QUALITY ASSURANCE MANUAL

December 2012

Laboratory Services Division

Colorado Department of Public Health

and Environment

8100 Lowry Boulevard

Denver, Colorado 80230

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Approved		**Date**
David A. Butcher, MBA, MT (ASCP) SM Division Director	_____	_____
Laura Gillim-Ross, Ph.D. Deputy Division Director	_____	_____
Richard Harris, Ph.D. HCLD (ABB) Laboratory Director	_____	_____
David Sikes, MS, MT Quality Assurance Officer	_____	_____

Table of Content

1. Introduction

1.1 This manual will be reviewed and approved annually by: The Laboratory Services Division Director, The Clinical Laboratory Improvement Act Director, and The Quality Assurance Officer. The dated signatures of the Laboratory Services Division Director, the Clinical Laboratory Improvement Amendment Director and the Quality Assurance Officer on the title page indicate approval of this manual.

1.2. This manual was written using the ISO 15189: 2003 format

1.3. The original manual will be maintained the QAO's office with an electronic copy found at I:\QA\QA Manual\ LSD QAM 2011.PDF

1.4. The effective date of this manual: December 20, 2012

1.5. This manual contains: 113 pages

1.6. The scope of this manual: To provide guidance that must be met by all personnel receiving, processing, testing, and / or posting results for any analyte tested at this laboratory or for any analyte that may be received by this laboratory and forwarded to another laboratory for testing. This manual contains the quality assurance principles constructed to ensure that analytical and support services provided by the Laboratory Services Division are of the highest quality. This manual is harmonized to applicable regulatory and certification requirements of U.S. federal agencies and professional societies.

1.7. The principles in this manual: Are implemented under the authority of the Laboratory Services Division Director through the Quality Assurance Officer with cooperation from the Quality Assurance Committee, Program Managers, and division staff. It provides policy and, where appropriate, procedural guidelines and requirements for the following units in the state laboratory in Denver, Colorado:

Public Health Microbiology
Molecular Sciences
Serology
Environmental Microbiology
Toxicology
Inorganic Chemistry
Newborn Screening
Radiochemistry analysis
Organic Chemistry
Filters LAB

This Quality Assurance Manual is intended to meet standards of the Clinical Laboratory Improvement Act and associated regulations, the National Environmental Laboratory Accreditation Conference, the Grade A Pasteurized Milk Ordinance of the Food and Drug Administration, EPA Safe Drinking Water Act, and analytical requirements of the Association of Analytical Chemists.

1.8. Revision of this manual: Any Laboratory Services Division employee may forward recommendations for change to his / her supervisor. Draft alterations are circulated electronically by the Quality Assurance Officer to the

Laboratory Services Division Director, Program Managers and other interested parties. All changes to this manual will be made by the Quality Assurance Officer.

1.9. This manual is intended: Internal use only. Release of this manual to outside agencies must first be approved by the Quality Assurance Officer and / or Laboratory Services Division Directory.

1.10. This manual is intended to be used by the:

The Colorado Department of Public Health and Environment
Laboratory Services Division
8100 Lowry Blvd
LAB Building
Denver, Colorado
80230

(303) 692-3090
Fax (303) 344-9989

2. Description of the Laboratory:

2.1. Scope of services: The Colorado Department of Public Health and Environment's Laboratory Services Division provides a unique integration of scientific analyses and regulatory programs that serve and protect the citizens of Colorado. The division functions as the state's principal public health and environmental laboratory.

2.2. Division History: In 1895, the State Board of Health established a small laboratory, in cooperation with the City of Denver, in Denver's City Hall. At that time, the laboratory's primary purpose was to perform *C. diphtheriae* culture work. During the laboratory's first year of operation, 1,487 examinations were conducted resulting in the recording of 224 cases of diphtheria in Denver, helping to isolate and limit this deadly disease. By 1923, the State Board of Health reported in its Biennial Report that in addition to performing tests for diphtheria, the laboratory was equipped to perform tests for syphilis and typhoid fever, examination of smears for various venereal diseases, examination of sputum for tuberculosis and detection of rabies virus. The Board also noted that the laboratory was capable of performing all analyses of water used for drinking and culinary purposes and food and drug analyses.

In 1941, the laboratory was officially viewed as a subdivision within the state's Division of Public Health.

In 1948, the department expanded laboratory services without charge to physicians, dentists and public health workers throughout the state. Restaurants were inspected; milk products were regulated, sanitized and pasteurized; and the department began exhaustive studies of stream pollution. The department also adopted new regulations on water supplies and plumbing.

In 1949, the state health department began licensing plants handling fluid milk for human consumption. These activities led to expanded laboratory activities.

In 1950, The laboratory conducted testing to determine the effects of exposure to small amounts of radioactive ores over a long period of time, the amounts and kinds of radiation existing in the mines and mills, the contamination of water supplies by radioactive materials, the effects of radiation on plant life and the effects that working radioactive ores have on persons living in the area.

In 1965, the state public health laboratory began testing newborns for Phenylketonuria (PKU), a disorder whereby the infant is unable to break down and use an essential amino acid building block, phenylalanine, resulting in mental retardation and in some cases, death.

In 2006 additional screening tests were added to the newborn test panel, to include Cystic Fibrosis and Tandem Mass Spectrometry technology was implemented with 23 additional disorders added to the screening panel.

Today the Laboratory Services Division offers over 290 laboratory tests and 14 services, to include expert testimony and on-site inspections and certifications as well as accredited training for testing professionals.

2.3. Vision of the Laboratory Services Division: The vision of the Division is to be recognized as an innovative and quality Public Health laboratory in the State of Colorado. As a leader in the industry, the Division will use advanced, leading edge technology, employ a highly skilled workforce, and have the respect of and support its customers, stakeholders, and partners. (October 15, 2004)

2.4. Mission of the Laboratory Services Division: The mission of the Laboratory Services Division is to protect the health, safety, and environment of all Coloradoans by providing accurate and timely laboratory analyses and information. (January 26, 2007)

2.5. Personnel Main Duties

2.5.1. Laboratory Services Division Director

2.5.1.1. Responsibilities: The Laboratory Services Division (LSD) Director is legally responsible for the quality of results produced in the laboratory and reported to clients. The LSD Director is the appointing authority as defined in the State of Colorado Statutes and Rules as assigned by the Executive Director of the Department.

2.5.1.2. Duties: Sets standards and policies for quality. Appoints a Quality Assurance Officer. Forms a QA Committee comprised of representative staff from each laboratory area involved in the pre-analytic, analytical, and post-analytic processes. Approves the hiring and promotion of qualified staff. Gives final divisional approval for Standard Operating Procedures (SOPs). Assures that LSD staff complies with state statutes and rules concerning confidentiality and proprietary rights. NOTE: The CLIA Lab Director has the responsibility of LSD Director for those lab programs certified under CLIA.

2.5.2. Quality Assurance Officer

2.5.2.1. Responsibilities: The Quality Assurance Officer (QAO) is responsible for implementing the quality assurance program established in this manual. The QAO reports to the LSD Director on issues relating to quality assurance.

2.5.2.2. Duties: Advises the LSD Director on quality assurance matters. Arranges or conducts directed evaluations (internal audits) of program activities to ensure conformance with policy and procedures. Monitors external proficiency testing (PT) or performance evaluation (PE) for trends or failure; report findings to Directors and Supervisors. Coordinates and schedules the QA Committee in the performance of monthly audits of program sample testing. Routinely evaluates compliance with SOPs and makes recommended changes necessary to improve quality. Reviews and approves SOPs for quality control compliance and proper format and recommends changes to the LSD Director for approval. Coordinates the selection and participation in PE, PT and other external audit studies (shared with LSD Director). Monitors historical performance on PE and PT material (shared with LSD Director). Coordinates with appropriate Program Managers to implement the quality assurance program established in this manual.

2.5.3. Quality Assurance Committee

2.5.3.1. Responsibilities: The Quality Assurance Committee will assist the QAO in carrying out audits and program reviews. Recommend changes necessary to reduce errors, correct deficiencies, and improve the quality of laboratory services.

2.5.3.2 Duties: Conduct monthly audits of the analytical process in each laboratory unit covering all steps in the pre-analytic, analytic, and post-analytic phases of testing to determine compliance with all SOPs and protocols. Provide an annual report to the Director on the overall effectiveness of the Quality Assurance Program as determined by the results of the quarterly assessments. Recommend changes in focus if necessary. Perform a trend analysis on customer complaints and recommend corrective actions necessary to improve service.

2.5.4. Program Managers and Supervisors

2.5.4.1. Responsibilities: The Program Managers and unit Supervisors are responsible for ensuring that services in their program comply with the quality assurance principles established in this manual.

2.5.4.2. Duties: Coordinate with the QAO to implement the quality assurance program established in this manual. Assess Professional Staff competency. Maintain initial staff SOP training records. Prepare and/or approve SOPs for technical accuracy and quality control compliance. Evaluate quality performance of program for which he/she has responsibility, and develop procedures to continually increase information quality. Review or delegate the review of all data and reports for accuracy and compliance with quality control requirements for release to clients. Activates corrective action investigations when necessary and forwards the program comments and suggestions to the LSD Director. Monitors daily operations of program to insure compliance with the quality control and confidentiality requirements. Coordinate with QAO for participation in external performance evaluations.

2.5.5. Professional Staff

2.5.5.1. Responsibilities: Professional Staff are responsible for performing tests and analyses in compliance with the quality control criteria established by this manual and program SOPs.

2.5.5.2. Duties: Perform tests and analyses in accordance with approved procedures and guidelines. Prepare complete and accurate SOPs incorporating required quality control actions. Prepare complete and accurate analytical reports as defined in program SOPs. Maintain instruments and equipment in accordance with program SOPs.

2.5.6. Administrative Staff

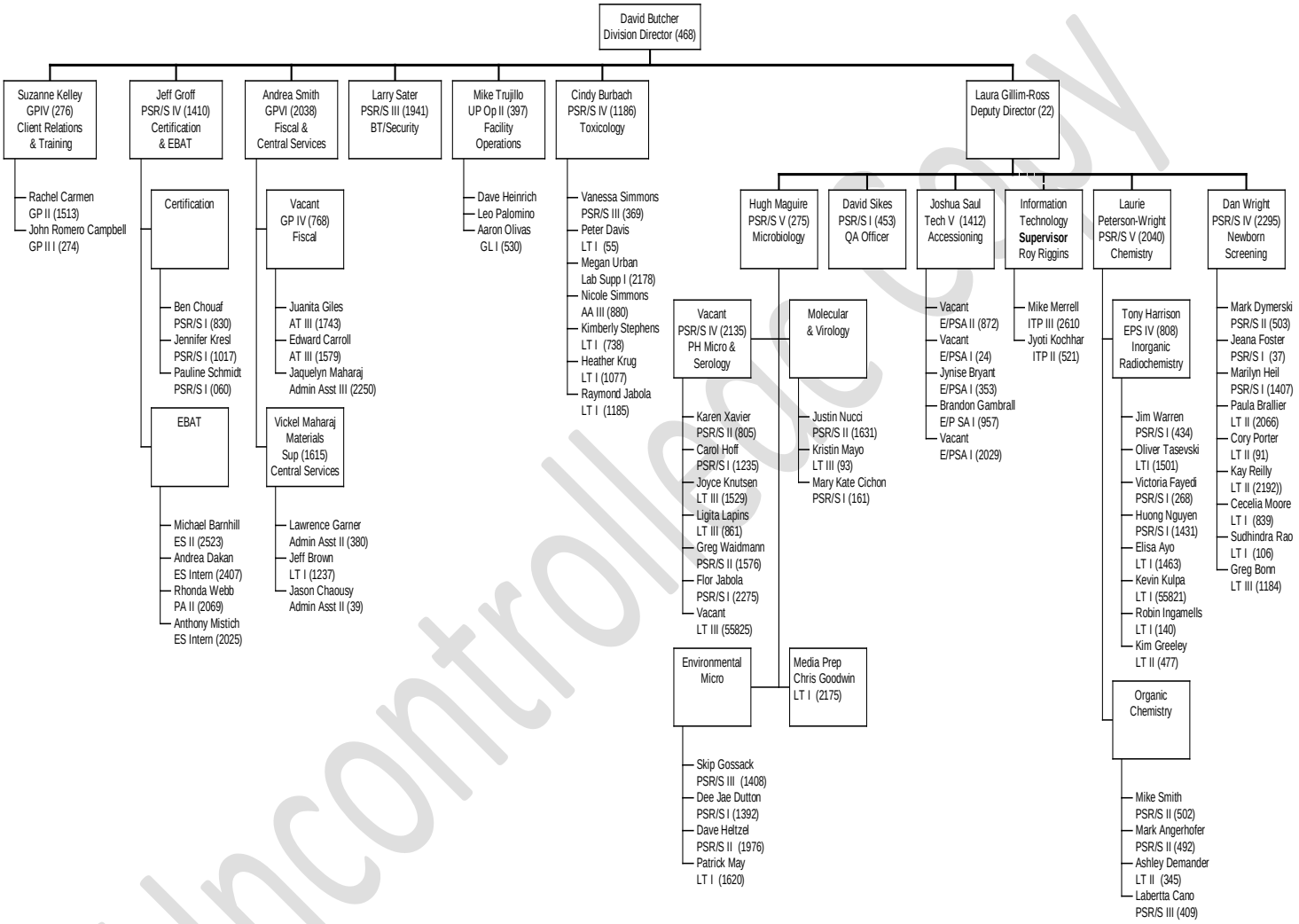
2.8.6.1. Responsibilities: Administrative Staff are responsible for preparing samples and specimens for laboratory analysis by receiving, unpacking, sorting, logging and applying quality assurance criteria, as detailed in Standard Methods for the examination of Water and Wastewater, CLSDI Document LA-A Blood Collection on Filter Paper for Neonatal Screening Programs, and CDPHE Laboratory and LITS+ SOP pertaining to milk samples, toxicology specimens, public health microbiology specimens, organic and inorganic chemistry samples, serology specimens and radiochemistry samples.

2.5.6.2. Duties: Receive and sort diverse types of environmental samples and human specimens for all laboratory areas and by test within laboratory area. Inspect for broken or leaking samples/specimens and other quality problems. Verify existing client record or create new client record in the laboratory information system for each sample/specimen received. Conduct login of sample and specimen demographic and test

order information. Assign a sequential laboratory number to each sample/specimen. Verify accuracy of client test orders entries and client information.

2.6. ORGANIZATION CHART

Laboratory Services Division
December 2012



3. QUALITY POLICY

The Laboratory Services Division of the Colorado Department of Public Health and Environment provides analytical services and scientific support to programs of the Department of Health, other state agencies, local agencies, and the citizens of Colorado to achieve public health objectives. Its mission is to:

Protect the health of all Coloradoans from infectious and metabolic diseases, environmental pollutants, and acts of terrorism by providing accurate and timely epidemiological and environmental laboratory analyses and information (testing, consultation, training, and certification) in support of healthcare providers, federal, state, and local public health and law enforcement agencies, companies, and individual citizens.

This manual contains the quality assurance principles constructed to ensure analytical and support services provided by the Laboratory Services Division are the highest quality. This manual is harmonized to applicable regulatory and certification requirements of U.S. federal agencies and professional societies.

The principles in this manual are implemented under the authority of the LS Director through the Quality Assurance Officer with cooperation from the Quality Assurance Committee, Program Managers, and division staff. It provides policy and, where appropriate, procedural guidelines and requirements for the following units in the state laboratory in Denver, Colorado:

Bacteriology,
Serology,
Environmental Microbiology,
Newborn Screening,
Toxicology,
Inorganic Chemistry,
Radiochemistry,
Organic Chemistry.

This Quality Assurance Manual is intended to meet standards of the Clinical Laboratory Improvement Act and associated regulations, the National Environmental Laboratory Accreditation Conference, the Grade A Pasteurized Milk Ordinance of the Food and Drug Administration, EPA Safe Drinking Water Act, and analytical requirements of the AOAC.

4. Staff Education and Training

Laboratory unit specific training plans will be developed and maintained by the Program Manager. These plans will describe training necessary to insure proper analytical performance and will address course work needed that cannot be obtained on the job. Each unit's plan shall address the individual needs of incumbents in analytical positions as well as offerings needed for new hires. On-going annual "refresher" training will be included as well. Resources available but not limited to: NLTN, CDC, EPA, FDA, CACMLE, State of Colorado, LSD State Training Coordinator, or vendor specific offerings.

4.1. Laboratory Services Division Training Guideline

PERSONNEL GUIDELINE
Laboratory Services Division

Colorado Department of Public Health and Environment

SUBJECT: Training

Effective Date: 1/15/99
Revision Date: 5/29/07

BACKGROUND The Laboratory Services Division's training policy is designed to promote organizational effectiveness, ensure staff competency and advance professional development through training of all permanent Division staff.

This policy addresses training of Division staff that involves Division resources, including funding, time on the job, administrative leave, and/or education leave.

DEFINITIONS

Training: consists of, but is not limited to, on-the-job instruction, courses, college classes, professional conferences, seminars and workshops. Training is broken down into the following categories:

Mandatory Training – Required under an agreement, grant or executive order. Examples include: Bioterrorism Training, FDA Milk Training, and Division retreats.

Training Required to Perform Job – New skill or skill enhancement required to perform employee's job responsibilities as defined in current job description for satisfactory job performance. Examples include: Lab equipment, scientific methodology and computer training.

Training to Correct Performance Problems – Required to correct performance problems identified by the supervisor.

Cross Training – Required to ensure back-up capabilities for essential Division functions. Examples include: COFRS processing, switchboard, and emergency response.

Job-Related Training – Related to job and may enhance job performance but it not required to perform current job responsibilities. Examples include: professional and technical conferences and workshops.

Skill Maintenance Training – Refresher training and skill enhancement.

On-the-Job Training: training received under the direction and supervision of a skilled Colorado Department of Public Health and Environment employee either at the Department or at a routine location within the State of Colorado where those job duties would typically be performed.

GOALS

Everyone has the basic skills to perform their assigned job(s) effectively and completely. Training will be prioritized on an individual, work unit and Division basis. Training should be cost effective. Where feasible, the Division will attempt to obtain training for groups of individuals, such as at Divisional meetings or retreats, or by inviting an instructor to the Division to train a number of individuals. The Division will seek to ensure that it allocates sufficient funding to meet its basic training goals. However, this policy recognizes that sufficient funding may not always be available and therefore training plans are essential for effective prioritization of Division training needs.

REQUIREMENTS

During the performance evaluation year, each employee in a scientific technical position will have at least 12 hours of training, and all other division staff will have at least 4 hours of training.

GUIDELINE STATEMENTS

Supervisors must have clearly defined and appropriate training requirements specified and documented for each position supervised. In addition (but not limited to) to job performance training and mandatory training, training requirements must include the required safety training. Furthermore, all safety-related training must be completed before beginning any job duties. The supervisor must document the training received for each supervised employee and maintain that documentation. An audit must be performed in July each year to make sure all documentation is up to date and correct. Unit specific training will be funded by the unit.

RESPONSIBILITIES

Prior to registering or signing up for any “training”, which does not include on-the-job training, recipients are responsible for completing a training description/justification form (see attached “Training Request” form). Individual who identify training needs are responsible for detailing:

Course Title;

Provider/Instructor;

Location;

Cost estimate, including travel (If applicable);

Duration; and

Expected benefit to the Division.

In addition, the employee is responsible for obtaining the appropriate approvals (See "Approval Section). There may be situations where the supervisor determines that, because of some urgent need or registration deadline, the approval/disapproval process will follow the registration. Approval is still required.

