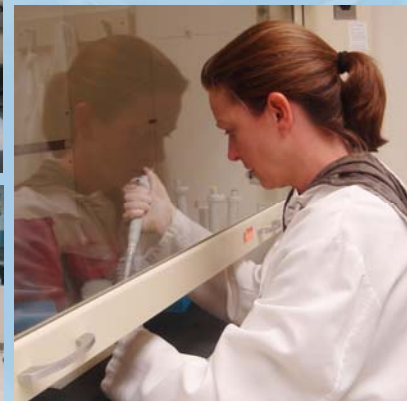
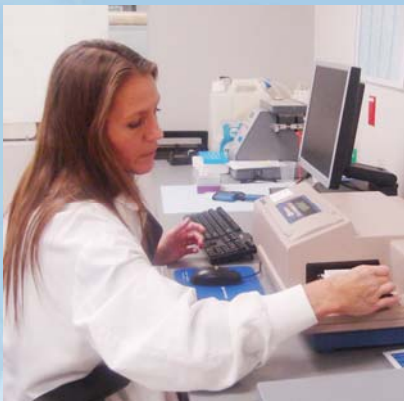


Laboratory Services Division Annual Report 2013



Rapid Detection for the Public's Protection



**Colorado Department
of Public Health
and Environment**



Mission

The mission of the Laboratory Services Division is to protect the health, safety and environment of all Coloradans by providing accurate and timely laboratory analyses and information.

Vision

The vision of the division is to be recognized as an innovative and quality public health laboratory in the state of Colorado.

As a leader in the industry, the division will use advanced, leading edge technology, employ a highly skilled workforce, and have the respect and support of all its customers, stakeholders and partners.

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Molecular Science Lab Develops New Methods to Detect Genetic Material of Bacteria and/or Viruses



The Molecular Science Laboratory has focused its resources on the development of increased capability with regard to new testing methods that can detect the genetic material of bacteria or viruses. The successful validation of a number of new test methods that can be used with existing instrumentation provide an expanded capability to support enhanced public health surveillance programs and

support a more rapid outbreak response. In previous years, much of the lab's effort focused on building capacity and development of a broadly cross-trained staff. The combination of these features has resulted in a nationally recognized public health laboratory that is rapidly responsive to the needs of our internal and external partners, and to the citizens of Colorado.

Support for these enhanced capabilities was provided through allocations from the Colorado General Fund and from Federal grants awarded to the Laboratory Services Division's Microbiology Program. Molecular-based test method implementation targeted priority areas and expanded the number of pathogens that can be detected rapidly. These capabilities also are utilized by external partners who refer pure culture isolates or clinical specimens to the laboratory when seeking confirmation of presumptive findings or expanded investigation of challenging cases.



The molecular-based testing options available at the CDPHE Lab provide an invaluable component to infectious disease clinicians and hospital infection control officers. Common features of the new technologies that were added or existing capabilities that were enhanced during the past year are sensitivity, specificity and speed.

The speed and sensitivity provided by molecular testing methods ensures early detection of infectious agents and allows multiple agencies a solid basis from which to mount a public health response sooner than could be done in the past. As our now broadly trained staff possesses a greater operational awareness, our



ability to identify clusters of patients infected by similar bacteria or viruses has increased. Many operations occur in parallel, rather than sequentially, resulting in an overall faster response to outbreak investigations. This feature is particularly important to our emergency response where suspicious packages or letters can be analyzed in under 2½ hours.

While much of this work unit's success occurs independently, a significant amount of work is performed in collaboration with the division's Public Health Microbiology and Environmental Microbiology Laboratories.

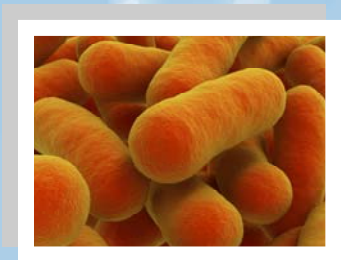


Colorado has been at the center of a number of other national foodborne illness outbreaks and the lab played an important role in each by using combinations of molecular methods in addition to conventional culture techniques to identify the disease-causing agent and establish clearly defined case clusters. Patient information and laboratory technology can provide an opportunity to establish a link to the contaminated food source.



These abilities were on display throughout the year as the lab contributed critical, decision-influencing data. For clinical partners, the lab performs DNA sequencing to confirm the identity of culture isolates that cannot be identified with certainty using traditional methods. Newly implemented polymerase chain reaction tests can be used to detect Middle East Respiratory Syndrome Coronavirus (MERS CoV), measles and mumps viruses, carbapenem-resistant *Enterobacteriaceae*, and rabies virus, while an alternative DNA sequencing method (pyrosequencing) is used to characterize tuberculosis-related isolates and identify influenza virus strains that carry mutations consistent with resistance to antiviral drugs.

A new molecular method for determining *Salmonella* serotypes benefits both clinicians and public health epidemiologists by defining cases and establishing clusters of illness. The application of Multiple-Locus Variable-number tandem repeat (VNTR) Analysis (MLVA) and Pulsed-Field Gel Electrophoresis (PFGE) was expanded to include new target organisms and has proved beneficial to outbreak investigations, both locally and nationwide, and to hospital infection control staff seeking to identify the source and extent of nosocomial infections. The lab now performs year-round surveillance for influenza viruses using reagents updated annually to ensure the detection of currently circulating virus strains. The results from this test are made available in near real-time for assessment by colleagues in the Communicable Disease Program and distribution to front-line primary care providers.



