



annual report

FISCAL YEAR 2013

MDH PHL 2013



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Message from the Director

Dear Reader,

It is my pleasure once again to introduce you to the annual report of the Minnesota Department of Health, Public Health Laboratory (PHL). This report summarizes the laboratory's activities and captures highlights from fiscal year 2013 (July 1, 2012–June 30, 2013).

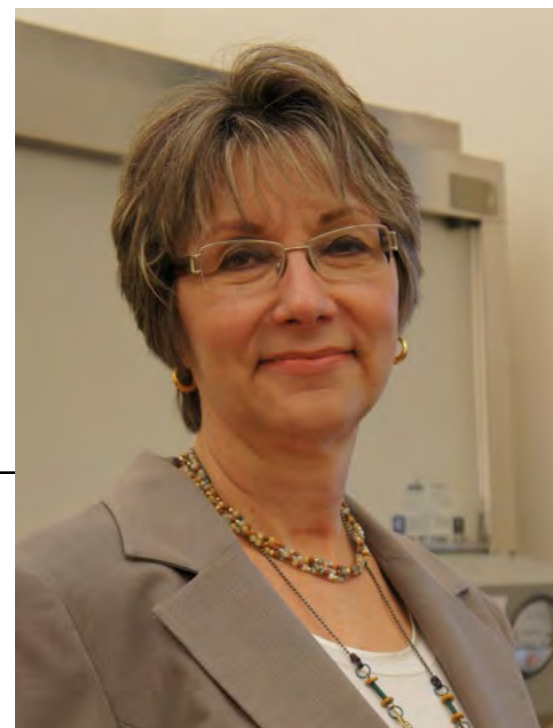
PHL performs a large variety of laboratory tests—many of which are not available in the private sector—in the areas of disease detection and prevention, food and water safety, environmental health and protection, and emergency response. This testing provides essential data to support state and national public health programs. While the broad areas of testing remain fairly consistent from year to year, the magnitude and specifics of the public health threats that the laboratory addresses each year vary widely. As I review this report myself, I never fail to be amazed by the laboratory's far-reaching impact on issues of both local and national concern.

Among the PHL activities highlighted in this year's report are:

- The implementation of testing for severe combined immune deficiency (SCID) and the celebration of the 50th anniversary of newborn screening in the United States
- Monitoring for swine-associated influenza virus variants at the state fair, topped off by an unusually severe influenza season and the identification of a rare case of infant botulism
- Testing samples from private wells to ensure the safety of drinking water following floods in the Duluth area and the identification of cyanide in samples tested from a local market
- Drafting legislation designed to improve flexibility for environmental laboratories accredited by PHL

This list is only a snapshot of what you will find in this report, and this report describes only a subset of the critical testing performed at PHL. Unfortunately, space does not permit us to detail all of the work that takes place in the laboratory—work that impacts the health of Minnesotans every day.

I would like to take this opportunity once again to thank PHL staff and partners for all the work they do throughout the year to help fulfill our mission of protecting, maintaining, and improving the health of the people of Minnesota.



“As I review this report myself, I never fail to be amazed by the laboratory's far-reaching impact on issues of both local and national concern.”

Joanne M. Bartkus

Joanne Bartkus, Ph.D.
Public Health Laboratory Director

at a glance

fiscal year 2013



67,631

NEWBORNS SCREENED FOR OVER 50 RARE DISORDERS AND FOR HEARING LOSS



62,667

SPECIMENS TESTED FOR INFECTIOUS DISEASE TRENDS AND OUTBREAKS



41,394

SAMPLES ANALYZED FOR CHEMICALS IN MINNESOTA'S WATER, SOIL, AND AIR



96

ENVIRONMENTAL LABORATORIES ACCREDITED TO THE NATIONAL STANDARD



2

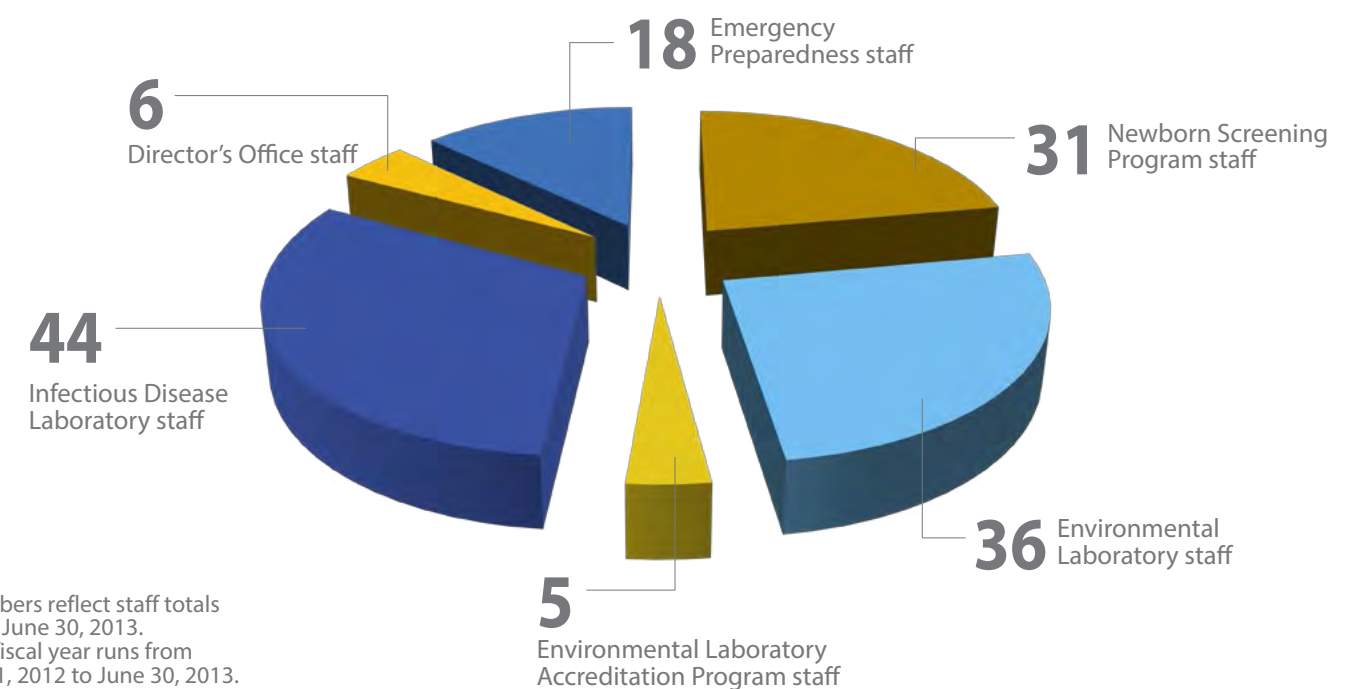
BOTTLES OF A DEADLY TOXIN IDENTIFIED IN MINNESOTA AND SAFELY DESTROYED

PHOTO/GRAPHIC CREDITS

Cover: APHL; MDH; MDH; CDC/Amanda Mills; MDH; MDH
Message from the Director: MDH
At a glance: MDH; MDH; MDH; MDH; MDH
Newborn Screening Program section: MDH; MDH; MDH; MDH; Masimo Corporation
Environmental Laboratory section: CDC/Amanda Mills; STAR TRIBUNE/MINNEAPOLIS-ST. PAUL 2013; MDH; MDH; MDH
Infectious Disease Laboratory section: MDH; CDC/Douglas Jordan
Environmental Laboratory Accreditation Program section: MDH; EPA
Preparedness and Emergency Response section: MDH; MDH; MDH
Laboratory Updates and Budget section: CDC; MDH; MDH; MDH; MDH; APHL

PHL STAFF BY PROGRAM

TOTAL: 140 STAFF*



*Numbers reflect staff totals as of June 30, 2013. The fiscal year runs from July 1, 2012 to June 30, 2013.

