

Indiana State Department of Health Laboratories

REFLECTIONS

2011 Annual Report



Indiana State Department of Health Laboratories



Dear Public Health Partners:

The staff of the Indiana State Department of Health Laboratories became leaner but no less productive in the past year. Reorganization of duties was made possible by continuing development and implementation of the Laboratory Information Management System, STARLIMS, which replaced much of our paper and clerical work with electronic information flow. We put our Standard Operating Procedures online and instituted electronic tracking for our pipettor calibrations. This reorganization enabled the expansion of our laboratory outreach team with the addition of a Laboratory Program Advisor. New outreach activities included providing training workshops, in collaboration with Epidemiology, in various districts regarding Communicable Disease Rule compliance. Educational table top exercises and workshops were also offered to medical residents and other public health partners, in collaboration with other ISDH program staff.

The ISDH Lab staff raised our national profile in 2011 with a number of presentations at national meetings and increased leadership roles in national and regional public health organizations and programs. At home, we were busy with preparations for the 2012 Indianapolis Super Bowl, helping to contain a major measles outbreak and providing the usual laboratory support for our public health programs. Because we had built strong relationships with Indiana's clinical laboratories, the ISDH Lab was able to detect and isolate the country's first influenza A(H3N2)v triple reassortant swine flu virus of the year and as well as a subsequent case later in the fall.

New test development included numerous molecular detection assays as well as sequencing/pyrosequencing testing for identification and susceptibility determinations.

The importance of Food Safety is gaining attention nationally, with the consequence that food testing laboratories are expected to become ISO 17025 accredited. A grant was obtained from the Food and Drug Administration to aid the ISDH lab in obtaining this accreditation.

We sent electronic customer satisfaction surveys to everyone we could identify who uses our services and received a respectable percentage of replies, most of which were favorable. We always appreciate learning ways we can improve our service.

We look forward to continuing our outstanding service providing for the health of Hoosiers in the coming year.

Sincerely,

Judith C. Lovchik, PhD, D(ABMM)
Laboratory Director

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Measles Outbreak

During the summer of 2011, the ISDH Laboratory became very busy testing specimens from an ongoing measles outbreak in northern Indiana. The outbreak began on June 3, when an unimmunized Indiana resident returned to the U.S. after living for one year in a country where measles is endemic. The individual was initially misdiagnosed and therefore continued to have social contact with family and other members of the community, many of whom were also unimmunized. Three weeks after the individual returned home, five family members visited an emergency department and were correctly diagnosed with acute measles infection. The diagnosis was confirmed by IgM testing, which was conducted by a private laboratory. After receiving the reported cases of measles infection, ISDH instructed the infected persons to self-quarantine in order to prevent the spread of disease to others.

Immediately, the ISDH Laboratories were alerted by the ISDH Epidemiology Resource Center (ERC) about the potential measles outbreak and that specimens would be submitted for confirmation testing. Both serum and nasopharyngeal (NP) swabs were collected and sent to the lab for testing. The serum was tested by the Serology Lab using antibody assays to detect the presence of both IgM and IgG antibodies to the measles virus. In addition to being able to confirm infection with measles virus by testing for IgM, the serology laboratory was also able to use the IgG assay to confirm immunity to the virus for those exposed persons with prior vaccination. This testing was especially critical following a potential massive workplace exposure in the affected region. The NP swabs were tested by the Virology Lab, using both virus isolation and molecular methods to confirm the positive measles result. At the time of the outbreak, the virology lab was beginning to validate and implement a measles polymerase chain reaction (PCR) assay. The addition of the PCR assay was especially beneficial to the ERC, as it produced more expedient results than current virus isolation techniques. The virology lab cultured the specimens and was able to obtain virus isolates. The isolates were then forwarded to the Centers for Disease Control & Prevention (CDC) for further characterization. In total, over 300 specimens from exposed person were tested, and 14 cases of infection with measles virus were positively identified during the outbreak.

