



INDIANA STATE DEPARTMENT OF HEALTH LABORATORIES ANNUAL REPORT

2012

Through effective use of leading edge technology and a highly skilled and highly motivated workforce, the ISDH Laboratories provide comprehensive quality data to address public concerns in Indiana and the nation.

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Director's Letter

Dear Public Health Partners:

The past year was marked by steady progress on numerous fronts—progress towards ISO 17025 accreditation of our Food Labs, further implementation of STARLIMS modules, installation of new equipment, as well as development and validation of multiple cutting-edge testing technologies. Quality of testing was maintained in the face of diminishing resources, as evidenced by excellent reports from regulatory auditors.

Response to various outbreaks of infectious disease is a constant for the Indiana State Department of Health Laboratories, and 2012 included multi-drug resistant tuberculosis, a large series of influenza A H3N2v in both pigs and people during the County and State Fair seasons, a major outbreak of measles, pertussis, norovirus, and multiple food borne outbreaks, including a major salmonella outbreak linked to Indiana-raised cantaloupe. The serious drought brought concerns about well water quality, and mosquito pools positive for West Nile Virus were earlier and greatly increased over previous years.

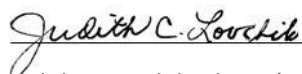
Members of our staff were honored with prestigious national recognition awards and elected leadership positions. Lab staff participated in numerous national public health and leadership activities, made award-winning presentations at regional and national meetings, and many staff members attended trainings out of state. Some long time employees retired, some staff members were promoted, and new staff joined our ranks. Our Outreach staff kept very busy providing trainings for laboratories and public health partners within the State. Our influence extended internationally with visiting ASM Fellows from Kenya and Mozambique.

Preparations for the public health impact of Super Bowl 2012 involved laboratory personnel, but fortunately this enjoyable event was not marred by threats to public health.

Federal grants continued to fund important laboratory activities, including Preparedness and Epidemiology-Laboratory Capacity. In addition, the Food and Drug Administration provided multi-year funding for our food laboratories to prepare for ISO 17025 accreditation. We were one of only two States to receive a grant from the Association of Public Health Laboratories to help us deal with multi-drug resistant health-care acquired infections, which enabled us to improve the ability of Indiana laboratories to correctly detect them.

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

Sincerely,



Judith C. Lovchik, PhD, D(ABMM)

Laboratory Director

International Ties

Chris Grimes and Jyl Madlem

Our Laboratory was pleased and honored to host three American Society for Microbiology (ASM) International Fellows from Kenya. They arrived July 9, 2012, accompanied by Dr. Aimee Nibagwire from ASM. Dr. Joseph Oundo, Dr. Jane Siminyu, and Waqo Boru had a primary goal to expand their understanding of quality systems in public health laboratory work. Laboratory management improvement was a secondary goal for our fellows.



Chris Grimes, Quality Assurance Coordinator, and Dr. Judy Lovchik, Laboratory Director, provided a three week mentoring program, which included interviews with selected Indiana State Department of Health (ISDH) laboratory staff and other ISDH program staff downtown. In addition, our fellows were invited to tour the Marion County Public Health Department Laboratory and the Purdue University Animal Disease Diagnostic Laboratory to gain a better understanding of how

these programs operate.

In October, Dr. Dinis Jaintilal, ASM consultant from Mozambique, visited our Laboratory for a week. His interests included Laboratory Information Management Systems (LIMS), Standard Operating Procedures (SOPs), Laboratory Quality Assurance, and Laboratory Administration. During Dr. Jaintilal's

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visit, he met with various laboratory staff members to gain a better understanding of higher level laboratory operations. In addition to sharing of information, expertise, and experience, our fellows felt welcomed by everyone and enjoyed a few social activities with various laboratory staff members.

Dr. Lovchik and Chris Grimes were invited to the Centers for Disease Control (CDC) in Atlanta for an ASM-CDC Global Fellowship Training Program workshop. Fellowship experiences were shared and improvements to the program and curriculum were proposed.