Newborn Screening Program

The Newborn Screening Program screens infants at birth for over 50 serious disorders, including hearing loss. Newborn screening aims to identify disorders before symptoms appear so that affected infants can receive prompt diagnosis and treatment to prevent serious health problems, developmental delay, or death.

Almost every day, the Newborn Screening Program identifies an infant with one of these health conditions. For a complete list of the disorders screened for in Minnesota, visit <http://www.health.state.mn.us/newbornscreening/docs/disorderpanel.pdf>.

MINNESOTA NEWBORNS SCREENED FOR SCID

With the help of a collaborative agreement award from the Centers for Disease Control and Prevention (CDC), the Newborn Screening Program began screening infants for severe combined immune deficiency (SCID) in January 2013. Children born with SCID experience multiple infections in infancy and generally do not live past their first birthday unless they are diagnosed and treated within the first three months of life. If identified through newborn screening, infants with SCID or other disorders that compromise the immune system can be successfully treated by bone marrow transplantation and enzyme replacement therapy.

Laboratory staff began training and developing a protocol for SCID screening in Minnesota in August 2012. After training with screening programs in Wisconsin, Massachusetts, and with the CDC,

Newborn Screening Program staff adapted the methods used in other states to create a unique and reliable method of screening for the state of Minnesota. After implementing further improvements to the protocol in April 2013, the program was able to adjust cut-off values to reduce the number of newborns with false positive results from approximately 156 to 88 every year.

By the end of the fiscal year, the program had not yet identified an infant with classic SCID but had identified three Minnesota infants with milder immune system deficiencies. With the disorder affecting approximately 1 in 50,000 infants in the general population and even higher rates in Amish and Somali populations, the program expects to identify at least two cases of classic SCID in Minnesota within the coming year.

Beginning in 2014, Minnesota newborns will be screened in three ways: blood spot screening, hearing screening, and pulse oximetry screening.

See page 7 for details.



NEWBORN SCREENING TURNS 50!

The Newborn Screening Program took part in a nationwide celebration marking the 50th anniversary of newborn screening. Minnesota was the first of 13 states to host the Association of Public Health Laboratories' traveling display depicting the history and life-saving role of newborn screening in the United States. The program hosted celebrations and educational events at the Minnesota Department of Health (MDH), the Science Museum of Minnesota, and the state Capitol.

Dr. Robert Guthrie, known as the "father of newborn screening," grew up in Minneapolis. After Dr. Guthrie's niece was diagnosed with phenylketonuria (PKU), he developed the filter paper method of testing still used today. Dr. Guthrie's niece and her mother—both Minnesota residents—attended the capitol celebration, and his sister-in-law spoke on the importance of newborn screening.



Everett, 5, and his mom at the Capitol celebration. Everett was diagnosed with galactosemia through newborn screening.



Relatives of newborn screening pioneer Robert Guthrie attended 50th anniversary celebrations at the Capitol in March.

GRETA'S STORY

Our daughter was born with congenital hypothyroidism, which was first detected by her newborn screen. The idea that she might have suffered from something preventable is difficult to comprehend. We can't possibly put into words what it means to our family that her health condition was caught early and she will now be given the best possible chance of growing up strong and healthy. She was a sleepy, calm, and healthy-looking baby when she was born; had she not been screened, we wouldn't have had any indicator that something was wrong until it may have been too late.

With prompt results from MDH and follow-up from our pediatrician that confirmed the diagnosis, she is responding to medication, and she is

We wouldn't have had any indicator that something was wrong until it may have been too late.

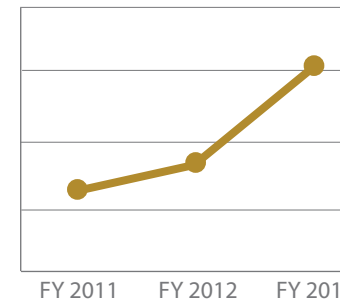


much more active and alert. We are still anxiously watching for milestones, but we are told that she now has the chances of any other child to grow up without developmental delay. We're new parents, so it would be hard to convince us to breathe easy in any circumstance, but both our pediatrician and endocrinologist have done their best to assure us that all is well.

The Newborn Screening Program has made such a difference for our daughter. Her results, and the quick treatment they set in motion, have preserved her ability to grow up as strong, as healthy, and as bright as she can. To us, because of all it will allow her to do, her newborn screen will remain among the most important moments of her life.

HEARING SCREENING: OUT-OF-HOSPITAL BIRTHS

The Newborn Screening Program documented a 75 percent increase in out-of-hospital birth hearing screenings in fiscal year 2013, after the Minnesota Council of Certified professional Midwives received an MDH-supported grant for 11 sets of hearing screening equipment in May 2012.



OUT-OF-HOSPITAL BIRTH HEARING SCREENING RATES:

FY 2011: 33%
FY 2012: 44%
FY 2013: 77%

ALL MINNESOTA NEWBORNS TO RECEIVE HEART SCREENING

With the recent addition of pulse oximetry screening to Minnesota's newborn screening panel, the Newborn Screening Program has been working to support the implementation of this screening statewide. Pulse oximetry screening is a simple, non-invasive test that can detect signs of critical congenital heart disease (CCHD). CCHD represents a group of heart defects that require early treatment to prevent significant health problems or death.

Although many hospitals in the metro area already perform pulse oximetry screening in the well-baby nursery as a standard of care, the Newborn Screening Program estimates that only about 40 percent of newborns statewide currently receive testing. With the addition of pulse oximetry screening to the state's newborn screening panel, this number will grow dramatically within the coming year.

The Newborn Screening Program is in the process of creating a system for effectively monitoring pulse oximetry screening results to ensure every Minnesota newborn receives both proper testing and follow-up care. The

program staff expects to have the new electronic reporting system for screening results up and running by early 2014.

The program also recently completed a year-long pilot project with the Fairview Health System, which will help guide the implementation of screening across the state. Once pulse oximetry screening has been implemented throughout Minnesota, the program expects to identify approximately 120 Minnesota newborns affected by CCHD every year.



Pulse oximetry is a simple, non-invasive test.

THIS YEAR IN NUMBERS

67,631
INFANTS SCREENED*
OUT OF
68,196
BIRTHS REGISTERED



134

Newborns with a disorder detected by blood spot screening*



Pulse oximetry screening is set to begin statewide in 2014



315

Newborns with hearing loss detected by hearing screening*

*Data calculated by date sample was received

Environmental Laboratory

The Environmental Laboratory supports the environmental protection functions of state government by performing chemical, bacteriological, and radiological analyses of environmental samples including drinking water, surface water, waste water, air, soil, and hazardous waste. The laboratory provides these testing services for programs at the county, state, and national level that work to keep Minnesotans healthy and safe. The laboratory also develops new analytical methods for detecting contaminants of emerging concern throughout the state.

