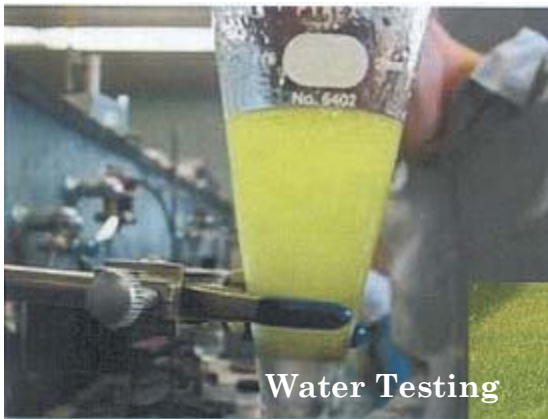


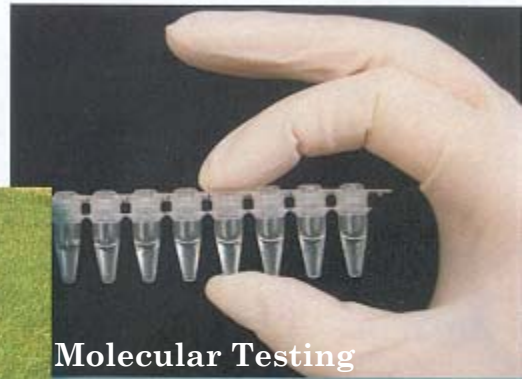
Laboratory Services Division – Annual Report 2006-2007



Colorado Department
of Public Health
and Environment



Water Testing



Molecular Testing



Food Testing



Newborn Screening

Rapid Detection for the Public's Protection

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.

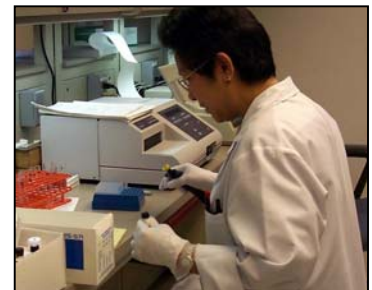
The Laboratory Services Division serves the people of Colorado by

- providing reliable, certified laboratory services to the public;
- screening all Colorado newborns for genetic diseases and disorders;
- testing water for public water providers and citizens;
- providing training for clinical laboratories;
- overseeing quality assurance by certifying clinical and environmental laboratories; and
- building relationships with local health and environmental labs to help them maintain and upgrade services.

For a comprehensive view of the Laboratory Services Division, visit us on the Web at:
www.cdphe.state.co.us/lr

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The Director's Office

The Director's Office provides support in the form of management, policy review and direction to the three main testing laboratories (Chemistry, Microbiology and Newborn Screening), the Grand Junction Branch laboratory and the Certification Program.

The following staff areas provide support services:

- Fiscal Office
- Quality Assurance
- Client Relations, Public Information Office and Training
- Information Technology
- Facility Operations

The Director's Office ensures that all the programs in the division provide exemplary customer service through timely and accurate delivery of results.

Strategic Planning

The division director convenes a strategic planning session annually, to examine and evaluate current and proposed projects to improve laboratory-testing services. This year's planning session focused on

- evaluating the feasibility of emerging technologies for public health laboratory testing;
- enhancing online resources available to the public and professional communities being served by the lab; and
- seeking funding to establish an isolation laboratory, which is crucial to the continuity of lab operations in a public health emergency.

A Message from the Director

October 1, 2007



Dear Customers:

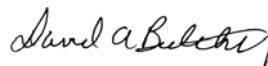
I am pleased to present the Annual Report of the Laboratory Services Division for our fiscal year ending June 30, 2007.

Fees were left unchanged this year, with the exception of the Certification Program Safe Drinking Water Laboratory audit fees that were adjusted to fully cover costs of administering the program. The division continues to rely on federal grants to maintain operations related to public health readiness.

The first year of expanded screening in the Newborn Screening Program using tandem mass spectrometry has proven to be successful at detecting additional treatable disorders. The program has taken several steps to improve quality and service, such as expanded holiday staffing; implementing sample transport manifests, and expedited sample delivery using a courier service. These actions are expected to improve turnaround time. The goal is to become less dependent on the postal service for sample delivery wherever feasible.

Work was completed on a redesigned sample receiving and sorting area, including relocated after-hours drop box. This will allow us to segregate samples from other deliveries to expedite sample processing.

Ever seeking to serve you better,



David A. Butcher, MBA, MT (ASCP) SM
Laboratory Services Division Director

Fiscal Office

Overview of Fiscal Year 2006-2007 Funding

Federal grant funding and cash revenues, generated through fees for laboratory services, represent the main sources of funding for the operation of the Laboratory Services Division's programs.

After reviewing the fee structure, cash revenues and fiscal year 2007 budget requirements, the Laboratory Services Division elected to continue most fiscal year 2008 fees at the same level as fiscal year 2007 pricing. The fee structure in the Certification Program was adjusted to reflect nationwide industry standards, while the Toxicology Program fees were revised to reflect the addition of blood drug testing.

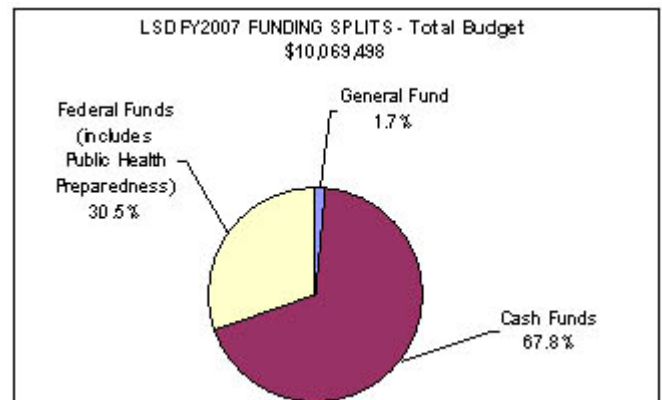
| Cash Revenues by Program – Fiscal Year 2006-07 | |
|--|--------------------|
| Laboratory Program | Revenues |
| Certification | \$53,007 |
| Public Health Micro (inc Chlamydia) | \$345,736 |
| Toxicology | \$439,157 |
| Chemistry | \$315,603 |
| EBAT | \$8,890 |
| ENV Micro | \$181,933 |
| Serology (inc HIV) | \$125,169 |
| Molecular/Virology | \$100,795 |
| NBS | \$3,609,431 |
| Total Fee Revenues | \$5,179,721 |
| Other Cash Revenues by Source | |
| Law Enforcement Assistance Fund (LEAF) | \$747,261 |
| Water Quality Control Division (WQCD) | \$479,657 |
| Various cash | \$2,793 |
| Total Other Cash | \$1,226,514 |
| Total Cash Revenues | \$6,409,028 |

| Expenditures – Fiscal Year 2006-07 | |
|------------------------------------|---------------------|
| Total Indirect Paid | \$1,268,089 |
| Total Personal Services | \$6,143,001 |
| Total Operating | \$3,571,921 |
| Total Expenditures | \$10,983,011 |

Procedural Changes in 2008

In response to the challenge of delayed invoicing and mailing resulting from separate physical addresses for main department and Laboratory Services Division fiscal offices, the laboratory **Fiscal Office** will assume these processes in fiscal year 2008.

| Grants Received – Fiscal Year 2006-07 | |
|---|--|
| Grant Provider | |
| Public Health Emergency Preparedness | |
| Epidemiology and Laboratory Capacity | |
| Tuberculosis Elimination and Laboratory Program | |
| Emerging Infections Programs | |
| Pandemic Influenza Grant | |
| Public Health Biomonitoring Planning Grant | |
| Refugee Preventive Health Grant | |
| Public Health Laboratory Interoperability Program | |
| Preventive Health and Health Services Block Grant | |
| Clinical Laboratory Improvement Amendments | |
| Disease Control and Environmental Epidemiology Division (DCEED)– Hepatitis C Serosurveillance Testing | |
| DCEED – Syphilis Serology Grant | |
| DCEED – Human Immunodeficiency Virus Grant | |
| Hazardous Waste and Waste Management Division (Rocky Flats) | |
| Air Pollution Control Division (Odor School) | |
| Prevention Services Division (Fluoride) | |
| *The entities listed above provide grant funds that vary in amount and duration to support the Laboratory's public health functions | |



Transporting, Handling and Disposal of Specimens

The **Central Services Unit** provides infrastructure support for the safe receipt, distribution and proper disposal of public health and environmental samples and specimens. The unit processes customer requests for supplies used in specimen collection and submission and oversees compliance with state-mandated document retention schedules and federal hazardous-waste storage and disposal guidelines.

During fiscal year 2007, the **Central Services Unit** oversaw the implementation of a statewide courier system. The new service has been well received by laboratory customers and fulfills a key public health preparedness requirement.



Quality Assurance

Established at both the state and national levels, proficiency testing is a quality assurance requirement of all clinical and environmental laboratories.

Regulatory agencies provide samples to the Laboratory Services Division for testing, to determine the aptitude of the laboratory scientists. The lab performs testing on the unknown samples, and reported results are evaluated against the correct value by the regulatory agency. For desired performance, 80 percent of test results must be within the accepted range.

During the Laboratory Services Division monthly **Quality Assurance Committee** meetings, committee members look at issues with the goal of improving overall quality of each laboratory section.

Issues examined by the committee originate from

- new standards set by regulatory agencies;
- deficiencies uncovered in self audits;
- incorrect results on proficiency tests;
- customer complaint tracking; and
- review of qualifications of the laboratory's scientists, technicians, and technologists, including training issues and competency assessments.

Quality benchmark results established by the **QA Committee** in 2006-07 include

- the establishment of an on-line issues tracking database;
- the storage of results at a separate location to insure data safety in case of fire, flood, or stolen equipment;
- the implementation of a packing slip requirement of all customers sending specimens into the laboratory;
- the creation of credentialing folders to maintain documentation on all division staff performing scientific testing, to include the current job description (Position Description Questionnaire) and supporting documents such as, training/education records, competency assessments, college diplomas/transcripts, continuing education certificates, and curriculum vitae or resumes;
- revision of a policy pertaining to job-related continuing education for all division employees designating a minimum number of 12 contact hours required of each scientist, technician and technologist during a performance rating period; and
- the review of current chlamydia testing procedures, for evaluation of a cost-saving sample pooling technique.