Environmental Microbiology Laboratory Identifies Contaminated Food, Milk and Water

The Environmental Microbiology Lab performs both routine food surveillance and outbreak response to foodborne illness. Staff members from this lab maintain the standards necessary to be

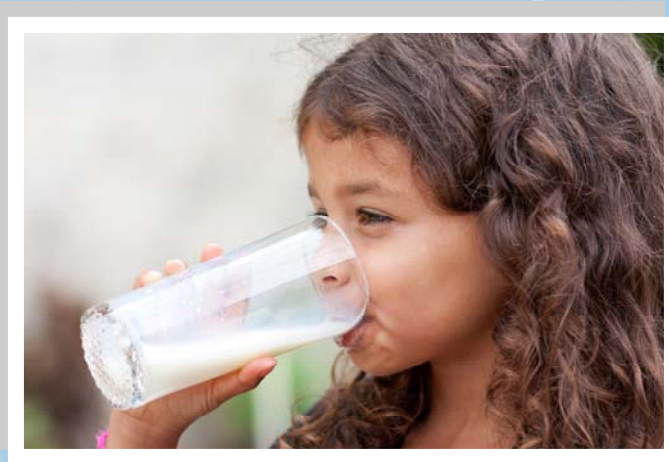


classified as a fully certified milk testing laboratory by the Food and Drug Administration (FDA). Similarly, staff is certified by the Environmental Protection Agency (EPA) as an accredited water testing laboratory. Staff test water samples from a variety of sources for bacterial contaminants and monitors

the quality of milk produced or consumed within the state.

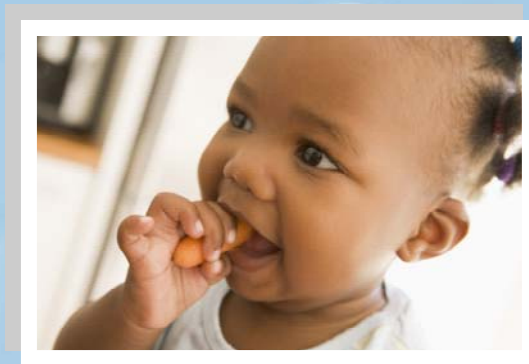
By using both standard microbiological methods and molecular-based testing methods, staff identified two separate outbreaks (one *E. coli* and one *Campylobacter*) that could be linked directly to the consumption of raw

milk produced in Colorado. The group performs analyses on large numbers of food samples suspected as being the source of foodborne or waterborne illness, and also participates in a number of programs

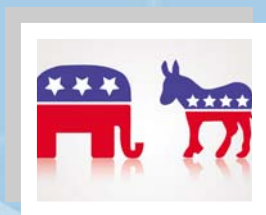


initiated by CDC to monitor the quality of retail food products.

In addition to the state general fund to support milk testing, the lab completed the fourth year of a cooperative agreement with the FDA designed to support enhanced investigative capabilities in the area of foodborne disease both locally and nationally. New instrumentation included with this award are fully operational and offer superior technology compared to what was available previously and are used to identify and characterize contaminants present in a wide variety of food products.



The detection sensitivity and staff speed and competency have been demonstrated locally during a number of outbreak responses and nationally through the Food Emergency Response Network (FERN). In these instances of food testing, the performance by the staff in this lab was considered exemplary by our federal partners.



FDA confidence in the lab's ability resulted in a "political assignment" and staff were asked to test food samples for the presence of *Salmonella* from both the 2012 Republican and Democratic National Conventions.

New capabilities include the development of test methods to detect the presence of Norovirus in food samples and the enhancement of electronic results reporting methods for rapid sharing of test results with both local and national partners.

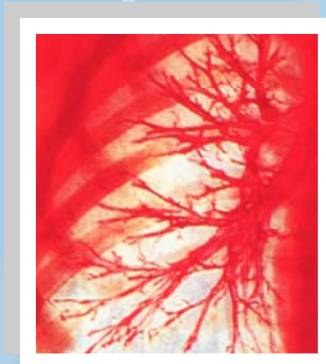
Chemistry Lab Expands Testing Capabilities and Collaborates to Serve Citizens and Partners

During 2013, the Environmental Chemistry Laboratory continued to support internal and external partners through continued testing. The laboratory is fully certified by the Environmental Protection Agency for the analysis of drinking water. The laboratory also participates in the Water Laboratory Alliance and the Food Emergency Response Network.

The Inorganic Chemistry section successfully developed an automated colorimetry method for orthophosphate in water, decreasing manual labor. Automation of data upload continues with the interface for alkalinity, biological oxygen demand, pH and dissolved and suspended solids.



The program collaborated with researchers at the University of Colorado Denver to measure the exposure of roofers to particulate matter and supported a pediatric asthma study in the San Luis Valley by modifying the method to analyze the concentrations of polyaromatic hydrocarbons from filters.



The group completed the fourth year of a five-year cooperative agreement with the FDA designed to support enhanced capabilities of food testing. Analyses for arsenic species and organic toxins were performed in a wide variety of food matrices. After participation in a Lean value stream mapping event, turnaround times were decreased from 14 days to seven days.

