

Indiana State Department of Health Laboratories



ANNUAL REPORT 2017

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MESSAGE FROM THE DIRECTOR



Dear Public Health Partners:

The Indiana State Department of Health Laboratory moved into its present light, airy, and comfortable building in March 2007. That was also one month before yours truly took the Deputy Director position at the lab, thus missing the challenges and agonies of preparing for, and executing, the big move. I will always be grateful for that fortuitous timing! Looking at the lovely and clean surroundings, I remember thinking, "I wonder how long this will last." Fortunately, the building looks just as good as it did back then, thanks to the excellent management of REI Real Estate Services and Margi Johnson, our facility manager, and her staff. This year we threw a lab party on the tenth anniversary of the move and honored Margi with a plaque and gift of appreciation.

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

The notable outbreaks and high-level public health threats to which the lab responded in 2017 included the threat of Zika virus infection and lead poisoning of residents living on a Superfund Site in northwest Indiana. Public awareness of lead in water after the Flint, Michigan, situation resulted in investigations and responses to perceived threats in several Indiana school districts. Lab chemistry and outreach staff worked with our environmental health and the new ISDH Lead and Healthy Homes Division as well as our Preparedness Division to provide lead testing of both water and children in affected areas.

Again in 2017, members of our lab staff were honored with prestigious national recognition awards and elected leadership positions. Jessica Gentry, TB Lab Supervisor, was recognized nationally at the 2017 TB Conference for her exceptional service. She also was awarded the Ed Desmond Laboratorian award at that meeting. Dr. Sara Blosser and Jessica Gentry were among ISDH staff awarded the CDC's Shepard Award for their role in responding to the Scott County HIV outbreak. Jessica and Dr. Blosser, as well as Dr. Nicolas Epie and Brian Pope, took on additional leadership positions in their respective national organizations.

Lab staff led numerous local public health and leadership activities, including providing valuable public health trainings in phlebotomy and detection of multidrug antibiotic resistance.

Our lab's International influence continued as an ASM/CDC Global Fellowship sponsored seven scientists and two interpreters from Armenia, Kazakhstan, and Georgia to visit the ISDH Laboratories to observe Quality Management Systems in place, especially internal auditing and analyst competency. They provided high praise for our demonstrations.

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

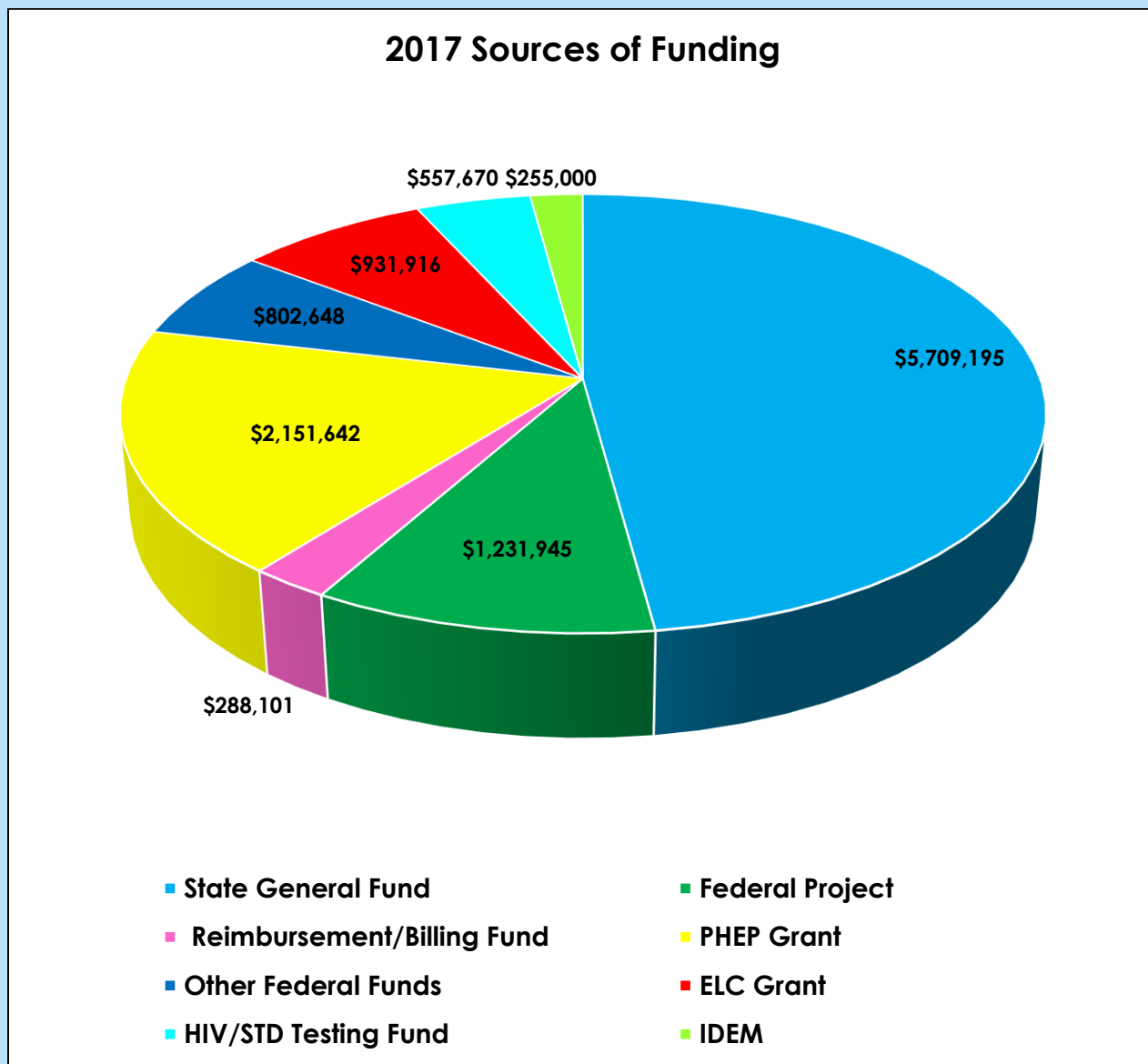
Judith C. Lovchik, PhD, D(ABMM)