CONTAMINANTS OF EMERGING CONCERN

The state Legislature recently approved the use of Clean Water Fund dollars for the Environmental Laboratory to determine the impact of contaminants of emerging concern on the citizens of Minnesota.

Since its inception in 1970, the U.S. Environmental Protection Agency (EPA) has conducted research and evaluation of environmental contaminants and their effects on both public health and the environment. With new chemicals entering the marketplace every year, the EPA often relies on local laboratories to help address potential concerns. Environmental Laboratory staff will now play an important role in determining the impact of contaminants of emerging concern on Minnesota's environment and residents.

The study of a new chemical is grounded in two main investigations: whether the chemical is harmful to humans and/or the environment, and whether the chemical is present in Minnesota's water. For years,

the Minnesota Department of Health (MDH) Health Risk Assessment Unit has taken the lead on the first question, researching available information on the potential toxic effects of chemicals nominated for review in Minnesota. Now, Environmental Laboratory staff will begin to answer the second question. By developing new methods and analyzing samples, the laboratory will provide data on the presence and concentration of these chemicals of interest.

So far this year, the laboratory has developed an analytical method to test for the contaminant acrylamide—a human neurotoxin—in water samples. Acrylamide is found in polyacrylamide, a chemical used for drinking water treatment and other industrial processes. The International Agency for Research on Cancer has classified acrylamide as a “probable carcinogen” to humans based on animal studies. Testing for acrylamide in Minnesota's environmental and drinking waters will begin in fiscal year 2014.

The Environmental Laboratory tests public drinking water throughout Minnesota to help ensure public safety.



WATER TESTING FOR FLOOD VICTIMS

In June 2012, Duluth and the surrounding communities were overcome with rain that caused significant potential for contamination of the drinking water in local wells. The Environmental Laboratory, along with the MDH Well Management section, worked with county and local responders to reach out to private well owners in the affected area to address bacterial contamination concerns.

Outreach began within a few days of the flood and continued heavily for more than six months. In general, any time floodwater comes within five feet of a well, there is potential for contamination. To assess the situation in the Duluth area, the Environmental Laboratory offered free private well testing for bacteria such as E. coli for all affected residents.

Within days of the flood, the Environmental Laboratory shipped 2,500 sampling kits to the affected counties for distribution.



The Environmental Laboratory tested nearly 1,200 water samples from the Duluth area where flood water contaminated many water sources.

Over the next year, the laboratory tested a total of 1,145 water samples from the Duluth area and found that approximately half of the samples received were contaminated with bacteria.

Distinguishing between contaminated and clean wells helped allow for a more efficient allocation of public and private resources in decontaminating affected wells in the area and protecting the health of affected residents.

In the months following the flood, the Environmental Laboratory and Well Management staff worked with hundreds of private well owners to assist with sample

collection, shipping issues, and to answer questions about bacterial contamination and long-term well monitoring. The Environmental Laboratory often provides this sort of critical support in natural disasters, and responds quickly and efficiently to ensure a safe environment for all residents.

MEASURING FIREFIGHTERS' CYANIDE EXPOSURE

In response to research indicating potentially dangerous levels of cyanide present during fires, the Environmental Laboratory teamed up with four Twin Cities fire departments to measure the cyanide levels in local firefighters and the concentration of cyanide present during fire responses. Hydrogen cyanide is a byproduct of the burning of many common household items, and it can produce a host of health effects such as dizziness, nausea, vomiting, and sometimes death at high exposure levels.

Over the last several years, Twin Cities fire departments have purchased air monitors that measure the amount of

hydrogen cyanide present while a crew extinguishes a fire. Because gases such as carbon monoxide can interfere with the monitors, however, more accurate testing was deemed necessary to confirm exposure levels.

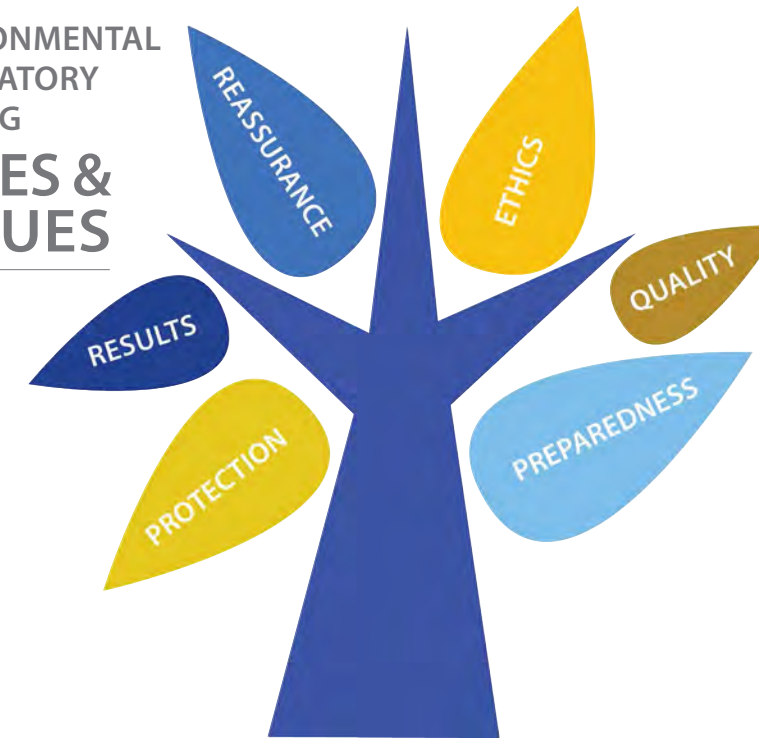
With cooperation from four fire departments, the Environmental Laboratory tested 73 blood samples from local firefighters and measured the amount of hydrogen cyanide present at the scene of two fires. The results of the study indicated no significant increase in cyanide in the firefighters' blood. The concentration of cyanide measured in the air by the monitors exceeded the levels

{ 20,729 }
MINNESOTA FIREFIGHTERS
CURRENTLY AT RISK FOR
CYANIDE EXPOSURE

found in the blood, indicating that the personal protective equipment provided to firefighters is effective in protecting them from this dangerous chemical.

The Environmental Laboratory will conduct a follow-up study in fiscal year 2014 to determine the amount and types of other toxic gases and particles that are present in fire smoke and that may be carried back to fire stations on protective gear and equipment. The laboratory hopes this information will lead to better treatment for smoke inhalation victims and better protection for Minnesota's firefighters.

ENVIRONMENTAL LABORATORY TESTING ROLES & VALUES



TESTING RECEIPT PAPER FOR SYNTHETIC CHEMICALS

In response to growing public concern over the possible negative health effects of Bisphenol A (BPA), the Minnesota Pollution Control Agency (MPCA) requested the Environmental Laboratory develop a method to test for the compound and the closely related Bisphenol S (BPS), used in thermal paper sales receipts.

BPA is a synthetic compound that was once tested as an artificial estrogen, but instead has been used commercially since 1957 to make some plastics and epoxy resins. BPA can be found in common products such as food and beverage container linings, sports equipment, CDs, and DVDs. Because BPA can mimic the role hormones play in the body, there is concern about exposure to fetuses and young children.