The number of host laboratories for this program is currently limited to four in the U.S. (Indiana, Iowa, Washington, and Wisconsin). The team effort in Atlanta produced a new mission statement for the program, a new vision for the program, a skeleton of the program curriculum, and a timeline for the entire planning process. The ISDH Laboratories now plays a vital role as one of the few laboratories in the country to provide the mentorship and experience needed by the ASM-CDC Global Fellows.

Financial Report

Ethan Simcox

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. State monies are appropriated by the Indiana State General Assembly. Federal funds are drawn from U.S. grants awarded by Federal government agencies such as the Food and Drug Administration (FDA) and the CDC, a division of the Department of Health and Human Services.

The largest source of Federal funding for the ISDH Laboratories is the Public Health Emergency Preparedness (PHEP) Cooperative Agreement from the US CDC. The purpose of this cooperative agreement is to protect the public from natural, unintentional, or intentional human health threats. This agreement is designed to protect the citizens of Indiana by preparing governmental jurisdictions, communities, health and emergency response systems to prevent, protect against, respond to, mitigate and rapidly recover from public health emergencies. The ISDH Laboratories also partially recovers costs by billing for some laboratory tests performed to ensure the safety and cleanliness of water supplies as well as tests for elevated blood lead.

2012 ISDH LABORATORIES FUNDING AND STAFFING: BY THE NUMBERS

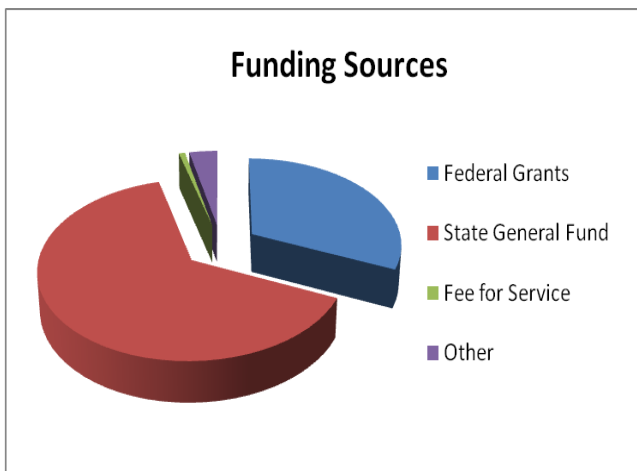


Figure 1: Laboratory Funding Sources

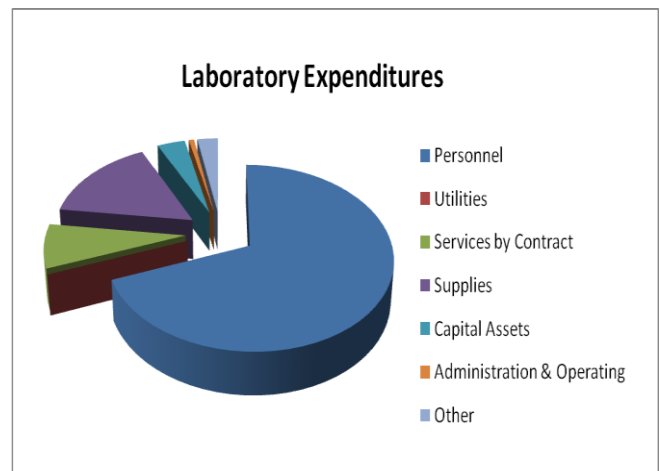


Figure 2: Laboratory Expenses

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Staffing at the ISDH Laboratories has gone through several changes over the past six years. The most significant came in 2008 when the Microbiology Department split off into two separate departments: Environmental Microbiology and Clinical Microbiology. Laboratory staffing has declined by approximately 9% since 2007. The reduction in staffing is representative of the agency's commitment to fiscal restraint, while continuing to provide the same levels of service for public health initiatives benefiting the citizens of Indiana. See Figures 3a and 3b.

