

Indiana State Department of Health Laboratories

REFLECTIONS

2010 Annual Report





Dear Friends and Supporters:

The state of Indiana's economic health dominated our concerns in 2010 as we shared the pain of public health laboratories throughout the country. The first goal of the Indiana State Department of Health (ISDH) Laboratories' Three-Year Strategic Plan, adopted in 2009, was to establish a sound financial basis. We obtained the services of an Operations Director and conducted a thorough cost analysis of all our testing. In the previous year, we documented the sources of the laboratories' funding. This year, we attempted to document how those funds are spent. We plan to further refine this budgetary analysis in the coming year.

The financial situation of the State impacted the laboratories in several ways. Cutbacks in hiring reduced our support staff, so remaining staff took on additional duties to cover the work. Some projects, such as the Indiana State Laboratory System Improvement Program, were put on hold. Out of state travel was reduced and purchases were scrutinized more carefully. Some testing was reduced, and programs were asked to reconsider the public health relevance of existing testing.

The silver lining of the financial cloud was the greater self-knowledge acquired through examining our fiscal management, as well as greater urgency in examining the public health import of existing practices and policies.

Even with reduced staff, the ISDH Laboratories made remarkable gains. Our Outreach team remained active throughout the year, providing trainings and public health information regularly to Indiana's clinical laboratories. New relations with academia were formed, and old ties strengthened. Staff acquired new skills and cross-trained in various areas, increasing their value to Indiana. Continued quality of testing was demonstrated by successful audits from several national agencies as well as our excellent performance on testing Proficiency panels. Implementation of our Laboratory Information Management System (STARLIMS) progressed exponentially as additional ISDH staff members were trained to develop their assays in this electronic reporting system. ISDH laboratory staff members demonstrated national leadership in STARLIMS development and were tasked by the CDC to develop bioterror and chemical threat modules.

ISDH Laboratories respond to adversity by becoming even stronger. We look forward to continually improving and contributing to public health in 2011.

Sincerely,

Table of Contents

Director's letter.....	2
Chemistry.....	3
Calendar.....	3
Inspections.....	4
FERN.....	6
Innovations.....	7
Financials.....	8

Editorial Staff

Jamie Hadley
Liz Church
Lyndsey Hensler
Kara Hammes

Thanks for contributions:

David Baize
Ray Beebe
Robin Bruner
George Burk
Tom Cronau
Dave Dotson
Hesham Elgaali
Jessica Gentry
Mark Glazier
Chris Grimes
Mary Hagerman
Jerry Hege
Lixia Liu
Judith Lovchik
Katie Masterson
Mike Oberthur
Robert Pawlak
Jon Radosevic
Jane Smith
Mark Starzynski
Mohammed Zaman
Dianna Zamani
Phil Zillinger

A Shining Year for Chemistry

In 2010, the ISDH Chemistry Laboratories had several unique opportunities. They were able to collaborate with three different professors at two universities in Indiana. They also participated in the making of a television production for WFYI, the Indianapolis local PBS station, about water supplies in Indiana.

One study, atrazine concentrations in the Upper White River Watershed, was conducted in collaboration with a researcher at Ball State University (BSU).

Samples were taken from this watershed and tested for atrazine. Since the method used for atrazine analysis is the same method used for 32 other synthetic organic compounds (SOCs), the Chemistry Laboratories could provide information about these other SOC's with no additional cost to either the university or ISDH.



Mohammad Zaman, performing calculations for Atrazine and Simazine(left), and samples to be analyzed on a gas chromatograph (right).

This researcher also approached the Chemistry Laboratories with a proposal to study the concentrations of man-made pharmaceuticals in Indiana waters. Samples from streams, rivers and Lake Michigan were analyzed for many different products such as DEET, caffeine, and antibiotics.

The laboratory also worked with a researcher at Indiana University – Bloomington (IU-B) to analyze water samples taken downstream from waste treatment outfalls. This study was investigating the presence of the same pharmaceuticals as the BSU study in the outfalls of wastewater treatment plants.

Previously, the Inorganic Chemistry and Metals Laboratories had worked on studies of three Indiana wildlife refuges for the U.S. Fish and Wildlife Service.



George Burk, using the Flame Atomic Absorption Spectrophotometer to detect the presence of metals in water samples (left), and the spectrophotometer detecting Strontium (right).

The laboratories were contacted in 2010 and participated in a similar wetlands study with another researcher at IU-B.