While BPA has been removed from many products in response to U.S. Food and Drug Administration warnings,

both BPA and BPS are still commonly added to certain types of cash register receipts. In these thermal papers, BPA and BPS are often present at concentrations that can be transferred to a person when handled.

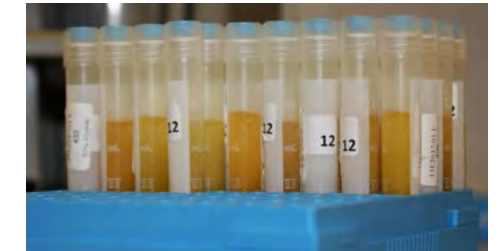
Using its new method of testing, Environmental Laboratory staff found BPA or BPS in all of the thermal paper tested in significant concentrations measuring between 1 and 2 percent of the weight of the receipt. The laboratory also tested recycled paper products, which did not consistently contain BPA or BPS; the concentrations of the chemicals, when present, were very low. These results laid the groundwork for additional studies by the MPCA, and may spur further national-level testing and outreach.

While BPA has been removed from many products in response to [FDA] warnings, both BPA and BPS are still commonly added to certain types of cash register receipts.

UPDATES

from previous reports

Great Lakes Restoration Initiative (GLRI)



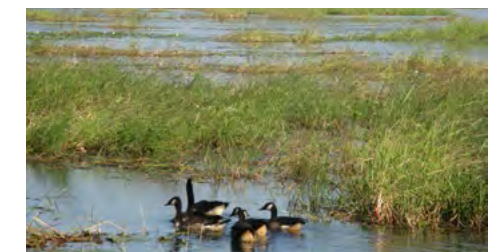
The laboratory has received 222 samples for the GLRI study and expects to receive all samples by the end of October 2013. All test results are expected by mid-2014.

The Infant Development and Environmental Study (TIDES)



All TIDES samples were received, analyzed, and reported. The laboratory staff continues to summarize and publish their method and results, which will aid in the design of future biomonitoring studies.

Study of sulfide in Minnesota wild rice



The wild rice study will continue through the end of 2013. The Minnesota Pollution Control Agency continues to gather, evaluate, and report all of the data generated.

Infectious Disease Laboratory

The Infectious Disease Laboratory (IDL) is composed of three laboratory units: microbiology, molecular epidemiology, and virology/serology. Throughout the year, IDL detects and identifies a variety of bacteria, viruses, parasites, and fungi that impact the health of Minnesotans every day. Clinical laboratories throughout the state are required to submit specific organisms for IDL to provide diagnostic, characterization, and surveillance services that are not otherwise available in Minnesota.

DETECTION OF A DEADLY OUTBREAK

The laboratory partnered with agencies in Minnesota and throughout the country to investigate an outbreak of the bacterium *Listeria monocytogenes* linked to eating soft cheese. The outbreak affected five people in four states, including two adults in Minnesota. Both Minnesotans were hospitalized and one of them died.


The investigation began when IDL identified two cases of *L. monocytogenes* that shared the same DNA fingerprint. A search of the national *L. monocytogenes* fingerprint database revealed three recent cases in different states with the same DNA fingerprint.

Minnesota Department of Health (MDH) epidemiologists conducted interviews to

determine what the two Minnesotans had eaten before becoming ill. They identified soft cheese from a Wisconsin producer as a likely source of the outbreak.

The Minnesota Department of Agriculture tested the cheese from this producer and found *Listeria monocytogenes* with the same DNA fingerprint associated with the outbreak. Implicated cheese was immediately recalled to prevent further illness.

Thanks to effective collaboration among multiple agencies in Minnesota and nationwide, the outbreak was rapidly detected, the source was quickly identified, and action was taken immediately to prevent additional cases of disease.



The IDL staff tests specimens for pathogens that may threaten the health of Minnesotans.

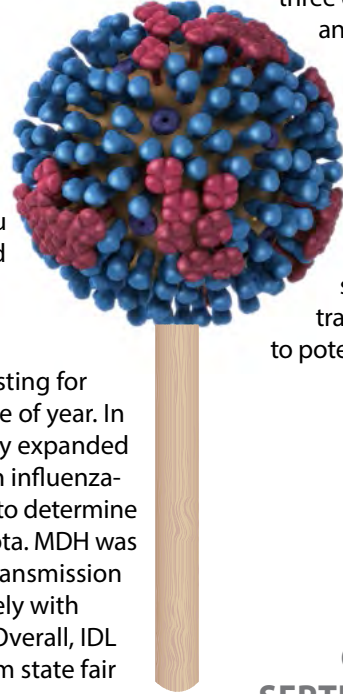
FLU ON A STICK

PHL'S ROLE IN THE SWINE FLU OUTBREAK

IDL played a key role in identifying the influenza virus known as "swine flu" in Minnesota during the 2012 summer.

This new variant strain of influenza was originally identified early in the summer when an outbreak of over 100 flu cases was found in Ohio and the eastern United States. Epidemiologists found that almost all flu cases had contact with swine while attending swine exhibits at agricultural fairs. This flu strain (H3N2v), which is common in swine, acquired the ability to infect and spread among humans because of a recent mutation.

During a typical summer, IDL performs limited testing for influenza since few cases are detected at that time of year. In response to the outbreak, however, the laboratory expanded influenza testing to include all individuals with an influenza-like illness who recently visited an agricultural fair to determine if this new strain had begun circulating in Minnesota. MDH was especially concerned about potential influenza transmission during the Minnesota State Fair and worked closely with fair officials to rapidly identify possible illnesses. Overall, IDL identified six cases of swine-related influenza from state fair attendees who had contact with swine.



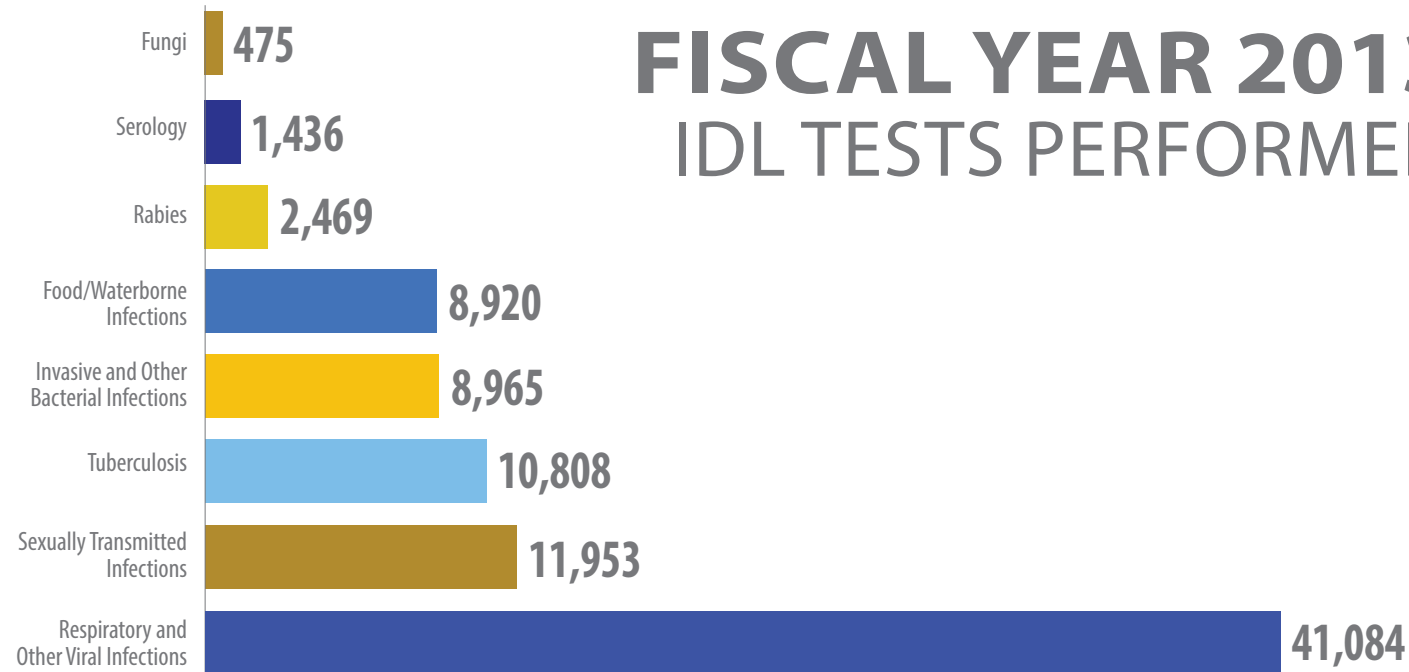
Because of the expanded influenza testing, IDL also identified three cases of swine influenza associated with live animal markets, which had not previously been identified as a potential source of influenza. With this new information, live animal market workers and patrons were able to take precautions to help prevent the spread of influenza.

