

State of Colorado



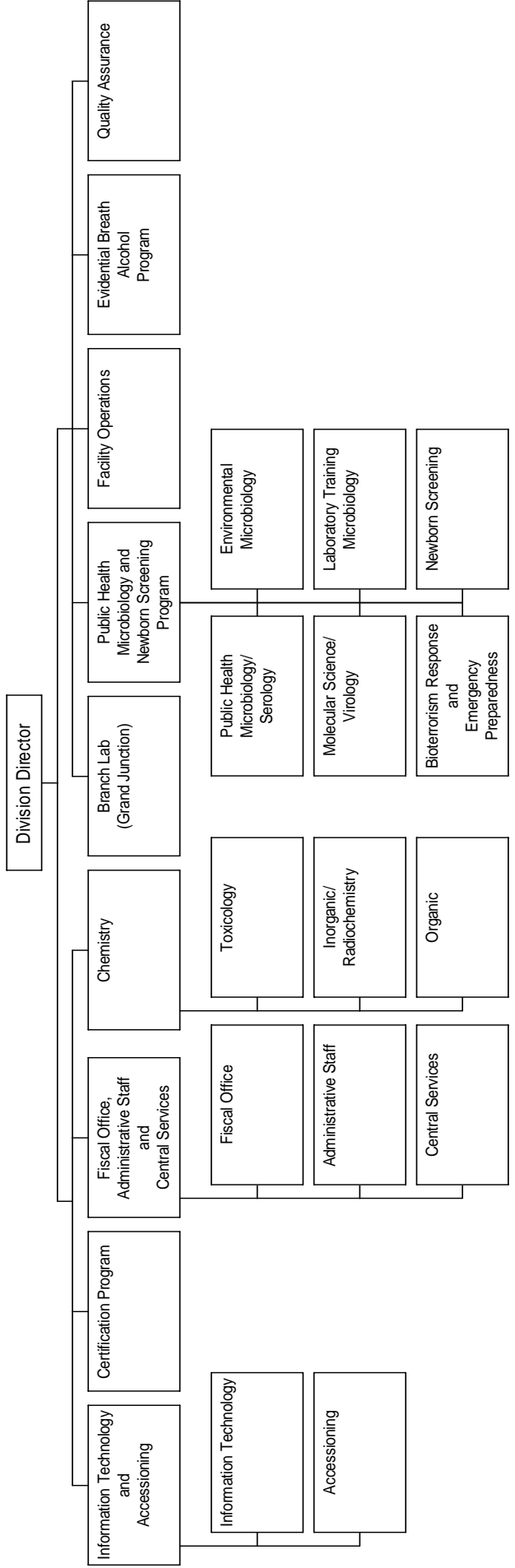
Colorado Department
of Public Health
and Environment

Laboratory Services Division

**Annual Report
Fiscal Year 2005 - 2006**



**Laboratory Services Division
Nov 2006**



STATE OF COLORADO

Bill Owens, Governor
Dennis E. Ellis, Executive Director

Dedicated to protecting and improving the health and environment of the people of Colorado

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Colorado Department
of Public Health
and Environment

September 26, 2006

Dear Customers:

I am pleased to present the Annual Report of the Laboratory Services Division for the fiscal year ended June 30, 2006. While some laboratory testing fees were modestly increased this year, most notably the Newborn Screening testing panel, some programs experienced a reduction in testing fees.

The division promulgated Newborn Screening Program regulations in preparation for the implementation of Tandem Mass Spectrometry testing. Tandem mass spectrometry has extended the program's testing capability by an additional 23 tests for metabolic disorders. This additional screening was successfully implemented July 1, 2006. A new instrument controller database was also implemented to replace an aging system that was no longer meeting the needs of the program.

Other changes include xeriscaping the grounds around the building for an estimated future savings of 1.3 million gallons of water each year. This project will result in substantial savings for the department.

While the design was completed on the All Hazards Triage and Response Laboratory, construction is on hold pending the identification of an adequate funding source.

Sincerely,

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

**Laboratory Services Division
Annual Report
Fiscal Year 2005 - 2006**

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Colorado Department of Public Health and Environment

Laboratory Services Division Annual Report FY2006

The mission of the Laboratory Services Division is to protect the health, safety and environment of all Colorado citizens from infectious and metabolic diseases, environmental pollutants and acts of terrorism by providing accurate and timely laboratory analyses and information. The Colorado Department of Public Health and Environment 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.

See the Laboratory Services Division's Web site at <http://www.cdphe.state.co.us/lr/lrhom.htm>

Director's Office

The Director's Office provides support in the form of management, policy review and direction to the Certification Program and the Chemistry, Microbiology, Newborn Screening and Grand Junction Branch Laboratories. The following staff areas provide support services:



- Fiscal Office, Administrative Services Staff and Central Services Unit
- Information Technology and Accessioning
- Facility Operations
- Quality Assurance

The division programs interact with customers through telephone calls, e-mail and walk-in visits. The Director's Office ensures that all the programs in the division provide exemplary customer service through timely and accurate delivery of results. *Customer Service Questionnaires* are distributed routinely and upon request. The division director reviews all returned questionnaires, replying to those with unresolved issues. He also initiates research and resolution of any problems or trends identified by the quality assurance committee and approves corrective action.

Quality Assurance

The division provides exemplary services through active review by a quality assurance officer and a quality assurance committee. The committee conducts internal audits, proficiency testing, procedure reviews and employee competency assessments. The division also complies with findings and recommendations from external audits.

The quality assurance officer, who reports to the director, oversees the activities of the quality assurance committee. The committee conducts internal inspections of all laboratories twice a year in addition to reviewing and resolving all other quality concerns.

Information Technology and Accessioning

The Accessioning manager supervises the Information Technology and Accessioning staff. Accessioning personnel receive all incoming specimens and samples, enter the information into the laboratory information system and route samples to the appropriate laboratories. Accessioning personnel provide most of the division's data entry, and the division databases are designed for ease of data entry.

Three Information Technology staff members manage databases for internal and external customers, providing information for use in reports and surveillance data for other divisions within the department. During the fiscal year, the Newborn Screening Laboratory replaced its old database with a new one in preparation for expanded testing. Accessioning personnel worked closely with the database provider to test the new database in parallel with the old



system. Testing was completed before the deadline and the new system is now fully operational.