Goals for the upcoming year are to obtain ISO 17025 accreditation for the food testing performed to support the Division of Environmental Health and Sustainability.

Newborn Screening: Testing a Drop of Blood Saves Lives



The CDPHE Newborn Screening Laboratory is responsible for testing all babies born in Colorado and Wyoming for potentially life-threatening disorders. During 2013, the laboratory which tests for over 30 conditions, received 137,758 samples and performed 2,599,438 analyses.

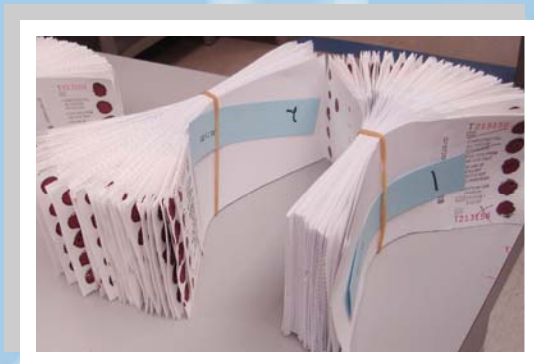
The Newborn Screening lab scientists are currently in the process of validating five new instruments which will replace six older technology instruments within the laboratory. Validation will be completed and the new testing platforms will be in production by the end of the calendar year.



In the spring of 2012, the Colorado State Board of Health amended Rule 5 CCR 1005-4 to require the collection of NBS specimens to occur within 24-48 hours after birth and to require that all specimens be transported to the laboratory via courier or overnight mail delivery. The table below summarizes the improvements of the timing of specimen delivery since the rule change was approved.



The CDPHE Laboratory continues to work with partners to decrease the time from birth to newborn screening completion and to improve to meet transport requirements.

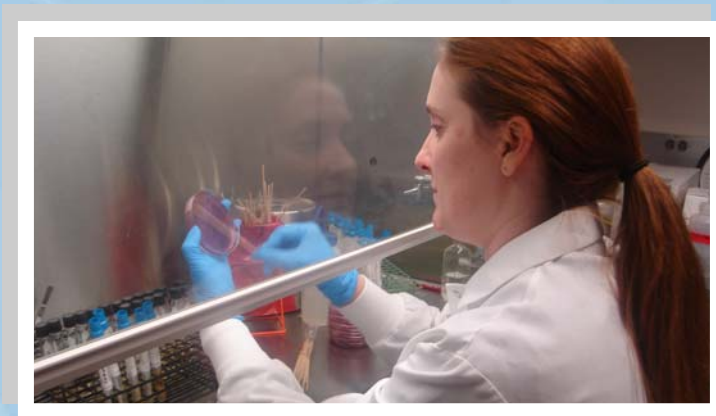


2012	Percent transported to the laboratory within 0-4 days
Quarter 1	63
Quarter 2	68
Quarter 3	72
Quarter 4	77
2013	
Quarter 1	78
Quarter 2	88
Quarter 3	88

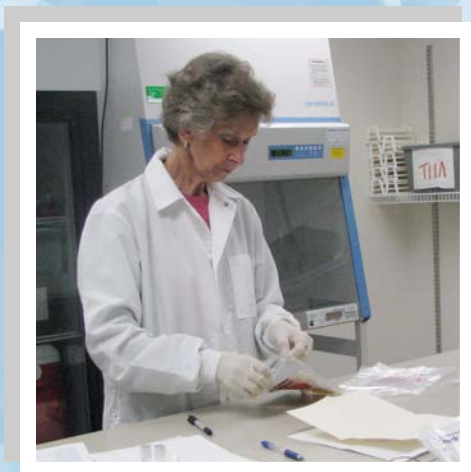
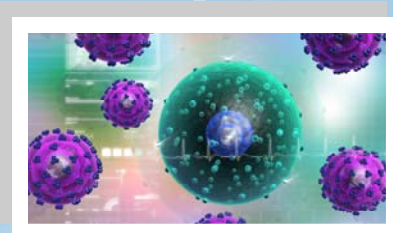
Public Health Microbiology Laboratory Expands Testing Capability and Continues to Assist Public Health Partners throughout Colorado

The primary function of the Public Health Microbiology Lab is to provide assistance to public health and clinical entities throughout Colorado in the investigation of disease outbreaks, the identification of unusual microorganisms, and the identification of organisms classified as potential bioterrorism agents.

During 2012, staff members completed extensive training in both molecular and traditional microbiological culture techniques, enhancing the capability of the laboratory to respond to outbreaks and other biological events.



At the start of 2013, staff completed a validation of the 4th generation HIV testing algorithm designed to simultaneously detect both HIV antigen and antibody which will allow for earlier detection of HIV infection. Earlier detection can help decrease transmission of HIV.



In collaboration with the Molecular Science Lab, the Public Health Microbiology Lab significantly expanded its testing capability, implementing molecular testing methods for the detection of vaccine preventable diseases including *Neisseria meningitidis* and *Haemophilus influenzae* organisms responsible for bacterial meningitis.