As a result of IDL's preparedness efforts, the laboratory was able to rapidly identify the novel strain of influenza to help control widespread transmission—an ability that is critical to responding to potential outbreaks and future pandemics.

47%

OF INFLUENZA CASES FROM JUNE-SEPTEMBER 2012 WERE SWINE-RELATED

FISCAL YEAR 2013 IDL TESTS PERFORMED



IDL staff performed a total of 86,110 tests on 62,667 human specimens in fiscal year 2013. Nearly half of all tests performed aimed to identify respiratory and other viral infections.

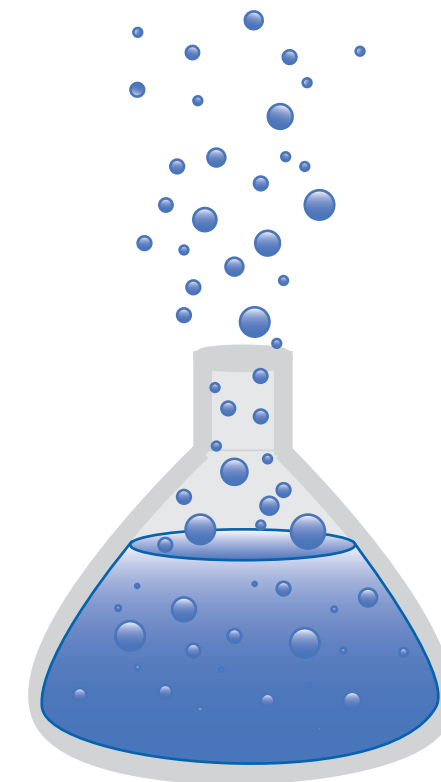
IDL BY THE NUMBERS

2 tests implemented in response to global concern for influenza H7N9 and MERS-CoV viruses

40 percent of staff members with 10 or more years of state service

78 specimens tested as possible bioterrorism agents—none indicated a bioterrorism event

621 hand washes performed by IDL staff daily



8 waterborne outbreaks detected, making 2012 a record year

50 foodborne outbreaks detected and characterized based on IDL testing

153 new tuberculosis cases diagnosed

2,473 animals tested for rabies—61 tested positive

BOTULISM TESTING: AN INFANT'S LIFE SAVED

In June 2013, a newborn was diagnosed with a rare type of botulinum toxin—one of only a few cases of type F botulism to ever be diagnosed in the United States. PHL is one of only 13 U.S. regional laboratories that perform definitive testing for the diagnosis of botulism. In this case, IDL botulism experts were able to perform specialized testing and identify the matching antitoxin in time to save the infant's life.

The Iowa newborn was only 10 days old when rushed to the intensive care unit with advancing paralysis. As medical professionals worked to keep the infant alive, IDL began testing the newborn's samples for botulism toxin.

One day after receiving the samples, IDL determined the initial diagnosis of the newborn's illness. Within a few hours, IDL staff began consulting with physicians and botulism experts nationwide to promptly determine and obtain the appropriate antitoxin from the Centers for Disease Control and Prevention.

A few weeks after diagnosis and the administration of antitoxin, the infant was progressing to a full recovery.

Infant botulism of any type is rare in Minnesota; on average only one case is diagnosed every two years. Infant botulism occurs when *Clostridium botulinum* spores are ingested, then grow and produce toxin in the body. Honey has previously been implicated in cases of infant botulism, but most often the specific environmental source is never identified. In contrast, classic botulism—which usually occurs in adults—results from ingesting a toxin that has formed in poorly preserved or stored foods. In both infant and classic botulism, antitoxin must be administered quickly to bind with the neurotoxin in a patient's body and halt the progression of disease.

1 CASE OF INFANT BOTULISM EVERY 2 YEARS IN MN

UPDATES

EXPANDED USE OF TECHNOLOGY

To meet quality improvement goals for streamlining its training resources, MNELAP expanded its use of technology to provide training and compliance assistance to laboratories.

The program established workgroups to review web resources, revise forms and templates, and develop training sessions to assist their counterparts in complying with accreditation and testing requirements.

MNELAP now delivers the majority of its training via interactive or recorded webinars. This delivery option allows regulated entities on-demand access to resource materials.

STATUTE CHANGES

Statute changes adopted in May 2013 (M.S. 144.98) allow MNELAP greater flexibility to accredit laboratories through the use of approved independent qualified assessors. As a result of the changes, laboratories may realize significant cost savings by undergoing one assessment to satisfy the requirements of multiple clients.

Environmental Laboratory Accreditation Program



ACCREDITATION OF CRYPTOSPORIDIUM TESTING



In October 2012, the U.S. Environmental Protection Agency's (EPA) Office of Water announced its intention to delegate its laboratory approval program for the analysis of *Cryptosporidium* to the states. MNELAP EPA-trained assessors, together with staff trained on the testing procedure, moved forward with the change and quickly established accreditation procedures within the state's system.

Cryptosporidium is a parasite that can live in the water where people swim. It is a leading cause of recreational water illness in the United States and can cause prolonged diarrhea, lasting two to three weeks. It can make anyone sick, but certain groups are more likely to become seriously ill when infected, including young kids, pregnant women, and individuals with weakened immune systems.

The Minnesota Environmental Laboratory Accreditation Program (MNELAP) is a nationally-recognized accreditation body established in 1989 to accredit environmental laboratories and ensure data of known quality are generated. Accredited laboratories instill public and regulatory confidence in the data produced and reported to various state and federal environmental programs. Accreditation requires that a laboratory's quality systems, staff, facilities, equipment, test methods, records, and reports be evaluated using objective and measurable criteria adopted by the National Environmental Laboratory Accreditation Program (NELAP) of The NELAC Institute (TNI).