Information Technology staff continued to update and improve upon the LITS+ database, provided to the division by the Centers for Disease Control and Prevention (CDC) five years ago. CDC released the Lits+ code to the state public health laboratory, and Information Technology staff is in the process of using the code to combine two information systems from the old LITS+ database into one database, to more efficiently provide information to users.

The Laboratory Services Division purchased its own server, which will generate interactive reports from customers' requests. Laboratory Information Technology personnel will maintain the server and provide services for laboratory customers. In the future, the division also will provide ordering forms and *Customer Service Questionnaires* that can be used interactively.

Facilities Operations

In FY2005, Laboratory Services Division employed a full-time facilities manager who reports solely to the division director. Currently, three employees report to the facilities manager.

Facilities Operations is responsible for maintaining all core building functions, including grounds, electrical, mechanical, plumbing, carpentry, emergency power, communications, security and safety.

During FY2006, the building grounds underwent a makeover that included xeriscaping and installing a new sprinkler system with more efficient water heads. It is estimated the xeriscaping and new sprinkler system installation will save 1.3 million gallons of water or more each year, resulting in substantial savings for the department.

A professional landscape architect designed the xeriscaping project. Two-thirds of the work was completed by

outside contractors. Facilities Operations staff completed the project, and division employees volunteered to plant annuals and pull weeds.

The grounds makeover included moving the Laboratory Services Division sign and flagpole adjacent to Fairmount Boulevard, increasing visibility to customers.

Fiscal Office, Administrative Staff and Central Services Unit

Background

The Fiscal Office, Administrative Staff and Central Services Unit report to the Laboratory Services Division's fiscal officer. The ten Fiscal and Central Services staff members oversee all financial transactions, purchasing operations, initial sample receiving and payment processing for the Laboratory Services Division.

During FY2006, Administrative Staff members were reassigned to the Fiscal Office and Central Services Unit. The Administrative Staff members provide administrative, professional and clerical support to the division's external and internal customers.

Customer Service

Personnel in the Fiscal Office and Central Services Unit interact with internal and external customers to provide laboratory supplies, requisition forms, payment options and receiving services, as well as to resolve invoicing and payment issues. *Customer Service Questionnaires* are distributed both by request and routinely as the transactions merit, and customer questions are researched in detail and answered quickly.

Staff members receive samples and process cash and credit card payments. They also prepare testing media and clean and sterilize test tubes, glassware and other supplies and equipment used by the lab.

Fiscal Office

The Fiscal Office manages all purchasing, accounts payable/accounts receivable, budgeting, federal grant, and cash fund functions for the Laboratory Services Division. The office establishes business plans and



Laboratory Services sign in its new location

practices to ensure optimal use of operating and personal service funding, provides information about the services of the division, responds to customer concerns regarding invoicing issues and provides financial information as needed.

In FY2006, the Fiscal Office developed, in conjunction with the Department's Accounting Office, a flat-file transfer of all electronic invoicing data to be uploaded directly into the department's accounts receivable system. The electronic transfer process decreases data entry errors and allows the department to electronically archive accounts receivable data.

Compliance

The Fiscal Office complies with all state of Colorado fiscal and procurements rules and regulations, as well as Colorado Department of Public Health and Environment guidelines.

Revenue

After reviewing the fee structure, cash revenues and FY2006 budget requirements, the Laboratory Services Division elected to continue most FY2006 fees at the same level as FY2005 pricing. In FY2006, the Laboratory generated nearly \$6 million in cash revenues.



Appropriations

For the FY 2005-06 Long Bill appropriations, see Figure 1, Laboratory Services FY2006 Funding Splits.

Central Services Unit

The Central Services Unit provides infrastructure support for the safe receipt, distribution and proper disposal of public health and environmental samples and specimens. The four-person staff autoclaves laboratory glassware and infectious substances, receives and distributes supplies and equipment to the division, provides materials management for laboratory consumable supplies, processes customer requests for supplies used in specimen collection and submission, and prepares media for use in the microbiology laboratories. The unit also oversees compliance with state-mandated document retention schedules and federal hazardous-waste storage and disposal guidelines.

During FY2007, the Central Services Unit, in collaboration with Laboratory Services Division's Information Technology staff and the laboratories, will refine the automated media-tracking database for improved laboratory testing services. The unit will also assess and modify the supply mail-out processes to improve customer service.

Administrative Staff

Four Administrative Staff members assist external customers by researching inquiries from customers, answering questions about tests, providing requested information to customers, publishing print materials and maintaining the Laboratory Services Division Web site. Administrative Staff members often work closely with personnel from other divisions to provide services requested by department customers. Internally, the Administrative Staff provides general office management and administrative functions.

Certification Program

The Certification Program encompasses four distinct regulatory programs

overseeing four types of testing facilities: clinical laboratories, water testing laboratories, milk testing laboratories and alcohol/drug/toxicology testing laboratories. The program is staffed with one program manager and three surveyors.

Customer Service

The Certification Program sends a *Customer Service Questionnaire* to each facility after its on-site inspection. Results are reviewed and researched, and any issues are resolved.

Oversight Through Certification

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 (EPA) Safe Drinking Water Act and state Board of Health rules and regulations. These rules and regulations establish standards of performance that testing laboratories must meet to gain certification. See Figure 2, Quality Assurance Goals.

As part of the certification process, laboratories are required to analyze proficiency-testing samples that contain analytes at levels unknown to the laboratory. These samples are provided by professional testing facilities. The laboratory determines analyte levels using the approved methods for which it holds certification, and submits the results for evaluation to the facility that provided the samples. The laboratory that is being tested and Health and Human Services Centers for Medicare and Medicaid Services (CMS) receive the results from the vendor. CMS maintains a database of results that is readily accessible by the Certification Program. The Certification Program reviews the results to verify the testing laboratory meets all criteria for initial or continued certification.

Certification Program surveyors conduct required on-site audits to ensure the laboratories meet certification standards in 12 areas. See Figure 3, Essential Elements of Laboratory Operation, on the next page.