FINANCIAL REPORT

Funding Sources

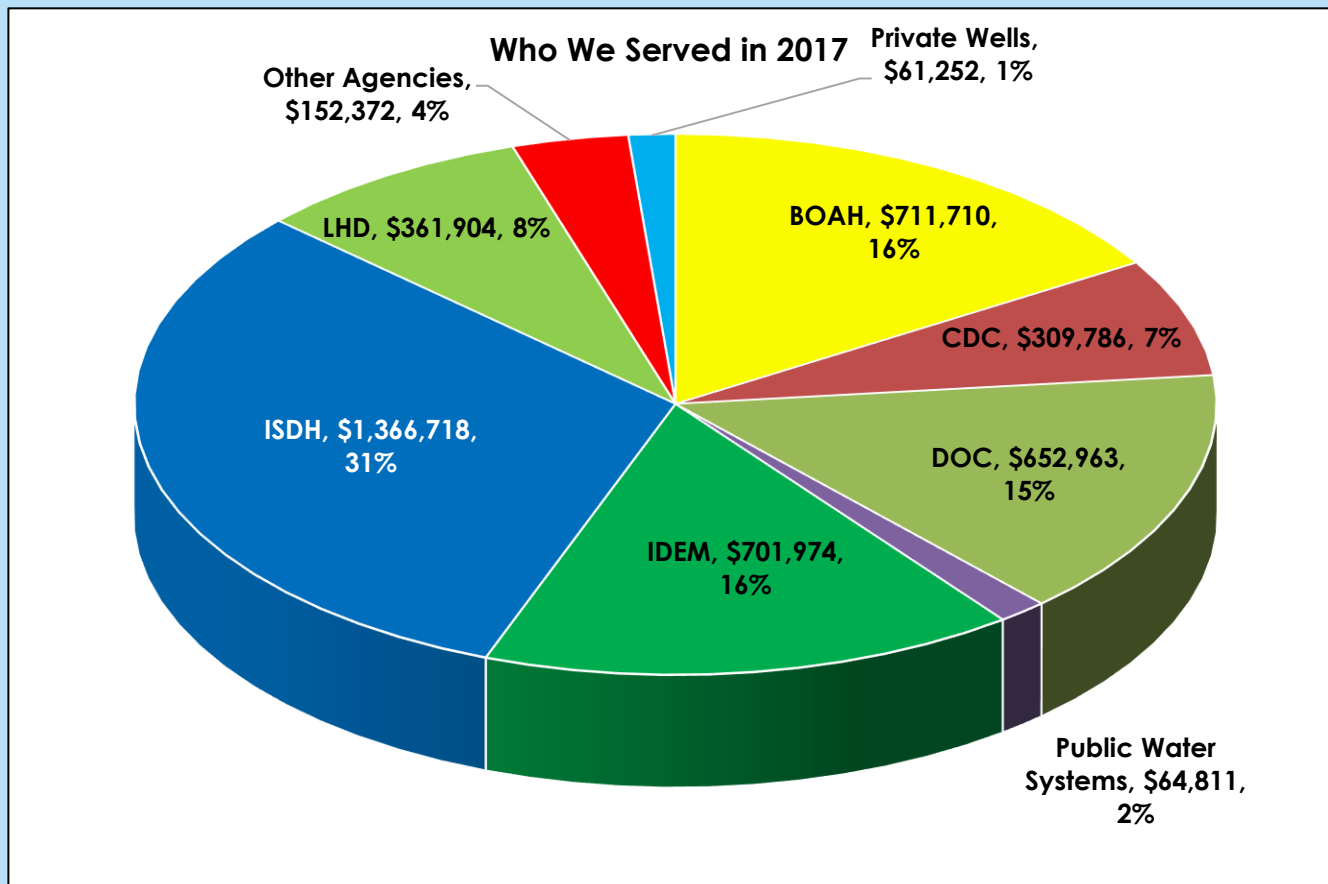
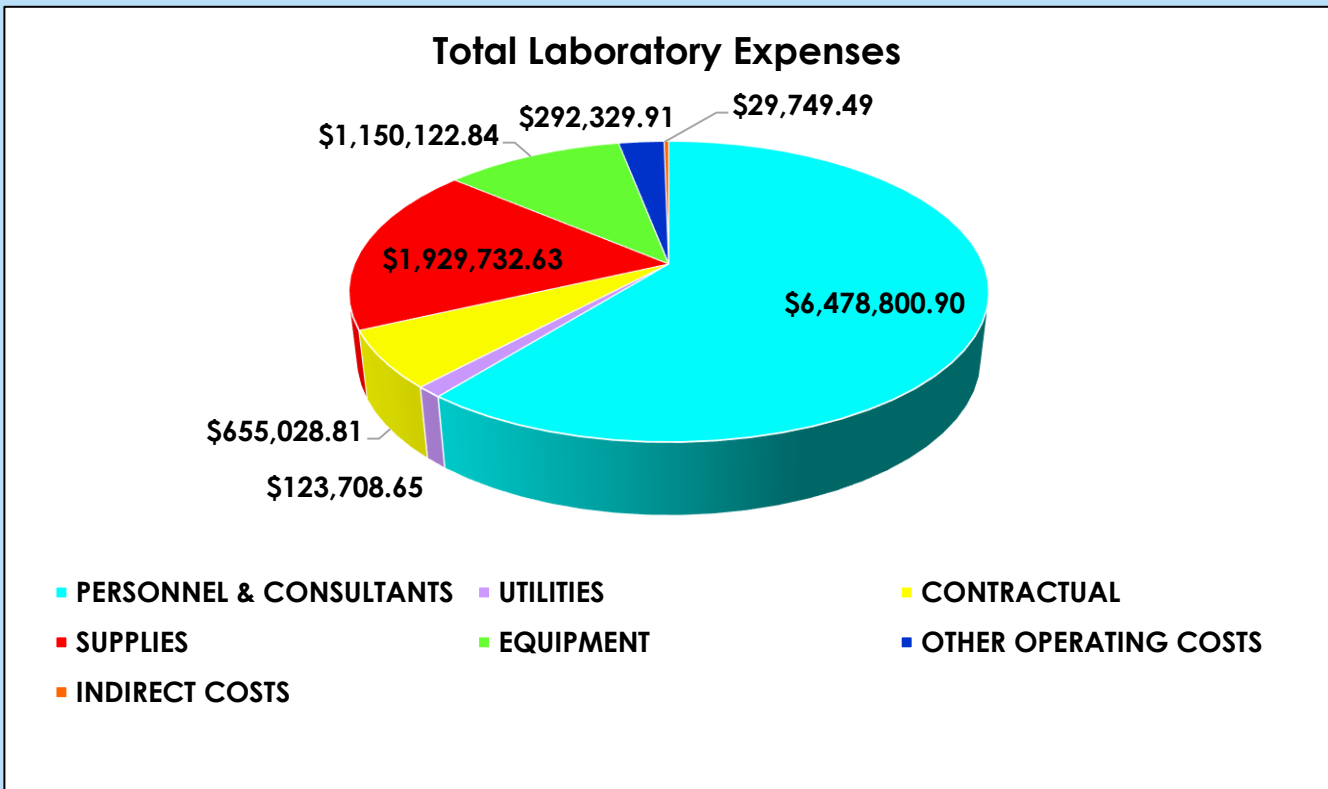
The Indiana State Department of Health Laboratories receives its funding from federal and state sources. However, the majority of funding the laboratory receives comes from the state.

Federal funds are drawn from U.S. grants awarded by federal government agencies such as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC), a division of the Department of Health and Human Services. Examples of these grants are the Public Health Emergency Preparedness (PHEP) and Epidemiology and Laboratory Capacity (ELC) grants.



Laboratory Expenses

The two figures below represent a summary of total laboratory expenses for 2017, as well as tests per who we served in 2017.



STAFFING

ISDH Laboratories Staff by Division (total = 95 employees)



- Virology/Serology
- Administration
- Clinical Microbiology
- Environmental Microbiology
- Biological Preparedness, Laboratory Outreach and Logistics
- Chemistry

Welcome New Staff!



Tracy Feeney, Food Microbiology Laboratory



Robin Williams, Media Preparation Laboratory



Carley Carroll, Assay Development Laboratory



Shreelakshmi Gopal, Biowatch Laboratory



Angela Lucas, Serology Laboratory

Farewell to Kathy Carroll: 3 Years of Excellence



In December and after three years of service as the ISDH Laboratories Administrative Assistant, Kathy Carroll transferred to the Adjutant General's Office as their new Purchasing Administrator. Kathy has been with the State of Indiana nearly ten years and began in the ISDH Human Resources Department until it was absorbed by Indiana State Personnel Department. Since then she has worked for the Indiana Department of Workforce Development and as the Facilities Coordinator for the ISDH Administrative Services Department before transferring to the laboratories in 2014. Kathy provided administrative assistance to Dr. Judy Lovchik, Dr. Kate Wainwright, and other senior staff at ISDH Laboratories. She also served as the laboratories' travel liaison, provided support to the Outreach and Training Team, and helped coordinate special events for the laboratories. ISDH Laboratories would like to recognize Kathy's dedication to the agency, her strive for excellence, and her warm friendship. She will be missed. Thank you, Kathy Carroll, for three years of excellence at ISDH Laboratories!