ISDH Lab Staffing Numbers by Year (2007 - 2012)

Department	2007	2008	2009	2010	2011	2012
Chemistry	35	35	31	31	32	32
Environmental Microbiology		10	14	13	16	16
Clinical Microbiology		22	24	24	24	22
Microbiology*	34					
Virology/Preparedness	10	11	11	10	12	13
Administration	24	27	20	19	10	11
Total	103	105	100	97	94	93
Percent Increase/Decrease		2%	-5%	-3%	-3%	-1%
Percent Decrease since 2007						-10%

ISDH Laboratory Staffing Numbers by Department (2007-2012)

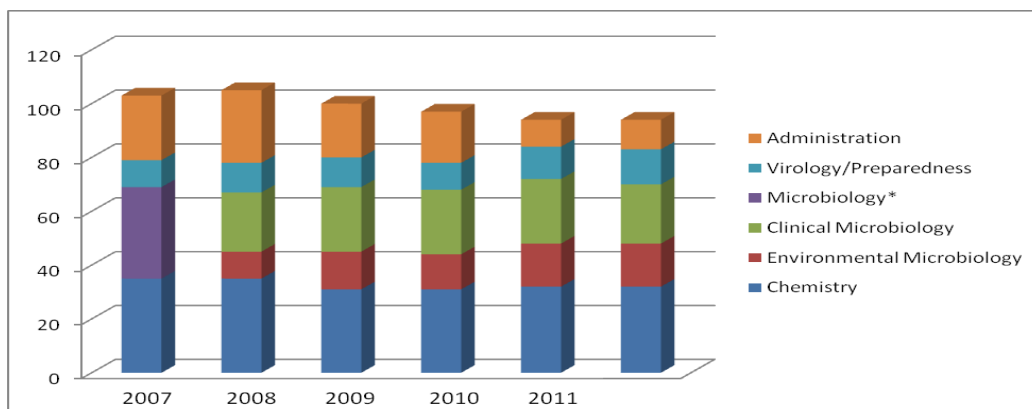


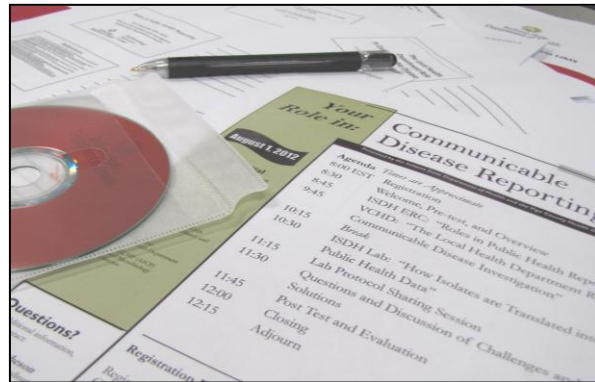
Figure 2a and b: Overall laboratory staffing has steadily declined over the last several years

* The Microbiology Department was divided into Environmental Microbiology and Clinical Microbiology in 2008.

Leveraging Resources and Partnerships

Jyl Madlem

While much of the ISDH Laboratories were getting used to the idea of the Lean initiative, efficiency became the buzz word for many of our staff. In order to provide laboratory services more efficiently, we needed to know exactly what our partners expected from us and how better to provide those services. In 2012, the ISDH Laboratories continued meeting with program



Laboratories continued meeting with program partners including the Immunization Program, the Food Protection Program, and the HIV/STD/Hepatitis Program. The ISDH Laboratories also continued regular face-to-face meetings with the Surveillance and Investigation Division staff. Additionally, new relationships were developed in 2012 and quarterly meetings with the Indiana Department of Environmental Management (IDEM) have been added. These meetings have proven fruitful in expanding both outreach efforts and laboratory services.

ISDH Laboratories offered district-wide Communicable Disease Rule trainings in collaboration with ISDH Surveillance and Investigation Division and Local Health Departments. ISDH Laboratories staff also



partnered with epidemiology to develop table-top exercises for pediatric medical residents aimed at providing a better understanding of vaccine preventable diseases and how to diagnose and report these cases. Due to the success of these exercises, they have been expanded from the IU Health Riley Pediatric Medical Resident Program to now include the St. Vincent Pediatric Medical Resident Program.