This outbreak caused Indiana to join the long list of states with recently reported measles cases. Measles, also known as rubeola, is a highly contagious viral illness that is easily transmitted from person-to-person. Following exposure to the virus, up to 90 percent of susceptible (non-immune) persons develop measles. Characteristic signs and symptoms of measles include runny nose, cough, conjunctivitis and a febrile rash illness. Measles infection can be prevented by the use of the highly effective MMR (measles, mumps and rubella) vaccine, especially for persons travelling overseas. According to the CDC, the use of the MMR vaccine has led



Picture of measles rash.

2011 Calendar of Events

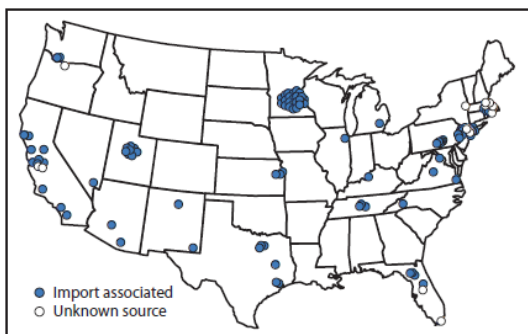
January/February

- ✓ The food chemistry group analyzed candy involved in a recall. The lab detected small quantities of lead in cherry candy but not other flavors.
- ✓ A paper about Lead Poisoning in the Burmese Refugee community in Fort Wayne was accepted for publication in *Clinical Pediatrics*.
- ✓ ISDH hosted the Picornavirus Summit.
- ✓ Chris Grimes was chosen as a member of a team on the CLSI Document Development Committee on Laboratory Internal Audit Program Proposed Guidelines.

March/April

- ✓ Chemistry lab continued to work with the FDA Partnership for Food Protection Laboratory Task Group Accreditation Subcommittee on accreditation standards as they move towards requiring ISO17025 accreditation of food testing laboratories.
- ✓ Clinton County Health Department asked about testing for Methamphetamine residue analysis and we began implementing the testing.
- ✓ Two posters were presented at the 2011 SCACM annual meeting. One was "Molecular detection of drug resistance conferring mutations in *Mycobacterium tuberculosis* and H1N1 pandemic influenza using pyrosequencing." The second was "Application of pulsed field gel electrophoresis (PFGE) and multiple locus variable number tandem repeat analysis (MLVA) for rapid detection of bacterial disease case clusters by a public health laboratory."

FIGURE 1. Distribution and origin of reported measles cases (N = 118) — United States, January 1–May 20, 2011



to a greater than 99 percent reduction in measles cases in the U.S.. Since measles is endemic in other parts of the world, measles transmission in the U.S. still occurs, as is evident by this outbreak. According to the CDC, between January 1 and May 20, 2011, a total of 118 measles cases were reported from 23 states, which marks the highest number of reported infections for this time period since 1996.

For more information regarding measles: <http://www.cdc.gov/measles/index.html>

Recognition of Service

Two long-standing employees of the ISDH Labs were recognized for their contributions during their years of service.

On May 10, 2011, when Governor Mitch Daniels presented the sixth round of Governor's Public Service Achievement Awards, Ray Beebe was among those who were honored. This ceremony was attended by Dr. Larkin, Loren Robertson, Sean Keefer and Dr. Lovchik. The efforts of those acknowledged produced an annual savings of more than \$20 million and one-time savings of about \$9 million to the state.

Ray plays a critical role in implementing electronic communication of laboratory information to other State agencies and to local health departments. His efforts have helped many customers of the ISDH Lab to submit test requests and view test results on the Internet. This provides more timely results and eliminates the labor and materials cost of printing and mailing test reports. As the laboratory liaison with IT, Ray has been an exceptional contributor to these projects, interfac-



Governor Daniels with Ray Beebe

ing between the laboratory and the programmers. His ability to speak both lab and IT languages has prevented loss of time and money due to miscommunication between two groups that have very different vocabularies and experience.