Employees may be required to make a report, oral and/or written, on the information and benefits received from the training.

The Program Lead or Unit Leader responsible for preparing each federal grant application will coordinate the development of the grant budget request with the Division Fiscal Officer to ensure that a request for training dollars, when appropriate, is included in the grant application.

The Division's Training Unit will maintain a training inventory database which detaiLSD all training received during the fiscal year by each Division employee. This database will contain information about course description, duration of training, cost, etc. The Training Unit P-card will be used for training registration costs for fiscal tracking purposes.

PRIORITIES

Prioritizing Individual Training (See the Definition section):

Mandatory

Required to Perform Job

Correct Performance Problems

Cross Training

Job Related

Skill Maintenance

Prioritizing Training Within the Unit:

1. Funding/Resources

2. The effects on the units productivity

3. Skill level maintenance

4. Correct performance problems

5. Skill Advancement

6. Amount of previous training received by an individual within a twelve month period and in comparison with other staff.

Prioritizing Training Within the Division:

Will be at the Division Director's discretion and will be based upon availability of funding and the overall impact on the Division.

APPROVAL/DISAPPROVAL:

Training that requires Division resources, funding and/or leave (administrative or educational) must be approved initially by the Supervisor and Division Director.

If dollars are involved, approval by the Fiscal Officer is also needed. Funding required for travel will be evaluated in accordance with the Division's Training/Meeting Criteria Priority Ranking.

The following reasons may be used for denying a training request by the Supervisor or Division Director:

Adversely affects unit's productivity

Insufficient Funds

Not directly related to job

Other training for staff is higher priority

Doesn't directly benefit the program

Authorized by: David A. Butcher Date: 5/29/07

4.2. Laboratory Services Division Chemistry Training Guideline

Training Plan October 28, 2011

Chemistry Program

Overview

The Chemistry Program, as part of an overall continuing quality assurance process, will insure that staff is trained in their areas of specialty. This training will be provided upon initial hiring and will, as necessary and available, be updated as procedures and methodologies change or are modified.

Qualifications

Permanent employees must meet the minimum qualifications for their positions as outlined in the initial job announcement. These include requisite education, experience, skills and abilities to perform their assigned duties in a competent fashion. All employees have on file their Curriculum Vitae, diplomas or transcripts, and certificates to attest that they have the educational and experience necessary for their position.

Chemistry Training and Development Policy

Continuous investment in training and development is essential for improving the performance of the Chemistry Program and enhancing the services provided by the Laboratory Services Division. Training and Development is essential in attracting and retaining a knowledgeable and skilled workforce.

Initial Training

New employees must undergo initial training during 12-month probationary period. During this period the employee must complete the New Employee Checklist and the online Chemical Hygiene Training. Bloodborne Pathogen Training may be required for some positions. After that employee will complete an initial training checklist for each procedure they will perform. Checklists are located at I:\QA__Training Plans\Chem-Training Checklists.

Each employee will undergo a competency assessment by direct observation for every analytical platform they are using to analyze samples.

Continuing Education

All employees must earn 12 scientific contact hours of continuing education during each performance period, which include scientific readings, webinars, college courses, conferences and seminars. These training opportunities are tracked and recorded by the division training coordinator.

4.3. Laboratory Services Division Environmental Microbiology Training Guideline

Division: Laboratory Services Division October 28, 2011

Program: Microbiology and Newborn Screening

Section: Environmental Microbiology Laboratory

Environmental Microbiology

Training Guidelines

Position Statement

Training is an integral part of the application of scientific principles to the detection and identification bacteria in the environment. Laboratory staff assigned to the work Unit employ standard methods in microbiology to demonstrate the presence or absence of target bacteria from a variety of sample sources. Members of the LSD who demonstrate the knowledge and technical skill to perform basic operations of analysis are welcome to undertake training in the laboratory. These opportunities may be used in the support of individual career development or in the future activities of other Units.

Policy

The Environmental Microbiology unit, as part of an overall continuing quality assurance process, will insure that staff is trained in their areas of specialty. This training will be provided upon initial hiring and will, as necessary and available, be updated as procedures and methodologies change or are modified. Assignment of personnel to specific tasks in the laboratory is based upon requisite subject matter knowledge and demonstrated in the methods and techniques required to perform practical operations. Additional training options will be considered by the Unit Supervisor following a determination of employee knowledge, skill, and ability, in addition to the immediate and long-term goals of the work Unit and the Division.

Training records will be maintained for Laboratory Services Division (LSD) personnel assigned to duties in the Environmental Microbiology Laboratory. Electronic records are stored on the J:drive in the Envmicro/training folder, while hard copies are kept in the preface of each SOPM.

Qualifications

Permanent employees must meet the minimum qualifications for their positions as outlined in the initial job announcement. Personnel with permanent assignment to the Environmental Microbiology laboratory are required to have a combination of education, experience, knowledge, skills, and abilities sufficient to demonstrate a basic understanding of scientific methods and possession of a technical skill set applicable to microbiological diagnostic techniques.

Training opportunities, beyond those available or assigned within the work unit, are encouraged for all unit members but are contingent upon demonstrated proficiency of the employee in prerequisite operations and upon need and funds available as determined by the Unit Supervisor.

Authorized, fully trained scientists who will make a preliminary assessment of the trainee's proficiency will deliver training to support career development or to correct deficiencies internally. Upon completion of the training exercise the Unit Supervisor will observe the trainee's performance of the operation. Blinded samples for proficiency testing will be arranged upon initial training and after successful completion of the specific test application, the employee is deemed fully competent to perform the operation. Proficiency must be determined at least annually through the successful performance on either internal or external blinded samples. Failure in this testing scheme requires corrective action using form CDPHE-LSD-001 and may include remedial training.

Resume or CV

All Environmental Microbiology laboratory staff will have a resume or CV on file with the Microbiology and Newborn Screening Program Director. These records will detail the individual's education, work experience history, and scientific activities.

The resume or CV kept on file is available for review upon request and may be used to determine whether an employee fulfills the minimum qualifications to support training. In lieu of CV, a completed application for the position held will constitute the minimum requirements for the basic resume, but may limit activities in the laboratory to those consistent with previous work experience.

In-Service Training, Out-service Courses, Seminars, Conferences

Refer to Laboratory Services Division, Personnel Guideline for Training.

Members of the Environmental Microbiology laboratory may undertake in-service training offered by the Colorado Department of Public Health and Environment or the LSD training coordinator following approval by the Unit Supervisor.

Attendance at scientific conferences, seminars, and meetings is encouraged. Activities in this area are available, in many cases, at no cost and personnel are referred to the web sites of various state and local agencies, health care facilities, or academic institutions for information related to educational opportunities. For meetings and conferences requiring funding support, consideration of an employee's attendance will be at the discretion of the Unit Supervisor, Program Director, and Division Director. The allocation of funding for such activity will be contingent upon availability of funds and justification of the benefit to the Unit or the Division.

Retention of Training Records

Records under this Training Guideline for the Environmental Microbiology laboratory will be kept for the duration of the employee's tenure with the work Unit. Following termination of service, the training record will be transferred to the employee's archived personnel file.

Approval: _____ Date: _____

Joe P Gossack, Lead Scientist

4.4. Laboratory Services Division Molecular Training Guideline

Molecular Science Laboratory

Training Guidelines

Position Statement

Training is an integral part of the application of molecular diagnostics to the identification and typing of bacteria and viruses. Laboratory staff assigned to the work Unit employs standard methods in molecular biology to demonstrate the presence of target-specific nucleic acid extracted from a variety of sample sources. Members of the Laboratory Services Division (LSD) who demonstrate the knowledge and technical skill to perform basic operations molecular analysis are welcome to undertake training in the laboratory. These opportunities may be used in the support of individual career development or in the future activities of other Units.

Policy

Training opportunities in the Molecular Science Laboratory are numerous and varied. Personnel assigned to the work Unit are designated to assume specific roles that contribute to the efficient function of the laboratory and the Division. Assignment of personnel to specific tasks in the laboratory is based upon requisite subject matter knowledge and demonstrated in the methods and techniques required to perform practical operations. Additional training options will be considered by the Unit Supervisor following a determination of employee knowledge, skill, and ability, in addition to the immediate and long-term goals of the work Unit and the Division.

Training records will be maintained for LSD personnel assigned to duties in the Molecular Science Laboratory. Electronic records are stored on the I:drive in the Molecular Science folder, while hard copies are stored under the same heading in a folder stored in cubicle area outside Room 137.

Qualifications

Personnel with permanent assignment to the Molecular Science laboratory are required to have a combination of education, experience, knowledge, skills, and abilities sufficient to demonstrate a basic understanding of molecular methods and possession of a technical skill set applicable to molecular diagnostic techniques.

Each staff member shall have documented credentials that meet at least the minimum standards for the position and title held.

Training opportunities, beyond those available or assigned within the work Unit, are encouraged for all Unit members but are contingent upon demonstrated proficiency of the employee in prerequisite operations and upon need as determined by the Unit Supervisor and the Microbiology Program Manager.

Authorized, fully trained scientists who will make a preliminary assessment of the trainee's proficiency will deliver training to support career development or to correct deficiencies internally. Upon completion of the training exercise the Unit Supervisor will observe the trainee's performance of a sufficient portion of the operation to assess competency and arrange to provide blinded samples for proficiency testing. After successful completion of the specific test application, the employee is deemed fully competent to perform the operation. Proficiency must be determined twice annually through the successful performance on either internal or external blinded samples. Failure in this testing scheme requires corrective action in a form to be determined by the Unit Supervisor and may include remedial training.

Resume or CV

All Molecular Science laboratory staff will have a resume or CV on file with the LSD Training Coordinator. These records will detail the individual's education, work experience history, and scientific activities.

The resume or CV kept on file is available for review upon request and may be used to determine whether an employee fulfills the minimum qualifications to support training. In lieu of CV, a completed application for the position held will constitute the minimum requirements for the basic resume, but may limit activities in the laboratory to those consistent with previous work experience.

Training Records

Training records will be maintained and kept current for each Molecular Science laboratory staff member. The documents will be stored both as electronic files and hard copy by the Quality Assurance Officer. Records will include the date training was completed, the training provider, and demonstration of proficiency by the trainee.

In-Service Training, Out-service Courses, Seminars, Conferences

Refer to Laboratory Services Division, Personnel Guideline for Training.

Members of the Molecular Science laboratory may undertake in-service training offered by the Colorado Department of Public Health and Environment or the LSD training coordinator following approval by the Unit Supervisor.

Attendance at scientific conferences, seminars, and meetings is encouraged. Activities in this area are available, in many cases, at no cost and personnel are referred to the web sites of various state and local agencies, health care facilities, or academic institutions for information related to educational opportunities. For meetings and conferences requiring funding support, consideration of an employee's attendance will be at the discretion of the Unit Supervisor, Program Director, and Division Director. The allocation of funding for such activity will be contingent upon availability of funds and justification of the benefit to the Unit or the Division.

Retention of Training Records

Records archived under this Training Guideline for the Molecular Science laboratory will be stored in the same manner and for the duration of the employee's tenure with the work Unit. Upon transfer to another Unit within the Division or the Department, a copy of the employee's training record will be delivered to the current Unit Supervisor. Following termination of service, the training record will be transferred to the employee's archived personnel file.

Approval: _____ Date: September 23, 2011

Hugh F. Maguire, PhD

4.5. Laboratory Services Division Newborn Screening Training Guideline

Newborn Screening Unit Training Plan

October 20, 2011

Introduction: The Newborn Screening Unit (NBS) exists to screen all Colorado newborns and those from various other states for a panel of genetic and metabolic disorders. These disorders are: biotinidase deficiency (BIOT), congenital adrenal hyperplasia (CAH), congenital hypothyroidism (CH), cystic fibrosis (CF), galactosemia (GALT), hemoglobinopathies (Hb), phenylketonuria (PKU) and tandem mass spectrometry (MS/MS) for amino acids and acylcarnitines. NBS processes approximately 160,000 specimens a year, or about 620 per day.

Basic Laboratory Training: When a new technician (tech) is hired, he/she will spend a total of ten weeks progressing through the rotation of benches in NBS. This rotation is:

Mail and GALT

Hb

CF and CAH

T4 and TSH (for CH)

PKU and BIOT.

MS/MS

SCID

The new tech is paired up with a training partner (usually a tech II) who will teach the trainee everything they need to know about the "bench". The trainer will use the NBS Standard Operating Procedure and NBS Training Log (attached) as guides. The NBS supervisor will observe the trainee during the end of each rotation to insure competency. When the trainee finishes this initial training period, they will be placed into the bench rotation independently starting with bench number 1 Mail and GALT the trainer will be placed directly behind the trainee in the rotation (i.e. on the PKU and BIOT bench). This will help the trainer to monitor the trainee in his/her first independent foray through the rotation. Again, the NBS supervisor will observe the trainee on each bench and complete a competency log on that person. At the end of that time, if the trainee is fully competent he/she will no longer be considered a trainee and will be placed in the Saturday morning rotation.

Continuing Education: Above and beyond the bench training, staff in the NBS unit will have continuing education opportunities provided by the NBS supervisor or NBS staff member of other CDPHE LSD personnel. In the past the NBS supervisor has invited experts in the disorders for which the lab test to educate the staff about each particular disorder. Traditionally these experts have been invited back every two to three years to speak, this will continue.

As required by the QA Manual, all members of the NBS staff are to have at least 12 contact hours of continuing education. This can be in the form of lectures, seminars, symposia, scientific reading, etc.

All NBS staff are responsible to insure they are up-to-date on their respective training requirements. Only supervisor or division director approved training shall count toward these 12 hours.

Dan Wright NBS Supervisor

Laboratory Services Division Serology / Public Health Microbiology Training Guideline

4.6. Division: Laboratory Services Division October 20, 2011

Program: Microbiology

Section: Serology and Public Health Microbiology

Serology and Public Health Microbiology Laboratory Training Guidelines

Position Statement

The Serology and Public Health Microbiology (PHM) Laboratories exists to provide scientific information regarding human and animal specimens, with regard to infection by communicable disease agents, to support epidemiologic investigations of communicable disease outbreaks and to provide reference, teaching, and consultation services for infectious diseases. Infectious diseases diagnosed by the laboratory include, but are not limited to: HIV, Hepatitis A virus, Hepatitis B virus, Hepatitis C virus, West Nile virus, Hanta virus, Rabies virus, *Yersinia pestis, Francisella tularensis*, syphilis, Chlamydia, gonorrhea, *Mycobacterium spp.,* and identification of microbial agents including *salmonella*, *shigella*, *E. coli, Neisseria meningitidis*, ova and parasites and other communicable diseases. The serology and PHM units process approximately 30,000 specimens a year.

Policy

The Serology and PHM work units, as part of an overall continuing quality assurance process, will insure that staff is trained in their areas of specialty. This training will be provided upon initial hiring and will, as necessary and available, be updated as procedures and methodologies change or are modified. Assignment of personnel to specific tasks in the laboratory is based upon requisite subject matter knowledge and demonstrated proficiency in the required methods and techniques. Additional training options will be considered by the Unit Supervisor following a determination of employee knowledge, skill, and ability, in addition to the immediate and long-term goals of the work unit and Division.

The unit employs two distinct job classes, the laboratory technician class and the physical scientist class. When a new technician or physical scientist is hired, he/she will be paired with an individual that will serve as their trainer (an individual with competency in appropriate methods). The trainer will teach the trainee each method/protocol that they will need to perform as part of their daily tasks, from specimen receipt, through processing and reporting of results. A spreadsheet, with a complete list of procedures, is used to track training. As the new employee is trained, the trainer and employee will sign off to verify training. The Quality Assurance officer maintains these job-specific training records. When the trainer deems the new employee competent in a given methodology, the supervisor, or other designee, will observe the trainee and complete a competency assessment on that person. If the trainee is fully competent, he/she will longer be considered a trainee. Current employees training to perform a new method/procedure will follow the same training plan. Additional training in laboratory safety and blood-borne pathogens with yearly refresher courses is required.

Qualifications

Permanent employees must meet the minimum qualifications for their positions as outlined in the position description questionnaire. These include requisite education, experience, skills and abilities to perform their assigned duties in a competent fashion. All employees have on file their resume or curriculum vitae to attest that they have the education and experience necessary for their position.

Continuing Education

All employees are required to complete 12 hours of continuing education and are encouraged and supported to seek out and attend additional training. The laboratory has a dedicated training unit and provides access to National Laboratory Training Network, APHL, and CDC websites on a regular basis. Training opportunities and attendance are tracked and recorded by the division training coordinator.

5. Quality Assurance

5.1. PERSONNEL COMPETENCY

The Program Managers are responsible for establishing minimum requirements for education and training, within the specifications issued by the Human Resources Division, to ensure that staff is qualified and competent to perform their assigned tasks. The Program Managers will recommend to the LSD Director, as the appointing authority, those personnel to be hired, reassigned, or promoted.

The Program Managers must assure that staff is adequately trained to maintain proficiency in the performance of their duties. The competency of each employee who performs pre-analytic, analytic, or post-analytic procedures must be evaluated and documented before the employee may perform a method independently. Training needs and accomplishments are documented according to the LSD Training Plan. (Section 4. Staff Education and Training, of this manual.) The Program Manager or his/her designee must document that the employee is capable and competent by reviewing as available:

5.1.1. Initial, Semi-annual (when applicable), and annual training documentation.

5.1.2. Test work sheets, QC, PT/PE, and preventive maintenance records.

5.1.3. Actual test performance.

5.1.4. Results on blind, split, Radiochemistry blind program, or previously tested specimens or samples.

5.1.5. Results of competency observations.

5.2. The Program Managers / Supervisors from non-chemistry sections will use the following steps to assess analytical staff competency annually (22.3.6. CDPHE-LSD 044: Competency Assessment of this manual.) Chemistry will follow the requirements set under the Method Detection Limit Verification (MDL) process.

5.2.1. Direct observation of routine test performance, including collection preparation (if applicable), specimen handling, processing, and testing.

5.2.2. Monitoring of the recording and reporting of test results.

5.2.3. Review of intermediate tests results, worksheets, quality control records, proficiency testing results, and preventive maintenance records.

5.2.4. Direct observation of the performance of instrument maintenance and function checks.

5.2.5. Assessment of test performance through: testing previously analyzed specimens, internal blind testing, or external proficiency testing samples.

5.2.6. Assessment of problem solving skills.

5.3. The Program Managers/Supervisors will provide the competency assessment documentation to the QAO, who will maintain these documents in an electronic database for tracking completion dates. The QAO will also transfer the hard copy documentation to the Training Unit, to be maintained in the employee Credentialing Folders.

5.4. Reagent / Expiration Date Policy

Any reagent, kit, chemical, or solution (here after referred to as "reagent") that is used for any testing procedure or a process leading to a testing procedure must have the following information:

5.4.1. Date Received and Initials of recipient – All containers must be labeled appropriately, kits may be labeled on the main container but kit components cannot be mixed unless manufactures product insert authorizes mixing. If mixing occurs then each reagent in the kit must be labeled.

5.4.2. Expiration Date – Expiration dates fall into three categories.

5.4.2.1. Manufacturers recorded expiration date – the date provided on the reagent by the manufacturer that does not change once the container is open.

5.4.2.2. Manufacturers recommended date – many items with a manufacturer shelf expiration date change to a 30-days-after-opening expiration date. This information is obtained from the manufacturers product insert. Items falling under this category must have a new expiration date placed on the container once it is opened.