YEAR AT-A-GLANCE

JANUARY

- A consumer complaint sample of purchased pediatric water received by the Chemistry Laboratory contained isopropyl alcohol from an unknown source.
- Reference Microbiology identified a *Capnocytophaga* species from the blood of a 59-year-old female, isolated *Achromobacter* species from a rectal swab, and identified an OXA-48-like *E. coli* specimen.
- The Dairy/Meat testing laboratory attended the annual FDA Laboratory Accreditation meeting required for the FDA ISO grant.
- The Virology Laboratory had an increased number of influenza positives (predominantly influenza A/H3) and tested three specimens positive for mumps.



FEBRUARY

- The Food Chemistry Laboratory's ISO 17025 audit went well; only minor deficiencies were found.
- Testing was made available for Carbapenem Resistant *Pseudomonas aeruginosa*. A letter was sent to select facilities announcing this pilot study, which is being funded by the CDC's Antibiotic Resistance Lab Network (ARLN).
- The Food Microbiology Laboratory's L-A-B (ANAB) audit was completed; no deficiencies were found.
- The Serology Laboratory started HIV confirmatory testing using the Biorad-Genenius.

MARCH

- The Chemistry Laboratory accepted fish samples for analysis of histamine due to a scombroid poisoning incident affecting students from Notre Dame. The laboratory analyzed eight fish samples, and one sample was positive for histamine at approximately 150 ppm.
- Thirteen Carbapenem-Resistant *Pseudomonas aeruginosa* isolates were tested as part of the CRPA pilot study.
- The Environmental Microbiology Laboratory attended the PulseNet Regional Meeting, the STARLIMS Configuration Training, a CDC workshop on Algorithms in Molecular Parasitology, the South Central Association for Clinical Microbiology Annual Spring Meeting, and the Indiana Branch of American Society for Microbiology (ASM) annual meeting.

APRIL

- Jessica Gentry, TB Laboratory Supervisor, was recognized nationally at the 2017 TB Conference for her exceptional service and was awarded the Ed Desmond Laboratorian Award. This award honors exemplary service, dedication, or leadership to a TB laboratory professional. Jessica presented a poster and conducted a presentation, "Equivocal TB Smears," at the conference. She also presented two lectures at the CDC's Diagnostic Mycobacteriology Workshop.
- The Chemistry Laboratory continued to receive blood lead and drinking water samples from East Chicago. The drinking water samples were collected for lead and ortho-phosphate testing.
- Jamie Yeadon-Fagbohun, Enteric Laboratory Supervisor, participated in ISDH's National Public Health Week Open House and presented a poster, "Why Was My Specimen Cancelled?," at the ISDH Public Health Nurse Conference.

MAY

- The Indiana Department of Environmental Management (IDEM) sent a letter to all public water supplies stating radiochemistry testing had become a fee-for-service test.
- The Antibiotic Resistance Laboratory Network started implementing Carbapenem-Resistant *Enterobacteriaceae* electronic reporting.
- One specimen tested positive for mumps in the Virology Laboratory.

JUNE

- The Chemistry Laboratory received a new mercury analyzer.
- The Clinical Microbiology Division Director, Dr. Sara Blosser, was introduced to the American Board of Medical Microbiology (ABMM) as one of the new diplomates. She also was awarded the CDC's Shepard Award, alongside TB Laboratory Supervisor Jessica Gentry, for a publication regarding their contributions to the Scott County HIV outbreak.
- The Food Microbiology Laboratory provided outstanding service and received a certificate of appreciation from the Illinois Department of Agriculture for providing meat sample testing during the Illinois laboratory's move.
- Several ISDH laboratorians attended the Association for Public Health Laboratories (APHL) annual meeting in Providence, Rhode Island.

JULY

- The Food Chemistry Laboratory received a sample of breast milk from a mother who had an elevated blood lead level (13 ug/dL). The concern was her milk was contaminated and being transferred to her baby. The analysis resulted in approximately 20 ppb of lead in the mother's milk. If the milk were water, it would be over the Safe Drinking Water limit.
- ISDH Laboratories received \$343,894 in CDC Epidemiology and Laboratory Capacity (ELC) grant funding to support Whole Genome Sequencing (WGS), PFGE, and Norovirus testing.
- One specimen received by the Virology Laboratory tested positive for Varicella Zoster Virus (VZV).

AUGUST

- The Chemistry Laboratory analyzed 70 well water samples from the Morgan County Fair for lead/copper/arsenic. Five out of 70 samples were high for lead, one was high for copper, and 14 were high for arsenic.
- One *Streptococcus pneumoniae* isolate was submitted/serogrouped as part of the Indiana Communicable Disease Rule. This isolate was typed as serogroup 19A, which is vaccine-preventable.
- The Water Microbiology Laboratory received its Environmental Protection Agency (EPA) Audit report from the 2016 onsite audit; the laboratory did not have any deficiencies.
- The Virology Laboratory received its first flu positive of the flu season; PCR was performed and the specimen result was Influenza A/H3.

SEPTEMBER

- The second of the two SEAL Analytical Autoanalyzers was installed; phosphorus, chloride, sulfate, and cyanide testing are now on the system.
- The Clinical Microbiology Division Director was asked to sit on a Council of State and Territorial Epidemiologists (CSTE) Workgroup for the AR Resistance Surveillance Task Force. This workgroup will identify and recommend strategies to improve the communication of standardized and timely information on AR from laboratories to public health.
- The Enteric/Parasitology Supervisor attended the FDA's WGS and GenomeTrkr workshop.
- The Virology Laboratory received a specimen that was positive for dengue virus.

OCTOBER

- The Chemistry Laboratory received turmeric powder for testing from the ISDH Food Protection Program (sample source from Indian market); the sample contained 675 ppm lead.
- An isolate submission guide was developed for *Streptococcus pneumoniae* serotyping requests for patients ages 6 – 12. This submission guide is on the ISDH website.
- The Virology Laboratory received three specimens positive for Influenza A/H3 and one specimen positive for Influenza B/Yamagata.

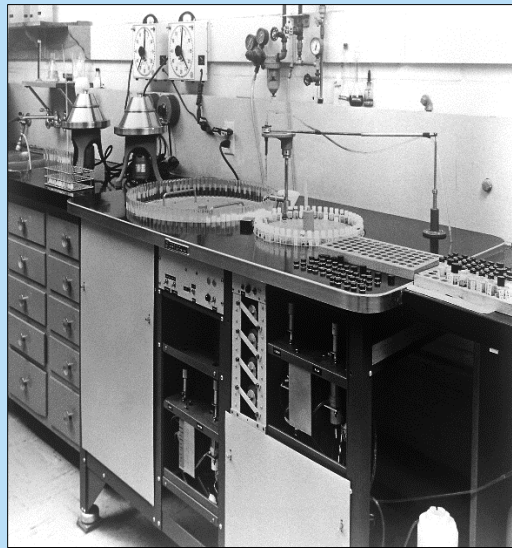
NOVEMBER

- ISDH Laboratories and Epidemiology Resource Center (ERC) investigated a *Mycobacterium chelonae* case, which was related to injection practices in a podiatry office.
- Several ISDH Laboratories staff attended the CDC InFORM conference in Garden Grove, California. Posters presented included “Not this child again! A Shift in PFGE Pattern Observed Following a 13-week Exclusion of Daycare Attendee” and “Enhanced Communication: Continual Improvement to Indiana's Rapid Response Team.”
- The Virology Laboratory received one positive measles specimen and one specimen positive for hantavirus.