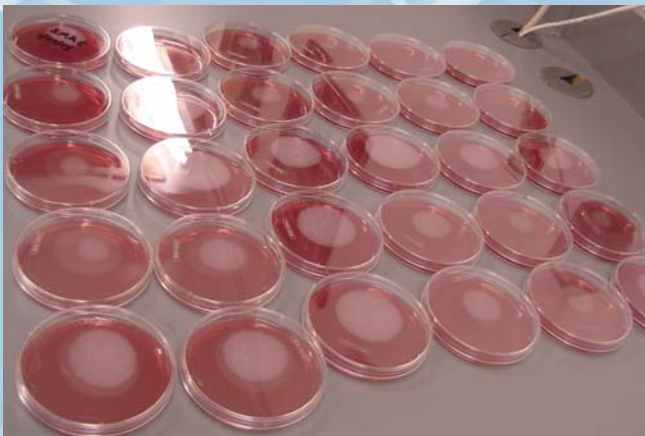
Implementation of these nucleic acid amplification methods significantly reduces the time to identify infections, allowing for rapid public health interventions.

The laboratory's ability to respond to diarrheal outbreaks was enhanced with the implementation of molecular serotyping for *Salmonella*.

In response to declining *Mycobacterium tuberculosis* (MTB) cases, the CDPHE tuberculosis lab

partnered with a consortium of northern plains and intermountain state public health labs in an Association of Public Health Laboratories (APHL)-funded shared services agreement to explore the feasibility of centralizing drug susceptibility testing (DST) for MTB.

The shared services model investigated in this study called for the Colorado Department of Public Health and Environment (CDPHE) to serve as the central testing laboratory for 1st line DST on MTB isolates from six state public health labs (Colorado, Wyoming, Utah, Montana, North Dakota and South Dakota) and one local public health lab (Denver Health). Cultures identified as MTB and requiring DST were to be referred to the department within 72 hours of identification.

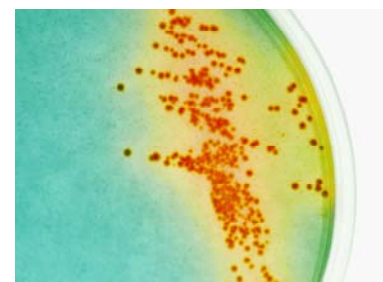
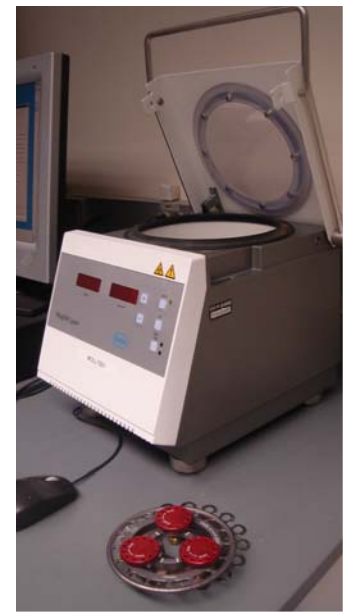


In order to assess the impact of regionalization on turnaround times (TAT), submitting labs performed DST in parallel on all referred MTB isolates following their laboratory's established procedures. DST results and TATs were compared for both the submitting laboratory and CDPHE. Results from this

study demonstrated that shared services for MTB DST are feasible provided proper specimens are submitted in a timely manner. This study also highlighted the importance of molecular methods for rapid identification of drug susceptibilities.



Throughout the year, the laboratory provided assistance to public health and clinical partners investigating outbreaks including: *Listeria monocytogenes* in cantaloupe, *Legionella pneumophila*, *Salmonella* and *E. coli*.

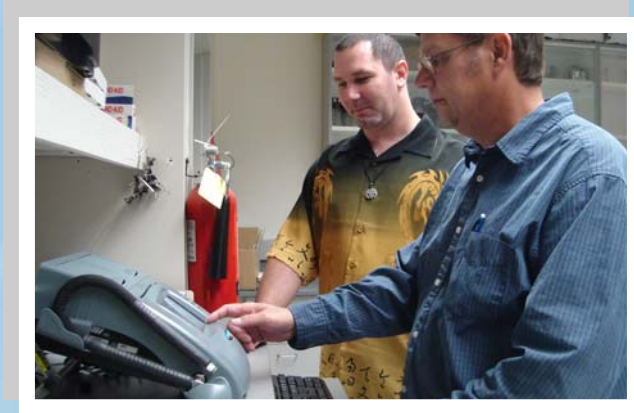


Colorado is First State to Deploy New Intoxilyzer Instruments

During 2013, the Evidential Breath Alcohol Testing (EBAT) Program deployed the new evidential breath alcohol testing instrument, the Intoxilyzer 9000 (I-9000), replacing the Intoxilyzer 5000EN, which was used by law enforcement agencies throughout Colorado since 1998 to determine whether a person is driving under the influence of alcohol.

Colorado's EBAT program is the first in the country to place these instruments in the field since they were developed and approved by the National Highway Traffic Safety Administration (NHTSA). Development related to the performance

of the instrument, how the operational software would work, training and certification of the officers, and communications all had to be completed prior to the switch date of May 1, 2013.



The I-9000 instruments were placed into service statewide with newly certified instructors, stationed at more than 160 law enforcement

facilities throughout the state, assisting the EBAT Program as the Intoxilyzer 5000-EN instruments were simultaneously decommissioned and taken out of service.

The project to replace the intoxilyzer instruments was a long and complicated process. Funding was secured and there was a state purchasing and bid process which was evaluated by law enforcement and others. The importance of ensuring that the results produced by the scientific instrument are accurate, precise and of evidential quality cannot be understated.