Ray has also shared his expertise and knowledge with other laboratory staff so that the lab can now create some custom Laboratory Information Management modules in-house, rather than paying the vendor; this has led to thousands of dollars in savings for the state. Ray also helps external customers who require assistance in using electronic communication with the laboratory. His help was extremely valuable during the pandemic, when he set up a lab phone bank to help with all the calls.

Ray's efforts have also resulted in considerable customer satisfaction. Customers often specifically thank and praise Ray for his assistance, especially for providing data they need for their programs and grants. Internal customers also frequently express their gratitude for Ray's assistance. His willingness to help in any situation led the laboratory senior staff to request that Ray be nominated for the Governor's Service Award.

Continued on page 5

May/June

- ✓ Measles outbreak in June which was included in an MMWR article.
- ✓ Ray Beebe received the Governor's Public Service Achievement Award.

July/August/September

- ✓ Dave Dotson received the Health Commissioner's Award.
- ✓ Influenza H3N2 triple reassortant virus identified by ISDH Virology lab. Article appeared in MMWR.
- ✓ Reference Bacti received and identified three *Listeria monocytogenes* isolates that were determined to be related to the outbreak of *Listeria* infections associated with contaminated cantaloupes.

October/November/December

- ✓ Hesham Elgaali attended a FDA/FERN sponsored training workshop on the isolation and detection of viruses in selected foods.
- ✓ Second case of Influenza AH2N2v was reported to the CDC. MMWR article was released.
- ✓ Shelby County respiratory outbreak involving school-aged children. Samples tested positive for four different respiratory pathogens (*Mycoplasma pneumoniae*, human metapneumovirus, picornavirus and adenovirus)
- ✓ Lixia Liu filmed webcast for the DIS on HIV and STDs.
- ✓ Two new trainings were implemented in 2011, Communicable Disease Rule training and Healthcare Associated Infections.
- ✓ Shelley Matheson was chosen for an APHL Emerging Leaders Cohort group.
- ✓ Jyl Madlem was chosen to receive an APHL Innovations in Public Health Grant.
- ✓ Confirmation testing on an isolate of *Listeria monocytogenes* from food involved in the Fair Oaks Dairy recall.

Recognition continued

On July 28, 2011, Dr. Gregory Larkin presented the State Health Commissioner Award for Excellence in Public Health to Dave Dotson, Emergency Preparedness and Virology Division Director.

Recently, Dave has led the lab's preparation and response planning for All Hazard emergencies. He has utilized federal grant funds to increase instrumentation, training and supplies to enhance the ISDH Lab's ability to perform Laboratory Response Network (LRN) test methods and provide support for partner LRN laboratories. He also acts as the Responsible Official in the Select Agent program and represents the ISDH Lab at national Preparedness meetings.



Dave Dotson with Dr. Gregory Larkin

Dave's skill in grant procurement is quite evident. He has made contributions to acquiring Epidemiology and Laboratory Capacity funds for testing in the lab. He has been successful at meeting deadlines and obligations for the CDC Preparedness Grant. He has also secured federal grant funds to purchase new equipment in all laboratory sections that is essential to respond to public health needs. He has collaborated with others in the agency to maximize federal grant dollars to sustain emergency preparedness, including supporting surveillance/epidemiology and response operations. Under his management, West Nile Virus testing and Pandemic Influenza testing have been implemented.

One of his greatest achievements was to secure funding for the implementation and maintenance of the Laboratory Information Management System (LIMS). He has been a constructive participant in STARLIMS development and implementation, making Indiana a national leader in this area. He also provides expertise in SNOMED coding.

Both of these men are assets to ISDH Labs and their recognition for contributions to public health are something to be celebrated.