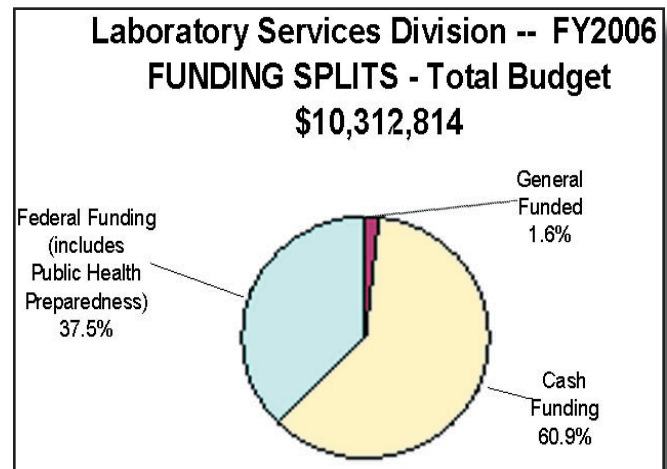


Figure 1: Laboratory Services FY 2006 Funding Splits
Total Budget \$10,312,814

Quality Assurance Goals

- 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 the staff is appropriately trained for procedures performed.

Figure 2: Quality Assurance Goals

Drinking Water Laboratory Certification

Any laboratory that analyzes drinking water samples for compliance with the Safe Drinking Water Act must be certified by the Environmental Protection Agency (EPA) or the state in which the testing is performed. The Certification Program maintains a current list of about 105 in-state and out-of-state certified laboratories online at <http://www.CDPHE.state.co.us/lr/Certification/SDWLIST.pdf>, or customers can obtain copies of the current list by calling (303) 692-3045.

Oversight

As part of the certification process, laboratories are required to analyze proficiency testing samples using the approved methods for which they hold certification. Additionally, Certification Program staff members perform on-site inspections every two years for in-state laboratories and selected out-of-state laboratories. Program staff works closely with the department's Water Quality Control Division. As the Water Quality Control Division develops and implements new rules and regulations, and as laboratories change methods or add new tests, the Certification Program verifies compliance with the modified or new needs. Between scheduled inspections, Certification Program staff members inspect areas of the laboratories and procedures that are affected by the changes, or areas where issues such as complaints or performance evaluation failures necessitate on-site evaluations.

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

Essential Elements of Laboratory Operation

The essential elements of laboratory operation are

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

Figure 3: Essential Elements of Laboratory Operation

Report

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.

Oversight

As part of the certification process, CLIA 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. Program staff conducts required on-site audits every two years to ensure sustained compliance with CLIA requirements. Staff members also investigate complaints involving clinical laboratories, usually by going on site and focusing on the specific complaint issues.

Training

State CLIA certification staff members attend training on new regulations, requirements and implementation strategies recommended by the Centers for Medicare and Medicaid Services. In partnership with the National Laboratory Training Network (NLTN), the department's CLIA Certification Program uses an educational approach to CLIA compliance.

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*, a document similar to the federal *Food Code*. In the state Certification Program, a milk laboratory evaluation officer evaluates and certifies dairy testing laboratories to assure compliance with the FDA's *Laboratory Quality Assurance Branch, Grade A Pasteurized Milk Ordinance*. The laboratory evaluation officer 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 milk laboratory evaluation officer inspects milk testing laboratories.



Oversight

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, verifying quality assurance.

Training

FDA's regional milk specialists offer seminars to state officials to promote uniformity in interpreting the *Laboratory Quality Assurance Branch, Grade A Pasteurized Milk Ordinance*, as well as on other issues such as laboratory analysis methods. The state laboratory evaluation officer attends training annually to maintain knowledge about FDA requirements for the program.

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

Oversight

As part of the certification process, Alcohol and Drugs/Toxicology Laboratories are required to analyze proficiency-test samples three times per year. Commercial vendors provide samples to the laboratories, evaluate the results and forward scores to the laboratories and to the Certification Program. Program staff members also conduct required on-site audits every year.

Evidential Breath Alcohol Testing Program

Background

The Intoxilyzer 5000 EN is the evidential breath alcohol-testing instrument used in Colorado. Only results from the Intoxilyzer 5000 EN can be used as evidence in court. One hundred eighty-five of these devices are located at 147 law enforcement agencies throughout the state. The instruments are certified, maintained and repaired by the Evidential Breath Alcohol Testing Program. Additionally, staff members conduct annual on-site evaluations of all law enforcement agencies that use these instruments. Training and certification are provided to intoxilyzer operators and operator instructors.

The program also pre-approves preliminary breath-testing devices, which are used by law enforcement to establish "probable cause" for arrest for driving under the influence. Preliminary breath-testing device results are not evidential, meaning result(s) obtained using these devices cannot be used as evidence in court.

Additionally, the program approves ignition interlock devices based on Colorado Department of Public Health and Environment *Rules and Regulations for the Approval of Breath Alcohol Ignition Interlock Devices*. The ignition interlock device may be installed by court order on a vehicle owned by a drunk-driving offender. The device prevents vehicle operation when the driver has alcohol in his/her system.

Program Tasks

Routine tasks in FY2006 included

- inspecting 147 intoxilyzer facilities in the state;
- troubleshooting and certifying 368 intoxilyzers;
- conducting six instructor classes;
- certifying a total of 90 instructors by class attendance and testing;
- re-certifying an additional 122 instructors by testing only;
- certifying 1,512 operators by class; and
- approving two ignition interlock devices and one preliminary breath testing device.



Evidential Breath Alcohol Testing Program staff teaches intoxilyzer operator classes.

Program staff testified in court in 10 cases in which the defendant challenged the intoxilyzer test results. The program also responded to 727 record requests from defense attorneys and prosecutors.

Training

Annually, the program offers six law enforcement officer instructor classes of up to 14 students in each class. The instructors train and certify the law enforcement officer operators in their own agencies, with direct oversight by the Evidential Breath Alcohol Testing Program.

In August 2005, program staff hosted the *Intoxilyzer 5000 EN Users' Group Meeting* in Steamboat Springs, Colo. Representatives from states that use this instrument attend this conference to stay abreast of new products and techniques presented at lectures and demonstrations. This year's conference included attendees and speakers from throughout the United States, as well as England, Australia, New Zealand, Canada and Norway.