In April, WFYI came to the laboratory to interview staff and film laboratory procedures for their production "Drop By Drop: Protecting Indiana's Water Supply." This television production was about the condition of water supplies in Indiana

with particular emphasis on the level of arsenic in a public water supply at mobile home park near Richmond. The laboratory tested the samples collected from a public well that supplied the water to the mobile home park; the samples were found to contain higher levels of arsenic than the allowable amount of 15 parts per billion. The show was aired in July on WFYI and clips of the program can be found on their website (www.wfyi.org).

As indicated by the projects and publicity received during 2010, the Chemistry Laboratories of ISDH Laboratories have been working hard to bring more recognition to ISDH. They have developed great working relationships with two of Indiana's Universities and are hoping to develop even more in the coming years.

2010 Calendar of Events

January

- ✓ The Mycology Lab isolated *Coccidioides immitis* from the pleural fluid of an 87-year-old male. *C. immitis* is considered a select agent by the CDC.

February

- ✓ The Tuberculosis Lab and Mycology Lab collaborated to rule out a *Mycobacteria tuberculosis* infection from a wound specimen.

March

- ✓ The ISDH Lab Outreach Team sponsored a hands-on workshop for Sentinel Laboratories: Biothreat Agents 101 at the ISDH Lab.
- ✓ They also sponsored an information booth at the 40th annual spring meeting of the South Central Association for Clinical Microbiology in Louisville, KY .

April

- ✓ During National Public Health Week, ISDH employees participated in the conference "A Healthier American: One Community at a Time" at IUPUI. The Outreach Team sponsored an informational booth and several presentations and table top exercises were provided by staff from the Clinical Microbiology and Virology and Emergency Preparedness Divisions.
- ✓ Packaging and Shipping Trainings for Division 6.2 Materials were provided April 20, 22, & 27 in Indianapolis, Fort Wayne, and Evansville.

Inspections, Inspections, Inspections

Inspections are nothing new to the ISDH Laboratories. All labs must be inspected periodically to ensure that the lab is in compliance with the specific rules and regulations governing it. These inspections can be grueling at times, but they are a normal part of lab life. In 2010, the ISDH Labs underwent several inspections and, in the end, received high marks on each one.



We began the year with an inspection by the CDC Select Agent Program. They visited our labs from January 12 – 14 to look at the BioThreat, Virology, and TB Lab areas. The inspection was focused on these labs' capacity to handle, store, and test for select agents.

It involved a detailed inspection of the facilities, staff interviews, and an extensive review of record-keeping and trainings. The inspectors noted only a few minor deficiencies in lab practices which have since been corrected. Some facility issues were also noted and are currently being handled by the builders.

On April 13, the Food and Dairy Laboratory was inspected by FERN (Food Emergency Response Network). The inspector checked on the progress of FERN projects outlined in the October 2009 grant and on the major equipment purchased with FERN money. During the inspection, he also verified the statements in our laboratory profile documented on FERNLAB.org. With very few corrections required, the inspection was a success!



Chris Grimes and Ray Beebe, reviewing Quality Control paper work.

huge success for ISDH Labs!
Continued on page 5.



ISDH File Storage Room

The AIHA (American Industrial Hygiene Association) visited the laboratories in May to assess the Environmental Lead laboratory. The inspector was very impressed with our facility and stated that the ISDH contains one of the best labs he has seen across the United States. Only a few minor documentation issues were listed, most of which have since been corrected. This biannual inspection was once again a

May

- ✓ Members of the ISDH Lab Outreach Team sponsored an information booth at the Public Health Nurse Conference.
- ✓ The Mycology Lab received a draft of a paper on a *Blastomycosis dermatidis* infection in a human resulting from a kinkajou (raccoon-like animal/pet) bite. The isolate was submitted by the ISDH Mycology lab to the CDC.

June

- ✓ Lyndsey Hensler received training for Influenza PCR from the CDC.
- ✓ Lixia Liu attended the TB National Meeting.

July

- ✓ The ISDH Lab Outreach Team sponsored a hands-on workshop for Sentinel Laboratories: Biothreat Agents 101 in Evansville at Deaconess Hospital.
- ✓ The Virology module moved from STARLIMS V9 to V10.
- ✓ Mary Hagerman attended the 2010 Emergency Response Chemical Laboratory Conference (ERCLC).

August

- ✓ Laura Taube went to Atlanta, GA for TB training.
- ✓ The Blood Lead Lab was invited to become a referee lab for the National Blood Lead Proficiency Testing Program.
- ✓ Hesham Elgaali attended the Annual Meeting of the International Association for Food Protection (IAFP).
- ✓ Tom Cronau attended the FDA sponsored "50 State Workshop: A United Approach to Public Health."