2011 New Employees

- ✓ Serology Lab
 - ✓ Jacalynn Surma—Microbiologist 2
 - ✓ Bachelor's degree in biochemistry from Indiana University.
- ✓ Food & Dairy Lab
 - ✓ Fatima McClain—Microbiologist 2
 - ✓ Bachelor's degree in chemistry with a minor in mathematics from Alabama A&M University.
- ✓ Virology/EP Lab
 - ✓ Stephanie Dalenberg—Lab Tech2
 - ✓ Bachelor's degree in food science from the University of Arizona.
- ✓ Outreach Team
 - ✓ Jyl Madlem—Program Director
 - ✓ Bachelor's degree in psychology from Illinois State University.
 - ✓ Master's degree in management from Indiana Wesleyan University.
- ✓ BioWatch Unit
 - ✓ Tiffany Bone—Biological Scientist
 - ✓ Bachelor's degree in Plant Biology from Southern Illinois University Carbondale.
 - ✓ Master's degree in Plant Biology from the University of Illinois Urbana-Champaign.



New Employees
In the order listed above from the left

2011 Retirees

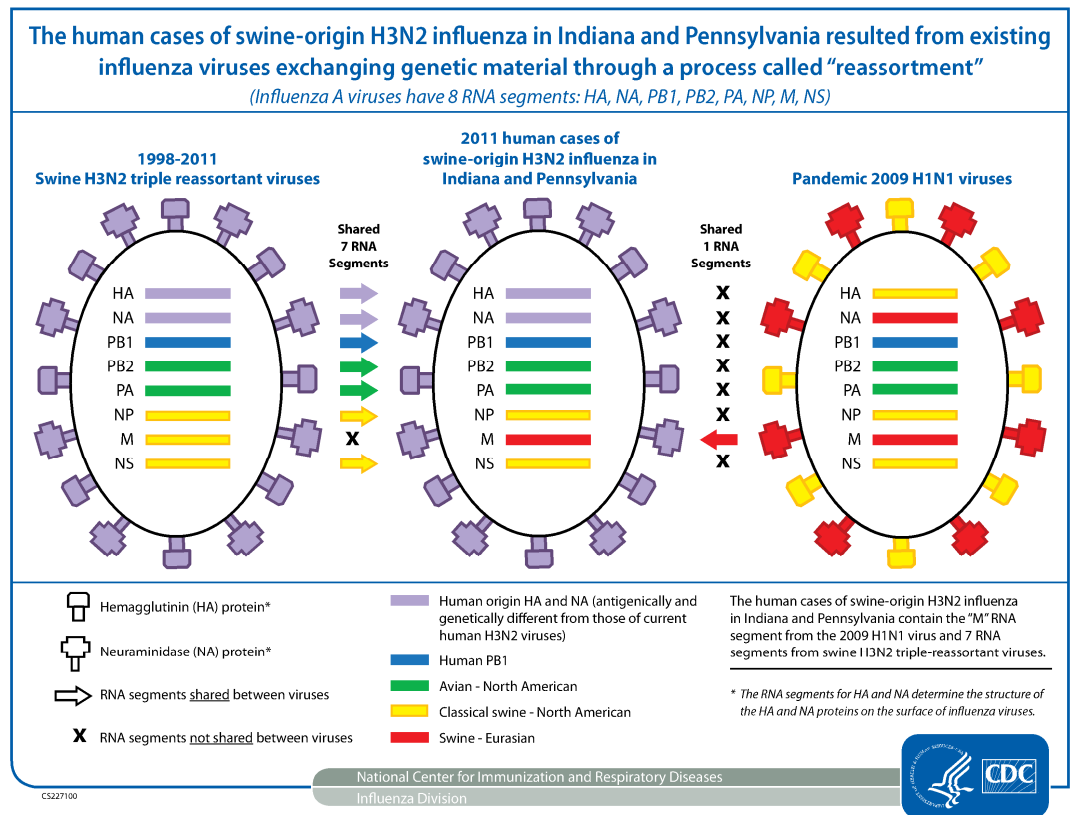
- ✓ Lillian Jackson retired after many years of service. Lillian was part of the clerical staff at the laboratory.
- ✓ Judy Kerst retired after many years of service. Judy was working as a laboratory technician in Central Accessioning.