The Rules Pertaining to Testing for Alcohol and Other Drugs (5 CCR 1005-2) had to be revised and approved and training needed to be developed and implemented. In order to start the development of training, the hurdle of the revision of the rule had to be cleared. There was a stakeholder process where more than 750 stakeholders were invited to provide their input and feedback about the revision of the rule. There are four rules in the entire division, one in Newborn Screening and three in EBAT. The revised Rules Pertaining to Testing for Alcohol and Other Drugs (5 CCR 1005-2) passed approval at the first hearing by the State Board of Health.

The expedient passage of the rule demonstrates the success of staying focused on the governor's model of the three E's (Elegance, Effectiveness, and Efficiency) and using the strategic mapping of the department. Creating partnerships statewide, using the evaluated state purchasing and bid process, and increasing the effectiveness of training as well as significantly increasing time savings were all critical factors.

The EBAT program had four months to install all the instruments and to train 5,500 law enforcement instructors and operators to use the latest technology. All law enforcement agencies resumed testing using the new I-9000 equipment without disruption.

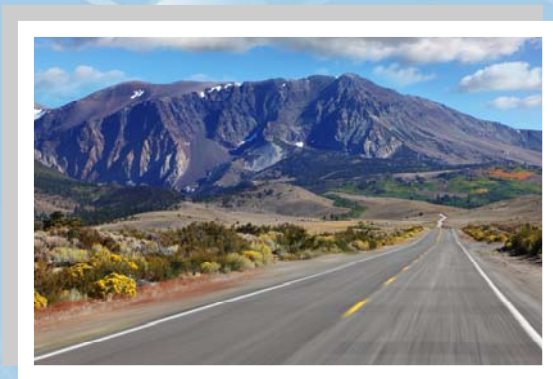
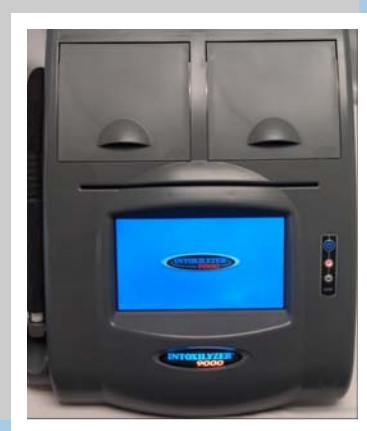
EBAT program staff has developed the operational software with the manufacturer, validated each instrument and certified the 200 I-9000's for field use. In addition, over 5,000 law enforcement officers statewide have been trained and certified on the I-9000 prior to implementation.

Prior to the I-9000, the legal communities had to contact the EBAT program for instrument records and the law enforcement agencies for instrument logs and officer certification records which resulted in a time consuming and inefficient way to obtain the necessary documentation required for the state's prosecution.

A strong partnership between the department and law enforcement ensured the objectives and overall success of the project.

A number of other states are interested in the instrument and they are waiting and watching to see how it works for Colorado. Some of these states include New Hampshire, Rhode Island, Georgia, Texas, Louisiana and New York.

Feedback from the manufacturer (CMI Inc) and other state programs are indicating that Colorado has set a new level of quality and transparency to the state's breath alcohol testing program and it is anticipated that many will follow the examples being set by the EBAT program.



The Laboratory Services Division Plans for and Responds to the Unexpected — Emergency Preparedness

Much of the testing performed by the CDPHE Laboratory Services Division is anticipated, with staffing schedules, supply orders and specimen turn-around times based on factors such as seasonal fluctuations, recent events and historical records. However, unpredictable events require additional planning, training and partnerships with other private, local, state, and federal agencies to ensure a rapid, effective response in protecting the health of Colorado's citizens. Resources at the state lab are dedicated to providing preparedness and rapid response to potential public health emergencies across the state. As in previous years, during 2012-2013, this division was called upon to respond to such events.

Surge Capacity

A key to effective response is surge capacity, the ability to scale up testing by redirecting human resources and testing capabilities to address a large increase of specimens resulting from an unanticipated event or outbreak. The CDPHE Lab is part of a CDC-sponsored group of local and state laboratories called the Laboratory Response Network (LRN). The LRN establishes national standards for testing and instruments of biological and chemical agents while



providing a stockpile of reagents that can be shipped on short notice to member laboratories. The CDPHE Lab received a site visit from an LRN team that included a tour of the laboratory facility and a discussion of capabilities and needs. Laboratory scientists were sent to CDC-sponsored training to

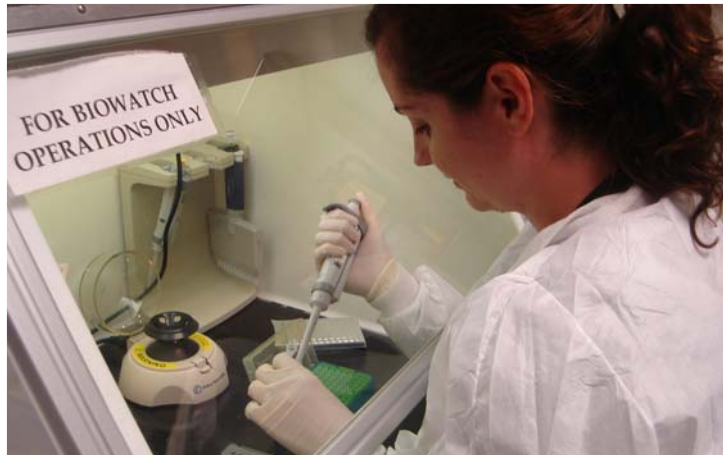
improve skills and to enable more testing to be performed at the laboratory rather than having to send specimens to the CDC, shortening the time between testing and receiving results.