During the last half of FY2006, the Evidential Breath Alcohol Testing Program staff worked on proposed changes to the *Rules and Regulations Pertaining to Tests for Alcohol and Other Drugs*. The changes will implement SB 04-159, which allows

Rocky Mountain Biomonitoring Consortium

The Rocky Mountain Biomonitoring Consortium has established the following goals for its Biomonitoring Implementation Program:

- Increase laboratory capacity for measuring environmental toxicants in people.
- Determine whether an association exists between diabetes and levels of arsenic in people's urine.
- Determine the feasibility of using newborn screening blood spots in assessing baseline data on exposure to heavy metals.
- Determine the feasibility of using excess urine specimens from health clinics for baseline analysis, including analysis of agents used in chemical terrorism.
- Determine whether a difference in urine arsenic levels and arsenic speciation ratios can be detected in individuals exposed to various levels of arsenic in drinking water.

http://www.cdc.gov/biomonitoring/biomonitoring_grants.htm

Figure 4: Rocky Mountain Biomonitoring Consortium (CDC)

the department to eliminate capture of a subject's breath sample and add a second breath testing-the-test sequence. The proposal will be taken to the Colorado Board of Health in September 2006. In conjunction with the rule changes, a new software package for the instrument is being evaluated.

Oversight

All law enforcement facilities must be certified by the Evidential Breath Alcohol Testing Program. As part of the certification process, facilities are inspected annually, and every instrument must be returned to the Evidential Breath Alcohol Testing Program for annual maintenance and recertification. The instrument ceases to operate if its recertification due date is exceeded and it has not been recertified.

Instrument operators earn certification by attending eight hours of classroom instruction, including comprehensive practical and written examinations. Operators are required to renew their certification every 180 days by performing a breath test in the presence of an operator instructor.

Operator instructors must be certified by attending 16 hours of classroom instruction provided by the Evidential Breath Alcohol Testing Program, including a comprehensive practical and written examination. Operator instructors must renew their certification every 12 months. To qualify to attend the operator instructor training, the person must be a certified operator.

In September 2005, the Intoxilyzer Program was removed from the certification program and the program manager now reports directly to the division director.

Chemistry Program

The Chemistry Program consists of the Organic Chemistry, Inorganic Chemistry, Radiochemistry, Toxicology, Chemical Terrorism Response, Human Biomonitoring and Consumer Protection Laboratories.

Customer Service

In FY2006, the Chemistry Program reviewed historical data and contacted the Water Quality Control Division to help develop groups of tests, or test "bundles," to determine water quality to meet diverse requirements. The bundles address testing needs such as potability, irrigation, livestock and poultry, bottled water distribution and real estate transactions. The bundles make it easier for occasional water testing customers to determine what tests they need.

Quality Assurance

The Chemistry Program is involved in toxicology, drinking water and wastewater proficiency testing programs. In addition, double-blind samples are run through the analytical process to test all areas of sample flow including login, final reporting and billing.

Chemical Terrorism Response Laboratory

While the Chemical Terrorism Response Laboratory specializes in identifying substances that might be the result of a chemical terrorism attack, its abilities also are used to analyze and identify any number of chemical contaminants that are not the result of attacks. In FY2006, the laboratory received a grant to purchase a tandem mass spectrometer with a liquid chromatograph for the analysis of nerve agent metabolites in urine. In March 2006, the laboratory analyzed 117 specimens from a public health agency regarding elevated urine arsenic values in Springer, N.M. Preliminary results were available in 24 hours.

An X-ray fluorescence instrument was purchased to provide rapid analysis of metals in swipes, soils and air filters. This instrument also can analyze paint chips for lead content.

Personnel attended a CDC-sponsored training on nerve agent metabolites in urine and metals in blood.

Future Goals

Program goals for FY2007 include developing testing methods for nerve agent metabolites in urine and metals in blood.

Human Biomonitoring

Human biomonitoring is the measurement of toxic substances in the human body. The purpose of human biomonitoring is to determine if an individual has been exposed to a toxic substance, how much of that toxic substance is in the body and whether the amount of the toxic substance in the body is enough to cause an adverse health effect. The goal is to test many individuals in the targeted population to establish the likelihood of exposure for persons living in the area.

Arizona, Colorado, Montana, New Mexico, Utah and Wyoming formed the Rocky Mountain Biomonitoring Consortium to address human biomonitoring needs in the Rocky Mountain West. See Figure 4 (opposite page) , for consortium goals.

To assist the New Mexico state public health laboratory, which did not have fully operational testing methodology, the CDPHE Chemical Terrorism response laboratory tested 400 combined urine and water samples for a sixteen metal panel.

Two studies that were initiated in FY2005 continued: a study of type-2 diabetes in the San Louis Valley and a study of arsenic in drinking water in New Mexico. A third study of arsenic in drinking water in Colorado was initiated in partnership with the University Health Science Center during FY2006.

The Human Biomonitoring Laboratory developed a method for determining the presence of manganese, copper, zinc and chromium in urine, and a separate method for measuring the concentration of fluoride in urine.

Personnel attended a CDC-sponsored training on volatile organic compounds in blood.

A direct mercury analyzer was purchased to test mercury levels in hair. The Western States Tracking and Biomonitoring Collaborative submitted a grant application to fund a Western States mercury-in-hair monitoring project.



Organic Chemistry

The Organic Chemistry Laboratory assists customers by

- analyzing environmental samples for contaminants of public health significance;
- assisting in the identification of chemical contamination in emergency situations; and
- providing analyses for contamination and levels of additives in foodstuffs and in public drinking water supplies.

Program Tasks and Quality Assurance

The Organic Chemistry Laboratory developed the capability to analyze for carbamate pesticides and diquat/paraquat.

The Organic Chemistry Laboratory responded to the need of a local health department and analyzed samples for permethrin and carbaryl, two insecticides used to treat mosquito pools. The concern was that the insecticides were contaminating a nearby stream.