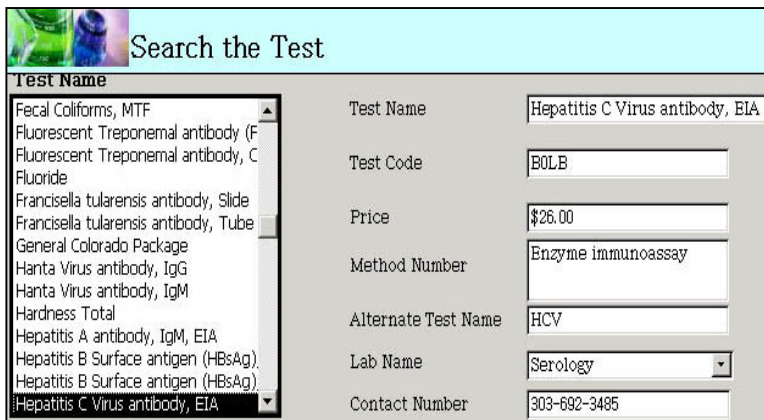
Customer Relations, Public Information and Training

During fiscal year 2006-07, oversight of the division's internal and external training and customer outreach functions was transferred to the new Client Relations, Public Information Office, and Training Unit. The new unit is responsible for monitoring customer satisfaction; arranging media site visits; generating press releases; oversight of publications, such as brochures and posters; and coordinating training for internal and external laboratory or health professionals.

Customer Service Improvements

Improvements in client relations during the fiscal year included the development of new online tools, such as the Customer Service Questionnaire and supply ordering (expected to expand in fiscal year 2008). Online bill payment is currently under development and is anticipated to launch in the upcoming year.

New packing slips for customers submitting specimens to the lab were designed, and the policy for their use was implemented, offering the benefit of better specimen tracking and rapid customer notification of missing specimens.



| Test Name | Test Name | Test Code | Price | Method Number | Alternate Test Name | Lab Name | Contact Number |
|----------------------|---------------------------------|-----------|---------|--------------------|---------------------|----------|----------------|
| Fecal Coliforms, MTF | Hepatitis C Virus antibody, EIA | B0LB | \$26.00 | Enzyme immunoassay | HCV | Serology | 303-692-3485 |

The unit oversaw the development of a database called the "Compendium of Testing Services" for use by internal and external customers. Once the database is completed, customers will be able to look on the Web for a listing of all lab tests, associated fees, specimens required for testing and other details related to each test.

Media Interest

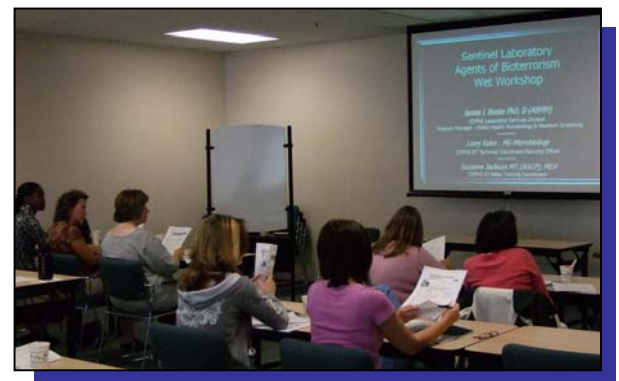
Laboratory testing during the national outbreaks of *E. coli* O157 in spinach (Fall 2006) and *Salmonella tennessee* in peanut butter (January 2007) brought media attention to the Laboratory Services Division.

Local news reporters interviewed the laboratory's molecular scientists to learn more about the DNA fingerprinting (Pulsed-Field Gel Electrophoresis) testing methods used to identify the causes of these outbreaks.

Preparedness Training

The Laboratory Preparedness online course, launched just prior to FY2007, continued to see strong enrollment and completion rates, strengthening Colorado's ability to respond during public health emergencies involving bioterrorism threats. The course received national accreditation through the American Society for Clinical Laboratory Science P.A.C.E.[®] Program in January 2007, and 118 laboratory analysts in Colorado received 12 continuing education credits each for completing the course.

The Laboratory Services Division hosted train-the-trainer wet workshops in Denver and Grand Junction, providing hands-on instruction to front-line hospital laboratory analysts on the testing methods used to recognize bacterial agents of bioterrorism. Additional workshops were conducted for local health department lab analysts, providing instruction on confirmation testing methods for these organisms.



More than 40 laboratories statewide participated in proficiency testing exercises offered bi-annually by the Laboratory Services Division.

This unique program enables laboratory analysts in all regions of the state to receive unknown organisms shipped by the state lab, for practice in testing methods and proper identification of the vaccine-strain, noninfectious bioterrorism agents.

To stay apprised of new scientific procedures necessary to provide the public with cutting edge technology for testing, the division's scientists enhance their own level of expertise through continued education coursework, conferences and workshops throughout the year. See Appendix B for a summary of employee continuing education.

Information Technology

The division currently uses a specimen tracking and laboratory results reporting system acquired from the Centers for Disease Control and Prevention/Biostatistics and Information Management Branch, known as LITS Plus. This system supports data processing needs in all laboratory areas with the exception of newborn screening.

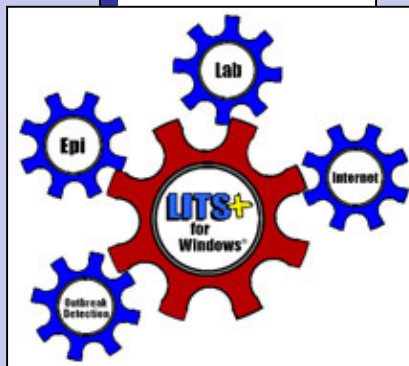
A newer, more robust system is being developed that will combine features of the original system plus Internet access and browser-based technology. This client server based system will enable seamless integration of laboratory and epidemiologic data to support outbreak detection, rapid surveillance reporting, and laboratory data management.

The division's Information Technology staff attended technical training in PowerBuilder to facilitate the conversion of the current system to the Laboratory Information System (LITS+2).

The new LITS+2 system merges two servers into one and redesigns testing classifications into four new categories:

Human Testing,
Animal Testing,
Environmental Testing and
Toxicology.

The redesign of LITS+2 is expected to launch on January 1, 2008.



Improvements to the current information technology system will

- simplify the collection and submission of specimens,
- expedite the reporting of test results,
- streamline billing processes, and
- ensure that all testing information regarding a single patient or environmental site is available to both the laboratory staff and the customer

to improve quality assurance practices.

Laboratory Testing and Validation Studies

Throughout the fiscal year, the Laboratory Services Division conducts validation studies prior to launching a new testing method; a new test kit or using newly acquired testing equipment.

Validation is the process by which the laboratory acquires the necessary information to

- assess the ability of a procedure to obtain reliable results,
- determine the conditions under which such results can be obtained, and
- define the limitations of the procedure

The validation process identifies aspects of a procedure that are critical and must be carefully controlled and monitored.

The two main types of validation required to implement or modify technologies for testing are

1) Developmental validation

This type demonstrates the accuracy, precision, and reproducibility of a procedure by the manufacturer, government agency or lab.

2) Internal validation

Required when there will be a complete change of detection platform or commercial kit. Internal validation studies must be sufficiently documented and summarized and should lead to the establishment of documented quality assurance parameters and interpretation guidelines.

Validations studies conducted by the Laboratory Services Division during fiscal year 2007 are referenced in subsequent sections of this report.

Chemistry Program

The Chemistry Program provides a wide array of tests for the detection of chemicals, from both environmental samples and human specimens that can pose a significant threat to the public's health or the environment.

Environmental samples tested by this program include drinking water, air filters, rivers, soil and factory waste. The program also performs radiological testing on both environmental sources and humans, to detect background measurements or contamination. Food sources also can be measured for additive levels or intentional contaminants.

Additionally, the Chemistry Program tests blood and urine samples to detect alcohol or drug abuse and assist in the enforcement of state laws.

Recent enhancements enable the Chemistry Program to provide specialized testing to detect intentional chemical or radiological releases by terrorists.

Preparedness

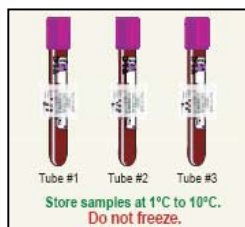
The **Chemical Terrorism Response Laboratory** is classified by the Centers for Disease Control and Prevention Laboratory Response Network as a "Level 2" laboratory, capable of detecting toxic chemical agents, such as cyanide, nerve agents and toxic heavy metals in human specimens.

Quality Assurance

To ensure competency in testing and maintain a high level of readiness to respond in a potential chemical terrorism incident, the **Chemical Terrorism Response Laboratory** participates in proficiency testing exercises and full-scale exercise simulations.

During the fiscal year, the laboratory successfully passed all competencies, including testing for the detection of toxic metals in urine and testing for the detection of cyanide in blood.

A full-scale packaging and shipping exercise between the **Chemical Terrorism Response Laboratory** and the Centers for Disease Control and Prevention was conducted, verifying the laboratory's ability to properly handle, package and ship blood sample tubes and urine sample cups, while maintaining chain-of-custody and correctly completing shipping manifests.



Blood sample collection tubes.



Human Biomonitoring

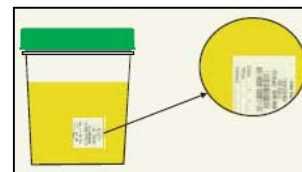
Biological monitoring, or biomonitoring, is the direct measurement of a person's exposure to toxic substances in the environment by testing for the actual substances or their metabolites in human specimens, such as blood or urine.

Biomonitoring is a tool that allows public health officials to evaluate the public's concerns about environmental exposures and improve the ability to make timely and appropriate public health decisions.

The Centers for Disease Control and Prevention (CDC) provides grant funding for the National Biomonitoring Program, and Colorado belongs to the Rocky Mountain Biomonitoring Consortium.

During the fiscal year, the Human Biomonitoring Program analyzed 20 urine specimens for metals, arsenic species, fluoride and creatinine and 45 water samples for metals, fluoride and nitrate/nitrite from Colorado in support of the Drinking Water Exposure in the Rocky Mountain States.

Additionally, 109 urine specimens were analyzed for metals, speciated arsenic, mercury and creatinine, and 219 water samples were analyzed for metals and mercury from New Mexico in support of the same project.



Urine sample collection cups.