DECEMBER

- Medicaid's Early and Periodic Screening, Diagnosis and Treatment (EPSDT)/Healthwatch was updated; blood lead testing requires a confirmatory venous sample if the capillary result is over 5 mg/dl. This aligns with the recommendations by the American Academy of Pediatrics.
- ISDH Laboratories began providing arsenic speciation to private citizens for \$80 per drinking water sample. This has enhanced the ability of citizens to treat their well water for high levels of naturally occurring arsenic.

LAB INNOVATIONS



CDC, 1963

- **New Instruments:**

- Roche MagNA Pure 96 and bioMerieux eMAG systems for high throughput nucleic acid extraction
- Illumina MiSeq for whole genome sequencing
- QIAGEN QIAcube for automated nucleic acid extraction in the Food Microbiology Lab
- LECO Protein Analyzer for food protein analysis
- Hologic Panther instrument for CT/GC testing for male urine, vaginal, endocervical, and urethral specimens
- bioMerieux GENE-UP PCR system for the Food/Dairy/Meat Microbiology Laboratory
- QIAGEN QIAxcel for the Enteric/Parasitology/Molecular Subtyping Laboratory
- SEAL Analytical Autoanalyzer for phosphorus, chloride, sulfate, and cyanide tests
- Ion Chromatograph for bromide, chloride, sulfate, and other anion analyses in water

- **Validations/Verifications:**

- Yeast MALDI-TOF validation
- *Staphylococcus* MALDI-TOF Library verification
- mCIM validation to detect the phenotypic production of carbapenemases
- Sensititre validation
- CSR Bead validation for 90-day extension of expiration date in the Food/Dairy/Meat Microbiology Laboratory
- CDC PulseNet certification and in-house verification for molecular subtyping of *Vibrio cholerae* and *Vibrio parahaemolyticus* via pulsed field gel electrophoresis (PFGE)

- **New Testing Methodologies:**

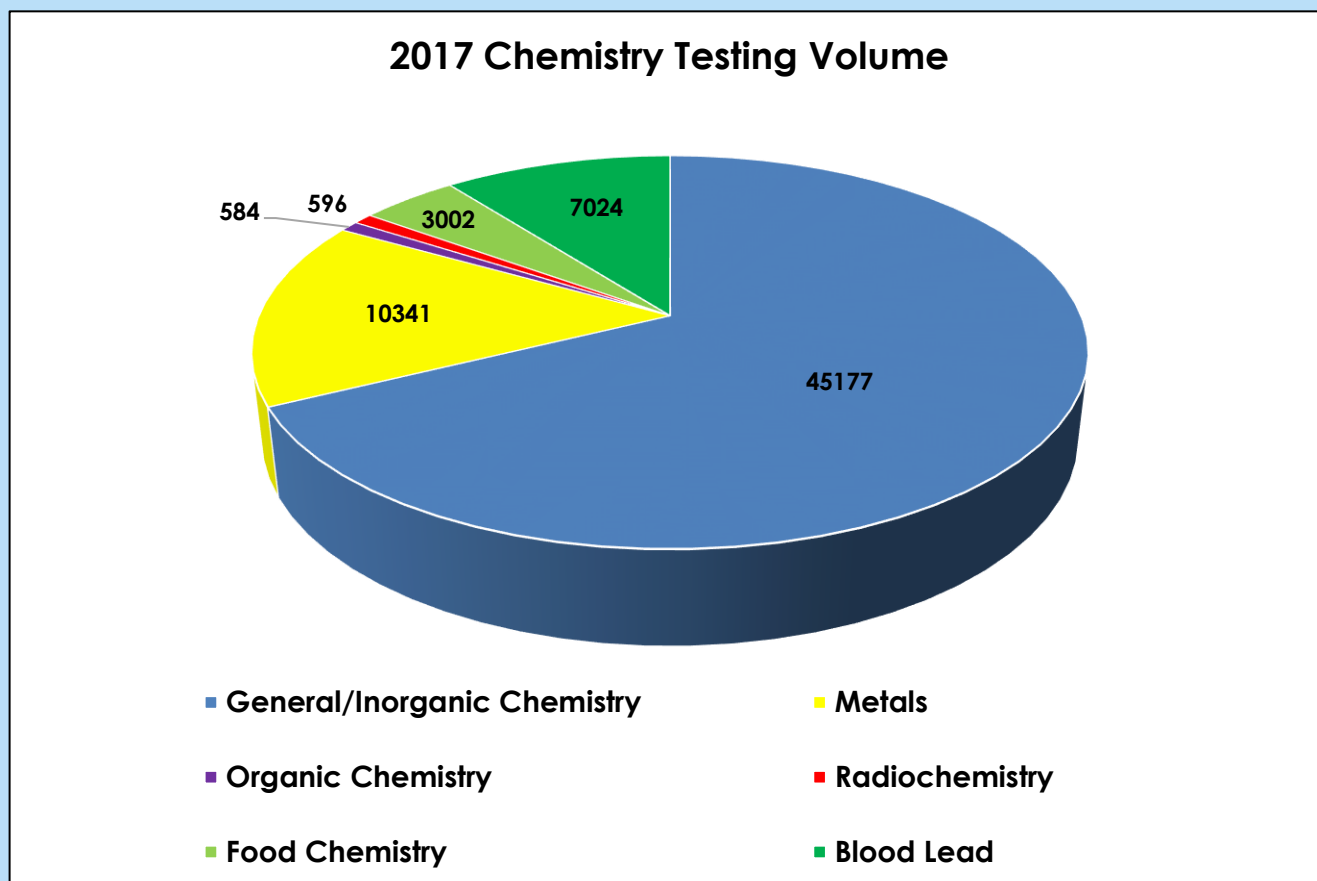
- A method comparison proposal was submitted, completed, and approved for the transition of Auramine O-phenol microscopy to Kinyoun staining for the confirmation of MGIT positive tubes.
- The Serology Laboratory started HIV confirmatory testing using the Biorad-Geenius.
- One run of WGS CP-CRE specimens was successfully completed and ready for analysis. In addition, the methodology for the gene-to-gene homology comparison was investigated and an analysis plan developed. This plan will primarily focus on comparing genes of antibiotic resistance to aid in outbreak analysis and investigation.
- Staff participated in several troubleshooting exercises to bring on Disk Diffusion Antimicrobial Susceptibility Testing as part of the ELC ARLN activities.
- Assay Development received a panel of *Legionella* isolates for WGS as part of a collaborative project with the CDC.
- The KPC typing assay project was initiated.
- A THC method was tested by the Food Chemistry Laboratory for possible testing of hemp oil supplements.
- The testing for the CA MALDI-TOF method comparison was completed and will expand the extraction methods acceptable for use with the CA MALDI-TOF system.



US PH Service, 1935

CHEMISTRY LABORATORIES

With five testing areas (Inorganic, Organic, Metals, Radiochemistry, and Food), the Chemistry Laboratory routinely performs analytical testing on soil samples, food, meat, and dairy products; environmental and blood lead samples; and multiple other water sources. In 2017, the Chemistry Laboratory processed approximately 66,725 tests supporting local health departments (LHDs), private citizens, IDEM, the Indiana Department of Natural Resources (DNR), Indiana State Board of Animal Health (BOAH), Indiana Department of Homeland Security (IDHS), private and public water systems, and other ISDH programs (e.g. Food Protection, Environmental Public Health, Lead and Healthy Homes, and Emergency Preparedness).



Roses are Red; Violets are Blue; Cyanobacteria are Blue-green and Can Be Harmful to You!