Consumer Protection

The Consumer Protection Laboratory analyzes samples collected by the Consumer Protection Division and submitted by private individuals. The food samples are analyzed for volatile organic compounds, metals, fat fillers, preservatives, pH status and water activity. In addition the Consumer Protection Laboratory conducts Odor School training for local and county health inspectors.

The Consumer Protection Laboratory applied for FDA funding to expand its capacity and capability to respond to suspected threats of Colorado's food supply.

The laboratory successfully analyzed a challenge (radiologically-contaminated) sample from the FDA.

Inorganic Chemistry

The Inorganic Chemistry Laboratory analyzes drinking water, river water, air filters and plant effluents to support the monitoring and compliance efforts of department programs. Staff also assists in the identification of chemical contamination in emergency situations and analyzes drinking water for radiological parameters, such as gross alpha/beta, radium and uranium.

New Services

The laboratory purchased a direct mercury analyzer for the analysis of mercury in fish tissues and a low-level mercury analyzer to perform EPA method 1631. A microwave digestion unit was purchased to allow rapid sample preparation of difficult matrices such as soil, sludge, toenails and hair.

A method for detecting arsenite (As III) and arsenate (As V) in drinking water was developed to support two CDC-funded drinking water projects.

Toxicology

Toxicology Laboratory staff members

- analyze urine samples for abused drugs to assist law enforcement agencies in administering drinking and drugged driver laws;
- analyze blood specimens for alcohol, volatiles and drugs;
- analyze urine specimens from clients in substance abuse treatment programs and professional peer assistance groups; and
- testify in courts of law regarding the analysis, the effects of drugs on the human body and how the drugs affect human performance and driving.

The Toxicology Laboratory provided statistical data to the Colorado Department of Transportation with regard to the average blood alcohol content in Colorado for FY2006. The average blood alcohol content for driving offenses during this period was 0.168 grams of ethanol per 100 milliliter of blood. This statistic was helpful in determining that the blood alcohol content for a persistent drunk driver is 0.170 grams/100 milliliters, lowered from a previous determination of 0.200 grams/100 milliliters. The data provided was instrumental in the promulgation of new legislation, *House Bill 06-1171, Concerning Alcohol- and Drug-related Driving*



Laboratory personnel test stream water, private wells and public water supplies to ensure Colorado citizens consume clean, pure water.



Laboratory Services Division tests food from restaurants, grocery stores, and any other vendor that sells food to the public.



Offenses. The bill was signed by the governor on June 1, 2006.

The Toxicology Laboratory gathers statistics from local Drug Recognition Expert Programs in Colorado. This data is compared with other state Drug Recognition Expert Programs. The data in Colorado for FY2006 indicates that the Drug Recognition Expert Programs in Colorado were 98 percent correct in their assessment of drugged drivers.

During FY2006, Toxicology Laboratory staff dedicated more than 60 hours to training police officers, prosecutors, defense attorneys and organizations that work with impaired drivers.

New in FY2006

The Toxicology Laboratory now has the capability to perform drug blood analysis using enzyme-linked immunosorbent assay and gas chromatography-mass spectrometry confirmation. These analyses provide law enforcement with better tools to confirm impairment at the time of the traffic stop, accident or incident.

Radiochemistry

The Radiochemistry Laboratory analyzes water, air and soil samples for naturally occurring and man-made radioactive materials such as radium, uranium, radon, plutonium and americium; detects contamination in lungs and other body tissues of radiation workers by whole-body counting in order to evaluate hazards and recommend follow-up actions; and monitors contamination in laboratories and industrial settings to ensure the safe usage of licensed radioactive materials.

Program Tasks and Quality Assurance

The Radiochemistry Laboratory analyzes water samples from public water supplies and private customers to ensure compliance with water quality standards, soil samples for the department's Hazardous Materials

and Waste Management Division to assist in the cleanup of uranium mills and other contaminated sites and contamination-survey samples to assist licensees with documenting safe use of radioactive materials. As part of the closure of the Rocky Flats Environmental Technology Site, the laboratory completed the analysis of air samples, assisted in publication of the data and dismantled the air-monitoring network.

In support of the Water Quality Control and Hazardous Materials and Waste Management Divisions, the laboratory led a workshop for chemists from private labs in testing methods for the analysis of naturally occurring radioactive material in residuals from drinking water plants.

Analysis of drinking water samples for radium-228, uranium, radium-226 and gross alpha activity continued, as did lung and whole-body counting for uranium mill and other radiation workers. Other samples, ranging from gross alpha/gross beta radioactivity to nickel-63 and carbon-14 assays, were analyzed to support the radiation safety programs of radioactive materials licensees.

The laboratory maintained its drinking water certification by successfully analyzing proficiency-testing samples for gross alpha/beta, uranium, radium-226, radium-228 and gamma emitting radionuclides.

Microbiology and Newborn Screening Program

The Microbiology and Newborn Screening Program includes the Environmental Microbiology, Public Health Microbiology, Newborn Screening, Serology, Molecular Science-Virology and Bioterrorism Response Laboratories.

Public Health Microbiology

The Public Health Microbiology Laboratory initiated *Mycobacterium tuberculosis* nucleic acid (ribosomal RNA) amplification testing for specimens obtained from acid-fast smear-positive patients. This rapid test has allowed the definitive recognition of a tuberculosis patient within one day, as opposed to culture

and DNA probe hybridization techniques that take as long as two weeks.

The laboratory participated in outbreak investigations providing confirmation of isolates of *Salmonella*, *Shigella*, *Campylobacter*, shigatoxin-producing *E. coli* and *Vibrio* isolates from sporadic cases.

Analyses performed for significant outbreaks

- 7 *Salmonella*
- 1 *Shigella*
- 2 *E. coli* O157:H7
- 1 *Campylobacter*

The Public Health Microbiology Laboratory continued to confirm and refer isolates to the CDC under the National Antibiotic Resistance Monitoring System, FoodNet and Active Bacterial Core Surveillance programs for isolates of *Streptococcus pneumoniae*, Group A and B *Streptococci*, *Haemophilus influenzae* and methicillin-resistant *Staphylococci*. The laboratory also confirmed the following food-borne pathogens: *Salmonella*, *Shigella*, *Campylobacter*, shigatoxin-producing *E. coli* and *Vibrio* isolates.