Chemistry Program

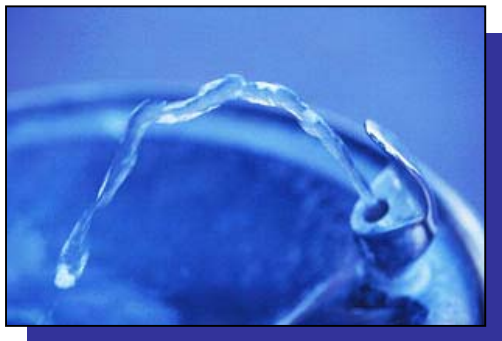
Water Testing

The **Organic Chemistry laboratory** continues to increase its capacity for testing drinking water with the addition of new processes and equipment each year.

The goal is to perform the full body of drinking water tests required by the U. S. Environmental Protection Agency Safe Drinking Water Act, which covers every public water system in the United States – more than 160,000 systems. The act does not regulate private wells.

Laboratory validation and certified drinking water proficiency tests have been completed for the analysis of chlordane, glyphosate (the herbicide Roundup) and toxaphene in aqueous matrices.

Due to the implementation of the new disinfection byproducts regulations by the Colorado Department of Public Health and Environment Water Quality Division, testing volume for the analysis of haloacetic acids and trihalomethanes has increased considerably this year.



Additionally, the laboratory analyzed 235 drinking water samples from sites in New Mexico and Arizona for inorganic arsenic species and metals, to support a CDC feasibility study for treating arsenic in drinking water.

Special Investigations

The **Inorganic Chemistry laboratory** analyzes drinking water, river water, factory effluents, soils and food to support the monitoring and compliance efforts of department programs and to fill the needs of private individuals and commercial customers.

The Environmental Protection Agency Lead and Copper Rule is a regulation to control lead and copper in drinking water. Lead and copper enter drinking water primarily through plumbing materials. Consumption of lead and copper causes a variety of health problems, ranging from stomach pain to learning disabilities, behavioral problems, seizures, coma and death.

During a special investigation in fiscal year 2006-07, the Inorganic Chemistry laboratory was involved in large-scale testing for lead and copper in the plumbing of the new University of Colorado Health Sciences Center at Fitzsimons campus.

Between October 2006 and January 2007, the laboratory analyzed approximately 330 samples.

Elevated levels of both lead and copper were detected and reported, resulting in the extensive remediation involving replacement of old pipes to render the facility's drinking water safe by state and federal standards.



Validation Studies

Inductively-coupled plasma mass spectrometry (ICPMS) is a flexible technique that provides a large range of detection and a high level of selectivity in detecting a variety of elements, while at the same time being relatively unaffected by most interferences found in clinical specimens or environmental samples.

During the fiscal year, the Chemistry Program validated the use of ICPMS for the detection of toxic metals in blood.

Volatile organic compounds (VOCs) are emitted as gases from certain solids or liquids, such as paints, cleaning supplies, pesticides, glues, permanent markers and office copiers and printers. VOCs may have short- and long-term adverse health effects and often are found in higher concentrations indoors.



Validation of a procedure for testing for VOCs in blood, using one of the most sensitive and interference-free methods, Solid-Phase Microextraction/Gas Chromatography-Mass Spectrometry (SPME/GC-MS), began during fiscal year 2006-07 and is expected to be completed next fiscal year.

Chemistry Program

Radioactivity and Human/Environmental Safety

The **Radiochemistry laboratory** analyzes water, air, soil and other samples for naturally occurring and man-made radioactive materials such as radium, uranium, radon, plutonium and americium.

The lab also tests water samples from public water supplies and private customers to ensure compliance with water quality standards and soil samples for the department's Hazardous Materials and Waste Management Division to assist the cleanup of uranium mills and other contaminated sites.

Use of the laboratory's whole body counter assists licensees with documenting safe use of radioactive materials by detecting levels of contamination in radiation workers and their workplaces.

In 2006, the **Radiochemistry lab** was selected by the South Dakota Department of Health to analyze isotopes of uranium on air filters collected near abandoned mining sites. Sampling began in March 2006 and is scheduled to continue for one year.

Preparedness

The **Radiochemistry lab** would play a key role in protecting the citizens of Colorado during and after an incident involving radiation or radioactive materials.

The **Radiochemistry lab** has the capability to detect and quantify nearly any sort of radioactive material in environmental and clinical samples, as well as *in vivo* using the whole body counter.

The lab routinely measures plutonium, uranium, americium and other alpha emitting radionuclides, as well as gamma emitters such as radioactive isotopes of cesium, cobalt, zinc and barium.

In the aftermath of a "dirty bomb" or act of terrorism with a nuclear device, the lab would be available to analyze air filters, soil and water samples from the affected area, and to screen victims, rescuers and first responders for contamination.

Innovation

After Alexander Litvinenko was poisoned by polonium-210 in London, it was learned other people had been exposed, including airline passengers.



When Denver airline passengers requested testing from the state lab, the **Radiochemistry lab** developed a rapid test to identify polonium-210.

Testing results were negative and provided peace of mind to concerned citizens.

Sharing the Knowledge

The Association of Public Health Laboratories held its first combined Annual Meeting and State Environmental Laboratory Conference in 2007.

The department's Radiochemistry lab was invited to join Iowa and Wisconsin in giving a presentation entitled "*Planning for Radiological Emergencies – A View from the Lab.*"

The lab also presented a poster on a new radiochemistry technique titled "*Rapid Analysis of Polonium-210.*"

Detection of Drug and Alcohol Abuse

The **Toxicology laboratory** routinely analyzes blood and urine specimens for ethyl alcohol, drugs of abuse and volatile substances to assist law enforcement agencies in administering drinking and drugged driver laws.

The lab also analyzes specimens in support of substance abuse programs and provides expert testimony in courts of law regarding the analysis of ethyl alcohol and drugs and the effects of those substances on human performance and driving.

The **Toxicology laboratory** experienced a 21-percent increase in blood alcohol specimens during fiscal year 2006-07 and a 10-percent increase in the total number of samples during that time.

Sharing the Knowledge

Obtaining quality specimens for toxicological testing is always a challenge faced by the laboratory. To improve the quality of specimens received, the **Toxicology laboratory** provided specialized training to nurses collecting specimens from sexual assault victims.

Properly introducing toxicology results into court record is a skill that many new deputy district attorneys lack. Recognizing this challenge, the **Toxicology laboratory** provided a customized training for new deputy district attorneys who prosecute cases where toxicology results are presented as evidence.

In addition to teaching the proper way to introduce these test results into court record, this training provided information on the significance of these results and the potential effects on the individual whose specimen was analyzed.

Drug Recognition Expert police officers are trained to be able to identify drug-impaired drivers. To ensure that proper specimens are collected for laboratory analysis, the **Toxicology laboratory** provided training to Drug Recognition Experts regarding the proper collection of specimens, types of analyses pertaining to their work, and the potential effects of alcohol and/or drugs on the individual.



Microbiology Program

The Microbiology Program performs testing to detect and monitor bacterial contamination in food and water and related outbreaks; to keep a watchful eye on the spread of known communicable diseases, such as tuberculosis, pertussis (whooping cough), HIV, chlamydia and gonorrhea; to track outbreaks of highly infectious diseases such as norovirus and influenza; and to provide surveillance for animal-borne diseases affecting humans, such as plague, tularemia, rabies and West Nile Virus.

This program also maintains readiness and surge capacity with regard to the detection of bioterrorist activities, as well as new, emerging bacterial or viral strains.

Food and Water Surveillance

The **Environmental Microbiology** laboratory routinely tests food, milk and water (drinking water and beach water), to determine whether harmful bacteria are present.

E. coli O157 is the leading cause of food-borne illness, often leading to bloody diarrhea and occasionally kidney failure.

The **Environmental Microbiology** scientists participated in a study, sponsored by the Food and Drug Administration (FDA), of advanced laboratory methods for the detection of Shigatoxin-producing *E. coli* in foods and successfully recovered the outbreak strain of *E. coli O157* involved in the nationwide spinach outbreak last year.

Food contaminated with the bacteria *Campylobacter* is another common cause of gastrointestinal illness in humans. The bacteria are transmitted to humans through improperly cooked and packaged meat products.

More than 500 retail meats were tested for *Campylobacter* by the **Environmental Microbiology** laboratory during the fiscal year, providing trend information on the contamination of meats.

Clostridium difficile are spore-forming bacteria that are normal inhabitants of the large intestine. The bacteria can cause severe diarrheal disease in hospital or nursing home patients taking antibiotic therapy.

However, in recent years, the bacteria have emerged as a threat to the general public, and infections are not always associated with antibiotic therapy.

In an effort to detect other community sources of infection, the **Environmental Microbiology laboratory** participated in a national pilot study of retail meat samples (ground beef and turkey) for the detection of *Clostridium difficile*.



Although no *C. difficile* were found in these food products, results allowed for the elimination of these foods as possible sources of community-acquired infections.

| Food Testing Performed by the Environmental Microbiology Lab | | Results by Year | | |
|--|---|-----------------|------|---------------|
| | | 2005 | 2006 | Jan-July 2007 |
| Total number of each type of food sample tested | | 120 | 110 | 70 |
| Beef | Number of samples positive for <i>Salmonella</i> | 0 | 0 | 1 |
| | Number of samples positive for <i>Campylobacter</i> | 0 | 0 | 0 |
| Pork | Number of samples positive for <i>Salmonella</i> | 0 | 0 | 2 |
| | Number of samples positive for <i>Campylobacter</i> | 0 | 0 | 4 |
| Chicken | Number of samples positive for <i>Salmonella</i> | 12 | 7 | 6 |
| | Number of samples positive for <i>Campylobacter</i> | 41 | 66 | 23 |
| Turkey | Number of samples positive for <i>Salmonella</i> | 17 | 15 | 9 |
| | Number of samples positive for <i>Campylobacter</i> | 0 | 10 | 2 |

Microbiology Program

Food-borne Illness Outbreaks

Public Health Microbiology and **Molecular Science laboratory** scientists maintained surveillance for food-borne bacterial contamination throughout the year and provided invaluable test results for the identification and monitoring of the following notable food-borne outbreaks in Colorado:

- spinach-consumption related *E coli* O157 infection (1 case)
- peanut butter related *Salmonella* Tennessee infections (11 cases)
- hospital neonatal-intensive care outbreak of *Salmonella* infections (12 cases)

The Molecular Science laboratory analysts employed pulsed-field gel electrophoresis testing to generate molecular typing data for more than 1,000 bacterial isolates in response to foodborne, animal-borne and hospital-associated outbreaks during fiscal year 2007.