Inspections, Inspections, Inspections continued

A second biannual inspection took place in 2010, and impacted many areas of the ISDH Laboratories. In June, the Regional CMS office sent inspectors to the ISDH Laboratories to verify our compliance with CLIA (Clinical Laboratory Improvement Act) requirements. The Blood Lead, Chlamydia/Gonorrhea, Central Receiving, Enterics, Media Preparation, Molecular Diagnostics, Mycology, Parasitology, Reference Bacteriology, Serology, Special Bacteriology, TB, and Virology areas were inspected. The inspectors toured the labs, reviewed various documentations (i.e. staff qualifications, procedures, reports, staff competencies, and training documentations) and conducted staff interviews. Once again, ISDH continued its streak of excellence by receiving only four minor deficiencies.



ISDH Lab employees basking in the glory of another successful year of inspections and audits!

The FDA (Food and Drug Administration) also completed an evaluation of the ISDH Laboratories in June. They visited the Dairy Product testing areas to examine the lab's adherence to specific protocols for dairy product testing. The lab was only cited for minor issues, which were quickly resolved.

Finally, in August, the Environmental Protection Agency (EPA) performed an audit of the lab. They inspected the Metals, Inorganic Chemistry, Organic Chemistry, Radiochemical, and Water Microbiology lab areas. This audit was very extensive and only a few documentation issues and two calibration issues were found. The Labs ability to score high marks on this inclusive audit is very impressive and highlights the outstanding practices and processes conducted at ISDH.

Overall, very few issues were discovered during these inspections and most of them were very easily corrected. The ISDH Labs were found to be in compliance with each inspection agency noted in this article. The consensus from all inspectors was that ISDH makes quality testing a priority. Because of the huge success for all lab testing areas, a large cookout was held in September as a thank you to all ISDH Laboratory employees. They are, of course, the ones responsible for displaying quality in the lab everyday. In addition to lab employees, Chris Grimes and Ray Beebe, the quality assurance coordinators for the ISDH Laboratories, have been instrumental in keeping the ISDH Labs in compliance. Thanks, Chris and Ray, for all that you do!



ISDH Lab employees enjoying the celebration of a Quality filled year!

September

- ✓ The ISDH Lab Outreach Team sponsored a hands-on workshop for Sentinel Laboratories: Biothreat Agents 101 at the ISDH Lab.
- ✓ Katie Masterson attended the NLTN sponsored workshop "Public Health Virology: Building a Bridge to the Future."
- ✓ The ISDH Virology and Emergency Preparedness Lab was chosen to participate in the LRN Clinical Specificity Study. The objective of this study was to determine the clinical specificity for selected LRN RT-PCR assays; testing was completed primarily by Lyndsey Hensler.
- ✓ Xian (Grace) Chi attended the "Testing Methods for Vaccine Surveillance and Control of Rotavirus Gastroenteritis" training.
- ✓ The Chemistry Division made a presentation to a group from the People's Republic of China about the role of the laboratory in food safety.
- ✓ Engra Castiglione received Send-Suite training through Pitney Bowes.
- ✓ The Outreach Team sponsored an information booth at the American Society for Clinical Laboratory Science and the Clinical Laboratory Management Association Indiana Chapters Annual Meeting in Indianapolis.

October

- ✓ The Outreach team attended the Indiana Fall SCACM meeting at Clarian Pathology Lab in Indianapolis.
- ✓ Two Packaging and Shipping Trainings for Divison 6.2 Materials were provided at the ISDH Lab.
- ✓ Robin Bruner attended the LRN National Conference as well as the LRN-C Level One Surge Laboratories Meeting.

Bonding Over Food: FERN brings together Microbiology and Chemistry Labs

Both the Chemistry and Microbiology Labs at ISDH have benefited from involvement in the Food Emergency Response Network (FERN). This partnership joins local, state, and federal food-testing laboratories into an organization that can respond to emergency situations involving potential biological, chemical, or radiological contamination of food. FERN operates on the basis of prevention, preparedness, response and recovery for food security and food defense. This network has provided opportunities for members of the ISDH Labs to attend trainings, conferences, and make connections through participation in projects.

Throughout 2010, there were several FERN training workshops that ISDH chemists and microbiologists were able to attend through funding from the FERN Cooperative Agreement.

Aaron Bolner from Food Chemistry traveled to Pearl City Hawaii in February.