A Public Health Microbiology Laboratory scientist reported on the study of the Biolog system at the American Society for Microbiology General Meeting in Orlando in May 2006, and also validated a micro-dilution antibiotic-susceptibility testing method for gram-negative bacteria.

The Public Health Microbiology Laboratory performed emergency testing services for the Denver Public Health Laboratory, performing amplification testing for chlamydia/gonorrhea screening from late January through May 2006. This service prevented the closure of the Denver Public Health Laboratory Sexually Transmitted Disease Clinic.

The Public Health Microbiology Laboratory confirmed multiple cases of *Salmonella typhi*.

Environmental Microbiology

The Environmental Microbiology Laboratory recovered *Campylobacter* from milk samples in the Colorado prison system. The campylobacteriosis outbreak matched the



pattern of two of the isolates from afflicted prisoners, as determined by pulsed-field gel electrophoresis testing. The laboratory also recovered *E. coli* O157 in a multi-state ground beef outbreak, determining the *E. coli* O157 matched the outbreak pattern.

The Environmental Microbiology Laboratory conducted on-site sample collections of water samples and analyzed 24 samples for a Legionella-case investigation for a Colorado Springs hospital.

FoodNet Program Retail Food Study

Throughout FY2006, the laboratory continued the CDC-FDA sponsored study of retail meats. The principal findings indicate that the recovery rate of *Campylobacter* in retail meat (chicken breast product) jumped from 35 percent in FY2005 to 55 percent during the first six months of 2006. For details of calendar year 2005 results, see Table 1 on the next page.

Serology

A cutover from a legacy HIV information system to the laboratory LITS+ database system with electronic reporting to the Disease Control and Environmental Epidemiology Division CTR system was completed in August, with a three-week parallel entry in the two systems in August 2005.

A serology scientist attended training on botulinum-toxin testing at the Alaska Public Health Laboratory in Anchorage, Alaska, in December 2005.

Two serology staff scientists performed a FDA-sponsored validation study for the development of a new serologic assay for pertussis.

A serology scientist validated and performed testing using a new enzyme immunoassay for a serologic survey for Q fever (*Coxiella burnetii*). The testing survey was performed on residents of Colorado City, Colo., who live within one mile of a ranch where an outbreak of Q fever was discovered in September. Of 159 specimens tested, 8 percent were positive.

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The Serology Laboratory performed necropsy and direct fluorescent antibody analyses for plague and tularemia on approximately 300 mammal carcasses for the zoonoses surveillance program. Eighteen percent were positive for plague and 3 percent were positive for tularemia. In 30 feline samples, 43 percent were positive. Numbers of rabies analyses reached new levels for the 2005-2006 season.

Molecular Science-Virology Laboratory

The Molecular Science-Virology Laboratory continued its forward-looking activities in both training and development related to endemic and emerging pathogens of public health importance. Through grant-supported federal programs, the lab has put in place new instrumentation to support higher analytic throughput with a commensurate increase in test sensitivity and specificity. The nine experienced staff members of the Molecular Science Laboratory demonstrate unique expertise in multiple areas of molecular diagnostics. Their testing skills complement each other in determining and confirming results. During outbreak investigations, their testing activities quickly determine the causative agent and confirm the results.

Pulsed-field Gel Electrophoresis (PFGE)

The capabilities of pulsed-field gel electrophoresis were enhanced by the installation of new, upgraded analytic software that allowed a more detailed analysis of molecular-typing data. When coupled with the existing technology available in our laboratory, the new software facilitates a more extensive exchange of molecular-typing data between Laboratory Services Division staff members and their counterparts at the CDC through the nationwide *PulseNet* organization. This enhancement is of particular importance as the lab analyzed and communicated to the public health community the restriction enzyme profiles of more than 1,000 isolates during the fiscal year. These analyses included, but were not limited to, *E. coli*, *Salmonella*, *Shigella*, *Campylobacter* and *Staphylococcus* species. These data were used in support of a myriad of outbreak investigations and to establish linkages with isolates appearing in other states.

Retail Food Study, Calendar Year 2005		
Type of Meat Tested		Totals
Chicken	Total samples	120
	<i>Campylobacter</i> positive	34%
	<i>Salmonella</i> positive	10%
	Percent positive	44%
Turkey	Total samples	120
	<i>Campylobacter</i> positive	0%
	<i>Salmonella</i> positive	14%
	Percent positive	14%
Pork	Total samples	120
	<i>Campylobacter</i> positive	0%
	<i>Salmonella</i> positive	0%
	Percent positive	0%
Beef	Total samples	120
	<i>Campylobacter</i> positive	0%
	<i>Salmonella</i> positive	0%
	Percent positive	0%
Total Samples	Total samples	480
	Positive	70
	Percent positive	14.6%
Percentage: Number of positive samples divided by total number of samples for the type of meat tested.		

Table 1: FoodNet Sample Analysis



For her work establishing a statewide database and rapid typing of outbreak isolates, Scientist Ann Woo-Ming was named a recipient of the prestigious *PulseStar Award* from CDC. In June 2006, a new scientist joined the molecular typing group and quickly received *PulseNet* certification in the analysis of multiple bacterial species.

Methodology in polymerase chain reaction continues to evolve to meet the challenges presented by endemic and emerging pathogens. Surveillance programs are in place both year round and seasonally. The laboratory's Plague and Tularemia Program completed its second year and test volumes continue to increase. West Nile virus surveillance is now in its fifth year and it can be accurately projected that the lab will process more than 3,000 samples by the end of the 2006 season. Influenza testing was enhanced by full deployment of polymerase chain reaction technology in support of virus detection and will be used as the primary analytic method in the future.

Laboratory staff collaborated to successfully develop, validate and deploy new real-time polymerase chain reaction methods for the detection of Norovirus; *Shigella*; enterovirus; and *Parainfluenza* types 1, 2 and 3. Additionally, CDC-generated tests were activated for detection of poxviruses and avian influenza (H5N1).

In response to regional mumps outbreaks, over a period of 10 days the lab implemented and validated methods for both polymerase chain reaction and cell culture identification of the virus from clinical samples. The test remains an active offering by the lab and is used by numerous hospitals and clinics within the state.