Laboratory results shared with epidemiologists at both local and national levels guided rapid and appropriate public health interventions.



PulseNet

PulseNet is a national network of public health and food regulatory agency laboratories coordinated by the Centers for Disease Control and Prevention (CDC).

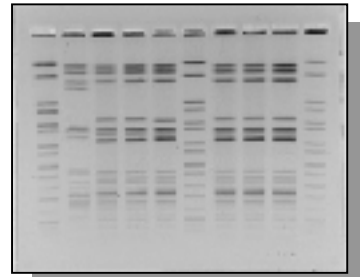
The network consists of state health departments, local health departments and federal agencies (CDC, U.S. Department of Agriculture - Food Safety and Inspection Service and the Food and Drug Administration)

The Molecular Science laboratory

is a participant in PulseNet, performing standardized molecular subtyping (or “fingerprinting”) of foodborne disease-causing bacteria found in Colorado, using pulsed-field gel electrophoresis (PFGE) and rapidly communicating these results nationally.

Analysts are fully certified by the CDC, demonstrating proficiency in typing bacteria causing food-borne illness such as: *E. coli*, *Listeria*, *Salmonella*, *Shigella*, *Campylobacter* and *Staphylococcus* species.

Testing data provided by the **Molecular Science laboratory** supported a large number of outbreak investigations in Colorado and established links with other outbreaks occurring in other states.



Microbiology Program

Animal-borne Disease Detection Outbreaks

Polymerase chain reaction (PCR) testing, performed in the Molecular Science laboratory, offers the greatest diversity in developing new test offerings in response to surveillance programs or the detection of new bacterial strains causing outbreaks in animals or humans.

Plague and Tularemia

During the 2007 season, the scientists and technicians of the **Serology, Public Health Microbiology and Molecular Science laboratories** collaborated to maintain a laboratory surveillance program for detecting plague and tularemia in mammals and insects.

The program tracks the rate of infection in animals (such as squirrels and rabbits) and evaluates the risk of human infection among hunters, veterinarians and outdoor hobbyists handling these diseased animals.

More than 500 animal samples were analyzed using a unique tandem PCR test for both plague and tularemia bacterial agents.

Outbreak at the Denver Zoo and City Park

A dramatic outbreak of plague illness was discovered in squirrels found dead in the central Denver area of the Denver Zoo and City Park regions.

Though no human cases were diagnosed, the **Molecular Science** lab responded by using an experimental testing method to analyze the *Yersinia pestis* bacterial strain causing plague illness in the squirrels.

The results of the pulsed-field gel electrophoresis method used by the lab indicated a unique bacterial strain uncommon to other strains seen in the state.

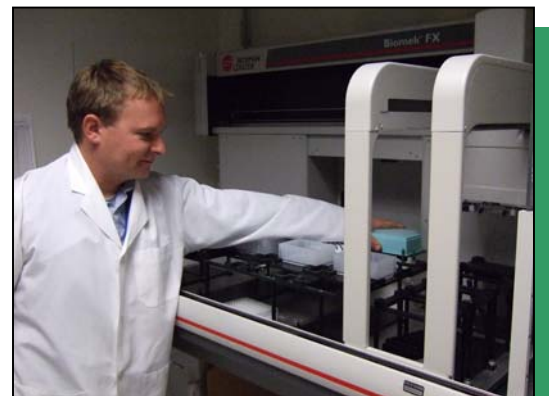


Brucellosis

The bacterial agent *Brucella*, which causes the disease brucellosis in livestock and is easily transmitted to humans via aerosol or unpasteurized milk, presents a laboratory testing challenge in identifying the exact species and strain.



Meeting this laboratory challenge, the **Molecular Science** analysts developed and implemented a lab procedure to identify both the species and strains of this organism.



While this method is still in validation, the procedure shows promise of providing the lab with the means of rapidly classifying the exact species and strain causing disease, enabling faster treatment options and ruling out an intentional terrorist incident.

Microbiology Program

Animal-borne Disease Detection Outbreaks *continued*

Q fever

Q fever is primarily an illness of livestock animals, which can be transmitted to humans by breathing contaminated barnyard dust, or occasionally, from drinking contaminated milk.

The Laboratory Services Division maintains testing capability to detect the bacteria causing Q fever, *Coxiella burnetii*, to monitor public health risk and distinguish between naturally occurring infections and a terrorist incident.

During fiscal year 2006-07, the laboratory participated in a study to determine background levels of *C. burnetii* to establish a baseline for testing in the event of a bioterrorism attack.

The **Molecular Science laboratory** used real-time PCR to determine the absence or presence of *C. burnetii* DNA.

Laboratory Services Division environmental sampling study to detect *C. burnetii* in rural and urban areas of Colorado
(Fall 2006)



Positive samples were found in 57.41 percent of the sites tested, including schools, grocery stores and post offices.

The laboratory is now equipped to conduct environmental sampling requiring the use of high efficiency particulate filter (HEPA) sampling, as occurs with institutional or agricultural outbreaks of human illness due to this bacterial agent.



West Nile Virus

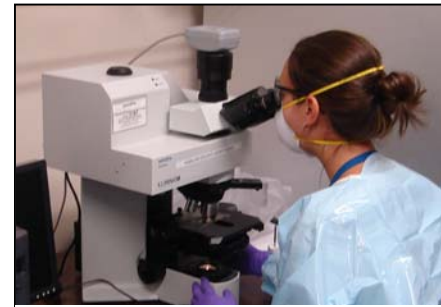
West Nile virus surveillance, now in its sixth year, resulted in the laboratory testing a record number of mosquito pool specimens (4,400) throughout the peak seasons of summer and early fall.

Microbiology Program

Preparedness

Environmental Microbiology scientists validated the use of an infrared spectroscopy (IR) instrument and demonstrated the use of the instrument for rapid identification of unknown powders.

The infrared spectroscopy instrument, called the *IlluminatIR* is now installed in the bioterrorism response laboratory and a total of eight laboratory scientists have been trained to use this equipment and the new technique.



Laboratory scientist using the *IlluminatIR*

Developing Technology

Avian influenza (“bird flu”) strain H5N1 is keeping public health officials alert to the possibility of a pandemic outbreak.

The public health laboratory will play an important role in detecting and tracking this strain in an outbreak situation.



Influenza testing in the **Molecular Science laboratory** was enhanced to full capacity using polymerase chain reaction (PCR) technology to detect the influenza A virus, followed by hemagglutinin (H) typing.

Using this method, the **Molecular Science laboratory** was able to provide real-time data indicating viral strains circulating in Colorado during the 2006-2007 influenza season.

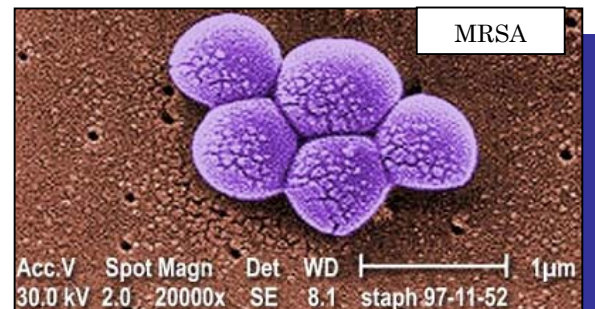
The Molecular Science laboratory also developed, validated and launched a new PCR method for the detection of *Shigella*, mumps virus, and *Bordetella parapertussis*.

In response to an outbreak of cough illness in Grand County, this newly developed PCR method was used to rule out *B. pertussis* and *B. parapertussis*.

Emerging Threats

Methicillin-resistant *Staph aureus* (MRSA) is a strain of bacteria that has acquired the genetic ability to be resistant to important antibiotics, such as penicillin and methicillin.

This “superbug,” previously encountered only in hospital settings, is now being identified in communities outside of hospitals.



The **Public Health Microbiology** and **Molecular Science** laboratories enhanced their partnerships with statewide hospital labs this year, maintaining a watchful eye on outbreaks caused by these bacteria by conducting surveillance for MRSA and reporting results to state epidemiologists.



Microbiology Program

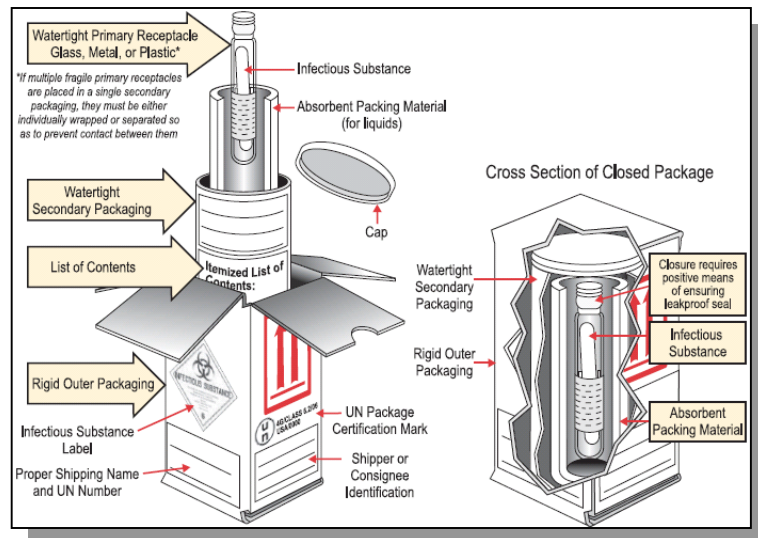
Sharing the Knowledge

Training and Conferences

Safe Specimen Handling

Safe transport of potentially infectious specimens to the state laboratory requires knowledge and expertise in the U.S. Department of Transportation's (USDOT) rules and regulations for proper packaging, documentation and shipment.

During the fiscal year, the state laboratory hosted a USDOT workshop, training 29 laboratory analysts statewide on how to properly package and ship infectious and diagnostic specimens..



Subsequently, the laboratory delivered a similar training to the first responders at the Tri-County Health Department and state epidemiologists at the Colorado Department of Public Health and Environment main campus.

Statewide Conferences

Twice a year, the laboratory hosts a statewide conference to educate Colorado laboratorians. During 2006-07, these conferences drew more than 80 laboratory workers from across the state and featured nationally recognized speakers presenting topics related to food-borne and respiratory diseases. Attendees participated in interactive preparedness exercises to enhance laboratory readiness in the state.