5.4.2.3. No expiration date provided – Any reagent that does not have an expiration date will need to have an expiration date assigned to it.

5.4.2.3.1. The first source should be from the manufactures product insert. If the manufactures product insert does not provide a recommended expiration date, a date will need to be assigned.

5.4.2.3.2. Any reagent recognized as unstable will be assigned an expiration date as indicated in the MSDS or, if not available in the MSDS, two years from the date opened.

5.4.2.3.3. Stable Reagents

5.4.2.3.3. 1. Any stable reagent will be assigned a five-year expiration date from the date opened. At the end of this five-year period, and if the reagent remains uncontaminated and un-deteriorated, the reagent expiration date can be extended for a one-year period. The reagent will need to be inspected (refer to section 5.4.2.3.3.3. of this manual) annually to insure that the integrity of the reagent remains intact and a new expiration date will need to be placed on the container after each annual inspection if applicable. The date of the annual inspection and initials of the inspector need to be added to the reagent label.

5.4.2.3.3.2. If at **<u>any time</u>** a reagent does not have a normal appearance refer to section 5.4.2.3.3.3. of this manual.

5.4.2.3.3.3. As all chemicals are different to determine the stability of any chemical after the initial five year period refer to the MSDS, Stability / Reactivity section.

5.4.3. Date Opened and Initials:

5.4.3.1. When a reagent is opened the person opening that reagent must place the open date and their initials on that reagent.

5.4.3.2. If the manufacturers recommended expiration date is effected (5.4.2.) then a new expiration date and initials must also be added.

5.4.3.3. If the reagent is part of a larger container and the received date and initials are on the larger container then received date information must be transferred to the reagent being opened.

5.4.4. Each reagent must have a minimal of two dates and two initials:

5.4.4.1. After the date received

5.4.4.2. After the reagent is opened

5.4.4.3. After the reagent is given a new expiration date and initials as defined in 5.4.2.

6. Document Control

The laboratory will define, document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation. A copy of each of these controlled documents will be archived for later reference and the laboratory director will define the retention period. These controlled documents may be maintained on any appropriate medium – including, electronically or on paper.

Documents will be:

6.1. reviewed and approved by the LS Director before going into use and before a significant revision.

6.2. have file name with the date of revision embedded by the QAO.

6.3. be archived electronically after a revision is introduced.

6.4. documents to be reviewed and approved include:

6.4.1. test requisition

6.4.2. laboratory reports

6.4.3. instructions for specimen collection, transport and filling out requisitions

6.4.4. instructions on report interpretation

6.4.5. any form used for tracking instrument operations, i.e. temperature charts, maintenance charts, etc.

6.5. SOP's, the Quality Assurance Manual, and other "Signature Controlled" documents must have watermarks. The file, How to Create a Watermark, can be found at I:QA "How to Create a Watermark".

6.6. Data Recovery, In the case of system data loss, LITS+ data is backed up each day after normal duty hours. This back-up data is stored at a separate location in case of fire, flood, or natural disasters. If data is needed a request should be made through the Office of Information Technology. The data recovery could take up to one week.

7. Records Maintenance and Archiving

All documents used in the following areas will be retained as prescribed in section 22.4. Document Retention of this manual.

7.1. sample testing

7.2. equipment evaluation, validation, or maintenance

7.3. reagent evaluation, validation, or QC

7.4. procedures

All documentation will be stored in accordance with appropriate regulatory agencies to include but not limited to HIPPA, CLIA, EPA, FDA, and the State of Colorado.

8. Laboratory Physical Environment

The QAO, PM, and/or program staff will make requests to the LSD Director regarding needs or deficiencies in facilities. Facilities (including space, lighting, temperature, ventilation, noise levels, etc.) must be adequate for staff to efficiently and safely perform their assigned tasks. Services (such as electricity, gases, water, air, and vacuum) must conform to standards required by regulatory agencies and equipment manufacturers.

9. Instruments

9.1. Equipment must be adequate in capability and capacity to perform assigned tasks.

9.2. Each program will have procedures for preventive maintenance to be performed on each piece of equipment and each instrument in use in the program. This will include all automatic pipets, pipetors, thermometers, balances, incubators and refrigerators as specified below. Manufacturers' recommendations must be followed. The procedures shall designate intervals of maintenance (to include daily, monthly, semi-annually, annual), whether operator or vendor-performed, and designate the location of logbook. (See below.)

9.3. Instrument operation procedures are normally included in analytical SOPs. When they are not, the program must have a separate written instrument operation procedure that is referenced in the SOP.

9.4. Each instrument in use must have maintenance /operating logbook linked to the instrument that is updated with each use. The logbook must contain entries for normal operation, changes in operating conditions, maintenance actions, service calls, etc. You can use the back of your "Temperature Log" as your maintenance log. If you are using a "Data Logger" than you will need a separate maintenance logs.

9.5. Pipets and Automatic Pipetors

All pipets and automatic pipetors will be checked for accuracy and precision at least annually by a qualified service vendor or following an approved procedure. Results will be documented by pipet serial number and reviewed by the unit Supervisor and records will be kept on file in the unit.

9.6. Temperature Monitoring

9.6.1. DEFINITIONS

Refrigerate: 1° - 8° C

Freeze: Below 0° C

Cold: Not to exceed 10° C

Cool: 8°-15° C

Room Temperature: Range of 15° - 30° C with 24-hour average of 20° - 25° C

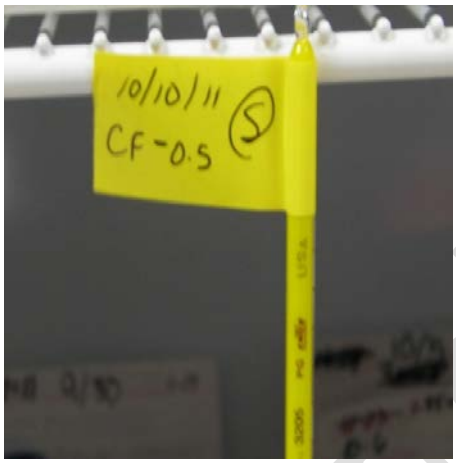
9.6.2. POLICY

All refrigerators, freezers, incubators, ovens, or other storage or incubation device and rooms located within the division that store temperature-sensitive samples, reagents, kits and/or supplies or are used for testing will be monitored daily to assure that the correct temperature range is maintained with respect to the items being stored. The temperature logs will be reviewed by laboratory supervisors or designated person on a monthly basis

and hard copy documentation of this monitoring process will be maintained for the prescribed period of time as listed in section 22.4. "Document Retention: of this manual.

9.6.3. GUIDELINES

All thermometers and electronic temperature measuring devices in use with any piece of laboratory equipment either must have a current calibration NIST-traceable temperature-measuring device or be checked annually against a valid NIST-traceable thermometer. Results from the latter must be recorded with the date performed and laboratory personnel's initials on the temperature log associated with the particular piece of equipment. In addition, a tag with the date of calibration, initials of the person performing the calibration, and the correction factor should be affixed to the thermometer (see example below.) NIST-traceable thermometers and temperature measuring devices must be re-certified or replaced when expired.



The assigned laboratory analyst shall manually check units monitored each working day. The analyst will:

9.6.3.1. For liquid thermometers document temperatures each working day on the log sheet that shows the acceptable temperature range in the same units as the thermometer used to measure temperature. Verify that the temperature is within the acceptable range (use the correction factor if required,) document any deviations from an approved temperature range and implement the corrective action. Verify and document that the corrective action was appropriate. Immediate notify Supervisor of all problems, who will in turn evaluate the situation and implement any additional corrective actions.

9.6.3.2. For "Data Loggers" check the "Temperature Warning Light" each working day. If the warning light is blinking annotate the temperature on the screen of the data logger. Document any deviations from the approved temperature range and implement necessary corrective action. Verify and document that the corrective action was appropriate. Immediate notify Supervisor of all problems, who will in turn evaluate the situation and implement any additional corrective actions.

9.6.3.3. When an infrared detection device is used to measure the temperature of samples, the device should be verified at least every six months using a NIST certified thermometer over the full temperature range that the IR thermometer will be used. This would include ambient (20-30°C), iced (4°C) and frozen (0 to -5°C). Each day of use a single check of the IR should be made by checking the temperature of a bottle of water at the temperature of interest that contains a calibrated thermometer. Agreement between the two should be within 0.5°C, or the device should be recalibrated.

9.7. Analytical Balances

All analytical balances used in the laboratory shall have their accuracy and precision verified annually by a qualified service vendor or by using in-house NIST-traceable (S) weights. Results will be documented by balance serial number and location, and records will be kept on file in the unit. The value of a NIST-traceable weight shall be recorded each day of use of any balance. Results will be recorded in a log associated with each balance. Each log must have an acceptable range for the value of that NIST-traceable weight. Any deviation from this range must be documented on the log with corrective action taken to correct the problem.

9.8. Temperature Controlled Equipment

9.8.1. All refrigerators, freezers, incubators, water baths, or other device that controls temperature used in the laboratory to conduct tests or store samples or reagents shall have an associated temperature-recording log posted on or near the equipment. The temperature of this device shall be recorded on each day of use at the beginning of the day. The laboratory personnel recording the temperature shall initial the log.

9.8.2. Each log must have an acceptable range for the temperature of that piece of equipment for the procedure performed. Any deviation from this range must be documented on the log with corrective action taken to correct the problem. Follow-up statements must be made to show that the corrective action worked.

9.8.2.1. To determine the acceptable range for any unit. Perform a complete inventory of all temperature sanative items recording all ranges. Take the highest low temperature and the lowest high temperature and this will be your range. See the example below.

Tradem Mass Spectrometry Kit:	2° to 8°
Auto DELFIA 17α-OH-progesterone:	2° to 8°
Auto DELFIA Thyroxine (T_4):	2° to 8°
Auto DELFIA IRT:	2° to 8°
JB Stain Activator:	2° to 30°
Acceptable Range	2° to 8°

9.8.2.2. A secondary concern is the location of the thermometer, in some cases there can be a difference between the temperature of the top shelf and the bottom shelf. It is suggested that this be checked.

9.8.3. A NIST-traceable computer-aided temperature-logging device may be used in place of a written log (9.8.1.), so long as the temperature-logging device is downloaded monthly. And the acceptable range of the device being monitored must be programmed into the computer-aided temperature-logging device (section 9.8.2. of this manual) so that the warning system of the computer-aided temperature-logging will activate when the temperature of the unit being monitored exceeds the acceptable range of that device.

9.8.4. The unit Supervisor or designated person must review all logs monthly.

10. Consumables Management

FISCAL GUIDELINE
Laboratory Services Division

Colorado Department of Public Health and Environment

SUBJECT: Consumable Supplies **Effective Date: 11/1/11**

BACKGROUND

The Colorado Department of Public Health and Environment (CDPHE) is charged with being fiscally responsible in overseeing State and Federal funding allocated to the Department to perform services. The Fiscal Office of the Laboratory Services Division is charged with verifying all funds are expended efficiently and appropriately and solely for the benefit of the Laboratory.

GUIDELINE

1. All consumable items purchased using State or Federal funds will remain within the Laboratory facility at 8100 Lowry Boulevard.

2. Consumable items are defined as: products or supplies that the Laboratory consumes or buys on a recurring basis, i.e., items which "get used up" or discarded. An example of consumable supplies would be paper, pens, file folders, post-it notes, computer disks, and toner or ink cartridges. Consumable goods do not include capital goods such as computers, fax machines, and other business machines or office furniture.

3. Consumable items may only be removed by employees working on State business outside of the Laboratory with the prior approvable of the employee's supervisor or the Fiscal Officer.

4. In no event are any consumable items to be removed from the Laboratory by an employee for personal use.

Authorized by: Orignal signed by David A. Butcher

Date: 10/27/11

11. Validation of Examination Procedures

11.1. Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:

11.1.1. Precision.
11.1.2. Analytical sensitivity.
11.1.3. Analytical specificity to include interfering substances.
11.1.4. Reportable range of test results for the test system.
11.1.5. Reference intervals (normal values).
11.1.6. Any other performance characteristic required for test performance.
11.1.7. Based upon the performance specifications verified or established, the laboratory must determine the test system's calibration and control procedures for patient testing.

11.2. Protocol to Establish Performance Characteristics
The verification protocol for establishing performance characteristics should include the elements listed here. Examples for two STD related tests are available as additional guidance.

11.2.1. Objective: This statement will include the purpose of the protocol, stating exactly which testing platform and methodology is being used to establish performance characteristics.

11.2.2. Study Design: The study design will be an overview of the verification procedure that will be used to establish the performance characteristics of the assay.

11.2.3. Materials and Methods: This section will include the actual procedure(s) for establishing the performance characteristics, including how specimens will be obtained, the number of specimens that will be tested, and the actual test procedure itself. Included in the Materials and Methods section should be the procedure for resolving discrepant results, or for addressing additional means to meet criteria, such as increasing the sample size, should this be necessary.

11.2.4. Acceptance Criteria: Prior to the initiation of the study, acceptance criteria will be established for each performance characteristic. The Laboratory Director or designee should approve these criteria before proceeding.

If comparing two like methodologies, accuracy may achieve 100% - all specimens should agree. However, if comparing two different methodologies, it would be unrealistic to set your accuracy performance characteristics at 100%. For example, culture may be the gold standard, but real time PCR will be more sensitive, so 100% correlation would not be expected.

A Coefficient of Variation (CV) of 10% or less could be an acceptable range for precision, but the actual numeric values that are measured must be taken into account, as very small variations in very low numbers can result in large CVs.

11.2.5. Evaluation and Conclusions: This section will be a summary of the results of the protocol. It will document how well the assay performed in each of the performance characteristics, and make a recommendation for either accepting or not accepting the new or modified assay.

11.3. Performance Characteristics:

11.3.1. Accuracy: Validations using authentic clinical specimens are preferred, but spiked clinical specimens are acceptable. When spiking specimens, the matrices should be true specimens (cervical swab, sputum, urine, CSF).

When documenting accuracy, a quantitative measurement should be used rather than qualitative measurements whenever possible. Examples are measurements in Relative Light Units (RLUs), or Crossing Thresholds. A minimum of 10 positive and 10 negative previously characterized specimens should be tested. Ideally, a total of 30 specimens should be tested, and results should be within the pre-established acceptance criteria set forth in the protocol.

These are minimal numbers for sample size. It may be necessary to either increase or reduce the sample size depending on the type of test being verified and the availability of appropriate specimens. There may be instances when it is difficult to obtain a sufficient number of positive specimens for every specimen source being verified. In this case, the sample size may need to be reduced. Random statistical error may require that a larger sample size be required in order to meet acceptance criteria. If this problem occurs, it is recommended that another 30 specimens be tested. If acceptance criteria still cannot be met, additional discrepant analysis may be required or the pre-determined acceptance criteria may need to be re-established.

If two different methods are being compared (e.g., culture and NAAT) with the object of validating one of the methods, then all discordant results need to be resolved. Attempts to resolve these discrepancies could include retesting by one or both methods or referral to another facility for testing.

Specimens for accuracy testing can be obtained by:

11.3.1.1. Collaboration with another laboratory who has already validated the assay
11.3.1.2. Spiking samples, preferably blinded
11.3.1.3. Commercially purchased validation specimens

11.3.2. Precision: Both Intra-run and Inter-run reproducibility should be documented using both a negative specimen and a positive specimen.

For Intra-run reproducibility, the same negative specimen is repeatedly tested in one run 10 times, and the same positive specimen is repeatedly tested in one run 10 times. The CV and Standard Deviation of these 10 specimens are determined and compared to acceptance criteria. Alternatively, if specimens are in short supply or the values obtained are only qualitative, the test specimens can be run in duplicate on one run.

For Inter-run reproducibility, the same negative specimen from the intra-run study is run 5 additional times on 2 subsequent runs. The first 5 observances from the intra-run study are included with the additional 10 observances resulting in 15 results, tested on 3 different test runs. The CV and Standard Deviation of these 15 specimens are determined and compared to acceptance criteria. This same procedure is performed using the positive specimen. Alternatively, if specimens are in short supply or the values obtained are only qualitative, the specimens need only be tested on a subsequent run, in singlet.

11.3.3. Analytical Sensitivity: Analytical sensitivity to determine the limit of detection can be determined using dilution studies. The lowest amount of target that can be detected should be tested at least 3 times to ensure the reliability of the limit of detection. When the assay can be performed on multiple specimen types (matrices), each matrix (cervical swab, sputum, urine, CSF) must be evaluated.

11.3.4. Analytical Specificity: To demonstrate that cross-reactions do not occur, and that there are no interfering substances, specimens positive for related organisms, or specimens containing inherent substances known to cause interference, need to be tested. Normal flora commonly found at the test site must also be shown not to cross-react with the test system.
To demonstrate that the test system detects all known strains, species or subtypes of the target, a representative sample of these strains must be tested.

11.3.5. Reportable Range of Test Results: Reportable range is defined as the upper and lower limits over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response. Establishment or verification of the reportable range of patient test results may be accomplished by assaying low and high calibration materials or control materials, or by evaluating known samples of abnormal high and abnormal low values. This may not pertain to an assay that is determining presence/absence of a target. However, if an equivocal range will be reported, you will need to verify the response of the test system by using QC or reference materials known to be in that range.

11.3.6. Reference Intervals: A reference “range” or “interval” is defined as the lower and upper limit expected for a designated population of healthy (normal) individuals. Establishment or verification of the reportable range may be accomplished by evaluation of an appropriate number of specimens from presumed healthy or uninfected individuals. This testing verifies published reference ranges or package insert data. The reference range for any laboratory-developed tests must be appropriate for the laboratory's patient population and reflect the type of specimen and demographic variables such as age and gender, as applicable.

11.3.7. Other Applicable Performance Characteristics: There could be instances when other performance characteristics need to be documented in the course of verification.

11.3.8. Calibration and Control Procedures: When establishing the calibration and/or quality control frequency, the laboratory must consider the stability of the instrument and reagents, the frequency in which testing is performed, how robust the test method is, how often quality control fails, and the training, experience, and competency of the laboratories performing the assay. In the early establishment of performance characteristics, it may be prudent to restrict testing to only one well trained laboratorian, and perform QC more frequently.

11.3.9. Standard Operating Procedure, including Quality Assurance measures: A standard operating procedure must be in place prior to a test being put into practice. This SOP must conform to section 14.1.6. SOP Format of this manual.

11.3.10. Training Documentation: Form 22.3.6. CDPHE-LSD 004: Competency Assessment of this manual must be complete for each member of the staff who will be performing the procedure, in addition to the person performing the verification.

11.3.11. Documentation Review and Approval by Laboratory Director/Designee: Verification studies must be approved and signed using 22.3.2. CDPHE-LSD 006: Procedure approval and revision form prior to a test being put into practice and prior to any results being reported.

12. Safety

12.1. Security Plan

12.1.1. Written Security Plan

This is the written security plan for the Colorado Department of Public Health, Laboratory Services Division. This written plan addresses and meets the requirements of the Select Agent Final Regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73.).

12.1.2. Site-Specific Risk Assessment Agent-Specific Risk Assessment:

This entity has reviewed the APHIS/CDC Security Information Document. Using the definitions of the APHIS/CDC Security Information Document, the overall agent-specific risk for this entity is: Moderate.