Pertussis testing also is performed year-round on a daily basis. Staff process and report test results of approximately 1,000 samples per year, with a 24-hour turn-around for clinical health care providers and local health departments.

In addition to clinical illness, the

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laboratory also performs testing related to bioterrorism preparedness. Monthly proficiency testing is performed on unknown samples containing one or more select agents. The laboratory demonstrated its surge capacity by accepting and successfully completing a 100-specimen challenge.

In active response, staff responded to a Q fever outbreak and analyzed more than 100 samples from the affected site. Positive identification of the causative agent allowed appropriate health measures to be taken.

Staff responded monthly, on average, to requests from public health and clinical partners for confirmatory or rule-out testing for other select agent targets using polymerase chain reaction testing capabilities. These activities frequently led to more extensive analyses, such as DNA sequencing.

DNA Sequencing and Sequence Element Characterization

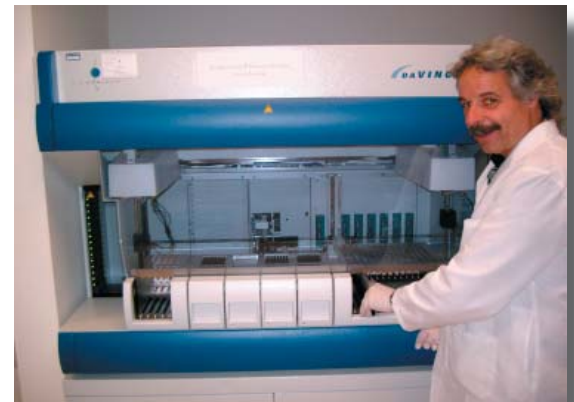
Sequencing determination was initially applied to Norovirus-containing samples as a demonstration of its utility. The technology is now an integral part of the characterization of Norovirus strains from outbreak samples submitted from agencies statewide. Sequences of virus-specific polymerase chain reaction products have been used to establish links between outbreaks and in the identification of a virus strain never before seen. The strain is now designated "Nucci" after its discoverer, Justin Nucci, a scientist in the Laboratory Services Division Molecular Science Laboratory.

This technology is now applied upon request to any viral or bacterial isolate that is accepted for testing by the state laboratory. A special application of DNA sequencing is used in response to the isolation of select agents from either clinical or environmental sources. This test capability has acquired stand-alone test status and is utilized by several area labs for both primary identification and for confirmation of preliminary results.

Multi-locus variable number of tandem repeat analysis (MLVA) is an extension of molecular typing methods and was developed in participation with CDC. The technology uses existing equipment and has elevated the analytic capabilities of the lab with regard to *E. coli* O157:H7 isolates. Owing to the successful deployment of this technology, the laboratory was selected by the CDC to participate in the charter development of a MLVA database and organizational network similar to PulseNet, described above.



Colonies of Escherichia coli bacteria are growing on blood agar culture medium.



Scientist working with the DaVinci automated specimen handling system that went online in the Serology Laboratory in FY 2006.



Professional Development and Training

Laboratory staff members provide training, participate in external training and attend national and international meetings throughout the year. The pulsed-field gel electrophoresis analysts attended a regional *PulseNet* meeting in Salt Lake City, Utah, and the national *PulseNet* meeting in Miami, Fla. Staff participated in training exercises to expand the number of bacterial types that can be analyzed using this technology, including most recently *Yersinia pestis*, the causative agent of plague. One analyst was selected to undergo training in the pulsed-field gel electrophoresis analysis of *Yersinia pestis* at the CDC-Fort Collins, Colo., campus. Other meetings attended by laboratory members focused on molecular diagnostics and emerging pathogens. Work completed independently in the laboratory or in collaboration with colleagues, both internal and external, resulted in co-authorship of a number of presentations at these scientific gatherings.

The Molecular Science Laboratory supervisor was invited by the Clinical Laboratory Improvement Amendments (CLIA) organization to speak at both regional and national meetings on the topic of *Polymerase Chain Reaction and Molecular Diagnostics*.

Other staff members have been directly involved in training local public health laboratory staff, clinical laboratory staff, medical technology interns, high school students and internal staff in polymerase chain reaction methodology and serve as consultants to those interested in establishing new molecular detection methods.

Bioterrorism Response and Emergency Preparedness

Quality Assurance

Proficiency testing programs have been extended to clinical (sentinel) and reference laboratories across Colorado. In addition to providing bimonthly internal proficiency testing for Public Health Microbiology, Serology and Molecular

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Science Laboratories at the Colorado Department of Public Health and Environment, the laboratory provided proficiency testing monthly to the Biowatch program, quarterly to six local health departments with biosafety level 3 (BSL-3) laboratories, and semi-annually to more than three dozen clinical and local health department laboratories. The result is an integrated, statewide network of laboratories experienced in working with bacterial select agents and able to quickly respond to both terrorist-initiated and naturally occurring biothreats.

Laboratory Services Division successfully met CDC standards and inspections, and its Select Agent Program Certification was renewed for another three-year term. Three local health department laboratories have joined the CDC's Laboratory Response Network, with three additional laboratories expected to achieve this status during the coming year. The Laboratory Services Division facilitated this process by training local health department staff, inspecting BSL-3 facilities and providing technical assistance to achieve Laboratory Response Network status.

Facility Improvements

The Bioterrorism Response Laboratory was renovated to include the installation of a solid, seamless ceiling; a HEPA-filtered exhaust system; and hands-free operated sinks and paper towel dispensers. Hand-held chemical and radiation detectors and a powder identification system have enhanced response capabilities. A multiplex system, capable of testing for several select agent bacteria and toxins simultaneously, improves surge capacity and reduces specimen-testing time.

Response Activities

Nearly 120 human, veterinary and environmental specimens were confirmed or tested presumptive positive for bacterial select agents during the year. These agents were responsible for brucellosis, plague, Q fever and tularemia. During the Q fever event, 112 specimens were collected from an infected goat herd and tested, and results were reported within 24 hours of receipt of specimens. A subsequent investigation of infected human residents in and around the site of the outbreak led to 158 serum specimens being delivered to the lab at one time. Testing

of the specimens was completed within 24 hours of receipt.