MNELAP offers the following services in support of laboratory accreditation:

1. Accreditation to the recognized National Environmental Laboratory Standard
2. Compliance assistance and onsite assessments for technical disciplines and management systems
3. Development and distribution of online training and an e-licensing and accreditation management system

Emergency Preparedness and Response

As an active member of the Centers for Disease Control and Prevention Laboratory Response Network (LRN), the Emergency Preparedness and Response Unit trains clinical microbiology laboratories on the identification, notification, and referral of potential agents of bioterrorism such as *Bacillus anthracis* (anthrax). The Emergency Preparedness and Response Unit staff is qualified to perform analytical testing and provide training to sentinel laboratories—clinical laboratories on the front lines of disease detection—and first responders. Staff members also provide large-scale planning and surge capacity assistance to other PHL laboratory units in the event that a sudden influx of specimens, such as seasonal flu cases, reaches epidemic levels.

SUICIDE BY CYANIDE INVESTIGATION

Following a recent suicide increase within a St. Paul community by the ingestion of an unknown chemical, law enforcement asked the Emergency Preparedness and Response Unit for assistance in identifying the substance involved. As a member of the Laboratory Response Network, the unit routinely receives requests from first responders to identify suspected hazardous materials.

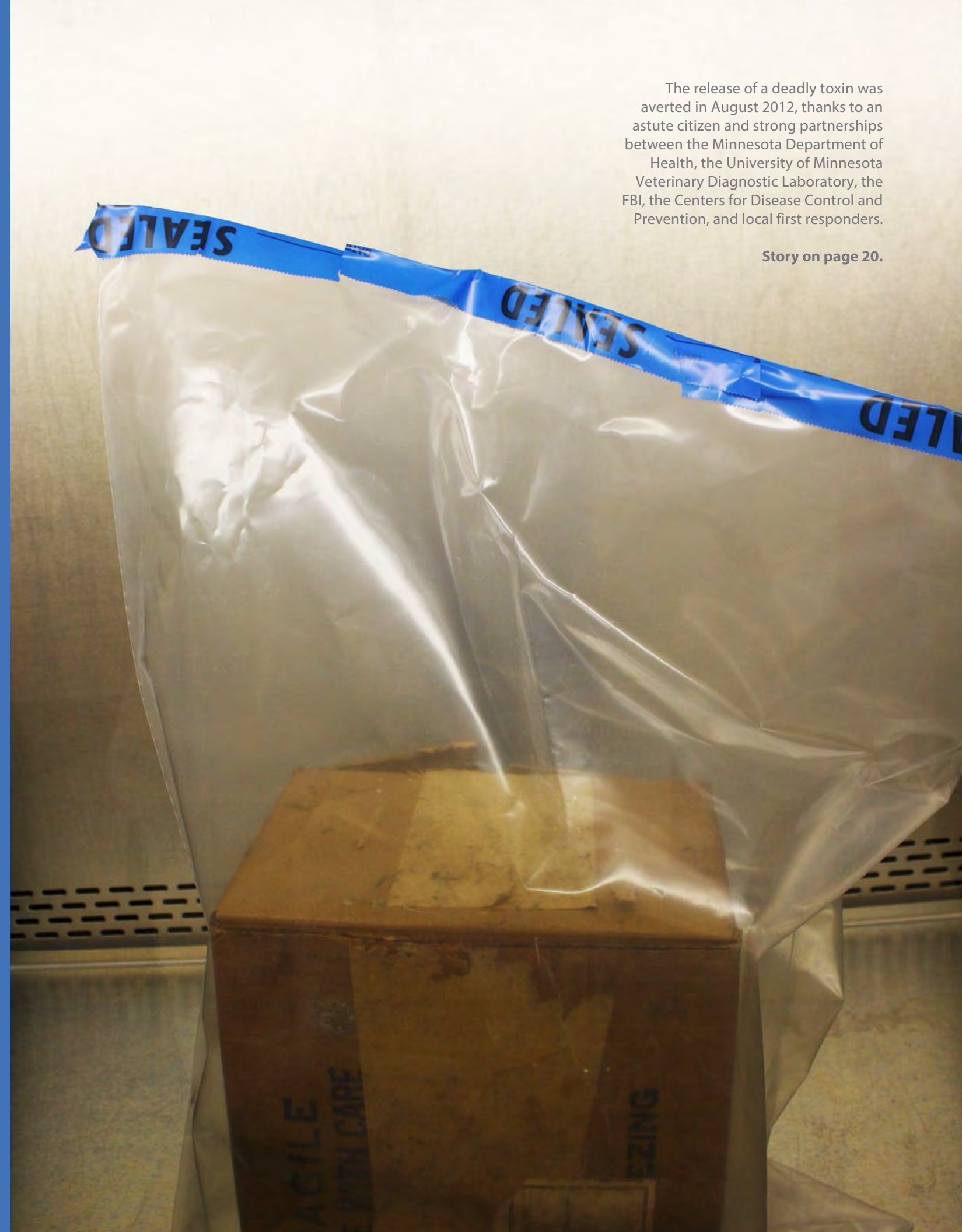
Upon receiving samples from the cases, Emergency Preparedness and Response Unit staff performed a series of screening tests followed by more targeted tests that helped characterize trace components of the substance. The chemical was identified as

sodium cyanide, which comes in many forms and in a variety of concentrations depending on its end use.

The laboratory staff was able to confirm suspicions that cyanide was involved and show the type, consistency, and purity of the substance in each case. This information proved critical for law enforcement officials searching for links among the cases to a common source or distributor. The information provided by the Emergency Preparedness and Response Unit was also used by law enforcement in addressing safety issues for officers responding to crime scenes where the presence of cyanide is suspected.

The release of a deadly toxin was averted in August 2012, thanks to an astute citizen and strong partnerships between the Minnesota Department of Health, the University of Minnesota Veterinary Diagnostic Laboratory, the FBI, the Centers for Disease Control and Prevention, and local first responders.

Story on page 20.



EXPECTING THE UNEXPECTED

RELEASE OF DEADLY TOXIN AVERTED

The release of a deadly toxin was averted in August 2012, thanks to an astute citizen and strong partnerships between the Minnesota Department of Health (MDH), the University of Minnesota Veterinary Diagnostic Laboratory (VDL), the FBI, the Centers for Disease Control and Prevention (CDC), and local first responders.


Upon discovering an unusual package in the attic of a private residence, the homeowner contacted the VDL, who immediately notified the MDH Infectious Disease Epidemiology Prevention and Control Division (IDEPC) of the situation. Per MDH protocol, IDEPC notified PHL to mitigate the situation.

The FBI was notified immediately and investigation of the package began. The Emergency Preparedness and Response Unit worked with the North Metro Chemical Assessment Team to secure the package and deliver it to PHL for analysis. The investigation uncovered two bottles of purified *Clostridium botulinum* toxin A and B in the rafters of the house. If distributed or misused, the amount of toxin could have killed more than 200,000 people.

Upon discovery, the original packaging materials were still in the box and the bottles remained unopened and intact. The box was addressed to a University of Minnesota researcher, and packing documents were dated Dec. 20, 1960. At the time the bottles were purchased, toxins and other biological products were not regulated as they are today, so the large quantities could have been ordered from a pharmaceutical company.

As part of the Emergency Preparedness and Response Unit's investigation, the CDC provided guidance on the best way to safely destroy the toxin to ensure no Minnesota lives were threatened.