Posters and Presentations

Laboratory scientists are honored each year by invitations to give presentations on timely topics related to public health challenges or present educational posters on studies performed at the state Laboratory. The Microbiology program was represented eight times at distinguished knowledge-sharing events at association conferences nationally and internationally during fiscal year 2006-07. A complete list of events appears in Appendix B.

Fellowship Program

Each year the Microbiology Program accepts a scientist from the Association of Public Health Laboratories fellowship program.

This one-year fellowship program emphasizes the practical application of technologies, methodologies and practices related to emerging infectious diseases.

The candidate accepted during fiscal year 2006-07 developed the most notable addition to the list of test offerings during a one-year tenure in the lab.

The new test combines Luminex technology (color coded tiny beads, coated with reagent specific to a particular analyte), with standard amplification to allow detection and identification of 19 respiratory viruses in a single reaction.

Newborn Screening Program

The **Newborn Screening laboratory** is the designated laboratory in the state to conduct tests for 30 metabolic conditions in newborns. This program is supported through fees for testing and follow-up.

Newborn screening is done shortly after birth by collecting a few drops of blood from the baby's heel on a special piece of filter paper. Colorado infants receive a second newborn screening, usually at the first well-baby checkup (at 8 to 14 days old).

A second screen is performed because some conditions may not manifest until later, following discharge from the hospital or birthing center.

The medical conditions that are detectable by this screen may show no obvious symptoms in newborns, but can cause severe illness, mental retardation and, in some cases, death if not found and treated very early in life.



Developing Technology, New Equipment & Cost Savings

The Newborn Screening laboratory successfully launched tandem mass spectrometry (MS/MS) screening of newborn blood specimens on July 1, 2006, expanding the number of disorders detected on the first screen specimen from seven to 30.

Inauguration of this testing procedure elevated the Colorado Newborn Screening Program to a standard of practice endorsed by the American College of Medical Genetics and the March of Dimes.

During its first full year of expanded screening using MS/MS, the Newborn Screening unit detected 25 cases of metabolic illness due to inherited defects for an incidence rate of approximately 1/3,300, which is the observed range nationally. Medium-chain acyl-CoA dehydrogenase deficiency, the most commonly detected disorder screened for by MS/MS, accounted for eight of these 25 disorders.



Implementation of MS/MS screening required the addition of two tandem mass spectrometers to the **Newborn Screening laboratory**.

Newborn screening scientists devised a method to more efficiently use the MS/MS screening kit to save approximately \$20,000 over fiscal year 2007; keeping price increases for the new, enhanced testing to a minimum.

Throughout the fiscal year, the **Newborn Screening laboratory** worked in conjunction with metabolic physicians from The Children's Hospital of Denver, refining the standards used to define abnormal MS/MS findings, and reducing the number of abnormal calls that did not result in the diagnosis of a true case of illness.

Sharing the Knowledge

Newborn Screening laboratory scientists are invited each year to attend the national Newborn Screening and Genetic Testing Symposium, not only to acquire knowledge from their colleagues, but also to share educational posters highlighting related accomplishments from the Laboratory Services Division.

A complete list of posters shared during fiscal year 2006-07 appears in Appendix C.

Evidential Breath Alcohol Testing Program

The Intoxilyzer 5000EN is the evidential breath alcohol testing instrument used by law enforcement agencies in Colorado. The results from the Intoxilyzer 5000EN are proven to be scientifically accurate and precise. They are the only breath testing results allowed as evidence in court.

One hundred eighty-nine of these devices are currently located at 156 law enforcement agencies throughout the state. The division's **Evidential Breath Alcohol Testing Program (EBAT)** routinely maintains, repairs, calibrates and certifies these instruments and conducts annual on-site inspections of all law enforcement agencies that have these instruments.

Additionally, the **EBAT Program** approves preliminary breath testing devices and ignition interlock devices. Law enforcement officers use preliminary breath testing devices to establish "probable cause" for arrest for driving under the influence; however, device results are not evidential and not admissible as evidence in court. Ignition interlock devices prevent vehicle operation when the driver has alcohol in his/her system and are installed under court order on vehicles owned by drunk-driving offenders.



Regulations Change

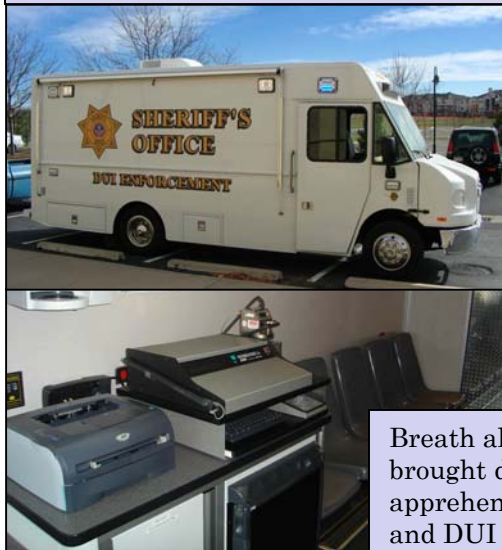
Changes to the Colorado Board of Health Rules and Regulations Concerning Testing for Alcohol and Other Drugs, 5CCR1005-2, became effective January 30, 2007. These changes eliminated the second sample captured in silica gel.

The change eliminates a procedure that was qualitative only (captured sample) and replaces it with a procedure that gives the subject two evidential quality breath test results to compare.

This rule change required an upgrade to Intoxilyzer 5000EN software, bringing the Colorado Evidential Breath Alcohol Testing Program in line with the recommended practices for evidential breath alcohol testing in forensic science.

The impact these changes will have on breath alcohol testing in Colorado is to tighten the quality control of each evidential breath alcohol test and provide a more scientifically reliable test result, improving the protection for Colorado citizens against impaired drivers on Colorado roads.

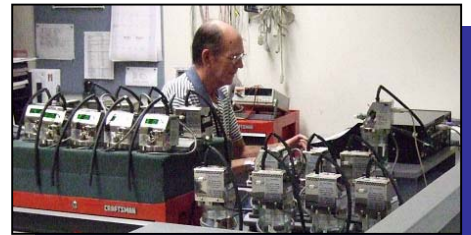
Breath alcohol testing (B.A.T.) vehicle



Instrument Upgrades

As a result of changes in the regulations, the **EBAT Program** performed 44 routine repairs, 291 routine calibrations and certifications, as well as 189 software upgrades, for a total of 480 instrument certifications during the fiscal year.

The software upgrades were completed by June 30, 2007, as required by the Colorado Board of Health Rules and Regulations.



Program staff repaired 49 simulators, performed four miscellaneous repairs for other laboratory sections and distributed 2,040 alcohol standards and 297 captured sample standards.

Staff also inspected 105 Evidential Breath Alcohol Testing facilities and found deficiencies in 78.

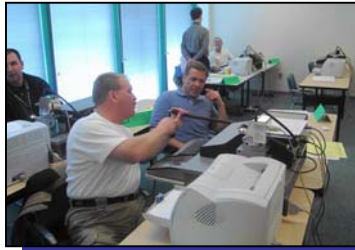
Breath alcohol testing technology brought directly to detection and apprehension sites during saturation and DUI checkpoints.

Evidential Breath Alcohol Testing Program

Training

Traditionally, the **EBAT Program** conducts instructor classes in “train-the-trainer” format for new instructors (“initial training”) or seasoned instructors (“update training”).

Upon successful completion of a written test and practical, the instructors are certified by the EBAT program, and the instructors return to their agencies and train operators on the use of the Intoxilyzer 5000EN.



Operators then become certified following the training at their agency and upon successful completion of a written test and practical.

Fiscal year 2007 was an unprecedented training year for the **EBAT Program**. As a result of changes to the rules and regulations and instrument software upgrades, it was necessary to update the training of all instructors and operators involved statewide in the operation of the Intoxilyzer 5000EN.

EBAT TRAINING & CERTIFICATION: 2006-07

Training & certification of law enforcement officers on Intoxilyzer 5000EN software upgrades

| <u>INSTRUCTOR TRAINING classes by EBAT</u> | <u>NUMBER CERTIFIED by EBAT</u> |
|--|---------------------------------|
| 6 New Instructor classes | 54 |
| 25 Instructor Update classes | 427 |
| Total Instructors Certified by EBAT | 481 |
| Recertification by written test | 124 |
| <u>OPERATOR TRAINING classes by EBAT certified instructors</u> | <u>NUMBER CERTIFIED by EBAT</u> |
| New Operator | 1,056 |
| Operator Update | 2,560 |
| Total Operators Certified by EBAT | 3,616 |
| TOTAL NUMBER CERTIFIED by EBAT | 4,221 |

ANNUAL PRODUCTION REPORT FY2006-2007 EVIDENTIAL BREATH ALCOHOL TESTING

| Alcohol Test Program (LEAF) | FY 06 | FY 07 |
|---|-------|-------|
| Technical and court assistance/expert testimony | 465 | 770 |
| Alcohol standard solutions | 2,160 | 2,040 |
| Breath test operator/instructor certification | 1,724 | 4,221 |
| Instrument certification | 368 | 480 |
| Facility on-site inspections | 109 | 105 |
| Number of facilities cited for deficiencies | 81 | 78 |
| Proficiency testing/quality assurance | 144 | 457 |
| Certified record and subpoenas processed | 851 | 1,080 |
| Alcohol class kits prepared | 195 | 157 |

EBAT Program laboratory



Certification Program

Certification programs are administered under various federal authorities, including:

Centers for Medicare and Medicaid Services - Clinical Laboratory Improvement Amendments (CLIA),

Food and Drug Administration (FDA),

Environmental Protection Agency Safe Drinking Water Act and

state Board of Health rules and regulations.

These authoritative agencies establish standards of performance that testing laboratories must meet to gain certification.

Laboratory Testing Quality Assurance Goals Required for Certification

- Ensure that all phases of the testing process are performed according to standard operating procedures.
- Ensure that all phases of the testing process are capable of providing quality results.
- Ensure that laboratory testing analysts are appropriately trained for procedures they are responsible for performing.

Essential Elements of Laboratory Operations

Essential Elements of Laboratory Operations

The 12 essential elements of laboratory operations are

- personnel qualifications;
- standard operating manuals;
- analytical processes;
- proficiency testing;
- quality control;
- security;
- chain of custody processes;
- specimen retention;
- work and storage space;
- records;
- results reporting;
- quality assurance.

The Laboratory Services Division **Certification Program** conducts on-site inspections on four types of testing laboratories:

clinical laboratories,
water-testing laboratories,
milk testing laboratories and
alcohol/drug/toxicology testing laboratories,

to ensure these laboratories meet certification standards in 12 essential areas.