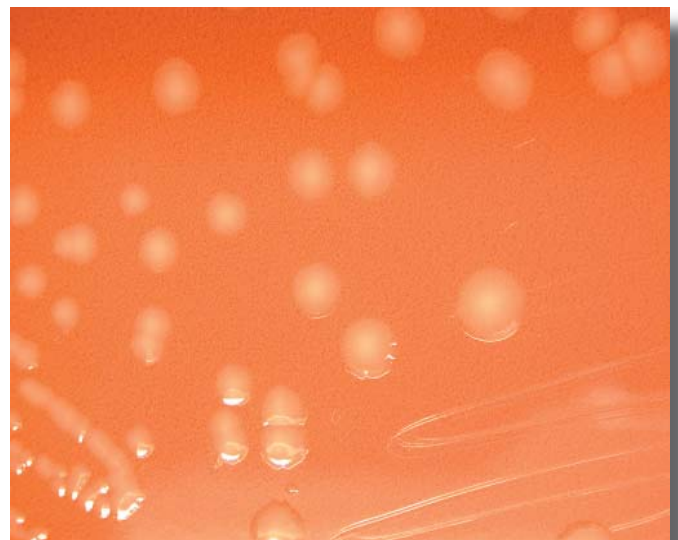
Bioterrorism Preparedness

A biothreat letter containing an unidentified powder was collected by the 8th Civil Support Team of the Colorado National Guard and delivered to the laboratory by the FBI. Laboratory personnel ruled out the presence of biological select agents within two hours of receiving the specimen. Laboratory Services Division response teams are on 24-hour call to respond to such events.

A 100-specimen surge capacity exercise was conducted jointly with the CDC-Division of Vector-borne Infectious Disease Laboratory at Fort Collins, Colo. Each facility received unknown specimens over a three-day period and conducted testing as if it were a real event. The exercise assessed the ability of each laboratory to test large volumes of specimens over an extended period of time. The exercise model and event results were successful and became the subject of a presentation to the 2006 International Conference for Emerging Infectious Diseases in Atlanta, Ga.

Laboratory Training

The Laboratory Services Division's state training coordinator, in collaboration with the National



H. influenzae has been cultured 72 hours on chocolate.



Laboratory Training Network, conducted an external training needs assessment with clinical laboratory supervisors to determine gaps in knowledge and training requirements and to develop an annual training plan. Collaborating with national training providers and local subject-matter experts, the state training coordinator delivered a variety of scientific laboratory training offerings to 300 laboratory professionals statewide.

The 2006 training year featured trainings via Webcast, teleconference, hands-on wet workshop and online-delivery formats. The launch of the online Laboratory Preparedness course resulted in enrollment of 180 laboratory professionals, representing more than one-half of the state's laboratorians who would respond in a covert bioterrorism threat.

Participation in the Laboratory Services Division's statewide proficiency testing challenge doubled this year when laboratory professionals at 36 facilities were sent interactive case studies supplemented with live unknown organisms to test their ability to identify these potential threats.

Colorado Laboratory Forum

The Colorado Laboratory Forum incorporates clinical, public health, forensic, veterinary, agricultural, military, federal and environmental laboratories. The forum convened two statewide conferences featuring scientific lectures by local physicians, Colorado Department of Public Health and Environment epidemiologists and speakers from the CDC and the FBI-Denver District Office. Collaborative learning through table-top exercises and Jeopardy!®-style challenges tested the rapid response of the Colorado laboratory professionals.

New in FY2007

The state training coordinator was assigned responsibilities for oversight of customer service and public information for the division. Two administrative staff positions have been reassigned to report to the new unit supervisor, including the

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Web coordinator/technical writer. The other position, a program assistant, coordinates travel for division training activities and will help with the customer service program.

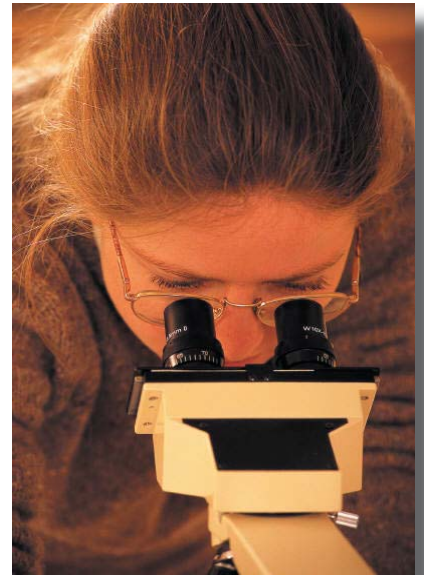
Newborn Screening

The Newborn Screening Program successfully transitioned to a new instrument controller/database system for processing newborn screening samples. During FY2006, the laboratory pilot tested and deployed tandem mass spectrometry technology to screen for 23 additional disorders as of July 1, 2006. The program added sections to the Newborn Screening Rules and Regulations to prepare for the new screenings. The new testing applies to first screenings for all Colorado and Wyoming newborns.

Branch Laboratory

The Colorado Department of Public Health and Environment maintains a Branch Laboratory in partnership with the Mesa County Health Department. 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, zoonotic disease support 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. Staff is currently using this platform for West Nile virus surveillance.



Laboratory Services Division continues to train local laboratorians.

Locations

Denver Laboratory

Colorado Department of Public Health and
Environment
Laboratory Services Division
8100 Lowry Boulevard
Denver, CO 80230-6928

Mailing address for samples/specimens:
PO Box 17123
Denver, CO 80217

(303) 692-3090 -- main telephone
(303) 344-9989 -- main fax
(303) 692-3074 -- bottle orders

Hours: 8 a.m. - 5 p.m.
Monday - Friday

Western Slope Branch Laboratory

Colorado Department of Public Health and
Environment
Laboratory Services Division
Mesa County Health Department
510 29 ½ Road
Grand Junction CO 81504

Mailing address:
PO Box 10,000
Grand Junction CO 81502

(970) 245-7800 -- main telephone
(970) 683-6608 -- main fax

Hours: 8 a.m. - 4:30 p.m.
Monday - Friday

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