Additionally, microbiology staff was cross-trained to be able to work in

multiple laboratory units, increasing surge capacity without the need to hire additional staff. Robotic instruments perform more of the routine laboratory tasks, freeing scientists and technicians to concentrate more on results interpretation. The West Nile virus and influenza virus outbreaks are annual examples of the value of having this laboratory testing surge capacity.

Planning

Cooperation with public and private partners is essential in developing the CDPHE Lab response plans. During the past year, these efforts included participation in a metro area table top exercise in advance of the presidential debates that were held at the University of Denver on October 3, 2012. This was the first large-scale exercise in Denver that involved Biowatch, a national program that continuously monitors the air in major U.S. metropolitan areas for bacteria and viruses that could be used as part of a bioterrorism attack.



Representatives from the CDPHE Lab participated in a two-year program, Wide Area Response and Recovery Program (WARRP). This program involved local, private, state, and federal

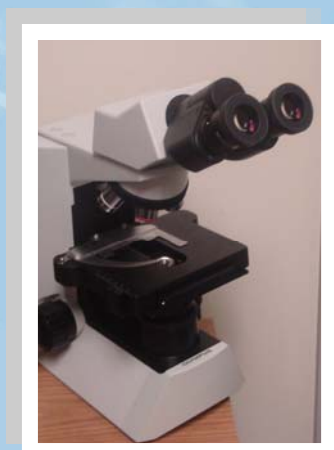
partners in determining the potential effects of a natural disaster or terrorist attack on the Denver metropolitan area. The WARRP programs concluded at

the end of 2012, with the development of a response template that can be used throughout the United States. This template outlined the resources, including laboratories such as the CDPHE Lab, which would be called upon to respond to the initial event and it identified the long range tasks required in the recovery process.

Additionally, the CDPHE Lab is an active partner in the Denver Weapons of Mass Destruction (WMD) workgroup. This group includes first responders, the FBI, U.S. Postal Service Inspection Service, USDA, 8th Civil Support Group of the Colorado National Guard, and local clinical/public health agencies. The CDPHE Lab is a key part of this group as clinical and environmental specimens would be tested in the laboratories to either confirm or rule out the presence of chemical and infectious agents.

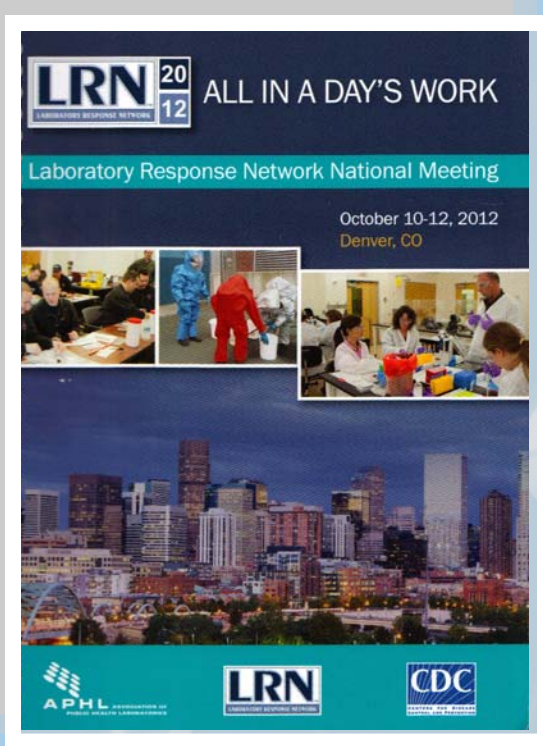


Training



Clinical and local public health laboratories are a critical part of the LRN as they see the ill patients first and make the initial assessments as to the causes of the illness. The CDPHE Lab works closely with these network partners, by providing training in several settings. Webinars and teleconferences are offered at the CDPHE Lab facilities. Online courses enable training access to laboratory technicians across the state. Hands-on training is important for laboratorians to actually see and work with

attenuated (safe strains) of bacteria that they may not otherwise see. During the past year, three dozen technicians from 14 laboratories across Colorado were trained during workshops. Two of the workshops were hosted at the CDPHE Lab facility and two more were hosted at the Mesa County Public Health Laboratory in Grand Junction. This outreach provides training for laboratorians in areas of the state that would otherwise not be possible due to the travel distances and the need to provide coverage while staff is being trained. The CDPHE Lab is a nationally recognized training site by the LRN, annually hosting a CDC sponsored training workshop that demonstrates the most current rapid methods, such as DNA testing, to public health laboratorians from across the United States. In addition to classroom instruction, hands-on training is provided through the use of live bacterial cultures and the operation of the latest analytical instruments for detecting DNA of infectious bacteria and viruses.