Proficiency Testing

As part of the certification process, laboratories are required to receive samples from professional testing organizations and analyze the samples, using the approved methods for which they hold certification, to demonstrate laboratory proficiency.

The **Certification Program** reviews the results to verify the testing laboratory meets all criteria for initial or continued certification.

Certification Program

Certification by Type of Lab

Drinking Water Laboratories

The Safe Drinking Water Act is the main federal law that ensures the quality and safety of drinking water for Americans.

Either the Environmental Protection Agency or the state in which testing is performed must certify laboratories that analyze drinking water samples for compliance with the Safe Drinking Water Act.



The **Certification Program** conducts on-site inspections every two years for in-state drinking water testing laboratories and select out-of-state laboratories.

The lab maintains a current list of both in-state and out-of-state certified “safe drinking water testing laboratories” online at www.cdphe.state.co.us/lr.

The **Certification Program** also collaborates with the Colorado Department of Public Health and Environment’s Water Quality Control Division to stay abreast of new rules and regulations and reviews areas of these labs that are impacted by new changes to verify full compliance.

Change in test methods or the addition of new tests requires review by the Certification Program as well.

Milk Laboratories

In July 1969, the U.S. Food and Drug Administration (FDA) assumed responsibility for assisting states in preventing disease transmitted through milk.

The FDA promotes and helps ensure compliance with the model Laboratory Quality Assurance Branch, *Grade A Pasteurized Milk Ordinance* (PMO), a document that is recommended for legal adoption by states, counties and municipalities to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States.



In the state **Certification Program**, a milk laboratory evaluation officer (LEO) evaluates and certifies dairy testing laboratories to ensure compliance with the FDA’s Laboratory Quality Assurance Branch, *Grade A PMO*.

The LEO reviews the quality systems used by laboratories testing raw and finished milk products as well as dairy plants that perform antibiotic screening of bulk milk tankers.

The **Certification Program** evaluates proficiency-testing scores, conducts on-site inspections and reviews systems to ensure the milk testing laboratories meet all criteria for

Certification Program

Certification by Type of Lab

Clinical Laboratories

Under the Clinical Laboratory Improvement Amendments (CLIA), a clinical laboratory is defined as any facility that performs testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease; or impairment or assessment of health.

The U.S. Congress passed CLIA in 1988, establishing quality standards for all clinical-laboratory testing and placing all clinical laboratories under the authority of the amendments.

The Centers for Medicare and Medicaid Services administer CLIA at the federal level.



Clinical laboratories that receive Medicare or Medicaid payments must be CLIA-certified.

Colorado provides CLIA certification for in-state clinical laboratories.

As part of the certification process, CLIA clinical laboratories are required to analyze proficiency-testing samples three times per year in the same manner and by the same individuals as those performing the patient testing.

The **Certification Program** conducts required on-site inspections every two years to ensure sustained compliance with CLIA requirements.

Alcohol and Drugs/Toxicology Laboratories

Under the Colorado Department of Public Health and Environment's Rules and Regulations Concerning Testing for Alcohol and Other Drugs, the **Certification Program** annually inspects all law enforcement intoxication and drug laboratories that perform tests on subjects arrested under substance abuse laws as they relate to driving and issues certifications when facilities demonstrate compliance with department standards.

The certified laboratories perform tests for one or more of the following:

- blood alcohol
- delayed breath alcohol
- blood drugs
- urine drugs



As part of the certification process, Alcohol and Drugs/Toxicology Laboratories are required to analyze proficiency-test samples from commercial vendors three times per year.

The **Certification Program** evaluates the results of the proficiency testing and also conducts required on-site audits annually.

Branch Laboratory – Grand Junction, Colorado

The Colorado Department of Public Health and Environment maintains a **Branch Laboratory** in partnership with the Mesa County Health Department on the western slope of Colorado.

The laboratory is located in the Mesa County Health and Human Services building in Grand Junction.



Services offered include water testing, syphilis serology testing, Group A Streptococcus testing, bioterrorism support, animal-borne disease detection and state-supported milk testing for dairy producers.

The **Branch Laboratory** is one of six regional laboratories in the state designated to perform DNA testing using real-time polymerase chain reaction technology, which extends and enhances current diagnostic capabilities.

The Branch Laboratory is currently using this platform for West Nile virus surveillance.



| Grand Junction Laboratory | FY 06 | FY 07 |
|--|------------------------------------|---------------------|
| <i>Environmental Microbiology</i> | <u># of tests performed</u> | |
| <u>Water Bacteriology</u> | | |
| Samples Tested | 3,851 | 3,283 |
| QA/QC | 127 | |
| <u>Milk Bacteriology</u> | | |
| Samples Tested | 610 | 414 |
| QA/QC | 444 | |
| <i>Total Environmental Microbiology</i> | <i>5,032</i> | <i>3,697</i> |
| <i>Public Health Microbiology</i> | | |
| Streptococcus Cultures | | |
| Specimens | 2,373 | 2,485 |
| Positives | 755 | 612 |
| Neisseria | | |
| Specimens | 0 | 0 |
| Positives | 0 | 0 |
| Syphilis Serology (RPR) | | |
| Specimens | 211 | 123 |
| Positives | 3 | 0 |
| Chlamydia Specimens | | |
| Tested by DNA Probe | 0 | 0 |
| Positive | 0 | 0 |
| West Nile | | 0 |
| Bird/Mosquito Specimens | 324 | 465 |
| Positive | 90 | 45 |
| <i>Total Public Health Microbiology</i> | <i>2,908</i> | <i>3,073</i> |
| Total PH Microbiology Positives | 848 | 657 |

Appendix A: Workload Reports

Workload reports represent work performed during fiscal years.

Fiscal year (FY) 06 = July 1, 2005 – June 30, 2006

Fiscal year (FY) 07 = July 1, 2006 – June 30, 2007

Chemistry Program

| ORGANIC CHEMISTRY | FY 06 | FY 07 |
|--------------------------------|------------------------------------|--------------|
| <i>Sample Submitter</i> | <i># of tests performed</i> | |
| Hazardous Waste | 61 | 17 |
| Water Quality Control Division | 24 | 11 |
| Permits | 0 | 0 |
| Cash - Municipal | 1,372 | 1,849 |
| Cash - Private | 298 | 192 |
| Dental Health | 0 | 0 |
| Consumer Protection | 12 | 14 |
| Air Pollution | 0 | 0 |
| Other Tests | 107 | 75 |
| Quality Control Audits | 49 | 45 |
| Total Analyses | 1,923 | 2,203 |
| Total # of Specimens | 304 | 324 |

| INORGANIC CHEMISTRY | FY 06 | FY 07 |
|--------------------------------|------------------------------------|---------------|
| <i>Sample Submitter</i> | <i># of tests performed</i> | |
| Hazardous Materials | 418 | 34 |
| Water Quality Control Division | 23,269 | 23,493 |
| Permits | 418 | 139 |
| Cash - Municipal | 4,909 | 6,641 |
| Cash - Private | 3,217 | 4,462 |
| Dental Health | 1,429 | 753 |
| Consumer Protection | 24 | 53 |
| Special Tests | 0 | 0 |
| Air Pollution | 0 | 0 |
| Colorado Geological Survey | 0 | 0 |
| Other Tests | 149 | 413 |
| Quality Control Audits | 149 | 93 |
| Total Analyses | 33,982 | 36,081 |
| Total # of Specimens | 5,625 | 5,739 |

| RADIOCHEMISTRY | FY 06 | FY 07 |
|--|------------------------------------|--------------|
| | <i># of tests performed</i> | |
| <i>Radiochemistry Sample Submitter</i> | | |
| Cash Funded | 226 | 228 |
| Rocky Flats Program | 2 | 95 |
| Hazardous Materials (non-Rocky Flats) | 0 | 138 |
| Water Quality Control Division | 2 | 258 |
| Other Agencies | 275 | 202 |
| Quality Control Audits | 9 | 21 |
| Total Analyses | 514 | 942 |
| <i>Radiation Counting Facility Analyses</i> | | |
| C-14 | 19 | 14 |
| Gamma Spectroscopy | 80 | 71 |
| Gross Alpha/Beta water | 122 | 108 |
| Gross Alpha/Beta contamination survey | 92 | 244 |
| Ni-63 Contamination surveys | 19 | 17 |
| Radon 222 | 32 | 36 |
| Radium 226 | | 72 |
| Radium 228 | | 97 |
| Americium 241 | | 17 |
| Plutonium-238/239 | | 20 |
| Isotopic thorium | | 54 |
| Isotopic uranium | | 173 |
| Total uranium | | 49 |
| Whole Body Counts | 90 | 9 |
| Quality Control Audits | 4 | 51 |
| Total Analyses | 458 | 1032 |
| Total Number of Analyses | 1,482 | 2,865 |

| TOXICOLOGY | FY 06 | FY 07 |
|--|---------------|---------------|
| <i>Specimens</i> | | |
| Blood Alcohol | 4,548 | 5,524 |
| Blood drug samples | * | 500 |
| Methamphetamine Wipes | 47 | 31 |
| Urine Analyses | 2,627 | 18,895 |
| Confirmations | 3,082 | 3,541 |
| Total Specimens Received | 7,222 | 24,450 |
| Total Analyses (includes confirmations) | 22,549 | 24,421 |
| QA/QC | N/A | N/A |
| Total Analyses | 22,549 | 24,421 |
| Court Appearances | 108 | 95 |
| Litigation Packages | 339 | 385 |
| Total Samples | 6,836 | 7,540 |

*Blood drug analysis began in FY2007

Appendix A: Workload Reports

Workload reports represent work performed during fiscal years.