Collaborative work with the ISDH Food Protection Program produced a sample submission protocol for local health

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departments to use as guidance for food submission to the laboratory. In addition, development of new collection and submission training program was very successful. This training was taken on the road to each of the six food protection regions around the state. Finally, in reaching out to a younger audience, the ISDH Laboratories hosted a booth at Celebrate Science Indiana in October. Children were fascinated to see organisms in the microscopes, learn how we digest and test food for “bad bugs”, play a matching game with PFGE (Pulsed Field Gel Electrophoresis) patterns, learn about fomites and where they may be hiding, and see how well they washed their hands. This last exercise may have been the highlight of the event for many attendees. Using Glo Germ® and an ultraviolet light; children could see the germs on their hands and learned the importance of good handwashing techniques.



With the assistance of an APHL grant, the ISDH Laboratories Outreach Team hosted the first Environmental Laboratories Meeting. This meeting was held in June and was the culmination of the grant work performed primarily by Jyl Madlem. As the first meeting of its kind in Indiana, goals included understanding the needs of environmental water laboratories throughout the state and

introducing them to the Indiana Laboratory System. Leveraging resources and working with agency partners has become integral to advancing the work of the ISDH Laboratories.

Oh, Those Outbreaks

Jyl Madlem

The management of outbreaks within the laboratory is, at times, more of an art than a science. Supply chain, sample delivery coordination and staffing management can read like a symphony. 2012 certainly proved to be a year of music to the ears of the ISHD laboratories staff. During this year, outbreaks were plentiful and included measles, melons, fungal meningitis, Influenza H3N2v and various enteric outbreaks of Norovirus.

The Virology Laboratory had a busy year starting with a measles outbreak in February, which brought 41 virus cultures to the ISDH Laboratories for PCR testing. An early influenza season seemed likely when our virologists detected a strain identified as H3N2v, a novel influenza virus formed by the reassortment of seasonal H3N2 with the pandemic 2009 H1N1 strain. The laboratory received over 400 specimens between July and September and reported 138 cases of H3N2v this year. In the fall of the year, as the kids return to school, so too does Varicella - there were four outbreaks identified this year.



West Nile Virus testing also kept the virologists busy this year. A total of 737/1941 pools of mosquitoes tested positive for WNV in 91 Indiana counties. High temperatures and drought conditions directly contributed to the increased testing volumes for West Nile Virus. The ISDH Virology Laboratory confirmed WNV in 576 pools of mosquitoes, including 16 in Marion Co. and 5 in Allen Co.

The Serology Laboratory was not immune from outbreaks this year, measles kept them busy with 195 samples for which all were tested for IgG antibodies and 72 were tested for IgM antibodies.

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Fungal meningitis plagued much of the country this year and Indiana was no exception, the Mycology Laboratory began receiving patient specimens for fungal detection related to a contaminated lot of methylprednisolone acetate during the first week of October 2012. Methylprednisolone acetate (MPA) is an anti-inflammatory corticosteroid commonly used to treat multiple sclerosis and disk disease.

The majority of the patient specimens have been CSF, but a variety of sterile body fluids, and tissue samples were also submitted. The ISDH Mycology laboratory submitted 84 CSF specimens, 14 culture isolates, and 18 other joint fluids, and tissue samples to the CDC for further examination.

The Food Microbiology Laboratory kept busy orchestrating the testing of melons in August, managing nearly 60 whole melons received in just over a two-week period during a *Salmonella* outbreak. The positivity rate of those melons received at the ISDH was 12% for *Salmonella* species. More than 260 people were affected nationally including 30 in Indiana, according to the final report issued by the CDC.

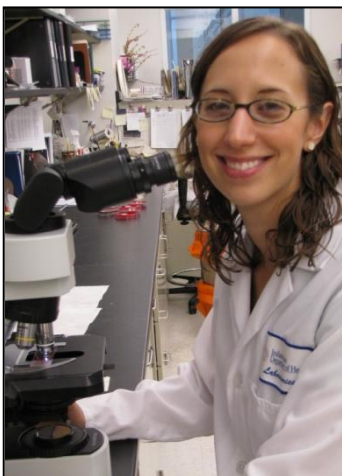


National Recognition

Jyl Madlem

It's one thing to be proud of where you work and proud of those with whom you work; it's quite another to be so impressed when you really stop to think about it, you find you are surrounded with some of the finest people in the business. The ISDH Laboratories certainly showed the country what they are all about in 2012.