At the Hawaii State Department of Health Labs, he attended a FDA/FERN training course about the detection of toxic compounds in food matrices using Gas Chromatography/Mass Spectrometry (GC/MS).

In March, Hesham Elgaali, supervisor of Food and Dairy Microbiology, attended a train-the-trainer workshop at the Virginia State Laboratories in Richmond. After completing this workshop, he was invited to be a trainer at the Food Microbiology and Rapid Methods Course for introductory-level laboratory analysts in Seattle twice during 2010.

Liz Church, a microbiologist in Emergency Preparedness, participated in a FERN training course about biosafety and biosecurity in a food testing laboratory in June. This hands-on workshop focused on *Bacillus anthracis* and was held at the Minnesota State Department of Health in St. Paul.

In August, Jim Kirkman, a food microbiologist, attended a FERN sponsored molecular-based workshop on real-time polymerase chain reaction (RT-PCR) that was held at the Arizona State Laboratory in Phoenix in August.

Travel was also supported so that Robin Bruner, Division Director of Chemistry, Jane Smith from Radiochemistry, and Hesham Elgaali from Food and Dairy, could attend the FERN National Training Conference over the summer in Minneapolis.

Continued on page 7



Hesham Elgaali, conducting trainings on how to accurately use the Vidas equipment for Food and Dairy Microbiology testing.

November

- ✓ The Rabies module went live in STARLIMS V10, including some new features of LIMSNET that are specific to rabies submissions and testing.
- ✓ The TB module went live in STARLIMS V10.
- ✓ Hesham Elgaali, Tom Cronau, Ken Hill, Phil Zillinger, and Pradip Patel volunteered to participate in the National Laboratory Task Group of the FDA sponsored Integrated Food/Feed Safety System (IFSS). Their work with this group will focus on the topic of lab accreditation in food chemistry and microbiology.

December

- ✓ The roll out of the Indiana Epi-Ready trainings was completed. The Indiana Epi-Ready Training Team held five workshops from September to December that were each two days each and were strategically held throughout the state in Allen, Vanderburgh, Porter, Dearborn and Marion counties. The goal of these trainings was to integrate the methods used to detect, investigate, and control foodborne outbreaks. The five trainings reached 169 attendees from State and Local health Departments with varied backgrounds including, Environmental Assessment, Public Health Nursing, Epidemiology and Laboratory.

Bonding Over Food: FERN brings together Microbiology and Chemistry Labs continued Lab Innovations

The Chemical Threat Lab and the Food Chemistry labs participated in the 2010 Joint Confidence Building Exercise in August. This response exercise included three national laboratory networks: FERN, the Laboratory Response Network – Chemistry (LRN-C), and the Environmental Protection Agency (EPA).



This apple is being shaken in dilute nitric acid to remove surface contamination. The apple had been spiked with americium-241, cobalt-60, and cesium-137. The acid leachate (without the apple) was analyzed by gamma spectroscopy.

In Indiana, the exercise involved the LRN-C and FERN. The Food Chemistry Lab, as part of FERN, received apple juice samples and the Chemical Threat Lab, a member of LRN-C, received blood specimens. Each lab analyzed their samples for Cyanide and reported back to their respective networks. This exercise was followed by a joint conference call to discuss what had gone well, along with areas for improvement. ISDH analyzed all samples correctly while 31 percent of the labs missed at least one.

In September Tom Cronau, Division Director of Environmental Microbiology, was invited to attend a one-day FERN sponsored table-

top exercise to evaluate the capability and capacity of FERN labs in the Central Region. This meeting, held in Pittsburgh, addressed the activation and immediate response activities following a mock foodborne illness outbreak in the Central Region. As a state partner lab, ISDH had successful participation because staff members responded when contacted and were able to provide surge support for the simulated emergency.

Funding from FERN Cooperative Agreement ended September 30 and was not renewed for 2011. However, Indiana remains recognized as an active FERN Laboratory in Chemistry, Microbiology, and Radiochemistry and is prepared to respond if emergencies arise.



The Radiochemistry Lab at ISDH.

CT/GC

- ✓ Participated in a *Trichomonas vaginalis* co-infection study with Gen-Probe and 20 other sites. As participants of this study, the CT/GC department tested approximately 1000 samples that had been previously tested for *Chlamydia trachomatis* and *Neisseria gonorrhoea*. The study was designed to observe the prevalence of female patients with co-infections of *Trichomonas vaginalis* and *Chlamydia trachomatis* or *Neisseria gonorrhoea*. The results of this prevalence study will be reported by Gen Probe's Trichomonas Review Board in a peer reviewed journal.