Fiscal year (FY) 06 = July 1, 2005 – June 30, 2006

Fiscal year (FY) 07 = July 1, 2006 – June 30, 2007

Microbiology Program

| MOLECULAR & VIROLOGY | FY 06 | FY 07 | MICROBIOLOGY | FY 06 | FY 07 |
|--|-----------------------------|--------------|--|-----------------------------|--------------|
| | <u># of tests performed</u> | | | <u># of tests performed</u> | |
| Tularemia | 393 | 521 | <i>Ova and Parasite Testing</i> | | |
| Positive | 34 | 25 | Specimens Examined | 1055 | 1003 |
| Varicella-Zoster Virus | 1 | 1 | Positives | 332 | 359 |
| Positive | 1 | 0 | Reference Bacteriology | | |
| Variola | 0 | 2 | Miscellaneous Cultures | 941 | 754 |
| Positive | 0 | 0 | <i>Y. pestis</i> (Plague) | 178 | 169 |
| West Nile, RT-PCR | | | <i>Y. pestis</i> (other) | 8 | 6 |
| Bird/Mosquito Specimens | 2,244 | 3,032 | <i>V. cholerae</i> (Vibrio) | 17 | 22 |
| Positive | 69 | 249 | <i>F. tularensis</i> (Tularemia) | 102 | 182 |
| Human | | 129 | <i>B. anthracis</i> (Anthrax) | 25 | 21 |
| Positive | 0 | 29 | Total Reference | | |
| Total Polymerase Chain Reaction | 5,079 | 6,751 | Identifications | 1271 | 1154 |
| Positives | 341 | 560 | Positives | 248 | 176 |
| <i>Influenza</i> | | | Specimens Submitted | 106 | 187 |
| Total Influenza A and B Cultures | 216 | 316 | Positives | 62 | 73 |
| Influenza A Positive | 74 | 126 | Streptococcus Culture | | |
| H1 Positive | | 51 | Specimens (Group A, Group | | |
| H3 Positive | | 56 | B, Strep pneumoniae) | 460 | 635 |
| Influenza B Positive | 10 | 14 | Positives ² | 87 | 3 |
| Total Virology | 388 | 624 | Tuberculosis Specimens | 1,343 | 1,779 |
| Total Virology Positives | 11 | 14 | Isolates: | | |
| OTHER PROGRAMS | | | <i>M. tuberculosis</i> Complex | 9 | 14 |
| <i>Biowatch (Federally staffed)</i> | | | Avium Complex | 0 | 0 |
| Screens (<i>Non-Add</i>) | 4,000 | 4,015 | Smear Positive | 33 | 59 |
| | | | Culture Positive | 58 | 85 |
| TOTAL TESTS | | 8,473 | ⁴ The Virology and Public Health Microbiology | | |
| TOTAL ABNORMALS | | 574 | laboratories submit specimens of sera and cultures | | |
| | | | to the Centers for Disease Control for the | | |
| | | | investigation of viral, bacterial and mycological | | |
| | | | agents. | | |
| | | | TOTAL TESTS | 43,279 | |
| | | | TOTAL ABNORMALS | 3,281 | |

Appendix A: Workload Reports

Workload reports represent work performed during fiscal years.

Fiscal year (FY) 06 = July 1, 2005 – June 30, 2006

Fiscal year (FY) 07 = July 1, 2006 – June 30, 2007

Microbiology Program

| SEROLOGY | FY 06 | FY 07 |
|-----------------------------------|-------------------|--------------|
| <i>Elisa Serology</i> | # of tests | |
| Measles IgM | 3 | 3 |
| Positive | 0 | 0 |
| Mumps IgM | 0 | 1 |
| Positive | 0 | 0 |
| West Nile Virus | 84 | 129 |
| Positive | 13 | 29 |
| Hantavirus | | |
| Human IgG | 137 | 122 |
| Reactive | 2 | 3 |
| Human IgM | 137 | 122 |
| Reactive | 4 | 9 |
| Rodent IgG | 0 | 0 |
| Reactive | 0 | 0 |
| Total ELISA Analyses | 361 | 377 |
| Total ELISA Positives | 19 | 41 |
| <i>Febrile Serology</i> | | |
| Brucella | 11 | 156 |
| Positive | 2 | 0 |
| Tularemia | 0 | 0 |
| Positive | 0 | 0 |
| Total Febrile Analyses | 11 | 156 |
| Total Febrile Positives | 2 | 0 |
| <i>Hepatitis Serology</i> | | |
| Hepatitis A | 22 | 6 |
| Reactive | 4 | 0 |
| Hepatitis B Surface Antigen | | |
| Refugee sera | 520 | 394 |
| Reactive | N/A | |
| Anti-Hepatitis B Surface Antibody | | |
| Refugee sera | 520 | 395 |
| Reactive | N/A | |

| SEROLOGY | FY 06 | FY 07 |
|---|-------------------|--------------|
| <i>Coxiella burnetii (Q fever)</i> | # of tests | |
| Phase I | 98 | 5 |
| Phase I Positive | 40 | 0 |
| Phase II | 98 | 5 |
| Phase II Positive | 53 | 2 |
| Total IFA Serology Analyses | 205 | 10 |
| Total IFA Serology Positives | 95 | 2 |
| <i>Plague – Animal</i> | | |
| Total plague specimens | 85 | 502 |
| Testing positive | 15 | 61 |
| <i>Plague – Human</i> | | |
| Total plague specimens | N/A | 18 |
| Testing positive | N/A | 2 |
| <i>Rabies</i> | | |
| Specimens Examined | 593 | 800 |
| Specimens with bite exposure | 299 | 309 |
| Specimens Testing Positive | 34 | 59 |
| <i>Rubella Serology</i> | | |
| Premarital Specimens Total | 2 | N/A |
| Specimens with titer <1:10 | 0 | N/A |
| Miscellaneous | 0 | N/A |
| Positive | 0 | N/A |

Appendix A: Workload Reports

Workload reports represent work performed during fiscal years.

Fiscal year (FY) 06 = July 1, 2005 – June 30, 2006

Fiscal year (FY) 07 = July 1, 2006 – June 30, 2007

Newborn Screening

| NEWBORN SCREENING <i>Submitter State</i> | FY 06 (7/1/05 – 2/22/06) | | FY 07 (7/1/06 – 6/30/07) | |
|---|---|-----------------------|---|-----------------------|
| | <i>Number of Specimens</i> | <i>Total Analyses</i> | <i>Number of Specimens</i> | <i>Total Analyses</i> |
| Colorado | | | | |
| Initial Screen | 42,354 | 300,713 | 70,165 | 2,034,785 |
| Second Screen | 40,913 | 290,482 | 65,578 | 459,046 |
| Totals - Colorado | 83,267 | 591,195 | 135,743 | 2,493,831 |
| Wyoming | | | | |
| Initial Screen | 4,086 | | 7,254 | |
| Second Screen | 1,774 | | 5,164 | |
| Totals - Wyoming | 5,860 | 30,785 | 12,418 | 246,514 |
| *Other – Initial Screen | <i>Totals listed by state/country below</i> | | 4756 | |
| *Other – Second Screen | <i>Totals listed by state/country below</i> | | 2526 | |
| Arizona | 2,657 | 18,865 | <i>*Beginning July 1, 2006, states other than Colorado and Wyoming are categorized as "Other"</i> | |
| California | 500 | 3,550 | | |
| Texas | 160 | 1,136 | | |
| Nebraska | 1 | 7 | | |
| S. Dakota | 1 | 7 | | |
| Guam | 1,644 | 11,672 | | |
| Japan | 647 | 4,594 | | |
| New Mexico | 9 | 64 | | |
| Totals - Other | 5,619 | 39,895 | | |
| TSH | | 9,297 | | 31,089 |
| QA/QC | | 33,094 | | |
| GRAND TOTALS | 94,746 | 704,266 | 155,443 | 2,927,040 |

| Abnormal Newborn Screening Results | FY 03 | FY 04 | FY 05 | FY 06 | FY 07 |
|--------------------------------------|--------------|--------------|--------------|--------------|--------------|
| Congenital Adrenal Hyperplasia (CAH) | 385 | 286 | 177 | 406 | 814 |
| Hemoglobin Abnormals | 3,875 | 3,567 | 3,814 | 2,242 | 2,920 |
| Phenylketonuria Abnormals | 146 | 214 | 177 | 90 | 66 |
| Biotinidase Deficiency Abnormals | 51 | 48 | 111 | 54 | 204 |
| Hypothyroidism Abnormals | 1,895 | 1,475 | 1,505 | 866 | 741 |
| Cystic Fibrosis Abnormals | 330 | 345 | 428 | 218 | 179 |
| Galactosemia Abnormals | 9 | 23 | 6 | 3 | 3 |
| MCAD (MS/MS) | N/A | N/A | N/A | N/A | 57 |
| Other MS/MS Abnormals | N/A | N/A | N/A | N/A | 752 |
| Total Abnormals | 6,691 | 5,958 | 6,218 | 3,879 | 5,736 |

Appendix B: Meetings, Conferences and Training

Laboratory analysts and management staff attend meetings, conferences and training throughout the fiscal year to network with national professional colleagues and stay apprised of new laboratory analytical technologies. Charts below provide a listing of all events attended during fiscal year 2006-07.

| Meeting/Conference | Lab Program Attending |
|---|---|
| 2007 American Water Resources Association Conference | Organic Chemistry |
| Public Health Laboratories Education Meeting | Organic Chemistry |
| Rocky Mountain Biomonitoring Consortium | Organic Chemistry |
| 2007 Association for Public Health Laboratories (APHL) Annual Meeting & First State Environmental Laboratory Conference | Chemistry & Inorganic Chemistry |
| Agilent GC/MS World Tour | Inorganic Chemistry & Toxicology |
| American Academy of Forensic Science Annual Meeting | Chemistry & Toxicology |
| Western Slope Infection Control Network Conference | Microbiology |
| 2006 Intermountain States Seminar; Region VIII American Society for Clinical Laboratory | Microbiology |
| 107th American Society for Microbiology General Meeting | Microbiology & Molecular/Virology |
| 2007 FoodNet Vision Meeting | Management |
| 2007 Newborn Screening and Genetic Testing Symposium | Newborn Screening |
| Newborn Screening Mid-Year Committee Meeting | Newborn Screening |
| Quality Assurance/Quality Control NBS Subcommittee Meeting | Newborn Screening |
| Intoxilyzer Users Group Conference | Evidential Breath Alcohol Testing Program |
| International Association for Chemical Testing Conference | Evidential Breath Alcohol Testing Program |
| Clinical Laboratory Improvement Amendments Western Consortium Meeting | Certification |
| Environmental Protection Agency- National Environmental Laboratory Accreditation Conference | Certification |