The CDPHE Lab is considered a leader among its national peer laboratories. Examples of this expertise were presented at the LRN National Conference held in Denver in 2012. Laboratory Services Division scientists gave presentations detailing their successful efforts at being one of the first U.S. member labs to develop and implement a direct link to the CDC to more quickly report test results to that agency. Another presentation described the rapid laboratory response in identifying and confirming important infectious bacteria (select agents) in Colorado patients.

Emergency Response



The value of these planning and training efforts was validated during the year when Colorado residents were threatened by outbreaks of disease and threat letters. Public officials and private citizens received both suspicious packages and threatening letters with powders that were implied to contain either infectious bacteria, such as those causing anthrax or hazardous chemicals. Local hazardous materials (hazmat), 8th Civil Support and FBI response teams carefully collected the letters and packages that posed the threats and transported them to the CDPHE Lab for analysis. As a result of training and good communication between these partners and the CDPHE Lab, the time required to test and to report results has been reduced significantly. Today a specimen that is received by the CDPHE Lab can be tested and results to either rule out or confirm the presence of a biological or chemical threat are reported in as little as two hours. Fortunately, all of the threats were discounted this past year, with anxious victims reassured that their health had not been compromised.

The realized health threats were from natural causes. During the year, human cases of plague and brucellosis were confirmed by the CDPHE Lab, as well as tularemia and plague in domestic pets and wildlife. The case of the child who was severely ill with plague made national headlines, while the CDPHE Lab rapidly confirmed the physicians' diagnosis that the bacteria *Yersinia pestis*, was responsible for the life-threatening illness.



While much of the laboratory testing was performed during typical business hours, the Laboratory Services Division staff is on call 24 hours a day, seven days a week. In several of the emergency responses, laboratory scientists either stayed late or returned to their labs late at night to perform vital tests in a timely manner.

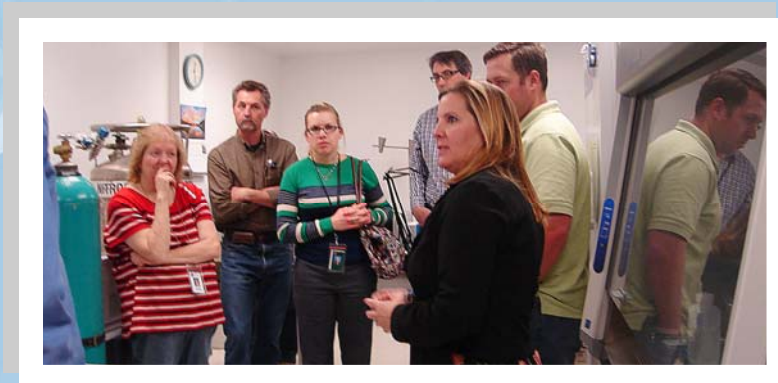
Outreach and the Future

Each year tours are given to nearly 200 visitors to the CDPHE Laboratory. Visitors include students, public officials, laboratory peers and



interested Coloradans. The tours demonstrate the breadth of testing performed in the fields of microbiology, chemistry, radiation chemistry, laboratory certification and breath alcohol analysis. It is particularly important to inspire students who will be the next generation of scientists and technicians in laboratories such as the CDPHE Laboratory.

The Association of Microbiology (ASM) has chosen our facility to showcase U.S. laboratories for a group of up-and-coming microbiologists in its ASM Young Ambassadors program. During the October 2012 LRN National Meeting, 17 doctoral and post doctoral candidates from 17 nations on six continents toured



the CDPHE Laboratory and asked how they could apply for internships and work. Some of the most gratifying tours are those with middle and high school science classes, observing their interest and

enthusiasm as they ask questions. Someday, these students may be the next Laboratory Services Division scientists who will be responding to the latest public health emergencies in Colorado.

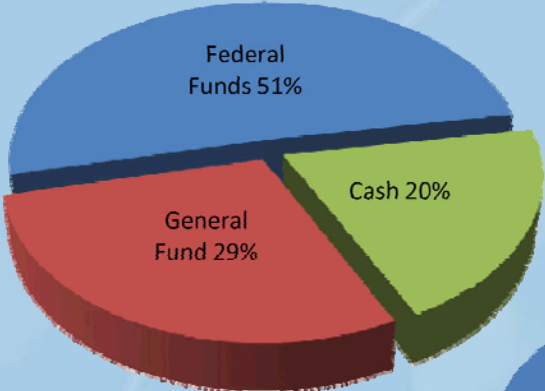
FINANCIALS

Federal Grant-Funded Testing 2013	
Microbiology (Human and Animal)	Public Health Emergency Preparedness Epidemiology and Laboratory Capacity Tuberculosis Elimination and Laboratory Program Emerging Infections Programs H1N1 Influenza Grant Refugee Preventive Health Grant Disease Control and Environmental Epidemiology Division (DCEED) - Hepatitis C Serosurveillance Testing DCEED - Syphilis Serology Grant DCEED - Human Immunodeficiency Grant National Wildlife Research Center - Shiga toxin- producing <i>E.coli</i>
Microbiology (Environmental)	Consumer Protection Division (CPD) - Food and Drug Administration Grant WQCD - River and Stream Testing Services Food Safety and Security Monitoring Project
Environmental Chemistry	Food Safety and Security Monitoring Project WQCD - River and Stream Testing Services Prevention Services Division (Fluoride)
Certification	Clinical Laboratory Improvement Amendments