This assessment is based on the entity's registration to possess and store the biological select agents and toxins which are all either HHS or Overlap Agents. According to the APHIS/CDC Security Information Document for this category, moderate risk is chosen because use of the registered agents is handled in a diagnostic or clinical manner. Only minimal amounts necessary for diagnostic purposes, including positive controls, is propagated. The registered agents for this entity include:

12.1.2.1. Overlap Agents

	Category
Bacillus anthracis	A
Bacillus anthracis, Pasteur strain	A
Brucella abortus	B
Brucella melitensis	B
Brucella suis	B
Burkholderia mallei	B
Burkholderia pseudomallei	B

12.1.2.2. HHS Agents

Botulinum neurotoxins	A
Botulinum neurotoxin producing species of Clostridium	A
Clostridium perfringens epsilon toxin	B
Coccidioides posadasii/Coccidioides immitis	B

Coxiella burnetii	B
Eastern Equine Encephalitis virus	B
Francisella tularensis	A
Ricin toxin	B
Shigatoxin	B
Staphylococcal enterotoxins	B
Yersinia pestis	A

12.1.2.3. Threat Assessment:

This entity has reviewed the APHIS/CDC Security Information Document. Considering all the threats listed in the APHIS/CDC Security Information Document (man, Nature, incident), the probability of their occurring are:

12.1.2.3.1. Man: Moderate

This assessment is based on the fact, that a person or group with malicious intent could start a fire, vandalize or detonate an explosive device at the entity, though there has been no history of this. Background checks are conducted of all entity staff, plus all SRA approved staff have been given an FBI background check before approval. However, the possibility will always exist that an insider could access the agents or damage the entity. Similarly, an outsider with limited access and system knowledge would pose a potential threat, but security alarm and access systems make this a lower risk.

12.1.2.3.2. Nature: Low

The most likely threats would be a severe thunderstorm or tornado that could cause wall and roof collapse of the entity building. The building is of sturdy construction and the tornadoes in this location are of low intensity. Even if the building was damaged or destroyed, the interior location of the registered BSL-3 laboratories, short span ceilings and heavy, locked freezers, refrigerators and incubators make it highly unlikely that a release of select agents would occur. Floods and earthquakes are other possibilities of risk. The construction of the building and agent storage containers mentioned previously also support a low risk assessment.

12.1.2.3.3. Incident: Low

Fire is a risk, but the entity building has smoke detectors, automated fire alarm system and the entire building is covered with a sprinkler system. Even if the facility burned to the ground, the agents would remain in secured containers and would be destroyed by the heat of the fire. The entity has a backup power generator that would activate within 20 seconds of a power failure. Additionally, the card access

and alarm systems have backup batteries. HAZMAT, biological and chemical agent incidents are also low risk due to the containment features of the registered labs that have been noted.

Considering all the threats listed in the APHIS/CDC Security Information document (man, nature, incident), the consequences should they occur are:

12.1.2.3.4. Man: Moderate

The amount of select agents or toxins at the entity would be of very low quantities, such As < 2 ml cryovials of seed stocks and any culture plates being incubated for diagnostic purposes. A person who removed these agents would not be able to immediately disperse the agents, but given more time and with expertise, could within a few days be able to propagate the agents. The loss of the agents would be detected by the alarm system, card access record review and/or review of video records and reported to law enforcement before the agents would be propagated and dispersed.

12.1.2.3.5. Nature and Incident: Low

As noted previously, in the case of fire, the heat would destroy the agents. In the other scenarios, the building might be destroyed, but the agents would remain onsite in secured storage containers.

12.1.2.3.6. Vulnerability Assessment

Based on a review of the APHIS/CDC Security Information Document, the security Weaknesses and deficiencies identified at this facility, and the corrective measures Considered, the overall vulnerability at this entity is Low.

12.1.2.3.7. Graded Protection (Mitigation Measures)

The entity has developed a graded protection system to address these vulnerabilities. Beginning with the select agent storage and work areas (rooms 159/160,178F):

Minimal quantities of seed stocks are retained in the repository in room 178F. The volume of each cryovials is 2 ml or less. All seed stocks and cultures are kept in either a locked freezer, refrigerator or incubator. The locks are opened either by a key card, key, or combination only by currently SRA-approved staff that has been granted access after CDPHE and FBI background checks, to lessen the threat of theft from an insider. Additionally, rooms 159/160 and 178E are under video surveillance which is reviewed by the ARO/SO and the RO.

The registered laboratories are located in the building interior with short span ceilings, providing no exterior visibility and less accessibility to an outsider. This design also minimizes the impact of structural failure during adverse weather or an earthquake. Each registered laboratory is linked to the fire alarm system and contains water sprinklers, as does the entire building. Access to these laboratories is through a locked door with restricted access to SRA-approved staff. The access records are reviewed by the ARO/SO, with monthly reports reviewed and reconciled by both the RO and the ARO/SO.

The registered laboratories are both located inside of another laboratory, which has key card access by only approved LSD staff.

The exterior laboratories are accessed through section corridor doors, also with key card access restricted to approved laboratory staff.

The entrances to the building require key card access, restricted to approved laboratory staff. The entrances and building exterior are under video surveillance. All doorways, including emergency fire exits and dock doors, are connected to an intruder alarm system.

Thus, to access the select agents and toxins, an intruder must pass through a minimum of 5 locks while under video surveillance and the potential of activating the intruder alarm system. Additionally, access is limited to staff who have been subject to periodic background checks. LSD staff is trained to note and report any unusual behaviors or suspicious activities by persons inside the building or on the grounds of the entity.

If the entity is destroyed or damaged by adverse weather, fire, earthquake, or human activities, Denver Fire Department will limit access to the site until the time it is considered safe for SRA-approved staff to recover and secure any surviving select agent and toxin materials.

12.2. Physical Security, Inventory Control, and Information Systems Control

12.2.1. The following physical security measures are in place at the Colorado Department of Public Health and Environment Laboratory Services Division located at 8100 Lowry Boulevard, Denver, CO 80230:

12.2.1.1. Building and grounds lighting is in place to clearly illuminate the building and grounds of the entity during darkness.

12.2.1.2. All building exterior doors, emergency exits and dock door are connected to an intruder alarm system. The system has both backup power and batteries to address any local power outages. If one of the entrances is breached, an alarm will be sent to the monitoring company, which will alert, in order, the Building Operations Supervisor, RO and the ARO/SO by phone. All exteriors doors are automatically locked outside of business hours, which are 8 am to 5 pm Monday through Friday. These doors remained locked during weekends and holidays.

12.2.1.3. A key card access system limits access to the entity building to entity staff approved by the RO. Additionally, access to registered rooms 159/160 and 178F is limited to only SRA-approved staff whose access has been approved by the RO. All visitors to these areas (such as analysts, service technicians, and maintenance staff) must sign in the visitor log located in the anteroom of the registered rooms, don appropriate PPE and must be accompanied by SRA-approved staff at all times while in this area. Following proper doffing of PPE and decontamination, the visitor must be signed out of the room by the escorting SRA-approved staff before leaving the area. The visitor will be escorted to the exit area for visitors, sign-out, return the visitor ID and leave the building.

12.2.1.4. All entity staff must clearly display a current photo ID card issued by the entity. All visitors must be signed in by entity staff, issued a visitor ID and be escorted at all times while present within the entity building.

12.2.1.5. A video surveillance system continuously monitors activity of the entity grounds, building exterior, all building entrances and the interiors of registered rooms 159/160 and 178F. As with the entity alarm and card access systems, backup power and batteries are in place to address any local power outages.

12.2.1.6. All select agents and toxins storage and work must be done in room 178F, with room 159/160 serving as the alternate laboratory during times when room 178F is shut down, or as an additional storage and work site during a surge response. When not in use, all select agents and toxins must be stored in a locked freezer, refrigerator, and incubator or other storage container. The keys, combinations and/or card access to these storage areas will be assigned by either the RO or the ARO/SO to only SRA-approved staff. An electronic inventory system, Freezerworks, is used by the RO or the ARO/SO to log in select agents and toxins into the repository in room 178F and the backup repository in room 159/160. This process is detailed in the inventory control part of this section.

12.2.2. Operational Security:

The staff personnel of the entity receive security training at the time of hire, annual refresher training, and additional training during the year when there are changes in security protocols. The training is documented for each entity staff. Details of identification of suspicious persons or activities, inspection of packages, key and access card control management are found in the security plan and in the following sections.

12.2.3. Inventory Control:

12.2.3.1. Receiving Select Agents

The (ARO/SO) will place all orders for select agents and toxins to the ATCC, USAMRIID, AFIP, USDA, CDC or other licensed select agent repositories. Requests for transfer of select agents and toxins from diagnostic laboratories will be received, signed for, and processed by the ARO/SO. The receipt of the select agents and toxins will occur in the receiving dock area directly from the delivery agent (Such as the FEDEX driver) to the ARO/SO. The received materials will be taken directly to room 178F, where it will be secured in a locked storage container such as a freezer, refrigerator or incubator and the select agent or toxin information will be recorded in Freezerworks, the electronic inventory database.

In the event the ARO/SO is unavailable, facility shipping and receiving personnel will contact the next available SRA authorized person on the Select Agent Form 1 Section 4 list to sign for, and take possession of any package labeled as “Dangerous Goods”. This authorized person will place the package in a locked, secure storage container located in room 178F, record the information in Freezerworks, and notify the RO of the transaction. The ARO/SO will be notified of the receipt and storage of the select agents and toxins when he/she returns. Acquisition of select agents and toxins will be documented with permanent hard copy record retention of shipping documents received with the select agent and toxin shipment. Select agent and toxin materials will be unpackaged and opened in room 178F to maximize safety and minimize security hazards associated with damaged or unknown packages.

The ARO/SO will notify the FBI Weapons of Mass destruction office in the event of the notification of LSD staff of any suspicious package(s). FBI agents will verify that packages or objects to be tested are screened for radiological, chemical and explosive hazards before they are brought in the LSD facility. If deemed appropriate

by RO, ARO/SO or PI, field testing for biological agents or sub sampling of objects and/or packages will be performed before the object is brought into the LSD facility.

A chain of custody (COC) form must be completed before the CDPHE Laboratory will accept and test packages containing suspected select agents. The ARO/SO or SRA-approved designee will review COC documents and examine packages with the submitters prior to accepting and moving the items into room 178F for testing.

Packages with known or unknown contents will be opened and processed in a Class II Biosafety cabinet in room 178F (See Appendix A and B in the Security Plan for triage of specimens and appropriate response protocols). All packages will be opened and stocks secured the day they are received. Trained, SRA-approved staff will open packages in room 178F while under video surveillance. Only trained, SRA-approved staff may remove packages and materials from room 178F. The RO, ARO/SO or PI must be present to inspect packages containing known or suspected select agents and toxins and/or other accompanying materials that may be subject to further testing or used as evidence in a criminal investigation. All known and/or confirmed select agents and toxins will be entered into the electronic inventory system, Freezerworks, once secured in room 178F, including the required information as detailed in Section III of this document.

Upon completion of testing, the select agents and toxins must be securely stored in either a locking refrigerator, freezer, or incubator in room 178F. The SRA-approved analyst performing the testing and either the RO, ARO/SO or PI must jointly store and witness the storage of the select agents and toxins. They must also document these actions in the Freezerworks inventory database. A CDC/APHIS Form 4 must be completed and forwarded to the Select Agent Program if the select agents and toxins are to be retained in the repository. If the select agents or toxins will not be retained in room 178F upon completion of testing, these agents must either be destroyed by autoclaving (or other recognized sterilization or neutralization process) in the presence of an SRA-approved staff and documented in both the Freezerworks inventory and Central Services autoclave records, or be transferred to an approved LRN facility using an approved CDC/APHIS Form 2 in accordance with 42 CFR 73.11.

The PI or Biological Safety Officer must approve all removal of equipment from room 178F prior to the action, to ensure that proper decontamination of containment packaging has been performed. COC, Form 2 and/or equipment transfer documentation must be completed and reviewed by either the RO, ARO/SO or PI before the items are removed from the laboratory. All activities in the registered rooms 159/160 and 178F are under 24-hour video surveillance, subject to recording and future review.

12.2.3.2. Transfer or Shipping of Select Agents

The RO or ARO/SO will oversee operations related to external transfer of agents to approved licensed laboratories. Packaging, labeling, and transport of select agents and toxins will conform to all applicable local, federal, and international transportation and shipping regulations, including U.S. Department of Transportation (DOT) regulations. Materials that are transported by airline carrier must also comply with packaging and shipping regulations set by the International Air Transport Association (IATA). Personnel who package, handle, and ship these agents (including import and export) will train appropriately and a record of training will be retained and made available for review by the Security Committee and other regulatory entities.

The RO and ARO/SO will be notified of all select agent transfers, internal or external. The RO, ARO/SO and PI will obtain required licenses and permits as are required to receive, transfer, possess and use select agents as granted by the U.S. Public Health Service, US Homeland Security, and USDA, DOT, U.S. Department of Commerce and are obtained before select agents are prepared for transport. The Security Co Committee will write such standard operating procedures as are required for import and export activities.

All select agents and toxins will be locked in secure storage in room 178F prior to approved transfer from the entity. When a FEDEX driver arrives at the entity to pick up the packaged select agents or toxins, the RO, ARO/SO or PI will be notified. An SRA-approved staff will remove the select agents or toxins from room 178F and transport the materials to the specimen receiving desk, where he will personally hand the packaged agents to the FEDEX driver. Upon confirmation of select agents and toxins pickup, the ARO/SO will document the transaction and update the inventory in Freezerworks.

12.2.3.3. Information Systems Control

The server, tape storage and telecommunication center for the Laboratory Services Division (LSD) of the Colorado Department of Public Health & Environment (CDPHE) is located in room 195 of this facility. Access to this room is restricted to approved staff and requires an enabled access card to be swiped across a reader located at the door entrance. Access to the area is recorded each time a card is used. Card user, card number and time of access are recorded in the system.

In the event of an emergency, physical access to this area is allowed to appropriate staff with approved card permissions. This includes: Office of Information Technology (OIT) staff, LSD Division Director, Security Officer, Building Operations Supervisor, Denver Fire Department (via access card in building Knox box)

The LSD building utilizes several operating systems, including Windows XP for the network workstations, AMAG for the card access system, VIP for the interactive camera and door buzz in system and Freezerworks for the select agent inventory tracking system. These operating systems are not connected to the internet. An HP backup system is used for the Windows HP system. The AMAG system retains activity history records for one year, with monthly activity reports for registered rooms 159/160 and 178F generated and reviewed monthly, with hard copies of these reports secured by the ARO/SO and secured in a locked cabinet for at least 3 years. The buzz in software is for attended use during business hours and records are not retained. The Freezerworks inventory system retains records in its database indefinitely, with a current hard copy of the select agents and toxins secured by the ARO/SO in a locked cabinet.

The computer systems are internally networked for the workstations. Administrative access to the AMAG card access and video systems is restricted to the RO, ARO/SO and the Building Operations Supervisor, all of whom are SRA-approved. Administrative access to the Freezerworks inventory software is limited to the RO and the ARO/SO.

The IT staff of the entity maintains an active system to prevent cyber attacks. Firewall systems are in place for the main network (Cisco) and the individual Workstations (Windows). Network passwords are routinely changed every 90 days, with no reuse of old passwords. Mc Afee anti-virus software is used. While there are no restrictions on internet browsing, such use can be monitored by IT administrators upon supervisor request. The e-mail servers are protected by a restricted download policy.

As noted, only SRA-approved staff has administrative access to systems Involved with the security of select agents and toxins. Loaner access cards, combinations and spare locks, hard copies of select agents and toxins inventories and sensitive documents and correspondence are kept in a locked cabinet in the ARO/SO office, with keys to the office restricted to the RO and the ARO/SO. This information is reviewed and discussed only on a need to know basis. Access logs are reviewed and signed off monthly by both the RO and the ARO/SO. All members of the Security Committee are SRA-approved staff.

12.2.4. Access Control, SRA Approval and Recording Access

Laboratory Services Division (LSD) staff will use key cards for access to the facility and restricted laboratory areas, including SRA registered rooms 159/160 and 178F at all times. The system as configured requires employees to swipe their card upon entry and before exiting the building at the end of their shift. This allows for tracking of staff on the premises by day and prevents re-entry if the employee fails to swipe the card upon exit. During non-business hours and weekends, the doors are locked to all but employees who have the required access privileges. Access is to be through the public reception (west), Franklin room (northeast) or specimen receiving office (south) entrances.

All LSD staff requiring access to restricted areas where select agents and toxins are possessed, used or transferred must first have an approved Security Risk Assessment (SRA) and be listed on the APHIS/CDC Form 1, Section B.

LSD staff with access key cards and passwords for databases is prohibited from sharing or divulging these items with others per department policies.

Laboratory staff must immediately report any suspicious persons or activities in or on the LSD premises immediately to the RO, ARO/SO or their designees. As required by the situation, appropriate law enforcement authorities will be contacted to remove the individual. The Security Committee, for follow-up, will document these events on an incident report form and review each case to determine if additional security measures should be implemented.

Reviews of video surveillance data will be conducted by the security committee members in response to alarms and other suspicious occurrences noted on the card key access system or their reports of an unusual event in the building and the Select Agent Program registered rooms 159/160 and 178F at any time.

The LSD inventory manager or designee will observe by video surveillance method any delivery staff and will open the truck delivery door and admit delivery personnel and product as required. The LSD inventory manager will receive and log the receipt of all items delivered through the truck delivery door. The door will remain closed at other times. If a select agent or toxin is presented for delivery, the ARO/SO or SRA-approved designee will sign for the package(s) and transport the materials to room 178F where it will be placed in a locked storage container (see inventory control procedures in Section III).

An LSD staff will accompany and escort visitors to the facilities at all times. Upon arrival, visitors will be required to present their identification and credentials before they sign in, are issued a visitor ID badge and

escorted into the laboratory by LSD staff. The visitor ID badge must be worn and displayed at all times while the visitors are within the facility. On leaving the facility the visitor must return the badge and sign out. Any maintenance personnel requiring repetitive access will be trained prior to admission. Approved visitors will be logged, escorted and monitored into and out of registered rooms 159/160 and 178F by SRA-approved staff.

An SRA-approved LSD staff member will accompany any individual who needs to enter Select Agent Program registered rooms 159/160 and 178F, which may contain biological select agents and toxins. A record will be kept of the name, organization, time of entry and exit of any individual (other than key card SRA-authorized staff) from the laboratory will be maintained, including initials of the escorting staff.

An authorized LSD staff member shall clean registered rooms 159/160 and 178F, which may contain select agents and toxins, or escort maintenance staff and/or non LSD contracted staff at all times (See Section 5 of this document).

All access to laboratory work areas are secured from the public areas of the building through the use of electronic key cards. Additionally, access to the registered rooms 159/160 and 178F, where select agents and toxins may be stored and worked with, requires entry through another key card accessed door. All freezers, refrigerators and incubators where the select agents and toxins may be stored have a lock in place or a hasp to accept a lock when needed. Access to these areas is limited to SRA-approved staff that has been cleared by the U.S. Department of Justice as indicated in 42 CFR Part 73. These staff will have a notation on their identification badge that indicates this authorization. All others entering rooms 159/160 or 178F must be escorted and monitored by authorized personnel. All entries to these areas are recorded in written log books by the visitor and by the card access system for SRA-approved escorting staff.

At the time of termination of employment with the LSD, employees must return their ID badges and key cards to their supervisor. The supervisor will notify the ARO/SO and IT Officer of the date of termination of employment. On that date the ARO/SO or designee will inactivate the employee's key card and the IT Officer will terminate the employee's access to the CDPHE computer systems.