1 Citizen emails the University of Minnesota VDL upon discovering an unusual package in the attic of a private residence
Wednesday, Aug. 22 2:45 pm




2 UNIVERSITY OF MINNESOTA VETERINARY DIAGNOSTIC LAB VDL notifies IDEPC
Wednesday, Aug. 22 2:57 pm


3 IDEPC involves PHL at MDH
Wednesday, Aug. 22 3:00 pm




4 PHL alerts the FBI of the situation
Wednesday, Aug. 22 3:15 pm




5 PHL works with the North Metro Chemical Assessment Team to secure the package and deliver it to the laboratory
Wednesday, Aug. 22 3:15-6:00 pm



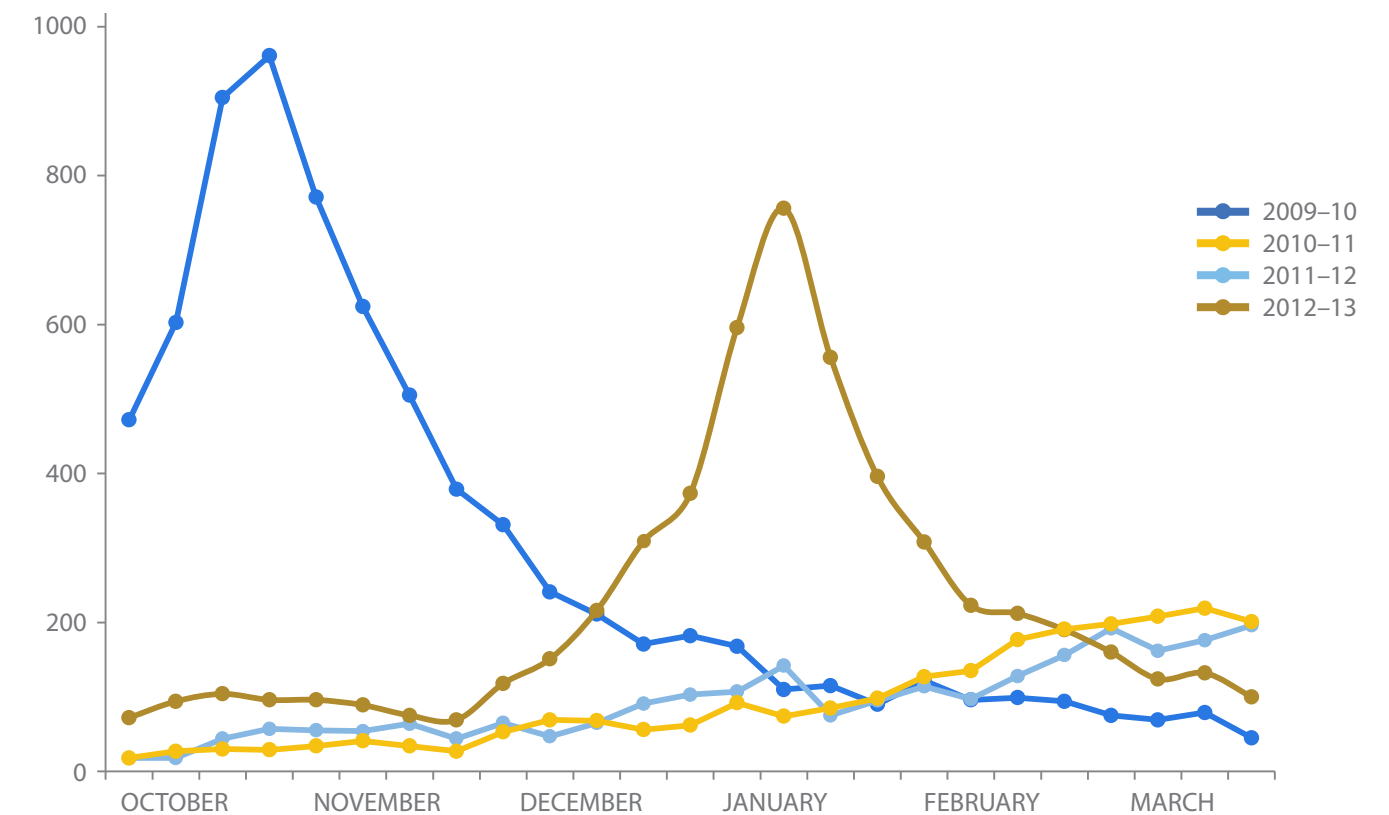
6 The package, containing two bottles of an unknown toxin, arrive at PHL for identification and analysis
Thursday, Aug. 23 9:00 am



7 As part of the investigation, PHL staff contacts the CDC for guidance on safely destroying the toxin
Thursday, Aug. 23- Friday, Aug. 24



SPECIMENS RECEIVED FOR FLU TESTING



The total number of flu specimens tested at PHL in 2012-13 rivaled that of the 2009-10 "swine flu" season. A targeted surveillance system and recent capacity-building initiatives helped staff handle the influx of specimens effectively and efficiently.

INFLUX IN FLU TESTING FOR SERIOUS CASES

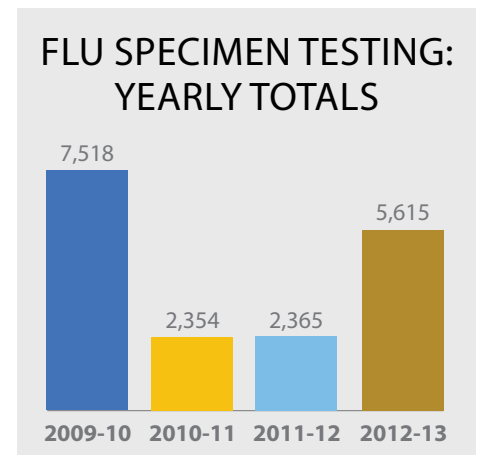
Despite alarmingly high numbers of influenza cases in the winter of 2012-13, testing of flu specimens at PHL this year was managed effectively and efficiently. Lessons learned from the 2009 pandemic and updates to the targeted surveillance system developed by Emergency Preparedness and Response Unit staff helped ensure specimen testing took place in a timely, controlled fashion.

Because the 2009 pandemic flu strain was new, PHL was the only laboratory capable of diagnostic testing for the more than 7,500 specimens collected in Minnesota, of which more than 2,000 were positive for influenza. This season's strain was typical, however, and therefore clinical laboratories had testing capabilities that could detect the majority of cases. As a result, PHL's surveillance system adjusted to focus testing on the most serious hospitalized cases.

Despite the lower percentage of total flu cases tested at PHL this year, the severity of the 2012-13 flu season still meant that approximately 5,600 specimens were tested at PHL to help confirm more than 2,500 cases of influenza. As staff observed specimen numbers rising early in the season, they were able to further target the surveillance system to identify only the most severe cases of the virus. The well-established Minnesota Laboratory System rapidly communicated these changing surveillance guidelines to clinical laboratories as the season progressed.

Capacity-building preparedness initiatives launched in response to the 2009 pandemic also helped staff more effectively handle the influx of specimens. Additional equipment acquired during the 2009 season was the first step in increasing the laboratory's

testing capacity, coupled with efforts to strengthen communication among laboratory staff and with external partners. Training of additional staff members on the assays, staff experience in testing a high volume of specimens, and more efficient workflows also helped PHL test more specimens in less time.