Brent Barrett was awarded the 2012 Scherago-Rubin Award by the American Society for Microbiology (ASM) in June. Brent was honored during the 112th General Meeting of the ASM in San Francisco, California. The ASM is the world's oldest and largest scientific society and strives to advance the microbiological sciences to improve health and well-being. Each year, the ASM recognizes an outstanding, bench-level clinical microbiologist. The award was established by the late Sally Jo Rubin, an active member of ASM's Clinical Microbiology Division, in honour of her grandfather, Professor Morris Scherago. Barrett was nominated by Judith Lovchik, Ph.D., Assistant Commissioner of Laboratory Services at the ISDH and Diplomate of the American Board of Medical Microbiology (ABMM). Dr. Lovchik said, "Mr. Barrett personifies the best of clinical



microbiology. His intense focus on clinical microbiology has no parallel."

Indiana is one of two state public health laboratories in the country to receive grant funding from the CDC and the APHL to initiate testing for multi-drug resistant organisms such as Carbapenem-Resistant Enterobacteriaceae (CRE). CREs have become a great concern nationally and the ISDH now has the capability of confirming organisms from Indiana clinical laboratories as CREs. Thanks to the hard work and dedication of Lixia Liu, Ph.D., D(ABMM), Deputy Director, Jon Radosevic,

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M(ASCP), RM(NRM), Reference Microbiology Supervisor, and Liz Church, Reference Microbiologist, the ISDH Laboratories is receiving, testing and reporting confirmatory results on suspect isolates from submitting laboratories throughout the state.

Lixia Liu, Ph.D., D(ABMM), Deputy Director presented a talk at the 2012 HIV Diagnostics Conference on her work with Jessica Gentry, Serology Laboratory Supervisor on the evaluation of the correlation between the signal to cutoff ratio (S/CO) of the VITROS anti-HIV1+2 chemiluminescent immunoassay and the result of confirmatory testing. Pooling 73,000 samples into 733, they determined when the VITROS anti HIV 1+2 CIA S/CO ratio is <23.9, HIV-1 confirmatory testing should be performed; while ratios of 23.9 or greater indicate confirmatory testing is not diagnostically valuable. This research may allow for significant cost savings when screening samples for HIV when integrated into screening algorithms.

The APHL Environmental Health Committee appointed Jyl Madlem, ISDH Laboratory Program Advisor, to their committee in 2012. This committee assists public health and environmental laboratories with new and existing environmental, chemical, and public health threats. This is a three-year appointment, during which Jyl will be working with other committee members on policy development, laboratory issues, awareness of environmental and public health conditions, providing outreach to the laboratory community and responding to new legislation.

Shelley Matheson, State Training Coordinator, was appointed to the APHL Network of Laboratory Leader Alumni (NOLLA). As an APHL Emerging Leader Program graduate, Shelley became a member of NOLLA this year. This group takes on issues such as workforce development and marketing strategies for cohort projects. They also coordinate forums on emerging public health leadership topics and serve as mentors for up-and-coming leaders. Shelley and her cohort presented a poster on Public Health Laboratory Awareness Toolkit at the 2012 APHL National Meeting, which won the best poster award at the meeting.

Mary Robinson joined the NELAC Institute (TNI) as a new Microbiology Expert Review Committee member in 2012 to help review and update the *TNI Standard, Volume 1, Management and Technical Requirements for Laboratories Performing Environmental Analysis, Module 5 –Microbiological Testing*.

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The committee's current focus is the incorporation of quality control requirements for new *Cryptosporidium* and qPCR testing methods.

Our Biothreat Laboratory was selected as part of the Multicenter Evaluation of the Laboratory Response Network (LRN) *Bacillus anthracis* Real-Time PCR Assay. Nikki Collins, Lyndsey Hensler, Katie Masterson, and Mark Glazier worked on this study. The objective of this study was to determine the reproducibility and repeatability of the LRN *B. anthracis* species real-time PCR assay in clinical matrices. Panels of blood and simulated sputum specimens were spiked with known concentrations of *B. anthracis* vegetative cells and sent to participating sites. Each panel consisted of 6 samples, 2 high positives, 2 low positives, and 2 negatives. Reproducibility and repeatability data was collected for a manual DNA extraction method as well as an automated DNA extraction method. PCR was performed using 2 real-time PCR instrument systems. .