All LSD staff will be given security training at the time of the start of employment, annually with a refresher course, and whenever a change of security protocol is made. All staff is advised to be vigilant in preventing piggybacking of individuals through secured entrances, individuals inside the secured areas that are not displaying a valid ID and/or unescorted by LSD staff, and any suspicious activities on the LSD premises.

Employees must report lost key cards, ID badges or passwords immediately to the RO and the ARO/SO. The ARO/SO will inactive the lost card and place it on "card watch"—the system will monitor if the inactivated card is used in an attempt to enter the CDPHE Laboratory facilities. Passwords, combination locks and key locks that the employee formerly accessed will be changed immediately.

The RO, ARO/SO, or PI will monitor access to registered rooms 159/178F through review of video surveillance, access card reports and visitor log in books. The access card reports will be reviewed and reconciled monthly, with hard copies of the signed reports and visitor logs retained for 3 years.

12.2.5. Routine Cleaning, Maintenance and Repairs Cleaning, Maintenance and Repair Provisions

It is the responsibility of the SRA-approved staff working in registered rooms 159/160 and 178F to perform routine housekeeping in these areas. This includes wiping down work areas, recording temperatures, securing and removing biowaste, cleaning walls and ceilings, and sweeping/mopping the floors. Appropriate PPE and disinfection agents such as freshly prepared 10% by volume bleach/water solutions will be used.

For other maintenance beyond the expertise of the SRA-approved staff, in-house building operations staff, visiting technicians and construction contractors will be required to work in these restricted areas. These occasions may include routine, scheduled operations such as instrument certification, filter replacement, HVAC calibration and inspections. Additionally, non-routine work may be required such as painting, instrument repair and emergency plumbing and electrical repairs. This includes any emergency repair work that may be required outside of business hours. All visitors approved to enter registered rooms 159/160 and 178F must:

12.2.5.1. Review, understand and abide by the safety statement in the front of the Visitor sign-in log (located in each anteroom) before signing the log and entering the registered rooms.

12.2.5.2. Be provided with appropriate PPE and have it checked by the escorting SRA-approved staff prior to entering the registered rooms.

12.2.5.3. Safety features in the registered lab must be noted and pointed out to the visitors, such as telephones, eye-wash stations, fire extinguishers, hand sinks and spill kits.

12.2.5.4. All visitors must be escorted into, and be in the presence of, an SRA-approved staff at all times while in the registered rooms.

12.2.5.5. Upon completion of work, the visitors must follow safety procedures to correctly doff PPE, decontaminate tools and equipment, and wash their hands before exiting the registered rooms. The escorting SRA-approved staff will ensure that these steps are correctly completed.

12.2.5.6. Upon exiting into the anteroom, the visitor must sign out in the visitor log and the escorting SRA-approved staff must initial the log entry.

12.2.5.7. An SRA-approved staff will escort the visitor to the building entrance, ensure that the visitor turns in his visitor badge, signs out at the reception area log book and exits the building.

12.2.6. Unauthorized or Suspicious Persons

SRA-approved individuals are required to remove all unauthorized and suspicious persons in and round the select agent area immediately and report them immediately to the RO and other management as appropriate. SRA-approved individuals also have the responsibility to police restricted areas and keep out other departmental staffs that do not belong. Individuals at this facility who are approved by the HHS Secretary or APHIS Administrator receive annual training regarding the removal of unauthorized or suspicious persons and the reporting requirements. Staff members at this facility have been trained to challenge individuals who have no identification badges or displayed credentials. Training also includes reporting and follow-up requirements and identification verification procedures.

12.2.7. Loss or Compromise of Keys, Passwords, Combinations Changing Access Numbers or Locks Following Staff Changes

Upon loss or compromise of keys, passwords, and combinations or upon staff changes, access to select agents controlled by electronic means (including computer passwords and combinations) are changed immediately. Access to select agents that are controlled by standard lock and key will have locks replaced immediately. Access to select agents that are controlled by standard lock and key will have locks replaced immediately, including the purchase of replacement of lock boxes.

When keys and access cards have been inadvertently left at home, the RO will ensure that a temporary access pass is issued for the day.

Inventory of select agents will be conducted prior to the issuance of new card-key codes, combinations and keys to SRA-approved individuals.

12.2.8. Reporting Unauthorized or Suspicious Persons or Activities Loss, Theft or Release of Select Agents or Toxins Alteration of Inventory Records

All entity personnel, whether authorized to possess, use, or transfer select agents or not, are instructed to immediately report any suspicious persons or activities to the RO and/or the ARO/SO.

Any suspected loss or theft of a select agent and toxin must be immediately reported to the RO or the ARO/SO. Upon notification of a loss or theft, the RO or the ARO/SO has the authority to suspend all select agents and toxins activity, disables all card-keys to the select agent activity area, and notifies APHIS/CDC as appropriate. APHIS/CDC Form 3 (Report of Theft, Loss or Release of Select Biological Agents and Toxins) must be completed and submitted to APHIS/CDC as appropriate within 7 days. If for any reason there is suspicion that the inventory and use records of the select agents and toxins have been altered or compromised, it must be reported to the RO or the ARO/SO. The RO or the ARO/SO will immediately initiate an investigation to further determine what has occurred. APHIS/CDC will be notified immediately in situations where a theft or loss has occurred. When directed, local law enforcement and/or the FBI will be consulted.

12.2.9. Understanding and Complying with Security Procedures

At this facility, training is conducted that addresses the needs of the individuals, the work they will do, and the risks posed by select agents and toxins. Training is also provided regarding the security procedures associated with select agents and toxins. This information is presented in a formal class setting. Validation of understanding the information is accomplished with a test.

All persons authorized to work with select agents and toxins shall review and be familiar with this site-specific security plan.

12.2.10. Access Approval

At this facility, all personnel working with select agents and toxins are approved by the APHIS Administrator or HHS Secretary (SRA approved) and are listed on APHIS/CDC Form 1, Section 4B.

12.2.11. Unescorted Access for Cleaning, Maintenance, and Repair Personnel

At this facility, unapproved individuals such as maintenance, cleaning and repair personnel cannot enter select agent areas for cleaning and repairs unescorted.

12.2.12. Means of Securing Select Agents and Toxins

Select agent areas are isolated from public access. Access to all areas where select agents and toxins are possessed, used, or transferred is controlled by card-key locks for personnel who are SRA-approved. These laboratories are locked and monitored at all times. No other facility personnel have access to these areas. Within the freezer unit select agents are secured by lock and key. The key and key log is controlled by the RO. A log (manual or electronic) is maintained that records name, date, and time of entry. Logbooks are maintained and secured in a locked file cabinet by the RO. Select agents and toxins are possessed, used or transferred in Rooms 159/160 and 178F.

The Select Agent laboratory has a motion detector that records when any person leaves the lab. Alarms and video cameras are monitored by the security staff on duty. Video cameras are security surveillance tools and not subject to recordkeeping requirements at this facility.

12.2.13. Inspection of packages

All packages, containers, carts, bags, and briefcases that appear to be of a suspicious nature are inspected by the PI or his designee. This applies to all packages of a suspicious nature entering or leaving the select agent areas.

12.2.14. Intra-entity Transfers

At this facility select agent work will be performed in room 178F, or the backup room, 159/160, thus no intra-entity transfers will be made. However, if there is an event that necessitates that both rooms are simultaneously used for select agent work, intraentity transfers would be required. All intra-entity transfers at this facility will be handled by the Responsible Official or the Alternate Responsible Official, who will ensure that the facility intra-entity transfer form is used along with the chain of custody and that the transfer or receipt of the select agent and toxin is accurately reflected on the inventory. This responsibility, at the discretion of the Responsible Official, may be delegated to a Biosafety Professional provided this individual is SRA approved. All biosafety and security provisions will be worked out and discussed prior to any intra-entity transfer at this facility. Police escort may be necessary to ensure transfers are conducted in a secure manner (within the facility). (Examples of the forms to be used are available in the Select Agent and Toxin Security Information Document).

12.2.15. Sharing Access

At this facility, individuals approved for unescorted access are not to share their unique means of access such as passwords, PIN numbers, keys, and key cards that allow access to the area(s) where select agents are possessed, used, or transferred.

12.2.16. Reporting Requirements to the Entity's Responsible Official

At this facility, the following must be reported to the Responsible official:

12.2.16.1. Any loss or compromise of keys, passwords, combinations, etc.

12.2.16.2. Any suspicious persons or activities

12.2.16.3. Any loss or theft of select agents or toxins

12.2.16.4. Any release of a select agent or toxin

12.2.16.5. Any sign that inventory or use records for select agents or toxins have have been altered or otherwise compromised

Once reported, the RO will take action to make all appropriate notifications and complete all forms, including the required follow-up.

12.2.17. Public Access

At this facility, rooms where select agents and toxins are possessed, used, or transferred are separate from public access areas.

12.2.18. Select Agent Reference Document

The document entitled Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents, published in Morbidity and Mortality Weekly Report (December 6, 2002; 51: RR-19:1-6) is available at this facility and is on file in the RO's office.

12.2.19. Drills and Exercises

Drills and exercises conducted at this facility that satisfy the requirements of the Biosafety, Security, and Incident Response Plans are conducted on an annual basis and the drills conducted by this facility are summarized as an attachment to our incident response plan. All written plans at this facility are updated annually and when drills and exercises warrant update.

12.2.20. Retention of Records

Records relating to security are required to be retained for 3 years and include the following: Inventory, transfers, theft, loss, and release, RO's records, security, biosafety, incident response, and training. Security cameras at this facility are used as security monitoring devices.

12.3. Biological Risk Assessment

12.3.1. Identify the Agents

All biological agents and toxins including fungi, parasites, viruses, and those classified as “Select Agents” routinely encountered or having the potential to be encountered in this laboratory have been evaluated for risk using the

agent summary statements in the BMBL 5th Edition. It has been determined that all biological agents normally encountered in this facility fall into Risk Group Classification 3.

12.3.2. Procedural Hazards

The routine biological work in this facility is performed using clinical, animal and environmental specimens and isolates from such specimens. No animal inoculations, cell cultures, or embryonated egg inoculations are performed in the laboratory. No large purified volumes of any of these agents are produced using the procedures routinely conducted in this facility. These procedures include pipeting, decanting, filtering, centrifugation, mixing/vortexing, and concentration of liquids containing biological agents. The potential for aerosol generation is to be expected with these sample types and the associated procedures.

12.3.3. Selected Biosafety Level

Based on the facts above and the review of the agent summary statements and recommendations in the BMBL 5th Edition, BSL-2 level safety protocols are determined to be adequate for all procedures performed in this facility with the exception of Mycobacterium tuberculosis and rabies virus. This is due to culture manipulation with the former and animal brain necropsy with the latter. Work with specimens and cultures for these two agents will be done using BSL-3 protocols in the TB lab (Room 183) and the rabies lab (Room 159), respectively.

However, all work with organisms classified as "Select Agents" or suspected of containing such will be conducted in the BT lab (Room 178F) which is classified as BSL-3. This is due to the biosecurity and access control required for these agents.

12.3.4. Staff Proficiency

The safety protocols prescribed above are within the scope of the training provided to all employees in this facility who works with these agents. No current employees are known to have any physical limitations preventing them from effectively using the required safety measures. Staff will be trained in these measures and competency assessed annually on proper biosafety procedures.

12.4. BIOSAFETY PLAN

12.4.1. PURPOSE:

The purpose of the Biosafety Plan is to advise personnel of standard safety practices, special hazards, procedures, and practices related to the operation and use of Biosafety Level 2 (BSL-2) and Biosafety Level 3 (BSL-3) laboratories in all sections of the Laboratory Services Division (LSD), CDPHE. The Biosafety Plan is designed to protect employees from health hazards associated with microbiological agents and toxins.

A documented review of the Biosafety Plan will be conducted annually. The plan will be revised as necessary by the laboratory's Biosafety Officer and Responsible Official. The review of this plan will consider the CDC/NIH publication, "Biosafety in Microbiological and BioMedical Laboratories," 5th Edition including all appendices. Drills or exercises will be conducted at least annually to test and evaluate the effectiveness of the plan. The plan will be reviewed and revised, as necessary, after any drill or exercise and after any incident.

12.4.2. POLICY STATEMENT:

The Colorado Department of Public Health and Environment (CDPHE), Laboratory Services Division (LSD) is committed to providing a safe working environment for each employee and all visitors.

The Director of LSD has the ultimate responsibility to assure the safety of all employees and visitors. However, operational and safety procedures described in this plan apply to all employees and visitors associated with the facility. Modifications to these procedures or to the facility cannot be made without written approval of the LSD Division Director.

The laboratory maintains and provides access to safety information and provides training for all employees. Personnel who work in the laboratory units must be properly trained and will be responsible for identifying potential hazards in either the facility or in work procedures. All hazards should be brought to the attention of the Unit Supervisor.

To assure a safe working environment, the LSD Director has appointed three Safety Officers: Chemical Hygiene Officer (CHO); Biological Safety Officer (BSO); and Radiation Safety Officer (RSO). The three Safety Officers function as the Safety Committee and act in an advisory capacity reporting directly to the LSD Director. Additional personnel are attached to the Safety Officers as needed. Safety Officers are listed in Appendix A.

12.5. CHEMICAL HYGIENE PLAN

12.5.1. PURPOSE

The Chemical Hygiene Plan is designed to protect employees from health hazards associated with hazardous chemicals, and keep exposures as low as possible, not to exceed the permissible limit. In accordance with 29 CFR 1910.1450(e), a chemical hygiene plan must include each of the following elements and shall indicate specific measures that the employer will take to ensure laboratory employee protection when working with chemicals on a laboratory scale of operation:

12.5.1.1. Standard Operating Procedures (SOP's).

12.5.1.2. Criteria used to determine and implement control measures to reduce employee exposure.

12.5.1.3. A requirement that fume hoods and other protective equipment are functioning properly and specific measures that shall be taken to ensure proper and adequate performance of such equipment.

12.5.1.4. Provision for employee information and training.

12.5.1.5. The circumstances under which a particular laboratory operation, procedure or activity shall require prior approval from the employer or the designee before implementation.

12.5.1.6. Provisions for medical consultation and medical examinations.

12.5.1.7. Designation of personnel responsible for implementation of the Chemical Hygiene Plan including the assignment of a Chemical Hygiene Officer.

12.5.1.8. Provisions for additional employee protection involving work with particularly hazardous substances including:

12.5.1.8.1. select carcinogens

12.5.1.8.2. reproductive toxins

12.5.1.8.3. acute toxicity (such as mercury & cryogenics)

The goal of this plan is to fully implement these requirements for the Colorado Department of Public Health and Environment, Laboratory Services Division (LSD)

12.5.2. POLICY STATEMENT - The Colorado Department of Public Health and Environment (CDPHE), Laboratory Services Division (LSD) is committed to providing a safe working environment for each employee and all visitors.

The Director of LSD has the ultimate responsibility to assure the safety of all employees and visitors. It is mandatory, however, that everyone know and comply with safety rules and safe work practices to assure safe conditions and laboratory practices.

The laboratory maintains and provides access to safety information and provides training for all employees. Personnel who work in any given laboratory unit should be properly trained and will be responsible for identifying potential hazards in either the facility or in work procedures. All hazards should be brought to the attention of the Unit Supervisor.

To assure a safe working environment, the LSD Director has appointed three Safety Officers, one of whom also functions as the Chemical Hygiene Officer, hereafter referred to as the Chemical Hygiene Officer (CHO). The other two Safety Officers are the Biological Safety Officer and the Radiation Safety Officer. The three Safety Officers function as the Safety Committee and act in an advisory capacity reporting directly to the LSD Director. Additional personnel are attached to the Safety Officers as needed from time to time. Safety Officers are listed in Appendix I-C.

This Plan is designed to address the chemical safety needs of both a microbiological and chemical laboratory. Therefore, many areas of the Plan have been written to meet the needs of the LSD multi-disciplinary laboratory operation. Unit procedures may contain additional information and instructions that are not specifically detailed in this plan. Procedures should always be consulted prior to the initiation of any laboratory operation requiring the use of chemicals. The Chemical Hygiene Plan is meant to address all issues concerning the handling and use of chemicals in the CDPHE, LSD.

13. Research and Development

No research and development is conducted in this facility.

14. Examination Processes and Procedures List

14.1. General Requirements

14.1.1. All laboratory procedures will be written in the format established below, maintained in good condition, suitably protected from deterioration and soiling, and be readily accessible to laboratory personnel.

14.1.2. All procedures will be written in MS Word 97 or later version, formatted and a copy stored on electronic media for easy retrieval, revision and update. The naming of procedure files will be such that the most current revision will be easily identified. All procedures will contain a document control header in the upper right hand corner of each page using the format shown in Appendix D.2.

14.1.3. Once a procedure is approved, the Program Manager will deliver an electronic copy to the QAO who will maintain an electronic copy of all procedures in a read-only file on the LSD LAN in I:_SOPS sorted into folders by laboratory name and then the procedure.

14.1.4. No testing is to be performed until an approved procedure is available to the analyst in the testing area, except as outlined in section III.D.4. of this manual, related to emergency public health testing.

14.1.5. Signatures of approval from the following individuals are required before a procedure is approved:

14.1.5.1. Procedure Author

14.1.5.2. Unit Supervisor

14.1.5.3. Program Manager

14.1.5.4. Quality Assurance Officer

14.1.5.5. LSD Director (or other individual as required by regulations or designated by the LSD Director)

14.1.6. SOP Format:

Operating procedures should be easy to follow and contain information in twelve required components. A suggested format is the CLSI or EPA Guidelines (in certain instances, more rigorous documentation may be required) as follows:

Title	Name of the substance, analyte or organism for which the test is to be performed. Examples: HIV Antibody by EIA (serum), Cadmium by AA, Calcium, ICP/MS, etc. Use the matrix in the title if it distinguishes it from another method.
References	Pertinent references including any manufacturer's instructions if available.
Method	The type of analysis to be used and a description of alternate methods, e.g., gas chromatography/mass spectrometry, ELISA, radio immunoassay, atomic absorption spectrophotometry, etc.
Principle	A description of the test, chemical reaction, and/or use of the procedure.

Sample	Type of sample or specimen preferred and any other acceptable specimen/sample; preparation for collection/sampling; acceptable containers; stability and preservation required; storage conditions and transport; criteria for acceptance/rejection/chain of custody; interfering substances and description of physical characteristics of specimens/samples affecting results.
Reagents	A list of reagents and supplies including acceptable grade, hazards, source, and directions for preparation of each reagent including measuring accuracy and precision, handling specifics, glassware, etc. Storage of reagents including temperature, expiration, containers. Quality control materials, type, source, preparation (controls and standards) and storage.
Equipment	List of equipment required including type and model of instruments. If an instrument manufacturer has supplied specific written operational procedures, they must be used to develop the in-house procedure.
Procedure	Procedures for instrument calibration, baseline, linearity or background checks with specific description of materials used unique to the SOP including acceptable limits for these checks. Quality Control including frequency of testing, placement in test runs, etc. Test procedure that must be recorded in stepwise fashion using the actual sequence of events, as they normally would occur. Flow charts may be used for clarity if necessary. Cleanup procedures and waste handling must be detailed. Corrective actions to follow when test systems become inoperable such as alternative test methods or sample preservation, etc.
Interpretation	Instructions/mathematics for calculation of test results. Quality control to include control ranges, how established and revised, corrective action procedures, and quality control data recording. Test result format including units, significant figures, etc. Limitations of the method that includes minimum/maximum concentration levels. Instructions on qualification of test results according to specimen condition, quality control parameters, etc. Specific instructions for data recording in individual lab notebooks (if applicable), reporting, and documentation. Any other information, notes, or comments that add clarity or provide better accuracy or precision.
Reporting:	Instructions regarding entry of results into computer systems with regard to values, codes, interpretive messages, etc
Pollution Prevention	A statement and methods the unit uses to minimize hazardous chemicals produced as a by-product of the procedure.
Waste Management	A chart detailing the disposal of chemicals and wastes generated as a byproduct of the procedure.
Appendices	All supplementary information pertinent to the method including validation, capability, MDL's, valid data, record of staff signatures for SOP changes, package inserts, etc.