**Photo: Center for Earth and Environmental Science
Lake of the Woods, Indiana, April 2010**

Blue-green algae, also known as cyanobacteria, can be found in various salt and freshwater ecosystems and are typically not problematic. However, under certain environmental conditions, they can quickly multiply to form harmful algal blooms and produce toxins (cyanotoxins). Exposure to these toxins can affect the human central nervous system (neurotoxin), the human liver (hepatotoxin), or human skin (dermatotoxin). According to the EPA, the most common cyanotoxins include

microcystins (produces hepatotoxins), cylindrospermopsin (produces hepatotoxins), anatoxins (produces neurotoxins), and saxitoxins (produces Paralytic Shellfish Poisoning, PSP, toxins).¹ Both humans and pets, such as dogs, can become ill following swimming or playing in impacted recreational waters. A rise in either nitrogen or phosphate is believed to be primary nutrients supporting the algal blooms. The ISDH Chemistry Laboratory is now assisting IDEM by providing low-level analysis of dissolved reactive phosphate. Specifically, dissolved reactive phosphorus was added to the list of requested analytes for 12 sites from two northern Indiana routes for the "fixed" station monitoring that we do for IDEM. With support from IDEM, the Chemistry Laboratory was able to purchase new instrumentation for this testing that helps protect our drinking and surface waters.

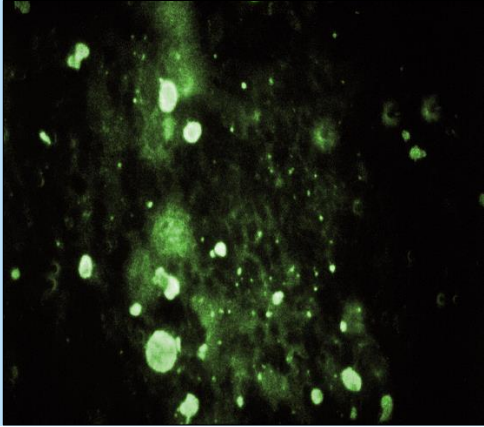
1. <https://www.epa.gov/nutrient-policy-data/cyanobacterial-harmful-algal-blooms-water>

BIOLOGICAL PREPAREDNESS AND OUTREACH

Rabies

"Dogs suffer from three diseases; these are named Rabies, Dog-strangles, and Foot-ill. Of these, Rabies produces madness, and when Rabies develops in all animals that a dog has bitten, except man; it kills them; and this disease kills the dogs too."

-Aristotle, [History of Animals](#)

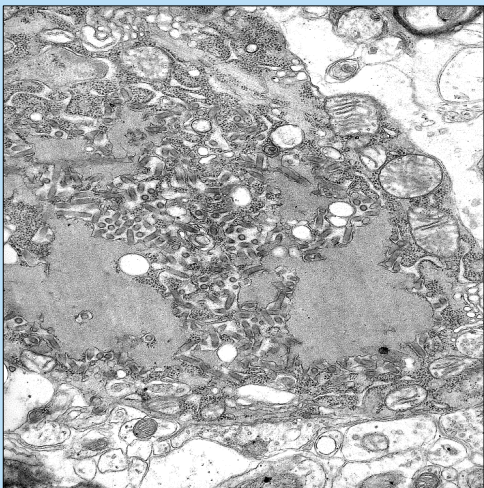


DFA positive result for rabies virus antigens (CDC PH Image Library)

Rabies, a Latin word for "madness, rage, fury," has been described plaguing both man and animal since at least the fourth century B.C. Caused by the lyssavirus, infections affect the central nervous system and, without treatment, will result in death. Louis Pasteur developed the first successful human vaccine in 1885, and this disease still remains vaccine-preventable in both humans and other mammals. Accurate and rapid diagnostic testing is also necessary for exposed individuals to receive required, post-exposure prophylaxis. The ISDHL is the only laboratory in the state performing rabies testing on animal specimens. Rabies is diagnosed by a direct

fluorescent antibody test (DFA), amplification method, or histologic/immunohistochemistry examination. ISDHL currently tests only animal specimens with the DFA test.

As highlighted above, laboratory test results are a critical step for preventing this fatal disease. As in all testing areas, ISDHL strives to excel in providing accurate, reliable, and timely test results. In conjunction with the internal audits ISDHL performs, the Rabies Lab was audited by an external organization and was the first rabies laboratory in the U.S. to achieve ISO 17025 accreditation!

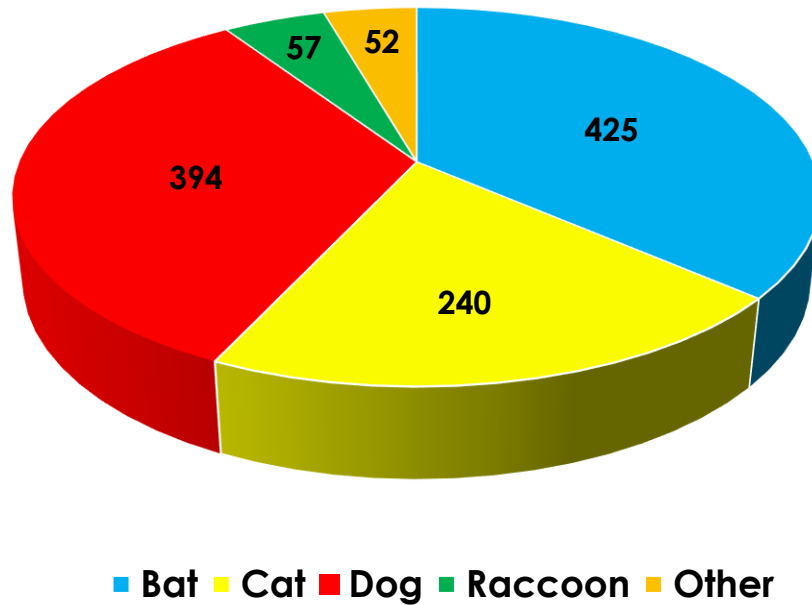


TEM of rabies virions in tissue sample (CDC PH Image Library)



Rabid dog (CDC PH Image Library)

Animal Species Submitted for Rabies Testing in 2017



“Other” Animals Tested for Rabies:

Animal	#'s	Animal	#'s	Animal	#'s
Camel	1	Goat	2	Opossum	8
Cow	3	Groundhog	4	Pig	2
Coyote	5	Horse	5	Rat	1
Deer	1	Mink	2	Sheep	3
Donkey	1	Mouse	1	Skunk	6
Fox	3	Muskrat	2	Squirrel	2

Biological Preparedness Laboratory

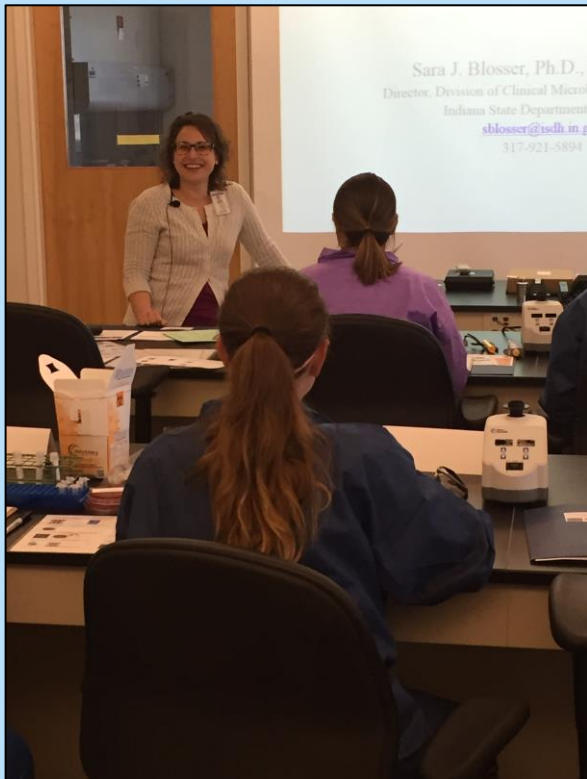
In addition to rabies testing, the Biological Preparedness, Laboratory Outreach, and Logistics (BLOL) Division at ISDHL also serves as a Laboratory Response Network (LRN) reference laboratory for confirmation testing of potential bioterrorism agents and tested 16 isolates and one suspicious environmental sample with LRN-B procedures in 2017. Our biosafety officer conducted biosafety risk assessment lab training visits at 29 clinical laboratories and served as a great resource for biosafety-related questions from these clinical laboratories. Each of the visited clinical laboratories completed at least one biosafety risk assessment in their labs.