Influenza Reassortment

In mid August, the Virology/EPR unit discovered the first of two suspected swine-origin influenza A (H3N2) infection cases, which was later re-named influenza A (H3N2)v. An infection of this type is unique in that the transmission of the influenza A virus occurred directly between a human and swine. Due to the design of the PCR assay, the ISDH Lab is able to presumptively distinguish between a swine origin virus and an influenza virus transmission through humans. The transmission between species occurs when there is a reassortment within the DNA of the influenza virus. The reassortment that occurred in the two Indiana cases was unique in that it contained a single gene segment (M gene) from the A/H1N1 2009pdm influenza viruses. Because of that, the new influenza A (H3N2)v virus contains seven genes most similar to the swine-origin influenza A (H3N2) virus currently circulating in North American pigs and one gene most similar to the A/H1N1 2009pdm influenza virus that might have been transmitted to pigs from humans during the 2009 H1N1 pandemic.

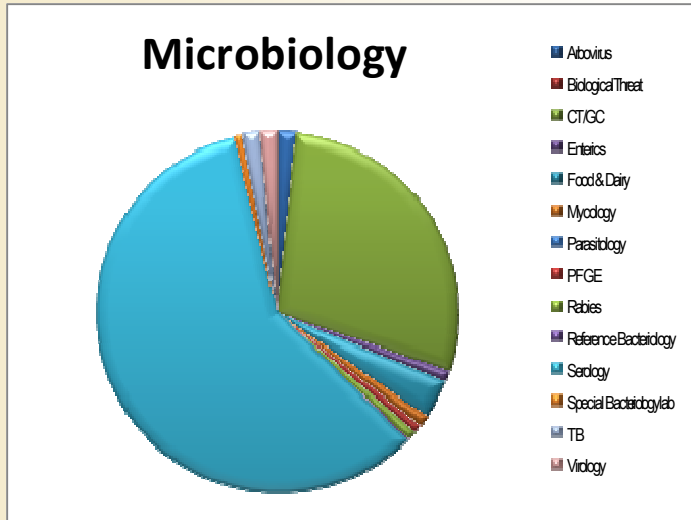
The first case in Indiana was from a boy who had multiple chronic health conditions and had been hospitalized. The lab tested the specimen through PCR testing. The sample was sent to the CDC for confirmation. The results from the CDC matched that of the ISDH Labs. The CDC was then able to further confirm the findings through genome sequencing. Although there was no direct exposure to swine with the child; a caretaker for the child reported direct contact with asymptomatic swine in the weeks prior to the onset of the child's illness.

The second Indiana case was discovered in late October. This specimen came from an adult male. Upon confirmation from the CDC, this case exhibited similar results as the previous case found in Indiana and other states since August 2011. The patient reported direct contact with swine during his work in the week before illness onset. He said he did not wear any personal protective equipment because the swine did not exhibit signs of illness. No illness was reported among the patient's household members or other close contacts.