Approvals	Procedure Author Unit Supervisor Program Manager QA Officer LSD Director or designee
Dates	Date placed in service Date removed from service
Revisions	A revision page is included at the end of each procedure that details revision author, computer file name, revision number, date of revision, page(s) of revision(s) and approval signatures as required by the LSD Director. See Appendix D.2. A copy of the SOP template can be found on the LAN at I:\refdocs\Procedures\2003 SOP template.doc

Note: Each program may have additional written procedures that do not affect the test results for specific non-testing purposes which do not require results be reported to customers. These procedures need not follow the SOP format, but must be approved by the Program Manager.

Examples of such non-testing procedures that may not require SOP format include:

Data processing equipment use
Laboratory work schedules
Instrument operation instructions
Records retention policy

14.1.7. SOP Review and Approval Process: The following procedures will be used to document the review and approval of all SOPs:

14.1.7.1. Each draft procedure when submitted for review shall include a routing sheet similar to that shown in Appendix D.1, listing all positions that must review and approve the procedure. This routing sheet Must accompany the procedure throughout the review and approval process.

14.1.7.2. The procedure author submits the procedure to the Unit Supervisor to start the review and approval process. After reviewing the procedure, each person signs and dates the appropriate space on the cover sheet, then forwards the procedure to the next person on the review list. Each reviewer must complete this initial review within 10 working days. Comments may be noted on the draft or on separate sheets with clear reference to the draft.

14.1.7.3 After all reviewers have made their comments, the draft is returned to the author through the Unit Supervisor to make the agreeable corrections and revisions. The author or manager may rebut suggested changes with justification for keeping the original text.

14.1.7.4. The final draft must be signed by the author and unit Supervisor and is then submitted to the next level for approval.

14.1.7.4.1. If the draft is the first version (revision=0) the original approval page must be signed.

14.1.7.4.2. If revision is being submitted for approvals, the original approvals page must accompany the revision draft and the revisions approval page should be signed.

14.1.7.4.3. The draft that was initially reviewed accompanies the final draft so that each approval authority can see that changes were made or reasoning in support of the original version. Each approval level must sign the procedure approval page within 5 working days, sign and date the cover sheet, and pass the package to the next approval level.

14.1.7.4.4. The QA officer will keep all outdated SOPs in a master dead file sorted by unit.

14.1.8. Emergency Public Health Testing

14.1.8.1. Under unusual circumstances, the signature of the LSD Director or an individual specifically designated by him/her is sufficient to allow initiation of testing. Testing may also be initiated without complete signatory approval under circumstances of rapid response to public health or environmental emergencies. In this scenario, documentation must be available and include reference testing, regulatory agency approval, literature references or other publications, and the LSD Director may require preliminary validation data. Full documentation and procedure approval should be initiated as soon as possible. Authorization to proceed under the rapid response scenario may be approved by the Program Manager, or, in his/her absence, the QAO or LSD Director.

14.1.8.2. Copies of pertinent data which demonstrate the validity of the method shall accompany the emergency procedure submitted for approval except for revisions or updates of methods of long standing use, if referenced, including:

EPA approved, and published, methods.
Standard FDA methods (Bacteriological Analytical Manual, latest revision).
Standard Methods for the Examination of Water and Wastewater (latest revision).
Bacteriological and chemical methods detailed by the Association of Analytical Chemists (AOAC).
Other reference methods from scientifically respected professional societies, organizations approved by the LSD Director or his/her designee.

14.1.9. SOP Manual

14.1.9.1. Active SOPs must be organized in a manual for each unit. Essential parts of a well organized procedure manual are:

14.1.9.1.1. Title Page

14.1.9.1.2. Table of Contents

14.1.9.1.3. Procedures (SOPs)

14.1.9.1.4. Review Page (see 22.3.2. CDPHE-LSD 006: Procedure approval and revision)

14.1.9.1.5. Unit specific safety requirements

14.1.9.1.6. Unit specific QA requirements including:

14.1.9.1.6.1. Review procedure of test data

14.1.9.1.6.2. Criteria for rejection of specimen

14.1.9.1.6.3. Criteria for invalidation of test results

14.1.9.1.6.4. Preventive maintenance and function check requirement

14.1.9.2. Each SOP must be reviewed annually but not to exceed 12 months since the last review by each individual of each category listed below:

14.1.9.2.1. Any technician who performs a procedure or has been designated as a backup technician for a procedure.

14.1.9.2.2. The Unit Supervisor for a procedure

14.1.9.2.3. The Program Manager for a procedure

14.1.9.2.4. The Quality Assurance Officer

14.1.9.2.5. The CLIA Director

14.1.9.2.6. The Laboratory Services Director

Each individual required to review this document should sign the review page.

14.2. Watermark – Once a SOP is finalized and ready for signature a watermark "Original" must be placed on each page and then printed out for signature. Once the signature copy has been printed the watermark must be changed to "Uncontrolled Copy". This copy must then be converted to "PDF" format. The "Word" formatted SOP should be saved in a safe area within the section for later updates and or changes. The "PDF" formatted SOP should be placed on the I drive. If this SOP is not a new SOP then older version must be removed before the newer update is put on the I drive. The file, How to Create a Watermark, can be found at I:QA "How to Create a Watermark".

15. Pre- Examination

15.1. Request Protocols

15.2. Collection and Sampling

Each program provides written instructions for properly collecting and transporting specimens/samples for its clients use. These instructions must comply with appropriate regulatory (EPA, FDA, CLIA, etc.) guidelines.

15.2. 1. Labeling

Each program must develop procedures for labeling samples. The minimum information for labels include:

15.2.1.1. Name and or ID#, date, time, and location of sample collection.

15.2.1.2. Name of person making sample collection.

15.2.1.3. When test materials are submitted to the Laboratory, a unique laboratory identification number or other means of tracking the specimen/sample must be affixed to the container label or sample container. The employee receiving the sample will insure compliance with the labeling guideline and accept the sample and hold for additional information or reject the sample if the name, ID#, or unique identifier is missing. The submitter will be notified of the non-compliance by the accessioning supervisor.

15.2.1.4. Accessioning labeling: When a sample or samples are separated from the requisition, a linking number must be placed on both the samples and the requisition when the sample container/letter/package etc is opened. It is not correct practice to separate the sample and the requisition --such as rack of tubes, and a stack of requisitions without the linking number being entered as each set is opened.

15.2.1.5. This linking number or code may be:

15.2.1.5.1. the accession number

15.2.1.5.2. a unique collection control number or ID that is applied to both the sample and requisition when the sample is collected

15.2.1.5.3. a preliminary number, sometimes called a QA number, that is used to link the sample(s) to the requisition until an accession number is generated and applied. The QA number may be simply a succession of numbers for a batch of similar accessions, such 1, 2, 3 etc, but is not a unique number as the accession ID must be.

15.2.2. Preserving, Transporting, and Storing Specimens/Samples

Requirements for specimen/sample preservation, transportation, and holding times should be included in the appropriate SOP. If not, the program must have a separate written procedure for preserving, transporting, and storing samples/specimens.

15.2.3. Requisitions

Each program must provide an appropriate form to order tests or to record requests for tests/analyses. Each sample/specimen submitted for analysis must be accompanied by the appropriate requisition form and include it in the data package produced. When the proper requisition is missing the submitter will be notified of the non-compliance by the accessioning supervisor.

15.2.4. Acceptability Criteria

Each program shall have written criteria to determine acceptability for each type of specimen/sample submitted for analysis. These criteria must be documented (such as an SOP, or a separate procedure) and approved by the LSD Director. Acceptability criteria will be made available to persons requesting tests/analyses.

The Program Manager or his/her designee must reject any sample/specimen that does not meet acceptability criteria unless approved by the LSD Director or submitted because of a declared emergency. The results must then be reported as specified in section H.4 of this manual. Samples that are deemed potentially hazardous or infectious and outside the scope of safety capabilities of the LSD shall be brought to the immediate attention of the Program Manager for decision on disposition. This decision shall be documented in the comments of the requisition/report.

15.2.5. Retention of Test Material

Each program must have an established procedure for retaining and/or disposing of material after analysis. The procedure addresses the following items:

15.2.6. Sample storage requirements

15.2.7. Security procedures

15.2.8. Duration period for retaining specimens/samples

15.2.9. Disposal requirements

15.2.10. Material retrieval from storage

15.2.11. Client notification of storage/disposal

15.2.12. Chain of Custody

Chain of custody, as used in the legal context, is the ability to track an item through collection, testing, reporting, storage and disposal. In the laboratory setting the item is most often a specimen or sample. The identity and integrity of the material must be maintained by tracking its handling and storage from the point of collection to final disposition. Any gap in the chain of custody record renders the sample unacceptable for legal purposes.

Each program will establish written procedures to maintain Chain of Custody within the program. These procedures must include but are not limited to:

15.2.13. Security during sample shipment or transfer.

15.2.14. Provision for a permanent log book.

15.2.15. A form to document sample receipt and transfer within the laboratory (accepting custody).

15.2.16. Secure sample storage.

15.3. DATA HANDLING

15.3.1. Requisitions

15.3.1.1. Requisitions supplied to lab users should provide clearly identified spaces for the information required for testing, including:

15.3.1.1.1. Name and address of requestor and the address to which report is to be sent, if different. The county and state of origin of sample may also be required.

15.3.1.1.2. Identity of sample/specimen—either patient name or, if confidentiality is requested, a unique identification code. For environmental samples the sampling site (i.e., water system or business), physical address, and description.

15.3.1.1.3. Collection date/time; collection number, name of collector and details of specimen delivery, if appropriate.

15.3.1.1.4. Test/analyses requested.

15.3.1.1.5. Billing information, if appropriate.

15.3.1.2. Requisitions received should be:

15.3.1.2.1. Legible.

15.3.1.2.2. Contain the minimum essential information (requestor, sample identification, tests requested) for the project and be unambiguously referenced to specimen/sample container.

15.3.1.2.3. If missing essential information, the sample/specimen will be handled per division policy relating to the collection of missing information.

15.3.2. Specimen/Sample Receipt

15.3.2.1The sample processing staff accessions samples/specimens received in a manner that allows:

15.3.2.1.1. Ready retrieval of information regarding any individual sample,

15.3.2.1.2. Inquiry on whether a sample had been received, and

15.3.2.1.3. Totals of samples received per time period.

15.3.2.2. A unique laboratory accession number is assigned to each specimen/sample, placing an indelible common identifier on all components of specimen submitted and the requisition document. Specimens/samples and requisitions must not be separated until the accessioning process is completed.

15.3.2.3. The time of receipt/accession and all pertinent information regarding the specimen that may affect the test result are recorded in the computer test record, requisition document or accession log. The time and date of receipt in the laboratory and identity of individuals who received the sample(s) and performed accession are recorded.

15.3.3. Test/Analysis Records

15.3.3.1. General Guidelines for the Maintenance of Analytical Records

15.3.3.1.1. All analytical data shall routinely be recorded in a permanent record, with all written entries and calculations recorded legibly in ink, and:

15.3.3.1.2. All computer calculation functions will be verified semi-annually.

15.3.3.1.3. All notebook entries and instrument printouts will contain a clear and unambiguous reference of sample identification.

15.3.3.1.4. Documents generated during testing/analysis will include date of analyses and analyst initials.

15.3.3.1.5. All instrument printouts containing data produced regarding baseline, calibration, and function check data will be stored in an accessible manner for a minimum of six months. Records older than six months are placed in archival storage.

15.3.3.1.6. Data and calculations entered will not be erased or covered; rather errors are crossed out, correct information entered in an adjacent space, and the correction will be initialed and dated by the person changing the information.

15.3.3.1.7. Data analyses that involve samples needing security handling or involving proprietary information will be handled using Chain of Custody protocol (see section 15.2.12 Chain of Custody in this manual.)

15.3.3.1.8. All laboratory electronic database records are to conform to the Colorado Department of Public Health & Environment Information Security policies

15.3.3.2. Records Retention

All analytical data and sample records will be kept in accordance To the Laboratory Services Division Record Retention Policy. Copies of all laboratory reports are to be maintained on file by the Laboratory Services Division and be available for a period required by statute, regulation, or accreditation guidelines.

The records retention schedule will comply with all regulatory requirements as well as the Division of Archives and Public Records policies. Each laboratory units Record Disposition Schedule will include the following information:

15.3.3.2.1. Description of record (form, worksheet, analytical records including instrument raw data, etc.)

15.3.3.2.2. Retention period

15.3.3.2.3. Special instructions (electronic data, transfer to microfilm, disposition of original after microfilming, etc.)

15.3.4. Data Quality Objective are determined by our customers, ideally prior to sample collection. For customers whose only objective is to satisfy Colorado drinking water regulations, the DQO is to comply with the prescribed methods and detection limits given in 40 CFR part 141.25. DQOs for other customers are determined at the time the sample is received, if not before. Lab staff members are always available to consult with customers regarding DQOs for compliance with state or federal regulations, or for their own purposes.

16. Validation of Results

METHOD VALIDATION

Each program must validate or demonstrate capability for all procedures. If there is no regulatory method from which the procedure is derived, then the program must have a means of validating the test or analysis. Where appropriate, the principles and procedures described in performance-based methodology approaches may be used.

The procedure must describe necessary steps to establish accuracy, precision, specificity, sensitivity, and range of linearity or regression fit, suitable selection of internal standards, surrogate materials and spikes. This data must be included with the written procedure when it is submitted for approval in accordance with section 14.1.6. SOP Format of this manual.

17. Quality Control

PROGRAM-SPECIFIC QUALITY CONTROL – All tests and analyses must comply with appropriate regulatory and certification requirements for quality control (QC). Specific quality control requirements must be included in the SOPs for tests or analyses. These QC requirements should include but are not limited to the following:

17.1. Calibration criteria, including method for documenting the tracing of standard material to certified source:

17.1.1. Positive/negative controls for qualitative tests

17.1.2. Recovery criteria for extraction surrogates and spikes

17.1.3. Criteria for duplicates, spikes, matrix spikes, blanks, etc.

17.1.4. Use of data acquisition and analysis systems

17.1.5. Control charts

17.1.6. Method validation

Note: Specific QC requirements are established by each program based on methodology used and applicable regulatory requirements.

17.2. When QC results exceed established limits the analyst must determine the reason for the "out-of-control" condition and correct the cause as detailed in the SOP. If the cause cannot be determined and corrected following the steps in the SOP, or the SOP does not give the action to take, then the following actions will be taken:

17.3. The analyst will document in the data package the failure, the steps taken to find and correct the cause, the results of those steps, laboratory conditions existing during the analysis of the failed QC sample, results of other QC contained in the same analysis, and any other pertinent information.

17.4. The Program Manager or his/her designee will decide if the results can be released with qualifications or if re-sampling is required using criteria established in the SOP.

17.5. Each program must establish written procedures for documenting QC results using the following guidelines:

17.5.1. Control charts and calibration data will be available

17.5.2. QC results must list the acceptable ranges

17.5.3. QC results should be included with the appropriate data

17.5.4. QC materials must have tractability documents

17.6. Reagent / Expiration Date Policy

Any reagent, kit, chemical, or solution (referred to as "reagent") that is used for any testing procedure or a process leading to a testing procedure must have the following information:

17.6.1. Date Received – All containers must be labeled appropriately, kits may be labeled on the main container but kit components cannot be mixed unless manufactures product insert authorizes mixing. If mixing occurs than each reagent in the kit must be labeled.

17.6.2. Expiration Date – Expiration dates fall into three categories.

17.6.2.1. Manufacturers recorded expiration date – the date provided on the reagent by the manufacturer that does not change once the container is open.

17.6.2.2. Manufacturers recommended date – many items with a manufacturer shelf expiration date change to a 30-days-after-opening expiration date. This information is obtained from the manufacturers product insert. Items falling under this category must have a new expiration date placed on the container once it is opened.

17.6.2.3. No expiration date provided – Any reagent that does not have an expiration date will need to have an expiration date assigned to it. The first source should be from the manufactures product insert. If the manufactures product insert does not provide a recommendation than an expiration date will need to be assigned.

17.6.2.3.1. Any reagent recognized as unstable will be assigned an expiration date as indicated in the MSDS or, if not available in the MSDS, two years from the date opened unless noted in Appendix 1 of this policy.

17.6.2.3.2. Any stable reagent will be assigned a five-year expiration date from the date opened. If at the end of this five-year period, and if the reagent remains uncontaminated and un-deteriorated, the reagent expiration date can be extended for a one-year period. The reagent will need to be inspected annually to insure that the integrity of the reagent remains intact and a new expiration date will need to be placed on the container after each annual inspection if applicable. The date of the annual inspection and initials of the inspector need to be added to the reagent label.

17.6.3. Date Opened must be placed on the container after the container is opened.

17.6.4. Initials– Each reagent needs a minimal of two initials:

17.6.4.1. After the date received

17.6.4.2. After the reagent is opened

17.6.4.3. After an expiration date is added or when the expiration dated changes as described in section 17.6.2.2.

18. Reporting of Results

18.1. Reporting Results

The responsibility for the release of information from the LS Division is delegated to the Program Manager. The LS Director expects the Manager to review, or cause to be reviewed, all information before it is released to the client/user of the service. Each laboratory unit should develop written review procedures based on program requirements. At a minimum, the data review procedure is to include a peer review of all raw analytical data. The review may be delegated to the unit supervisor or to other qualified professional staff, but the responsibility for the quality of the information remains with the LS Director. The review must be documented in the data package.

18.2. Referral of Specimens

If a specimen is referred to another laboratory for testing, a log should be maintained to track the sending of the specimen and the receipt of returned results. The log should clearly indicate the date and name of the person who sent the specimen and the date of receipt of results and who received them. If any communications occur between the reference laboratory and the program, especially in regard to preliminary reports, the names of the individuals communicating, the date and time, laboratory accession numbers and test results should be recorded and kept with the log record.

When results are received from the referral laboratory, they should be transcribed and reported as soon as possible. All pertinent information should be recorded. The laboratory report must identify the laboratory that performed the testing. If both the LS Division laboratory results and the reference laboratory's results are being reported, there must be a clear indication of source of the individual tests. All normal values, limits, and other pertinent information as reported by the reference laboratory are reported along with the in-house testing results.

18.3. Laboratory Information System Downtime

Each laboratory unit shall have in place a system to accession, label, work list, result, and report tests in the event of a computer failure or outage exceeding 12 hours. For downtime less than 12 hours, samples will be stabilized, held, and analyzed on the next shift. If this will result in the sample holding time being exceeded, then the downtime procedure must be implemented instead. The downtime procedure will be unit specific and include log sheets, labels, accession numbers, and hand-written report forms necessary to accomplish this task. Following the resolution of the computer problems, all specimen information and results will be entered into the information system in the normal fashion.