Outreach and Training

The Outreach and Training Team, under the BLOL Division, was engaged in 37 events, educating 236 external partners, in 2017. The team coordinated and presented trainings such as the ever-popular Biothreats 101 Course, Phlebotomy, Division 6.2 Packaging and Shipping, Carbapenemase Producing-Carbapenem Resistant *Enterobacteriaceae*, Blood Lead & Case Management, First Responder

Environmental Sample Collection, the Local Health Departments' Environmental Health Specialist (EHS)/Public Health Nurses (PHN) Orientation, and others.



In addition, the Outreach and Training Team hosts vendor booths at a variety of events. Events in 2017 included the ISDH Public Health Nurse's Conference; Chemical, Biological, Radiological and Nuclear (CBRNe) World Conference; Indiana Environmental Health Association (IEHA); Indiana Water Works Association (InAWWA); and Indiana Emergency Response Conference (IERC). The team attends and hosts vendor booths at other events as needed.

Dr. Sara Blosser conducting a CP-CRE Training for Indiana Laboratories

Other outreach activities include responding to public health emergencies such as the HIV outbreak in southern Indiana and the lead contamination situation in northwest Indiana, assisting county health departments in events such as the Howard County Head Start Blood Lead specimen collection,



Jyl Madlem conducting a Phlebotomy training for Indiana public health nurses

presenting on relevant topics at the Public Health Nurse's Conference, and attending Train-the-Trainer and the National Laboratory Training Conference (NLTC-9) to improve our training offerings. The team presented posters on mycology and blood lead trainings at the annual meetings for the American Society for Microbiology (ASM) and the Association of Public Health Laboratories (APHL), respectively; the team also serves on the Board of Directors for the South Central Association for Clinical Microbiology (SCACM).



Shelley Matheson (ISDH Laboratories) and Jeff Larmore (Marion County Public Health Department) conducting a training for Indiana first responders

ENVIRONMENTAL MICROBIOLOGY

In April 2017, ISDH was chosen to host FDA's annual Laboratory Examination of Dairy Products course. FDA uses these annual training sessions to provide important information to the state and private sector labs to ensure consistent, high-quality dairy testing. Such dairy testing is federally required as part of routine surveillance. This two-and-a-half-day course was attended by 26 people training to either

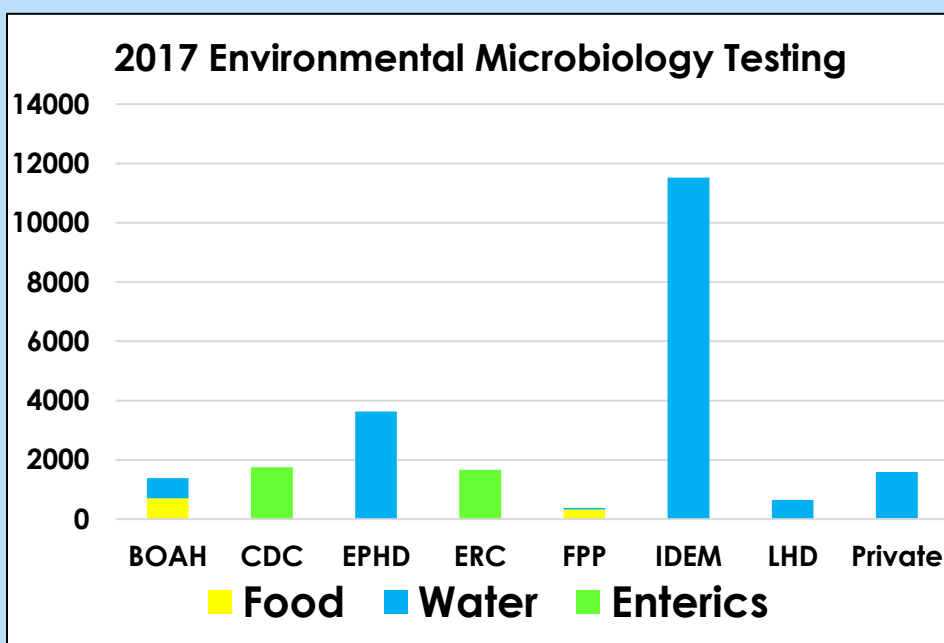


test products in a private sector dairy lab or become a state laboratory evaluation officer (LEO). Lectures and wet lab sessions focused on the methods in which FDA and state LEOs certify individual laboratorians. Weeks of intense planning were required to coordinate FDA supply orders, sample preparation, attendee registration, food and beverage logistics, course handouts, and vendors' product information.

Housed with the Food Microbiology Laboratory, dairy testing includes evaluating dairy products with multiple methods for antibiotic residues, confirming the percentage of fat present in the dairy product, and testing the products for the presence of bacteria such as *E. coli* and *Staphylococcus* species.

Food Microbiology also tests other food and meat products related to consumer complaints and potential foodborne illness/outbreaks or as part of federally required routine surveillance activities.

Partnering with BOAH, the ISDH Food Protection Program (FPP), and LHDs, ISDH's Food Microbiology completed 15,065 tests in 2017 to support such partnerships. As an entire division, Environmental Microbiology completed 36,594 tests in 2017 in support of multiple programs and agencies including the CDC, the Environmental Public Health Division (EPHD), the Epidemiology Resource Center (ERC), IDEM, and private citizens.