Laboratory Performance and Budget

A FOCUS ON QUALITY

As PHL increases collaboration with other divisions and agencies throughout the state and country, the laboratory staff has prioritized the need for a more efficient system of tracking organizational structure, procedures, processes, and resources. This year, PHL partnered with colleagues in the Department of Agriculture laboratory to purchase a single software system to assist both the health and agricultural laboratories in managing quality. The new system will provide centralized, controlled, web-based access to all laboratory documentation.

At the end of the fiscal year, PHL staff had begun training with the new quality management software (QMS) and preparing for lab-wide implementation in the fall of 2013. PHL staff expects the electronic system to help improve efficiency and collaboration with partners, thereby reducing cost and improving customer service. For PHL programs making a transition from paper-based documentation, the new system will also significantly reduce storage costs. For the laboratory as a whole, the new web-based approach offers greater security, a more environmentally-friendly option, and improved disaster recovery capabilities for business-critical functions relying on quick access to these records.

Environmental, agricultural, and clinical regulatory compliance requires rigorous record-keeping for the procedural documents used in laboratory testing, in addition to tracking of chemicals, equipment, training of personnel, and workflows for corrective and preventive actions. The new QMS system will help ensure the laboratories' services and products meet or exceed regulatory needs, as well as national and international quality standards (e.g., ISO/IEC 17025:2005, ISO/IEC 15189).



AWARDS

PHL STAFF STAR AWARD WINNERS

- Chris Brueske
- Patti Constant
- Courtney Demontigny
- Sondra Rosendahl

The Minnesota Department of Health (MDH) Star Honors Program allows staff members to formally recognize colleagues at all levels for their exceptional accomplishments and outstanding contributions which are models of public service. A limited number of Star Honors are awarded each year.



2012-13 ASCLS-MN SERVICE AWARD WINNER:

PAULA M. VAGNONE
MICROBIOLOGY SUPERVISOR
INFECTIOUS DISEASE SECTION

The American Society for Clinical Laboratory Science of Minnesota awarded Paula Vagnone the 2012-13 MN Member Service Award. The award was presented at the annual membership meeting in St. Cloud, Minn., in April 2012.

Ms. Vagnone was also appointed to serve on the Centers for Disease Control and Prevention (CDC) Clinical Laboratory Improvement Advisory Committee from July 2012-June 2016.

EXCELLENCE IN PUBLIC HEALTH RESPONSE AWARD WINNER

The Association of Public Health Laboratories (APHL) awarded Minnesota's PHL the 2012 Excellence in Public Health Response Award. PHL was honored for its "depth and effectiveness in public health preparedness efforts over the last decade." The Excellence in Public Health Response Award is a national, annual award given to a Laboratory Response Network (LRN) member laboratory that made significant contributions to the LRN and its mission by responding to public health threats, unique cases, or incidents, or by exemplifying a surge capacity response. This year's award was given in response to the Inhalational Anthrax case, which PHL staff identified and investigated.

PHOTO: Maureen Sullivan, Emergency Preparedness and Response Unit supervisor, accepted the Excellence in Public Health Response Award on behalf of PHL. The award was presented by APHL Executive Director Scott Becker at the 2012 LRN National Meeting in Denver, Colorado.

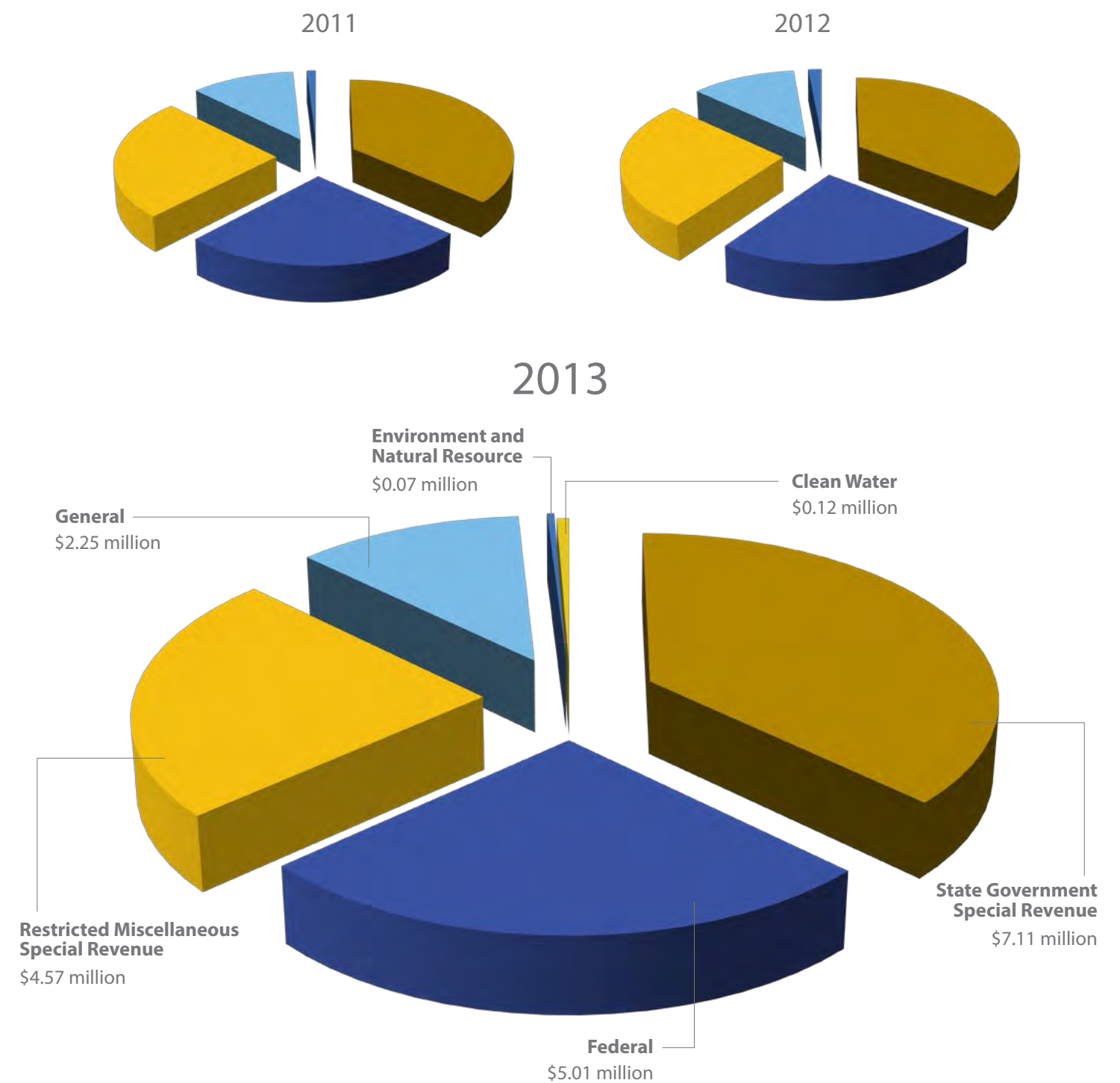


PHL BUDGETS



For past annual reports and budgets, visit: <http://www.health.state.mn.us/divs/phl/pastreports.html>
 For a description of fund categories, visit: <http://www.health.state.mn.us/divs/phl/funds.html>

BUDGET BREAKDOWN BY FUND CATEGORIES





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PUBLIC HEALTH LABORATORY**