18.4. Report Protocols

Each program will establish written procedures for reporting results generated by the program. These written procedures should include guidelines concerning the release of data, security of data, and its confidentiality. Reports must contain the following elements:

18.4. 1. A heading or letterhead that identifies the Colorado Department of Public Health & Environment, LS Division.

18.4. 2. The dates of sample/specimen collection, receipt, analysis, and report.

18.4. 3. The complete identification of the sample—patient, sample description identification number.

18.4. 4. Analyses performed.

18.4. 5. Name of client receiving report.

18.4. 6. Results and interpretation, if applicable.

18.4. 7. If results are compromised, the reason for the deficiency in data quality.

Copies of all laboratory reports are to be maintained on file by the LS Division and be available for easy retrieval for a period required by statute, regulation or accreditation guideline. (May vary from 2-25 years, see section 22.4. Document Control of this manual.)

Verbal reports should be kept to a minimum and are always presented as preliminary with final written reports to follow. In order to assure that verbal reports are being provided to the appropriate individual or agency, telephone reports can only be given when the LS initiates the call. Results may be faxed to qualified customers.

18.5. Analytical reports to drinking water suppliers and programs should contain sufficient information to establish the validity of the reported results for the required analyses. It should be designed as a summary form that contains the sampling and analytical information described above. At a minimum, these reports should contain the following information:

18.5.1. Name and location of the water supply, including its PWSID.

18.5.2. Location in the water supply where the sample was taken.

18.5.3. Date and time of sampling.

18.5.4. The name of the person responsible for taking the sample.

18.5.5. Sample receipt date at the laboratory.

18.5.6. Date and time of analysis.

18.5.7. The method used for the analysis.

18.5.8. The laboratory and the initials of the person responsible for performing the analysis.

18.5.9. The analytical result, including the calculated uncertainty of the measurement.

18.5.10. If the result is below the calculated detection limit for that sample, the result should be reported as less than the calculated detection limit.

Analytical reports are available upon request to any customer.

18.6. Critical Results Policy

Each laboratory unit shall maintain and update, as needed a list of critical results that require telephone notification of customers. Critical results are test results—either quantitative or qualitative—that require immediate customer notification due to potential medical management requirements or environmental response actions. Establishment of critical results that require the approval of a program manager. Supervisors shall establish procedures to ensure that results are called and a record of the call—including the actual result, the name of the person who took the call (first and last names), the time and date of the call—is made in such a manner as to allow easy retrieval.

18.7. Trend Analysis:

The Program Manager must document customer complaints. Response to complaints should address corrective action on systems and procedures found to be deficient. Records of complaints and corrective actions should be available for review by management and auditing authorities. The QA Committee will conduct a review of complaints and concerns annually, noting any repeat concerns or trends and recommend corrective actions to the LS Director.

18.8. Confidentiality Assessment Process

The Laboratory Services Division has a confidentiality policy that is signed by all employees at hire and reviewed annually. This policy addresses protection of patient sensitive information in compliance with HIPAA. As a part of the quarterly analytical process audits, the auditors will observe and document compliance with the confidentiality policy at each step where patient information is accessed and used. The auditors shall observe staff handling of patient-labeled samples, requisitions, computer work lists, computer screen displays, faxes, and printed reports as well as phone communications with clients to insure that they are handled in a fashion the protects patient information in accordance with policy. Variations will be noted and reported with suggested remediation reported to the director.

19. Remedial Actions and Complaints

19.1. Corrected Report Policy

A Corrected Report must be generated if a customer has already received a report and when one of the following conditions occurs:

19.1.1. Typographical Error – If a typographical error occurs that creates a question as to the identity of a sample or its interpretation, a corrected report must be generated.

19.1.2. Incorrect Result – If the wrong result is placed on a report a corrected report must be generated.

19.1.3. Wrong patient name or environmental site description - If the wrong name or site designation is given on a report, a corrected report must be generated.

19.2. A copy of the original report and a copy of the new report must be stapled together and placed into a filed labeled "Corrected Reports (with a year ID)."

19.2. 1. The corrected report must show the original result and date reported in an appropriate field that allows an audit trail to be maintained. For example, record " Corrected Report: Culture result originally reported 8-15-05 as 'no growth' in the comments field of the report with the new result and a new report date in the test reporting area.

19.2. 2. A copy of the original report, a copy of the new report, and a copy of the cover letter must be stapled together and placed into a filed labeled "Corrected Reports (with a year ID)."

19.2. 3. A report must be generated, regardless of the number of reports, by each reporting section no later than the 20th day of each month and provided to the QAO. The report will include; the original report identification, the date of the original report, the reason for the correction (original data and the corrected data), the date of the corrected report, and the name of the person who generated the corrected report.

19.2. 4. The QAO will compile a report and present it to the QAC each month. The QAO will generate a master report annually and present the report to the LS Director.

19.3. A copy of the original report, a copy of the new report labeled "Corrected Reports", and a cover letter explaining the reason for the correction must be sent to the customer as soon as possible.

20. Communications

20.1. Patients, customers, and health professionals

20.1.1. CLIENT/LAB SERVICE RELATIONS

Each program in the Laboratory Services Division will develop strategies for identifying, measuring and responding to customer needs. As cited in the Laboratory Services Division Plans (see references), the plans must address the following issues: customer-oriented employee selection and training, policies toward employee empowerment and accountability, sufficient resources to support rewards and recognition of employees who model exceptional customer service, and policies and procedures for continual process improvement. Periodic customer satisfaction surveys will be used to measure success. The QAC will conduct quarterly audits of representative client communications (both phone and written) to observe compliance with desired customer relations and confidentiality. All written and verbal customer interaction will be conducted in a professional and courteous manner. Violations may result in disciplinary action.

20.1.2. Laboratory Services Division Information Management Guideline

INFORMATION MANAGEMENT GUIDELINE
Laboratory Services Division

Colorado Department of Public Health and Environment

SUBJECT: INFORMATION MANAGEMENT Effective Date: 9/1/11

PURPOSE: The Division will comply with all requirements set out in the Colorado Department of Public Health and Environment (CDPHE) policy #15.39 – Audit and Evaluation. In addition, it is the policy of the Division that internal audits will be periodically performed on critical information systems and confidential data to ensure compliance to these policies. This includes monitoring data access rights and network ID security levels. At least once per year, the Division will retain an independent firm to conduct a comprehensive security assessment for compliance to this policy and regulatory requirements

Violations of any of these provisions may be subject to state personnel system disciplinary action. Other non-employee workforce members shall be disciplined with appropriate action, up to and including termination and possible referral for criminal prosecution.

20.2. Suppliers

20.2.1. If a purchase is less than $1,000 Chief Fiscal Officer must sign off on request. Procurement-Cards may be used for purchases less than $5,000. You may not exceed $5,000 per vendor per fiscal year with a Procurement-card. Once the $5,000 threshold has been reached a Purchase Order must be put in place.

20.2.2. If a purchase or services is greater than $5,000 the Fiscal office must put a Purchase Order in place.

20.2.3. If a purchase or services is greater than $10,000 a competitive bid or state price agreement must be done.

20.2.4. If purchase or services are greater $25,000 a competitive bid or state price agreement must be done.

20.2.5. Fiscal rules require a contract at $100,000 for services and $150,000 for goods. One may not procure goods or services over $5,000 without a Purchase Order in place first.

20.2.6. All these rules are based on a "per vendor, per fiscal year" scenario. Aka. If you buy $4,900 with a vendor you do not need a Purchase Order. If your next purchase is greater than $100 you need a Purchase Order.

21. Audits

21.1. Internal Evaluation Program

The Quality Assurance Officer oversees reviews or conducts specific audits as defined below to verify program compliance with quality control requirements and other aspects of the quality assurance program described in this manual.

21.1.1. Internal Audits

The QAO will oversee once or twice yearly audits (depending on certifying agency) of laboratory program analytical processes to be conducted by members of the QA Committee. The auditor will look comprehensively at specimen labeling, specimen preparation/preservation, login, work listing, reagent preparation, equipment maintenance, testing, SOPs, data review, resulting, reporting, customer delivery, and any/all steps involved in the process to determine compliance and insure test process quality. These audits may also include following a sample completely through the analytical process in the laboratory from sample receipt and login to result entry and reporting. The audits should be conducted as follows.

21.1.1.1. Notification of Audit

The QAO will publish a master list each calendar year with the months that a section will be audited. The QAO will contact the section supervisor at least 10 working days prior to the month shown on the master list to establish the exact date and time, which will insure staff and process availability. Once the date and time have been established, the QAO informs the LSD Director and Program Manager of the date and time for the audit, the type of audit, and the specific area(s) being audited.

21.1.1.2. Audit

The audit team will use the CDPHE Audit form to ensure that all areas designated are looked at. This will include multiply areas of pre-analytic, analytic, post-analytic processes and personnel requirements. Each member of the team will give an assessment to the supervisor of what they found during the audit. Each member of the audit team must sign and date page 4 of the CDPHE Audit form and provide the QAO with his or her CDPHE Audit forms.

21.1.1.3. Notification of Audit Findings

The QAO will compile the CDPHE Audit forms into a master copy and forward the CDPHE Audit form with all findings, within 5 working days, to the program and requests a corrective action response. All findings will be addressed on page 3 of the CDPHE Audit form. Each response will consist of three parts:

21.1.1.3.1. Issues: What was found
21.1.1.3.2. Recommendation: What can be done
21.1.1.3.3. Action: What was done by the section to address the issue
21.1.1.4. Addressing the Audit Findings

Within 10 working days of receiving the CDPHE Audit form, from the QAO, the section supervisor responds to the QAO. The corrective actions will be listed in the "Action" block of the CDPHE Audit form. If an issue cannot be corrected within the 10 days after receiving the CDPHE Audit form, then a plan of action with the expected completion date should be placed in the "Action" block.

21.1.1.5. Verification of Actions

The QAO will insure that the actions taken or the plan of action suggested by the section will meet all requirements as set by the QAM. If actions do not meet all requirements the QAO will discuss his/her concerns with the supervisor and/or director of the section. If a solution cannot be reach by these individuals than the QAO will, in writing, inform the LSD Director asking for arbitration. If a plan of action is presented the QAO must follow up on the issue to ensure the action was implemented within a reasonable amount of time. If the section as stated in the plan of action does not comply with the plan of action the QAO will address the issue with the director of the section. If the director of the section does respond within a reasonable amount of time than the QAO will, in writing, report the issue to the LD Director.

21.1.1.6. Reporting Results of the Audit

The QAO prepares or reviews reports of reviews for the LSD Director. These reports shall be delivered to the LSD Director no later than 15 working days following a specific area review and no later than 20 working days after a complete records review. The report contains the following sections:

21.1.1.6.1. Type of audit, section involved, and date of audit
21.1.1.6.2. Members of the audit Team
21.1.1.6.3. Section personnel involved in the audit
21.1.1.6.4. Findings
21.1.1.6.5. Corrective Actions
21.1.1.6.6. Verification data
21.1.1.6.7. First attachment, CDPHE Audit form
21.1.1.6.8. Other attachments, any supporting documents including, if applicable, but not limited to;
21.1.1.6.9. Customer request
21.1.1.6.10. Customer instruction
21.1.1.6.11. LITS audit trail
21.1.1.6.12. Work list
21.1.1.6.13. QC documentation
21.1.1.6.14. Crystal report
21.1.1.6.15. Continuing education records of all analyst involved in the testing process

21.1.2. Targeted audits

The QAO through the QA Committee arranges or conducts the following types of audits at the intervals indicated as required by regulation or at the QAO's discretion:

21.1.2.1. Proficiency testing/Performance evaluation (PT/PE) – The QAO will review the program's participation in external and internal blind performance programs to assure coverage of program tests or

analyses. The number of yearly external/internal PT/PE challenges will be determined by the programs certifying agency and should be run by each program unless not available by subscription or internal PT methods.

21.1.2.2. Double blind samples – Samples submitted to the program upon request and funding for analysis by methods normally used in the program and that are not otherwise identifiable as an audit sample.

21.1.2.3. Exams – Administer subject matter exams to staff.

21.1.2.4. Personnel competency evaluation – Direct observation of analysts' adherence to procedures (see section 22.3.6. CDPHE-LSD 044: Competency Assessment of this manual.).

21.1.3. The QAO may be requested by the Director to investigate a single area or laboratory operation (or a limited number of areas) that can be evaluated in a short time period. The area may be a complete analytical method, or any part of the laboratory test process such as sample login, report generation or standard preparation. It may include the verification of the method developed.

21.2. External Evaluation Programs

Each program will participate in external performance evaluation studies as necessary to satisfy regulatory or certification agency requirements and to monitor laboratory performance. Programs may participate in additional studies as needed to assure quality. The QAO will inform Program Managers of the existence of possible studies in which they might want to participate. The number of yearly external PT/PE challenges will be determined by the programs certifying agency and should be run by each program unless not available by subscription or internal PT methods.

The QAO monitors enrollment in performance evaluation studies. The LSD Director or his/her designee receives the study results and distributes to the appropriate program(s). For each analyte judged not acceptable by the evaluation program, the Program Manager will supervise the completion of a PT Survey Challenge / Analyte Report / Review (22.3.4. CDPHE-LSD 001: PT Survey Challenge /Analyte Report / Review of this manual). The Problem Identification/Corrective Action Report should be submitted to the QAO for review no later than 10 working days after the Program Manager receives the PT results.

After review and signatures of the attestation page (22.3.5. CDPHE-LSD: Attestation Statement), the original report shall be maintained in the program files with the study results and all written, printed, and electronic records, including but not limited to bench sheets, instrument strip charts or printouts, data calculations, and data reports, resulting from the analysis of any PT samples/specimens for five years or for as long as is required by the applicable regulatory program, whichever is greater. These records, maintained under the supervision of the respective Program Manager, shall include a copy of the PT study report forms used by the laboratory to record PT results. All pertinent laboratory records shall be made available to the inspectors/surveyors during on-site surveys of the LSD.

The LSD management and all analysts shall ensure that all PT samples are handled (i.e., managed, analyzed and reported) in the same manner as ordinary samples/specimens to the extent possible. The LSD shall utilize the same staff, procedures, equipment, facilities, and frequency of analysis for PT samples/specimens as for ordinary samples/specimens.

21.3. Proficiency testing/Performance Evaluation programs

To ensure that yearly required challenge specimens are made available for testing, programs may elect to secure challenge specimens from peer laboratories to be tested internally, by compounding mock specimens approximately test matrices, spiking of normal samples and other methods. Samples should be coded to ensure the analyst is ignorant of expected test results. Reporting of incorrect analytic results should follow that prescribed for external PT/PE analyses.

If the Program Manager or the LSD Director wishes to test the entire laboratory process, double-blind evaluations may be used. Blind samples are necessarily unannounced performance evaluations. The QAO may contract with local commercial vendors who will prepare appropriate samples using LSD-issue bottles and labels and work with the client to submit the samples as genuine samples. The client receives the results and forwards them to the QAO for evaluation. The QAO forwards a report to the LSD Director with explanation of the process and results of the evaluation. The LSD Director may request the program to further evaluate the results in comparison with other performance audits and/or internal quality control systems.

21.4. Peer Inspections

If deemed advisable by the Director with QAO and QA committee input, a peer laboratory expert group may be solicited to inspect one or more laboratory units. Results of and responses to such inspections will be maintained by the QAO and made available to appropriate authorities.

21.5. Attestation Statement

Each PT/PE must have an accompanying Attestation Statement with the signatures of each analyst, the section supervisor, and the LSD Director or their designee. Organizations such as College of American Pathologist provide their own Attestation Statement for all other PT/PE use the LSD Attestation Statement. (22.3.5. CDPHE-LSD: Attestation Statement). If a PT/PE is filed electronically names should be typed for all analysts, supervisors, and the LSD Director or their designee on any electronic attestation page provided but the original paperwork must have signatures.

22. Appendices

22.1. DEFINITIONS

ACCURACY - The degree of agreement of a measured value with the true or expected value of the quantity of concern.

BIAS - A systematic error in a method due to a change in conditions or processing of the test specimens/samples.

CALIBRATION - Systematic standardization of a procedure, measuring device or instrument, usually by setting a signal response with a known standard or calibrator.

CHAIN OF CUSTODY - Legal procedure for tracking samples from collection through reporting.

COMPARABILITY - The confidence with which one data set can be compared to another.

COMPLETENESS - The measure of the amount of valid data obtained from a measurement system. Compared to an expected amount of data, usually expressed as a percentage.

CONFIRMATION - To affirm the correctness of a test result by further analysis, using another analytical method of equal or greater sensitivity and/or specificity.

CONTROL CHART - A graphical plot of test results with respect to time or sequence of measurement together with limits within which they are expected to lie when the system is in a state of statistical control.

CONTROL SAMPLE - A material containing a known (empirically measured) amount of analyte that is analyzed concurrently with test samples to evaluate test system stability and testing accuracy under actual conditions.

CORRECTIVE ACTION - Specified and documented actions taken in response to measurements that fail established criteria.

DATA QUALITY OBJECTIVES – A statement of overall level of uncertainty that a decision maker or client is willing to accept in results derived from environmental data.

LIMIT OF DETECTION - In quantitative analytical chemistry, the constituent concentration in reagent water that produces a signal 2 standard deviations above the mean of blank analyses.

LIMIT OF QUANTITATION
The constituent concentration that produces a signal statistically greater than the blank so that it can be detected within specified limits by good laboratories during routine operating conditions.

The lower limit of concentration or amount of substance that must be present before a method is considered to provide quantitative results. By convention, LOQ = 10so where so is the estimate of the standard deviation at the lowest level of measurement.

MATRIX - The environment or substrate (e.g., surface water, drinking water, soil, air, blood, feces, etc.) that contains the analyte of interest.

MATRIX INTERFERENCE - Deleterious effect of matrix composition on analyte measurement.

MATRIX SPIKE - An aliquot of actual sample spiked with a known concentration of target analytes.

METHOD - An assemblage of measurement techniques and the order in which they are used.

METHOD DETECTION LIMIT
The minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix type containing the analyte.

The constituent concentration that, when processed through the complete method, produces a response with a 99% probability that it is different from the blank.

PERFORMANCE AUDIT - A process to evaluate the proficiency of an analyst or laboratory by evaluation of the results obtained on known test materials.

PRACTICAL QUANTITATION LIMIT - A practical and routinely achievable quantitation limit with a high certainty that any reported value is reliable.

PRECISION - The degree of closeness among a set of replicate measurements without assumption of knowledge of the true value, measured as the standard deviation about the mean of the replicates.

PREDICTIVE VALUE - The measure of the ability of a system to

PROCEDURE - The steps or operations that make up a set of systematic instructions for using a method of measurement or sampling.

QUALITY ASSESSMENT - Procedure for determining the quality of laboratory measurements by use of data from internal and external quality control measures.

QUALITY ASSURANCE - A definitive plan for laboratory operation that specifies the measures used to produce data of known precision and accuracy.

QUALITY CONTROL - A set of measures within a sample analysis methodology used to measure precision and to conclude that the test process is in control.

SENSITIVITY - The measure of a testing system to detect all members of population with particular illness or abnormality.

SPECIFICITY - The measure of a testing system not to detect members of a population which do not have a particular illness or abnormality.

STANDARD - A substance or material with properties believed to be known with sufficient accuracy to permit its use to evaluate the same property of another.

STANDARD OPERATING PROCEDURE - A process adopted for repetitive use when performing a specific task, test, analysis, or other operation.