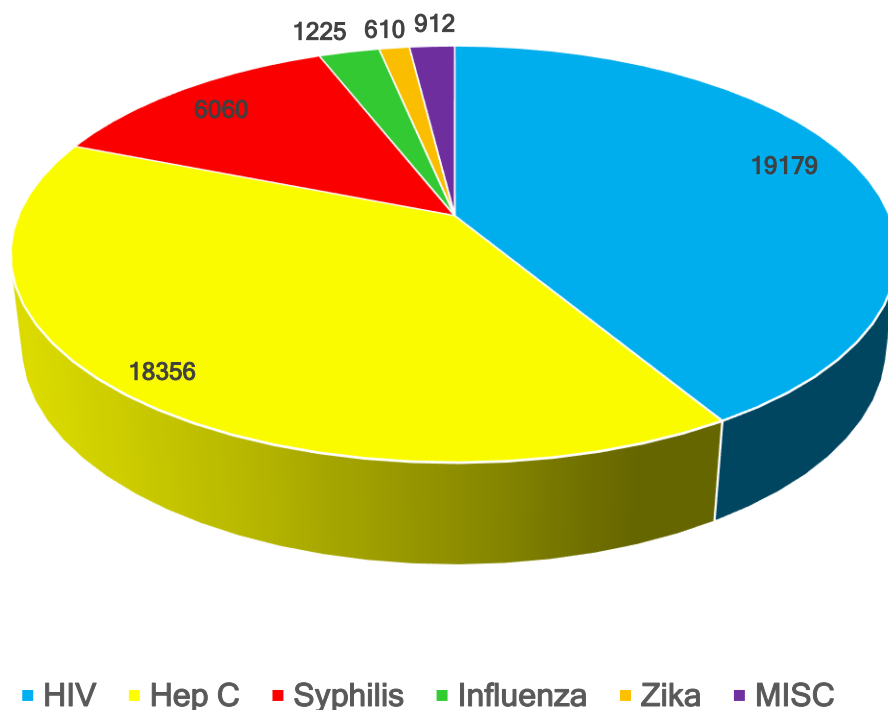
VIROLOGY/SEROLOGY

The ISDHL Virology and Serology Division tests human specimens for mosquito-borne diseases, including Zika, chikungunya, and dengue, through serological and molecular methods. In 2017 serological testing for Zika resulted in four positive specimens and 423 negative specimens. Using molecular testing methods, 183 specimens were evaluated in 2017 with two specimens positive for dengue; 49 negative for Zika, chikungunya, and dengue; and 132 negative for Zika only. In conjunction with the Biological Preparedness and Outreach Division, ISDHL also tested mosquito pools for West Nile virus (WNV), St. Louis Encephalitis (SLE), and Eastern Equine Encephalitis (EEE) as part of active surveillance activities in partnership with ISDH Vectorborne Epidemiology.

In 2017, there were 2,137 mosquito pools that were tested, with 499 pools in 90 of 92 Indiana counties positive for WNV. No mosquito pools in 2017 were positive for either SLE or EEE.

Testing approximately 46,000 specimens annually, the Virology and Serology Division also tests for several microorganisms of public health importance including hepatitis, HIV, syphilis, and influenza.

2017 Virology and Serology Testing



*MISC: Measles, Mumps, Rubella, Hepatitis B, HSV, VZV, Enterovirus

2017: The Year in Mosquitos

Nothing beckons the call of the beginning of summer as that first mosquito bite of the season. With over 3,500+ species, these prehistoric bloodsuckers (and only the females draw a blood meal) are easily the most successful transmitters of disease worldwide. Although mosquitoes live only days (males) to a few months (females), these resourceful and hardy insects are able to breed in limited amounts of stagnant water, are gaining resistance to insecticides, and are also expanding their habitat ranges due to climate changes while vector control programs lack capacity for adequate abatement.¹ More than just a pesky creature that can ruin any outdoor activity, mosquitoes can spread a laundry list of diseases including Zika, WNV, chikungunya, yellow fever, dengue, malaria, La Crosse Encephalitis (LAC), Western Equine Encephalitis (WEE), EEE, SLE, California Encephalitis (CE), Jamestown Canyon virus, and dog heartworm (*Dirofilaria immitis*). Here in Indiana, the dominant species of mosquitoes that are trapped and tested for disease include:

- *Culex pipiens* and *Culex restuans* (WNV, SLE)
- *Aedes albopictus* (WNV, SLE, LAC, dengue, chikungunya, Zika)
- *Aedes japonicas* (WNV, SLE, LAC, EEE)
- *Aedes triseriatus* (LAC, WNV)
- *Coquillitidia perturbans* (EEE)
- *Anopheles quadrimaculatus* (Malaria)
- *Anopheles punctipennis* (Malaria)
- *Aedes vexans* (dog heartworm, nuisance biter, possibly a EEE vector but not clear)



C. pipiens (IL Dept. of Public Health)



A. albopictus (CDC PHIL/J. Gathany)



A. triseriatus (CDC PHIL/J. Gathany)

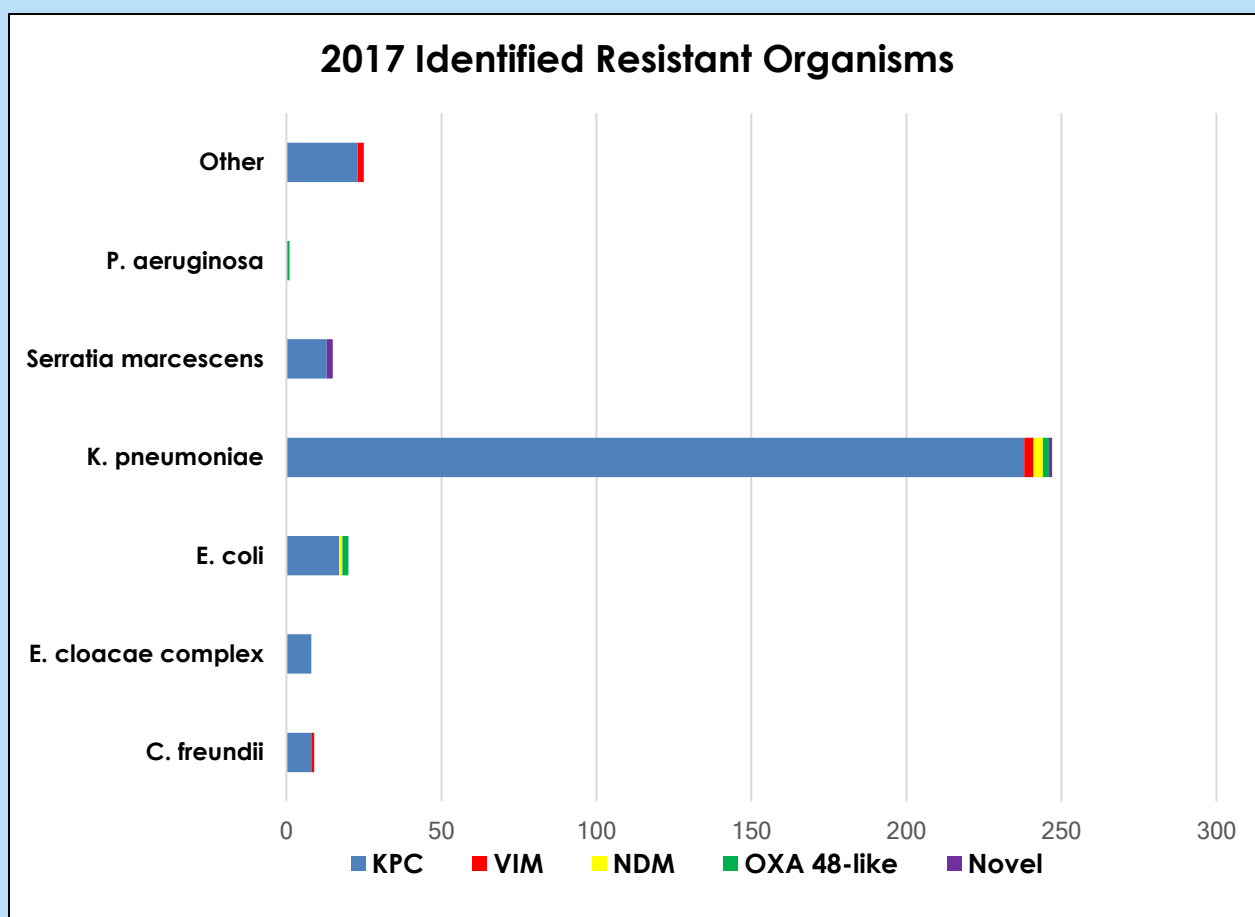


A. japonicas (CDC PHIL/J. Gathany)

CLINICAL MICROBIOLOGY

KPC, VIM, and NDM, oh my!! ... The year of persistent resistance and laboratory innovations

More than alphabet soup, antibiotic-resistant organisms remain an ongoing challenge and great concern of public health. The ISDHL's Clinical Microbiology Division remains a committed and active statewide player in identifying these organisms and their resistance mechanisms. From submissions from our clinical partners, 325 resistant-positive organisms and their resistance mechanisms were identified in 2017.