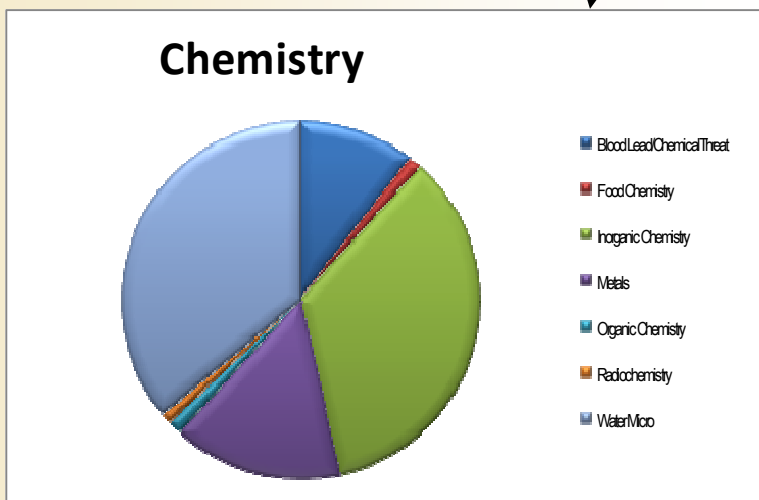
The first influenza A (H3N2)v case of 2011 in the U.S. was identified in Indiana as a result of the ISDH Lab's relationship with its Sentinel Laboratory network. One of the Sentinel Labs routinely shared its respiratory virus panel (RVP) testing data with the ISDH Virology Lab. When the ISDH Virology Lab noticed that the Sentinel Lab had identified an out-of-season influenza A/H3, the Sentinel Lab was willing to submit that specimen for confirmatory testing to the ISDH Lab. This same Sentinel Laboratory also submitted a subsequent early-season influenza A/H1N1pdm for confirmatory testing. Both of these specimens were later identified as influenza A (H3N2)v at the CDC. Neither of these could have been identified by Sentinel Laboratory test methods alone.

2011 Sample Submissions



| LAB AREA | SAMPLES |
|--------------------------|---------|
| Arbovirus | 2149 |
| Biological Threat | 14 |
| CT/GC | 34588 |
| Enterics | 1212 |
| Food & Dairy | 4383 |
| Mycology | 1168 |
| Parasitology | 57 |
| PFGE | 835 |
| Rabies | 1003 |
| Reference Bacteriology | 274 |
| Serology | 71736 |
| Special Bacteriology lab | 910 |
| TB | 1920 |
| Virology | 1776 |

| LAB AREA | SAMPLES |
|----------------------------|---------|
| Blood Lead/Chemical Threat | 5347 |
| Food Chemistry | 633 |
| Inorganic Chemistry | 17838 |
| Metals | 7872 |
| Organic Chemistry | 670 |
| Radiochemistry | 440 |
| Water Micro | 18426 |



Lab Innovations

Containers

- ✓ 60,000 containers were shipped out for sample collection for clinical and environmental testing.

Blood Lead

- ✓ STARLIMS went live in February.
- ✓ Dried Blood Spots (filter paper) are now accepted from submitters for Blood Lead Screening.

Food Chemistry

- ✓ Received an Agilent Gas Chromatograph/Mass Spectrometer (GC/MS) instrument from the Chemical Threat Laboratory. This increased the capabilities of the Food lab with respect to efficiency and timely isolation and identification of a mixture of unknown compounds in food.
- ✓ A new method to analyze organic acids in food products using HPLC was added.
- ✓ A method to analyze methamphetamine on wipes by Liquid-Liquid Extraction and GC/MS was developed.

Food & Dairy

- ✓ Upgraded testing capability with the real time PCR BAX Q7. This new system replaces the traditional BAX system and is used for testing the 6 NON 0175 E. Coli and E. Coli 0175:H7 Shiga Toxin in raw meat products.

Inorganic Chemistry

- ✓ New Lachat QuickChem 8500 series 2 system was installed.

Molecular Development

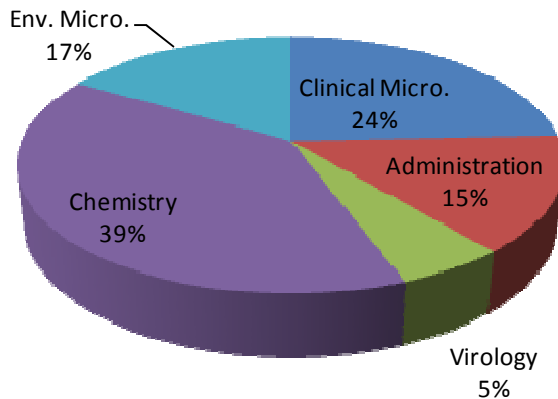
- ✓ Implementation of new protocol for Enterovirus typing by sequencing which is more sensitive.
- ✓ Implementation of procedure for identification of *Nocardia* species by 16S sequencing and pyrosequencing.
- ✓ Implementation of protocol for real-time PCR detection of *Bordetella parapertussis* and *Bordetella holmesii*.
- ✓ Acquired and validation of an ABI3500 genetic analyzer

Mycology

- ✓ Actino Assay was added which increases the number of tests and makes the SOP easier to follow.

