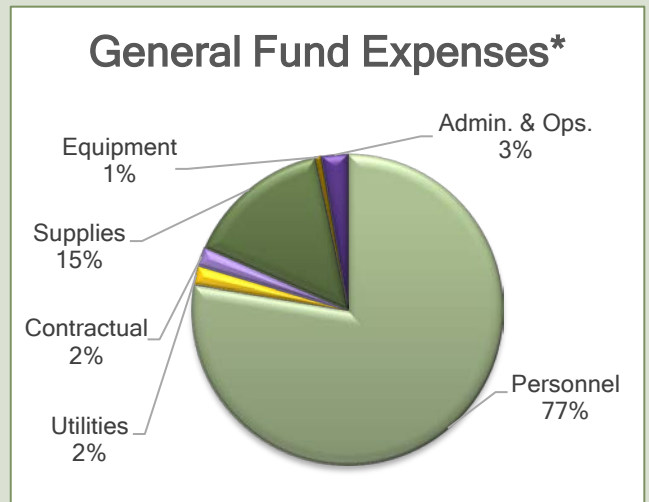
Funding Sources

General Fund*	\$ 5,842,740.02	51%
Water Rotary Fund	\$ 34,516.46	0.3%
Federal Projects	\$ 857,527.17	7%
Various Grants	\$ 4,621,875.20	40%
Medical Insurance	\$ 108,049.64	0.9%
Total Funding	\$ 11,464,708.49	100%



*General Fund (GF) Expenses

Personnel	\$ 4,535,155.30	78%
Utilities	\$ 113,475.96	2%
Contractual	\$ 115,814.07	2%
Supplies	\$ 882,181.55	15%
Equipment	\$ 37,940.74	0.7%
Admin. & Ops.	\$ 158,172.40	3%
Total GF Expenses	\$ 5,842,740.02	100%



PROTECTING THE HEALTH OF HOOSIERS

One Test at a Time

Indiana State Department of Health Laboratories

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Indianapolis, IN 46202

Phone: 317.921.5500

Fax: 317.927.7801

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Website: <http://www.in.gov/isdh/22421.htm>



Indiana State
Department of Health



Our Mission

To promote, protect, and improve the health and safety of all Hoosiers

Our Vision

A healthier and safer Indiana