Employees on the Move

Jyl Madlem

LOUIS DOUGLAS: YOU CAN'T KEEP A GOOD MAN DOWN



Louis Douglas was honored by Governor Daniels as being the longest standing employee in ISDH history. Louis served in the Army Air Force before earning a degree from Purdue University in Biology and Chemistry in 1947. Retiring after 65-years of service, Louis was presented with the Indiana Distinguished Service Medal by Governor Daniels and Adjutant General Martin Umbarger on October 15th at a

ceremony at the Statehouse. The Douglas family was present for the festivities and was thrilled with the honors and accolades bestowed upon Louis. As for Louis, he simply said he couldn't understand what all the fuss was about. He did say he tried to convey a strong work ethic not only to his children, but to the "youngsters" in the laboratory.

Louis came to the Indiana State Board of Health (ISBH) Laboratories in 1947. His skills were used in the Serology Laboratory, after which he moved to the Rabies Laboratory, then to the Food Microbiology Laboratory. Still wearing the ISBH cap long after the agency name had been changed to the Indiana State Department of Health (ISDH), Louis became an icon of sorts. With his charming quiet nature, kind words and his signature cap, he graced the halls of the ISDH Laboratories. He shared many stories of fellow employees drawing connections between him and others. Louis found connections in many things such as children's birthdays, initials, and anniversaries.



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Louis mentioned having second thoughts about retiring. He loved his work and the people with whom he worked. During a reception at the ISDH Laboratories, he surprised everyone with a performance on the cello - a talent he picked up years ago. Louis shared some words of wisdom, "Do what you love and love what you do. Be kind to those around you and you will have a good life." When asked what he would do to keep busy, he answered this way, "I plan to get up at the same time every day and do some volunteer work." He will be volunteering at the War Memorial Museum.

LIXIA LIU, PHD, D(ABMM): A RISING STAR

Dr. Liu earned her PhD degree from the University of Illinois at Urbana–Champaign studying bacterial genetics; she continued her postdoctoral training in bacterial pathogenesis at the University of Texas Southwestern Medical Center at Dallas. She came to the ISDH Laboratories from the University of Michigan where her interest in molecular epidemiology first sparked. She started as a contracted employee to work on molecular method development. In 2004, she joined the ISDH Laboratories as the Supervisor of Molecular Development and Immunology/Serology Laboratories.



Moving to the Director of Clinical Microbiology in 2008, she was heavily involved in the development and implementation of the laboratory information management system (LIMS) projects to bring tests online so that users could request services through the LIMSNet web portal, which was reminiscent of DOCS for DOCS. These electronic reporting systems have modernized the ISDH Laboratories, resulting in faster delivery of results to submitters. Dr. Liu has also spearheaded the addition of approximately 30 new tests in molecular development and serology. Dr. Liu partnered with the ERC to provide Communicable Diseases Rules trainings to all districts in Indiana. The continuous improvement efforts have been recognized by the CDC during a site visit of the TB laboratory. The ISDH Molecular Subtyping Laboratory was the first public health laboratory to be certified by the CDC

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PulseNet for use of the new improved nucleic acid sequencing platform for the Multiple Locus Variable Analysis (MLVA) analysis, a molecular subtyping method.

In addition, the competitiveness of the clinical microbiology division among the public health laboratories in the nation has been illustrated by the following grant awards; one of the two public health laboratories in the nation to be awarded a grant for the “State-Based Multi-Drug Resistant Organism Detection and Reporting” project by the APHL, and one of the nine public health laboratories in the nation to be invited to participate in the “Evaluation of TB laboratory performance indicators” study by the Laboratory Branch of the Division of TB Elimination at CDC.

In August 2012, Dr. Liu earned her Diplomate of the American Board of Medical Microbiology (ABMM) certification. This certification recognizes excellence in the practice of clinical microbiology. When asked about her goals, Dr. Liu says they are the same, “to help build a modern public health laboratory that meets the ever changing needs of public health”. In October, Dr. Liu was promoted to Deputy Director of the ISDH Laboratories. Congratulations to Dr. Liu.

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