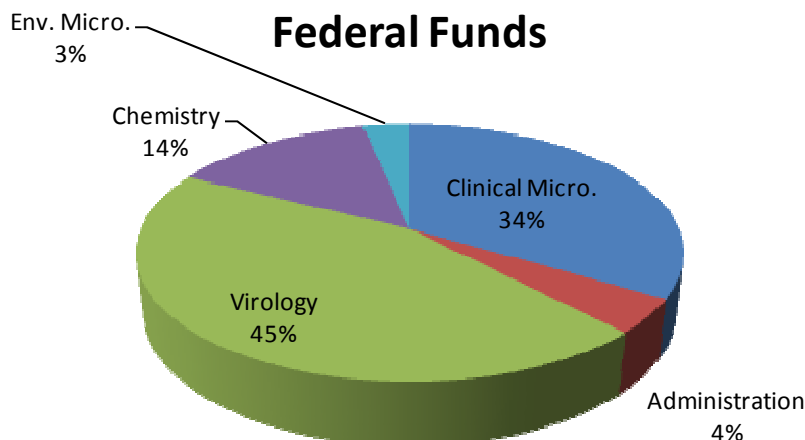
2011 Funding Overview

ISDH General Fund



| ISDH General Funds | | Federal Funds | |
|---------------------|-----------------------|---------------------|-----------------------|
| Administration | \$760,196.97 | Administration | \$92,420.25 |
| Chemistry | \$2,036,707.04 | Chemistry | \$301,471.85 |
| Clinical Micro | \$1,265,699.29 | Clinical Micro | \$710,558.52 |
| Environmental Micro | \$864,243.57 | Environmental Micro | \$69,907.86 |
| Virology | \$283,250.00 | Virology | \$944,924.74 |
| TOTAL | \$5,210,096.87 | TOTAL | \$2,119,283.22 |

Federal Funds



Monetary figures and percentages represent funding source income from the State General Fund and Federal partners for the 2011 calendar year.

Lab Innovations continued

Serology

- ✓ New assay verification study for Syphilis TREP SURE EIA to replace the CAPTIA IgG EIA assay. New assay is more sensitive and includes IgM.
- ✓ New analyzer Ortho 3600 verified for HIV 1&2 and Hepatitis A, B, & C. This instrument has a greater capacity for samples than the Ortho ECI instrument.
- ✓ New assay verification for HIV-1 and HCV RNA NAAT using GenProbe reagents which shortens time for detection.
- ✓ HIV NAAT testing for pooled serum was initiated.
- ✓ Validation of new method for Mumps IgG.
- ✓ Validation of HIV 1&2 Multisport assay as an antibody confirmatory test and distinguishes between HIV1 and HIV2.

Special Bacteriology

- ✓ Performed Modified Hodge Test with known positive and negative controls along with unknown test organisms.

TB

- ✓ Pyrosequencing for TB specimens to detect antibiotic resistance to Isoniazid and Rifampin was validated.
- ✓ Automated extraction method for PCR was validated.
- ✓ LJ Gruft validation study completed which allows for a new type of media for culture.

Virology

- ✓ Pyrosequencing based detection of H274Y mutation in Influenza A/H1N1 neuraminidase gene conferring resistance to oseltamivir was verified.
- ✓ Verification of CDC Influenza PCR for typing and subtyping Influenza specimens.
- ✓ E-mix shell vial cell line was validated for detection of enteroviruses.
- ✓ Verification of an improved media formulation for virus isolation.

Water Micro

- ✓ Procedure for testing dairy chiller water was updated by Board of Animal Health. New procedure is a semi-quantitative test.