Enterics

- ✓ Validated serotyping for the top six, non-O157, Shiga toxin-producing *E. coli*. These six *E. coli* are O26, O45, O103, O111, O121, and O145. With the ability to serotype O157 and these six new serotypes, the Enterics department can now identify the top seven outbreak causing *E. coli*, approximately 94 percent, found in the United States.

Molecular Development

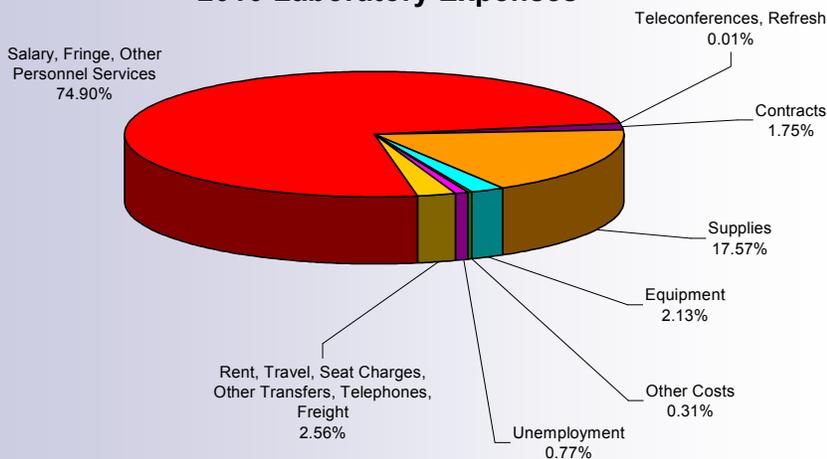
- ✓ Implementation of pyrosequencing protocols for Influenza testing.
- ✓ Implementation of Antibacterial Susceptibility testing of *M. tuberculosis* using pyrosequencing techniques.
- ✓ Validated the detection of Isoniazid resistance conferring mutation katG315 in *M. tuberculosis*.
- ✓ CDC/CalciNet certified for Norovirus typing by sequencing.
- ✓ Validated Enterovirus typing by sequencing.
- ✓ Implementation of 16S rRNA gene sequencing for microbial identification.
- ✓ Implementation of 16S rRNA gene pyrosequencing for Mycobacterial speciation.

PFGE

- ✓ The PFGE lab can now type eight pathogens with the addition of Non-O157 STEC *E. coli*, *N. meningitidis*, *Campylobacter jejuni*, and MRSA.

2010 Financial Expense Profile

2010 Laboratory Expenses



Expense	Dollar Amount	Percentage
Salary, Fringe, Other Personnel Services	\$ 5,594,682.52	74.90%
Teleconferences, Refresh	\$ 961.61	0.01%
Contracts	\$ 130,385.33	1.75%
Supplies	\$ 1,312,493.94	17.57%
Equipment	\$ 158,866.33	2.13%
Other Costs	\$ 23,280.00	0.31%
Unemployment	\$ 57,404.14	0.77%
Rent, Travel, Seat Charges, Other Transfers, Telephones, Freight	\$ 191,394.25	2.56%
TOTAL	\$ 7,469,468.12	100.00%

Lab Innovations continued

Serology

- ✓ Measles IgM EIA assay was validated using a new brand of reagents because previous brand was discontinued.
- ✓ WNV IgG EIA assay was validated using FOCUS reagents which decreased the time needed for testing
- ✓ A validation of the time between collection and testing was performed for Ortho ECi HIV and HCV assays which allowed transit time to increase to seven days.

TB

- ✓ TB Drug Susceptibility assay was moved from Bactec 460 instrument to MGIT 960 instrument which allows for faster test results.
- ✓ TB PCR testing was implemented on smear negative TB sputa which allows all first time patient specimens to be tested by PCR for TB.

Virology

- ✓ Adenovirus extraction was validated using the Roche Automated Compact system with the nucleic acid kit .
- ✓ Adenovirus PCR was validated to run on the ABI 7500 Fast Dx system.
- ✓ VZV Isolation completed using A549 cells and MRC-5 cells.
- ✓ VZV extraction was validated using the Roche Automated Compact system with the nucleic acid kit .
- ✓ VZV PCR was validated to run on the ABI 7500 Fast Dx system.
- ✓ R-mix shell vial cell line was validated for detection of respiratory viruses.



ABI 7500 Fast Dx System