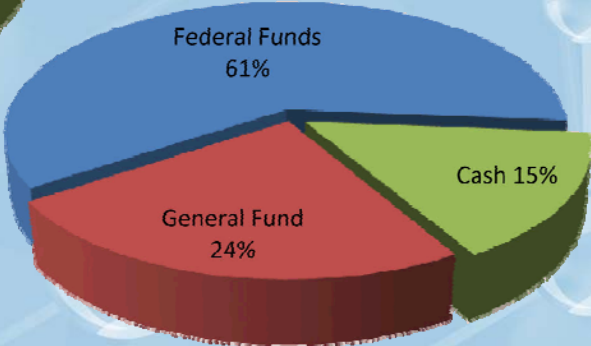
Fiscal Year 2013

FINANCIALS

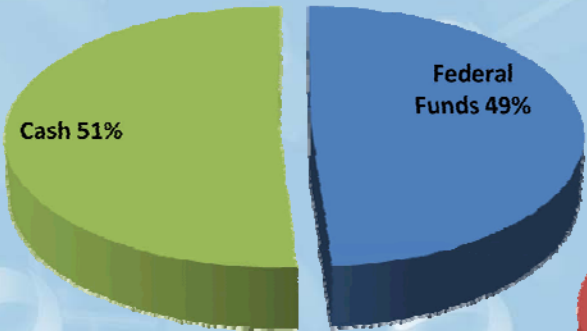
Microbiology (Human & Animal)



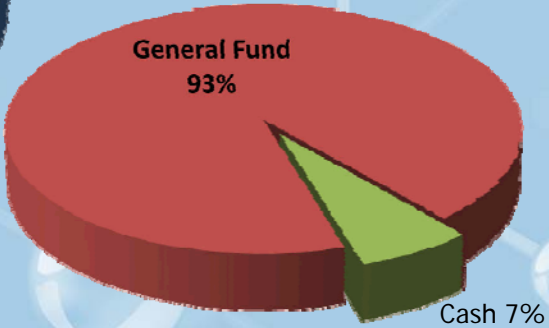
Environmental Microbiology



Environmental Chemistry
General Fund 0%



Radiochemistry

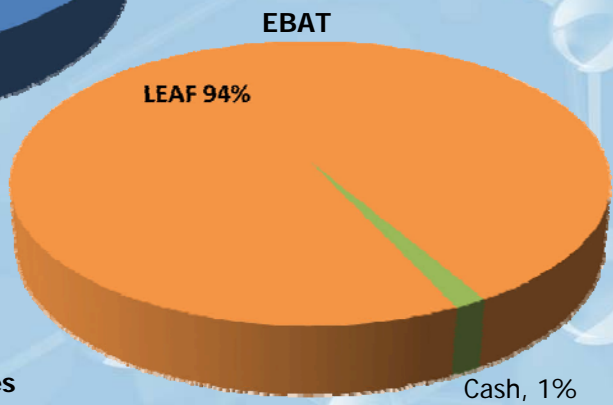
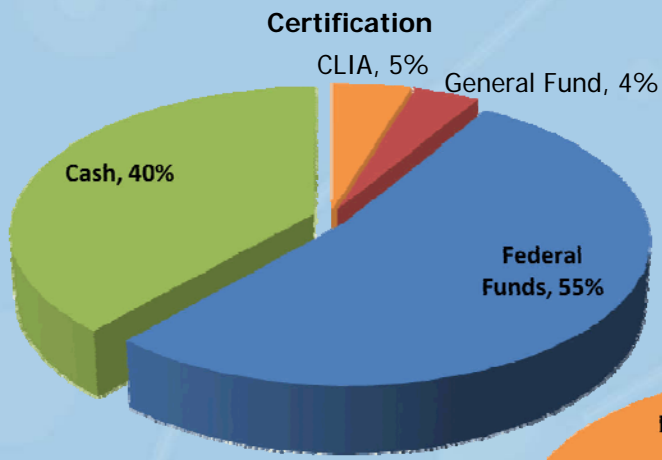


Newborn Screening

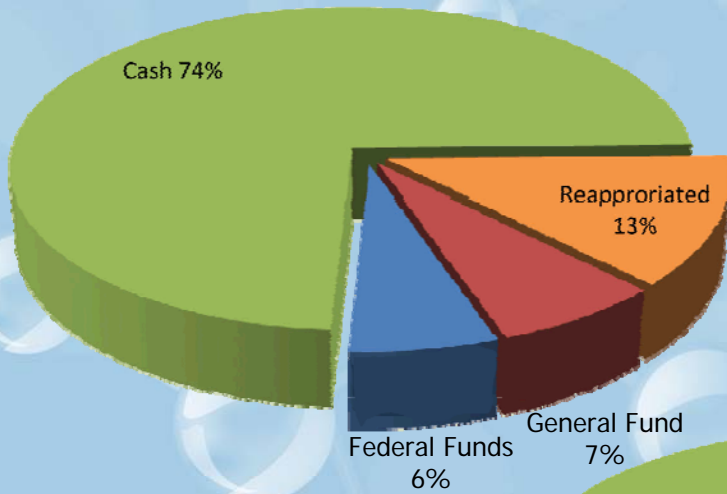


Fiscal Year 2013

FINANCIALS



Administrative and Support Services



Toxicology