To increase the success of a correct identification, the Assay Development branch of the Clinical Microbiology Division developed several assays and validated new testing equipment, including:

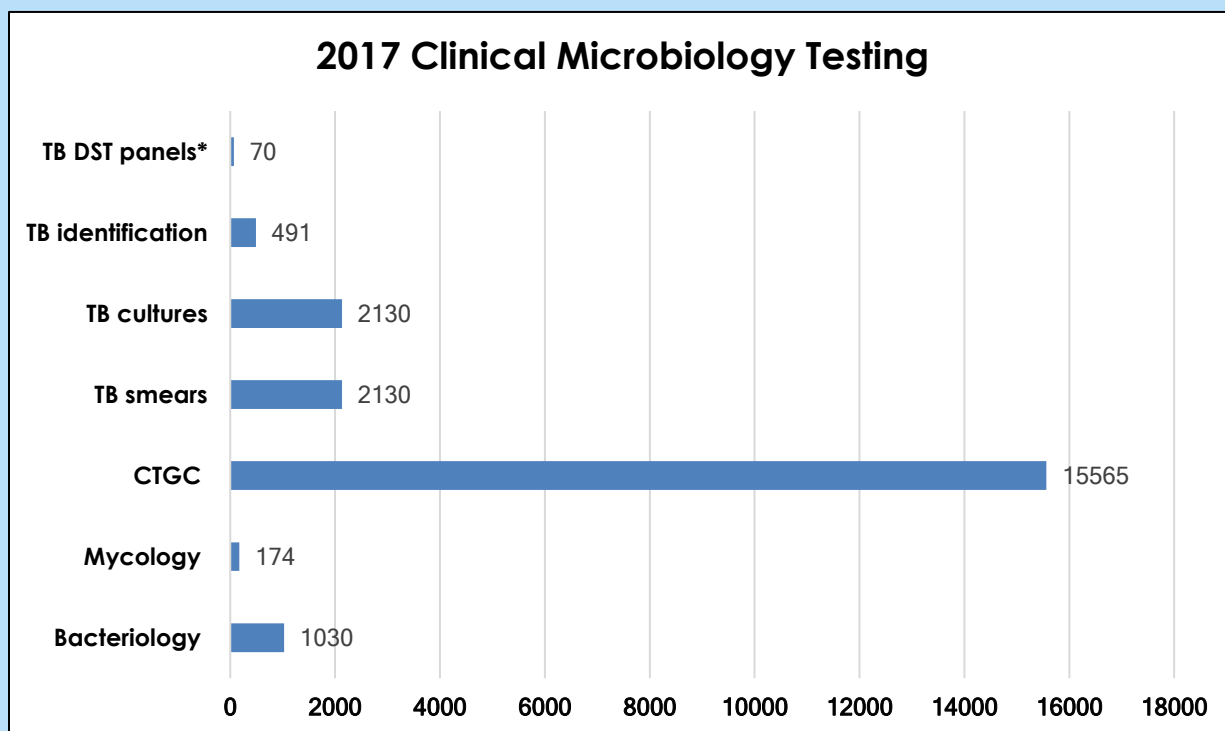
- A *mcr-1/mcr-2* multiplex PCR: Previously ISDHL had validated *mcr-1* PCR to detect this emerging mechanism of colistin resistance; *mcr-2* was added in 2017.
- Sensititre Gram Negative Broth Microdilution Assay: Expanded antibiotic susceptibility testing capabilities were added.

- BioMIC: A digital imaging system for use in reading Kirby Bauer Antibiotic Susceptibility Test (AST) results versus AST results manually, which is time-intensive.
- MALDI-TOF MS for Reference Bacteriology isolates: This validation tested almost 200 isolates from the ISDHL freezer and was able to greatly expand the number of species validated at ISDH.
- Upgrades for Bruker RUO for the MALDI-TOF MS: New library upgrades were released by Bruker Daltonics. To continue testing using the new library, a data validation was completed, documented, and signed off by the laboratory director.
- Bruker FDA-approved CA System for the MALDI-TOF MS (in progress): A new library upgrade was released by Bruker Daltonics. As this system is FDA approved, the assay must be re-verified to continue testing using the new library.

A significant contribution to the success of the Clinical Microbiology Division (and other divisions) to effectively develop or validate new testing was the creation of ISDHL's Validation Team in 2016 and subsequent validation team charter in 2017. Consisting of the Director of Quality Assurance (QA), the Director of Clinical Microbiology, and the Assay Development Supervisor, the primary goal of this group is to provide clear guidance and guidelines for assay validations, verifications, and method comparisons at the ISDHL. The Director of QA determines whether a proposed project plan meets the criteria outlined by CLIA, or other governing body, and looks for possible areas of weakness in the validation/verification from a QA perspective. The Assay Development Supervisor provides technical expertise regarding the lab work or study design. The Director of Clinical Microbiology provides expertise in both the technical aspects as well as QA, thus bridging the gap between technical and QA review. This team has developed a process for undertaking a validation, verification, method comparison, or addendum at ISDHL, including templates for each step of the process of the project plan. Prior to beginning a project, the team proposing the project writes a study plan and presents it to the Validation Team. This study plan outlines the use and justification of the assay; the cost analysis of the assay, including the total cost of the validation; and the validation strategy, including an isolate list, validation timeline, type of samples, range of results, acceptable limits, and discrepancy analysis. After approval is received from the Validation Team, the proposing team is free to begin the project. After the project is complete, the proposing team writes up the validation/verification/addendum/method comparison paperwork and submits it to the Validation Team for review. The Validation Team reviews the document for data integrity, sensitivity, specificity, and cohesiveness of overall writing, with the goal to provide strong documents that will provide not only auditors, but also the ISDH Laboratory Director and future employees with clear reasoning for the conclusions reached by the validation testing. All documents (plan, write-up, approved validation) are kept on the ISDHL SharePoint QA site, and all ISDHL employees have access to these documents in this location. By creating a validation team, the ISDHL has established a process that creates continuity between departments. By writing a study plan, departments save money on validations because troubleshooting steps and specimen lists

are prepared ahead of time, eliminating the need to run additional specimens when problems arise. This level of planning also eliminates interpretation bias and excessive retesting, which are red flags for QA and auditors. In 2017, the Validation Team reviewed proposals and/or validation write-ups for a total of 26 projects.

Beyond testing for antibiotic-resistant organisms, other testing from the Clinical Microbiology Division totaled 21,590 tests and included:



*TB DST panels = Mycobacterium tuberculosis drug-susceptibility testing panel

QUALITY ASSURANCE

ISDH Laboratories Collaboration with ASM/CDC's Global Fellowship Program



During the week of September 18, 2017, ISDH Laboratories Quality Assurance (QA) Director Chris Grimes hosted seven public health laboratory QA officers and directors from three countries that have been the focus of this ongoing collaboration: Armenia, Kazakhstan, and Georgia. These countries were selected to support the ongoing efforts of the U.S. Defense Threat Reduction Agency (DTRA) in that region. To improve public health infrastructure, fellowships were offered to pivotal individuals, so

they could travel to the ISDH Laboratories to learn how to better implement laboratory QA policies and procedures, how to improve laboratory safety, and how to achieve accreditation for their public health laboratories.

ISDH Laboratories welcomed the ASM/CDC global fellows and their CDC escorts with open arms. We provided them with in-depth demonstrations of our internal audit processes, document control, non-conforming event reporting, and overall QA/safety policies, as well as a visit to the City Market and Farmers' Market. Previously, whenever ASM/CDC global fellows return home from their sessions at ISDH Laboratories, they have made significant improvements in their national laboratory networks and public health laboratory quality systems.



PROTECTING THE HEALTH OF HOOSIERS

One Test at a Time

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Our Mission

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

Our Vision

A healthier and safer Indiana