Appendix B: Meetings, Conferences and Training

| Chemistry Program Training | | | |
|---|---|--|----------------------------------|
| Training Title | Section Attending | Training Title | Section Attending |
| Is your Worksite Prepared for Emergencies? | Organic Chemistry | Chemistry Hygiene Officer Certification | Chemistry (Manager) |
| LT2 Enhanced SW Treatment Training | Organic Chemistry | The Secrets of Exceptional Gas Chromatography | Inorganic Chemistry |
| Toxic Chemical Exposures: Is Your Lab Prepared to Respond? | Organic Chemistry | M-8000 Mercury Analyzer Optimization and M-8000 Operational Training | Inorganic Chemistry |
| SPHL LRN Organophosphorus Nerve Agent Metabolites via Liquid Chromatography with MS/MS Deletion | Organic Chemistry | Perchlorate: Overview of Issues, Status and Remedial Options | Inorganic Chemistry |
| Chromera Short Course | Organic Chemistry | CDC Bioterrorism Focus Area D Training for ICP-MS Analyses | Organic & Inorganic Chemistry |
| CDC Bioterrorism Focus Area D Training for GC-MS Analyses | Organic Chemistry | CDC Chemical Terrorism Response Sample Packaging and Shipping Training | Inorganic & Organic Chemistry |
| Volatile Organic Compounds via Gas Chromatography with Mass Selective Detection | Organic Chemistry | Laboratory Productivity Seminar (FIA vs Discreet Analyze) | Inorganic Chemistry & Toxicology |
| Analysis of Cd, Hg and Pb in Blood by ICPMS | Organic Chemistry | Water and Wastewater Analysis | Inorganic Chemistry & Toxicology |
| LC/ICP-MS Instrumentation with Metal Speciation | Organic Chemistry | The Robert F Borkenstein Course on DUI: The Effects of Drugs on Human Behavior | Toxicology |
| Treatment Technologies for 1, 4-Dioxane: Fundamentals and Field Applications | Organic Chemistry | Optimal Combination of Emerging Biomarkers for the Accurate Detection of Alcohol Use and Abuse | Toxicology |
| EPA Webinar - Pharmaceuticals In The Environment | Organic, Inorganic Chemistry & Toxicology | The Analytical Basis of Forensic Toxicology | Toxicology (Manager) |

| Certification Program Training |
|---|
| CLIA Current Issues 2007: Proficiency Testing – The Performance Tool |
| Clinical Laboratory Improvement Amendments -- Basic and Beyond Training |
| Forum on Laboratory Accreditation |
| Environmental Protection Agency- Radiochemistry Assessors Training |
| CLIA Basic and Beyond Laboratory Surveyor Training Course |

Appendix B: Meetings, Conferences and Training

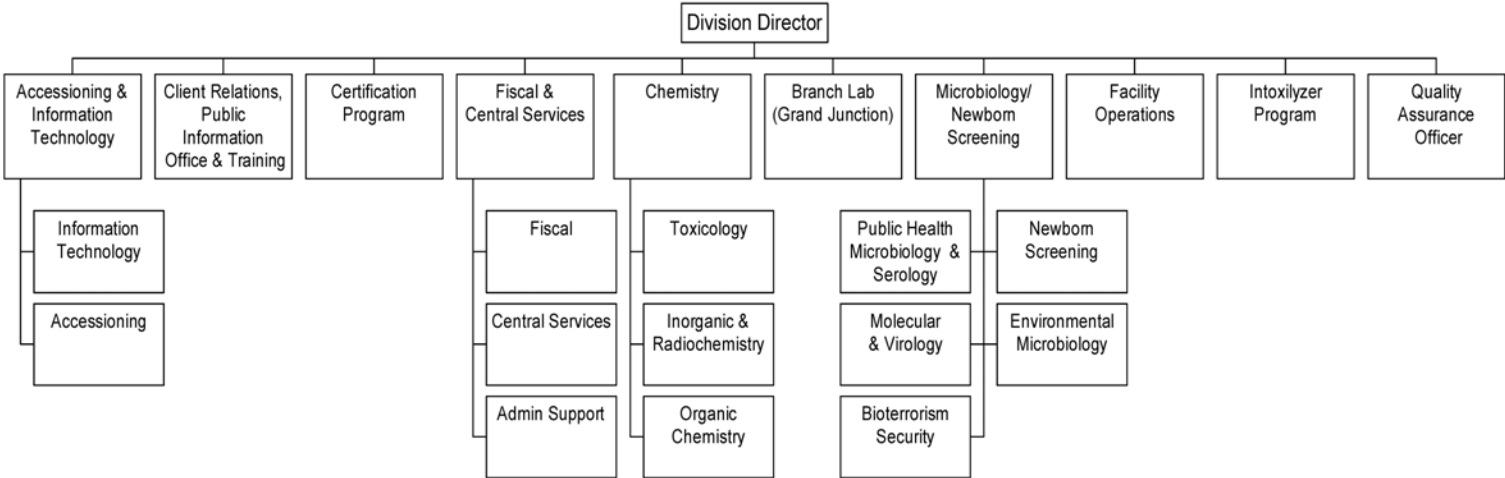
| Microbiology Program Training | | | |
|--|---|---|--|
| Training Title | Section Attending | Training Title | Section Attending |
| Convergence of Animal and Human Health in a New Era | Environmental Microbiology | <i>Campylobacter</i> Foodborne Illness | Public Health Microbiology |
| Laboratory Investigation of Foodborne Illness Public Health Series | Environmental Microbiology | Molecular Techniques for Parasitic Diseases | Public Health Microbiology & Molecular Science |
| Food Emergency Response Network Real Time PCR Training | Environmental Microbiology | Is Your Laboratory Secure? | Public Health Microbiology |
| Laboratory Detection of Food and Waterborne Viruses | Environmental Microbiology | Laboratory Response Network (LRN) Sentinel Laboratory Definition & Certificate Guidance | Public Health Microbiology |
| USPS Regulatory Changes for Packaging and Shipping | Environmental Microbiology | FBI Agroterrorism Workshop | Public Health Microbiology |
| Epi-Ready Team Training Food Borne Illness Response | Environmental Microbiology | CDC Training on Methods for Identification and Serotyping of <i>Salmonella spp.</i> | Public Health Microbiology |
| <i>Salmonella</i> Foodborne Illness | Environmental & Public Health Microbiology | QuantiFERON®-TB Gold test Implementation | Public Health Microbiology |
| Select Agent Regulations with Special Focus on Public Health | Public Health Microbiology Molecular-Virology | Mycobacteriology Series: Safety, Turn Around Time, And Newest Testing Methods | Public Health Microbiology |
| Laboratory Testing Algorithm for Pustular Rash Illness | Microbiology - Virology | The 2007 CLSI Standard for Susceptibility Testing | Public Health Microbiology |
| Verification of Infectious Disease Molecular Assays | Molecular Science & Virology | Micro Labs as a Sentinel for Emerging Infectious Disease | Public Health Microbiology |
| Is There Molecular Beyond PCR? | Molecular Science & Virology | LRN: Sentinel Lab's Role in Responding to BT or Emerging Infectious Diseases | Public Health Microbiology |
| <i>Salmonella</i> Serotyping Training | Molecular Science & Virology | Epidemiology of Community-Associated MRSA in the United States | Public Health Microbiology |
| Agents of Bioterrorism: LRN Rapid Detection Methods Update | Molecular Science & Virology | Community-Associated Methicillin-Resistant <i>Staphylococcus aureus</i> | Public Health Microbiology |
| Annual Influenza Update: Is Your Laboratory Prepared? | Public Health Microbiology, Molecular Science | Shiga Toxin Producing <i>E.coli</i> : Your Role in Discovering the Connection | Public Health Microbiology |
| Packaging and Shipping of Infectious Substances Workshop | Central Services (Shipping dept), Organic Chemistry, Molecular-Virology,, Environmental Microbiology, Public Health Microbiology, Serology, | Antimicrobial Resistance in Gram-Negative Bacteria | Public Health Microbiology |
| Transportation of Infectious Substances Course | Molecular, PH Microbiology, Serology | Hepatitis C - Understanding the Virus, Serology and Testing Algorithms | Serology |

Appendix C: Posters and Presentations

| Conference | Date | Location | Poster Title | Authors |
|--|-----------|------------------------|--|--|
| American Society for Microbiology 107 th General Meeting | May 2007 | Toronto, Canada | “Confirmation Testing and Pulsed-Field Gel Electrophoresis Typing of Four Brucella Isolates Received in a Three-Week Period: Implications for Bioterrorism Laboratory Response.” | Karen Xavier, James Beebe, PhD, Hugh Maguire, PhD, Justin Nucci, and David Heltzel (Laboratory Services Division) |
| American Society for Microbiology 107 th General Meeting | May 2007 | Toronto, Canada | "Improved Respiratory Virus Surveillance in Colorado Using a Luminex-Based Detection Assay" <i>(Also presented at the 2007APHL Annual Meeting, June 2007)</i> | Karlyn Beer, James Beebe, PhD, and Hugh Maguire, PhD (Laboratory Services Division) |
| 2007 Newborn Screening and Genetic Testing Symposium | May 2007 | Minneapolis, Minnesota | “Detection of 3-methylglutaconic Aciduria in a Newborn and Later in a Male Sibling.” | Jeff Rivera, James Beebe, PhD, Daniel Wright and Cory Porter (Laboratory Services Division), and Erica Savino and Renata Gallagher (The Children’s Hospital’s Clinical Genetics and Metabolism Program) |
| 2007 Newborn Screening and Genetic Testing Symposium | May 2007 | Minneapolis, Minnesota | “Detection of Congenital Adrenal Hyperplasia (CAH) by First and Second Screens in Colorado, 2000-2006.” | Laura Taylor (Prevention Services Division - Newborn Hearing and Screening Program), James Beebe, PhD and Daniel Wright (Laboratory Services Division), and Phillip Zeitler, MD (University of Colorado at Denver and Health Sciences Center). |
| 2007 APHL Annual Meeting & First State Environmental Laboratory Conference | June 2007 | Jacksonville, Florida | “Rapid Analysis of Polonium-210.” | James Warren (Laboratory Services Division) |
| 2007 APHL Annual Meeting & First State Environmental Laboratory Conference | June 2007 | Jacksonville, Florida | “Planning for Radiological Emergencies” | Tony Harrison (Laboratory Services Division) |
| 2007 American Water Resources Association Summer Specialty Conference | June 2007 | Vail, Colorado | “Comparative Methods for the Trace Analysis of Volatile Organic Compounds in Complex Environmental Matrices.” | Patrick Ayres, Ashley Demander, Laurie Peterson-Wright, Michael Smith. |

Appendix D: Organizational Chart

Laboratory Services Division July 2007



Additional copies of this annual report are available at no cost by downloading from the Laboratory Services Division Website at: www.cdphe.state.co.us/lr

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