SURROGATE STANDARD - A pure compound added to an actual sample in the laboratory just before processing so that the overall effectiveness of a method can be determined.

VALIDATION - The process by which a sample, measurement method, or a measurement is deemed useful for a specified purpose.

VERIFICATION - Process whereby data is reviewed before reporting and deemed to be correct in comparison to a set of criteria.

WARNING LIMITS - The limits shown on a control chart within which a defined quantity of control results is expected to lie when the system is in a state of statistical control.

22.2. REFERENCES

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22.3. LABORATORY SERVICES DIVISION FORMS

22.3.1. CDPHE-LSD 007: Routing sheet for procedure review and correction

22.3.2. CDPHE-LSD 006: Procedure approval and revision

22.3.3. CDPHE-LSD 002: Annual SOP Review

22.3.4. CDPHE-LSD 001: PT Survey Challenge / Analyte Report / Review

22.3.5. CDPHE-LSD 003: Attestation Statement

22.3.6. CDPHE-LSD 004: Competency Assessment

CDPHE-LSD 007 **Approved: October 19, 2011**

ROUTING SHEET FOR PROCEDURE REVIEW AND CORRECTIONS

REVIEWED AND CORRECTIONS NOTED:

Signatures: Dates:

_____ _____
Program Manager

_____ _____
Quality Assurance Officer

_____ _____
CLIA Director

_____ _____
LS Director

I:\QA|Forms\ROUTING SHEET FOR PROCEDURE REVIEW AND CORRECTIONS

CDPHE-LSD 006 **Approved: October 19, 2011**

PROCEDURE APPROVALS AND REVISIONS

File Name: _____
Revision #: _____
Date of last Revision: _____
Date of last Review: _____

PROCEDURE APPROVAL

WRITTEN BY: _____ DATE: _____

APPROVED BY: _____ DATE: _____
Program Manager
_____ DATE: _____
Quality Assurance Officer
_____ DATE: _____
LS Director

Entered Into Service DATE: _____
Deleted From Service DATE: _____

REVISIONS

Written By: _____ APPROVAL: _____
File Name: _____
Revision # _____ BY: _____ DATE: _____
Date: _____
Page: _____ of _____ QA: _____ DATE: _____

Written By: _____ APPROVAL: _____
File Name: _____
Revision # _____ BY: _____ DATE: _____
Date: _____
Page: _____ of _____ QA: _____ DATE: _____

Written By: _____ APPROVAL: _____
File Name: _____
Revision # _____ BY: _____ DATE: _____
Date: _____
Page: _____ of _____ QA: _____ DATE: _____

I: \QA\Forms\Procedure Approvals and Revision

CDPHE-LSD 002 Approved: 24 August 24, 2011

Annual SOP Review – Each technician or scientist working with any section of this SOP must review this SOP annually. Name of SOP: _____

Section Supervisor:	Date
Program Manager:	Date
QA Officer: David Sikes	Date
CLIA Director: Richard Harris	Date
LS Director: Dave Butcher	Date

Name	Signature	Date

Maintain this document for the life of the SOP. Once this SOP is retired this Annual SOP Review document should be retired with the SOP.

I:\QA\Forms\Annual SOP Review

CDPHE-LSD 001 **Approved: 24 August 2011**

PT SURVEY CHALLENGE/ANALYTE REPORT/REVIEW

1. ***Survey Information***:
   Section: _____ Survey: _____

Date Survey Tested: _____ Survey Results Received:

2. Instances of Unacceptable Performance on Graded or Upgraded/Unevaluated Results? Yes _____ No _____
   If "Yes", complete sections 3 - 6. If "No", go to "Reviewer" blocks below.
   All Upgraded or Unevaluated Results must be assessed for acceptability of performance.
   IF MORE THAN ONE INSTANCE OF UNACCEPTABLE PERFORMANCE, USE ADDITIONAL FORM (I.E., ONE FORM FOR EACH INSTANCE).

3. ***Analyte***: _____ ***Instrument:*** _____ ***Technician:*** _____

   Classification of Unacceptable Performance — Challenge Failure (Total score < 80%) — Analyte Failure (Total score =/> 80%)

   Laboratory's Result: _____ Mean/Acceptable Result: _____

   Test Repeated: Yes _____ No _____ Repeated Result: _____

4. ***Assessment Review***: (attach any supporting documentation)

   Yes___No ___ a. Survey report examined for failures/discrepancies/clerical error(s).
   Yes___No ___ b. Method history reviewed (e.g. QC, maintenance, reagent lot number, etc.).
   Yes___No ___ c. History of previous survey problems (list and describe).
   Yes___No ___ d. Manufacturer consulted
   Yes___No ___N/A___ e. Instrument(s) recalibrated.
   Date of last Calibration if "No" _____
   Yes___No ___N/A___ f. Analytic Measurement Range (AMR) study performed.
   Date of last AMR study if "No" _____
   Yes___No ___ g. Survey material problem investigated (I.e. handling, reconstitution, storage, analysis sequence, matrix effects, etc.)

5. Identified Cause of Unacceptable Performance After Investigation:

   [ ]Methodology Problem [ ]Survey Material Problem [ ]Technical Problem
   [ ]Clerical Error [ ]Other [ ]Unexplained After Investigation

6. ***Analysis and Corrective Action(s) Taken***:

_____
_____
_____
_____
_____
_____

Reviewer	Name	Signature	Date
Testing Reviewer			
Supervisor, Testing Area			
Supervisor			
Quality Assurance			
Laboratory Director			
Division Director			

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CDPHE-LSD 003 Approved: 24 August 2011

Attestation Statement

As stated in the February 28, 1992 *Federal Register* under Subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient work load using the laboratory's routine methods." The laboratory director or designee and the testing personnel should sign on the result form.

Retain this page in your laboratory for your records and inspection purposes.

We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens.

PT Provider: _____ PT Name: _____ PT Date: _____

Director (or Designee) _____ Supervisor: _____

Testing Personnel	Testing Personnel	Testing Personnel

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CDPHE-LSD 004 Approved: 24 August 2011

Competency Assessment for all Testing Personnel

Name: _____ Procedure: _____

The purpose of this competency assessment format is to evaluate each person performing any test / procedure within the Laboratory Service Division using the same standards for each assessment. Competency assessment must be performed and documented at least semiannually during the first year of employment, or when a new test method is added, and annually thereafter for all testing personnel. Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff **must include** but are not limited to the following:

			Evaluator	Tech	Date
1.	Direct observation of routine test performance, including collection preparation (if applicable), specimen handling, processing, and testing				
2.	Monitoring of the recording and reporting of test results				
3.	Review of intermediate tests results, worksheets, quality control records, proficiency testing results, and preventive maintenance records				
4.	Direct observation of the performance of instrument maintenance and function checks				
5.	Assessment of test performance through: testing previously analyzed specimens, internal blind testing, external proficiency testing samples, or MDL's				
6.	Assessment of problem solving skills				

22.4. DOCUMENT RETENTION

22.4.1. Sample Testing – All patent / customer test results will be maintained as follows:

Environmental Microbiology – depends on the test + Current Year

Inorganic Chemistry – 5 years + Current Year

Molecular – 2 years + Current Year

Newborn Screening – 5 years + Current Year

Organic Chemistry – 5 years + Current Year

PH Microbiology – 2 years + Current Year

Radiochemistry – 10 years + Current Year

Serology – 2 years + Current Year

Toxicology – 5 Years + Current Year

22.4.2. Equipment Evaluation, Validation, or Maintenance – Documentation must be maintained for the life of the equipment. When the equipment is retired copies of all documentation must accompany the equipment in the event the equipment is acquired by another laboratory.

22.4.3. Reagent Evaluation, Validation, or QC:

Environmental Microbiology – 5 years + Current Year

Inorganic Chemistry – 5 years + Current Year

Molecular – 2 years + Current Year

Newborn Screening –5 years + Current Year

Organic Chemistry – 5 years + Current Year

PH Microbiology – 2 years + Current Year

Radiochemistry – 10 years + Current Year

Contamination Surveys (wipes) – Life

All others – 5 years + Current Year

Serology – 2 years + Current Year

Toxicology – 10 Years + Current Year

22.4.4. New Procedures:

Environmental Microbiology – 5 years + Current Year

Inorganic Chemistry – 5 years + Current Year

Molecular – 2 years + Current Year

Newborn Screening –5 years + Current Year

Organic Chemistry – 5 years + Current Year

PH Microbiology – 2 years + Current Year

Radiochemistry – 10 years + Current Year

Serology – 2 years + Current Year

Toxicology – 5 Years + Current Year

22.5. ABBREVIATIONS

AA - Amino Acid

AMR - Analytic Measurement Range

AOAC - Association of Analytical Chemists

BIOT - Biotinidase

C - Celsius

CA - Competency Assessment

CACMLE – Colorado Association of Continuing Medical Laboratory Education

CAH - Congenital Adrenal Hyperplasia

CDC - Center for Disease Control

CDPHE - Colorado Department of Public Health & Environment

CF - Cystic Fibrosis

CH - Congenital Hypothyroidism

CLIA - Clinical Laboratory Improvement Act

COFRS – Colorado Financial Resource System

CV - Curriculum Vitae

DQO - Data Quality Objective

EIA - Enzyme Immuno Assay

ELISA - Enzyme-linked Immonosorbent Assey

EPA - Environmental Protection Agency

FDA - Federal Drug Administration

GALT - Galactosemia

Hb - Hemoglobinopathies

HCFA - Health Care Financing Administration

HIPAA - Health Insurance Portability and Accountability Act

HIV - Human Immunodeficiency Virus

ICP/MS - Inductively Coupled Plasma / MASS Spectrometry

ID - Identification

LITS+ - Laboratory Information Tracking System Plus

LOD - Limit of Detection

LOQ - Limit of Quantitation

LS - Laboratory Services

LS Director - Laboratory Services Director

LSD - Laboratory Services Division

MDL - Mean Detection Limits

MDL - Method Detection Limit

MSDS - Material Safety Data Sheets

NBS - Newborn Screening

CLSI - National Committee for Clinical Laboratory Standards

NIST - National Institute of Standards and Technology

NLTN - National Laboratory Training Network

PE - Performance Evaluation

PHM - Public Health Microbiology

PKU - Phenylketonuria

PM - Program Manager

PT - Proficiency Testing

QA - Quality Assurance

QAC - Quality Assurance Committee

QAM - Quality Assurance Manual

QAO - Quality Assurance Officer

QAP - Quality Assurance Program

QC - Quality Control

SDWA - Safe Drinking Water Act

SOP - Standard Operation Procedures

T4 - Thyroxin

TSH - Thyroid Stimulating Hormone

22.6. APPROVED PROCEDURES FOR THE LABORATORY SERVICES DIVISION

10 DRUG PANEL (BLOOD)

10 DRUG PANEL (URINE)

6-MONACETYL MORPHINE

7-AMINO - CONFIRMATION

Aerobic plate count

ALCOHOL - CONFIRMATION

ALCOHOL SCREEN

Alkalinity, Phenolphthalein

Alkalinity, Total

Aluminum, Total

Americium-241

Americium-243

AMPHETAMINES - CONFIRMATION

AMPHETAMINES SCREEN

Anaerobe culture

Antibiotic susceptibility, disc diffusion

Antibiotic susceptibility, Etest MIC

Antibiotic susceptibility, microdilution MIC

Antimony

AQUEOUS QUANT

Arsenic III

Arsenic V

Arsenic, Total

Avian Influenza Virus H5N1RT-PCR

Avioq HIV-1 (oral fluid)

Bacillus anthracis confirmation

Bacillus anthracis culture

Bacillus anthracis PCR

Bacillus anthracis, TRF human

Bacillus cereus Culture

Bacillus cereus Toxin

BARBITURATES - CONFIRMATION

BARBITURATES SCREEN

Barium

BENZODIAZEPINE - CONFIRMATION

BENZODIAZEPINES SCREEN

Beryllium, Total

Beryllium, Total Recoverable

Bicarbonate

Biochemical identification

Biological Oxygen Demand (BOD)

BioWatch Screen

BLOOD AMPHETAMINE CONFIRMATION

BLOOD AMPHETAMINE SCREEN

BLOOD BARBITURATES CONFIRMATION

BLOOD BARBITURATES SCREEN

BLOOD BENZODIAZEPINE CONFIRMATION

BLOOD BENZODIAZEPINES SCREEN

BLOOD CANNABINOID CONFIRMATION

BLOOD CANNABINOID SCREEN

BLOOD CARISOPRODOL SCREEN

BLOOD CLONAZEPAM CONFIRMATION

BLOOD COCAINE CONFIRMATION

BLOOD COCAINE SCREEN

BLOOD ETHANOL

BLOOD FLUNITRAZEPAM SCREEN

BLOOD KETAMINE SCREEN

BLOOD LSD SCREEN

BLOOD METHADONE CONFIRMATION

BLOOD METHADONE SCREEN

BLOOD METHAMPHETAMINE SCREEN

BLOOD OPIATE CONFIRMATION

BLOOD OPIATE SCREEN

BLOOD OXYCODONE SCREEN

BLOOD PHENCYCLIDINE SCREEN

BLOOD PROPOXYPHENE SCREEN

BLOOD SALVIA

BLOOD TRAMADOL SCREEN

BLOOD ZOLPIDEM SCREEN

BOD, Carbonaceous

Boron

Bromate

Bromide

Bromite

Brucella confirmation

Brucella PCR

Burkholderia spp. PCR

C. difficile, CDC study

C. perfringens toxin

Cadmium, Total

Calcium

Calcium (Carbonate)

Campylobacter confirmation

Campylobacter culture

CANNABINOIDS - CONFIRMATION

CANNABINOIDS SCREEN

Carbamate Pesticides

Carbon-14

Carbonate

CARISOPRODOL GCMS SCAN

CARISOPRODOL SCREEN

CDC Referral

CDC Result

Cesium

Chemical Oxygen Demand (COD)

Chlamydia TMA

Chlamydia-Gonorrhea TMA

Chlorate

Chloride

Chlorinated Herbicides

Chlorinated Pesticides

Chlorine, Total Residual

Chlorite

Chlorophyll - a

Chromium

Chromium, Hexavalent

cis-1,2-Dichloroethylene

Clostridium perfringens Culture

Cobalt

COCAINE - CONFIRMATION

COCAINE SCREEN

Coliform

Conductivity

Corrosivity Langlier

Corynebacterium diphtheriae confirmation

Corynebacterium diphtheriae culture

Creatinine

Cyanide, Direct

Cyanide, Distilled

Cyanide, WAD

Cyanobacteria

Dalapon

Direct Exam

Dissolved Oxygen

DMSCC

DNA Sequence Analysis

E. coli MPN

E.coli H: antigen

E.coli MPN

E.coli O: antigen

E.coli PA

E.coli shigatoxin-producing, confirmation

E.coli shigatoxin-producing, culture

E.coli virulence marker - eae

E.coli virulence marker - E-hly

E.coli virulence marker-stx1

E.coli virulence marker-stx2

ECSTASY SCREEN

Enterovius RT-PCR

Epidemiology investigation

Equilibrium pH

Escherichia coli O157

Escherichia coli PA

Fecal Coliforms, MTF

FLUNITRAZEPAM SCREEN

Fluorescent Treponemal Antibody (FTA)- CSF

Fluorescent Treponemal Antibody, FTA

Fluoride

Francisella tularensis antigen, DFA

Francisella tularensis confirmation

Francisella tularensis culture

Francisella tularensis DFA human-testing

Francisella tularensis PCR

Freeze point

FTIR Scan

Fumigants

Fungus confirmation

Gamma Spectrometry

GC confirmation

GC culture

GC/MS SCAN

GCMS DRUG SCAN

Glyphosate

Gram stain

Gross Alpha

Gross Beta

Group A Strep confirmation

Group B Strep confirmation

H1N1 Influenza

Haemophilus confirmation

Haemophilus culture

Haloacetic Acids

Hanta virus, IgG

Hanta Virus, IgM

Hardness Total

Hepatitis A antibody, total

Hepatitis C (RIBA)

Hepatitis C virus antibody

Heterotrophic Plate Count

Hexachlorobenzene

Hexachlorocyclopentadiene

Hexchlorobenzene

HIV-1 Antibody, WB

HIV-1, 2 plus O EIA

HIV-1/2 Multispot

Human Metapneumovirus (hMPV) RT-PCR

Hydroxide

Influenza A virus Culture

Influenza A virus, RT-PCR

Influenza B virus culture

Influenza B Virus RT-PCR

Influenza subtyping by RT-PCR

Inhibitors charm S/L

Inhibitors delvo P5

Insecticides

Iron

KETAMINE SCREEN

Lead

Legionella confirmation

Legionella culture

Leptospira culture

Listeria confirmation

Listeria Culture

Listeria monocytogenes by PCR human-testing

Listeria PCR

Lithium

LSD CONFIRMATION

LYSERGIC ACID SCREEN

M. Tuberculosis complex TMA

Magnesium

Measles IgM

Mercury

METHADONE - CONFIRMATION

METHADONE SCREEN

Methoxychlor

Methyl Methacrylate

Methyl tert-butyl Ether

MIC interpretation

Microdilution susceptibility test group

Minimum Inhibitory Concentration (MIC)

MLVA

Molybdenum

Mumps virus RT-PCR

Neisseria gonorrhoeae NAAT

Neisseria meningitidis confirmation

Neisseria meningitidis culture

Nickel, Total

Nickel-63

Nitrogen, Ammonia

Nitrogen, Inorganic Total (TIN)

Nitrogen, Kjeldahl, Total

Nitrogen, Nitrate

Nitrogen, Nitrate/Nitrite

Nitrogen, Nitrite

Nitrogen, Total

Non-Chlorinated Herbicides

Norovirus RT-PCR

Oil & Grease

OPIATES - CONFIRMATION

OPIATES SCREEN

Orthopox PCR

Ova and parasites

Oxamyl

OXYCODONE SCREEN

Percent Fat

Percent Moisture

Pertussis culture

Pertussis PCR human-testing

Pertussis PCR Panel

pH

PHENCYCLIDINE - CONFIRMATION

PHENCYCLIDINE SCREEN

Phenol

Phosphatase

Phosphorus, Ortho-Phosphate

Phosphorus, Phosphate Total

Platinum

Plutonium-238

Plutonium-239+240

Plutonium-242

Polonium-210

Polychlorinated biphenyls

Potassium

PROPOXYPHENE - CONFIRMATION

PROPOXYPHENE ADDDITONAL CONFIRMATION

PROPOXYPHENE SCREEN

Psudomonas culture

Pulsed field gel electrophoresis

Rabies virus RT-PCR

Rabies virus, DFA

Radium-226

Radium-228

Radon-222

Rapid Plasma Reagin Antibody (RPR)

Respiratory syncytial virus RT-PCR

RSV PCR

Rubella IgM

Salinity

Salmonella confirmation

Salmonella Culture

Salmonella PCR

Salmonella serotype

Salmonella test group

Selenium

Semi-Volatile Organic Compounds (SVOC)

Shigella confirmation

Shigella culture

Shigella spp. PCR human-testing

Shigella test group

Silicon

Silver

Sodium

Sodium Adsorption Ratio

Solids, Dissolved

Solids, Settleable

Solids, Suspended

Solids, Total

Solids, Volatile

SPC

Specific Gravity

Spore sterility test

St. Louis encephalitis virus RT-PCR

Staph aureus Culture

Staph aureus Toxin

Staphylococcus confirmation

Staphylococcus enterotoxin assay

Starch

STEC confirmation test group

STEC culture test group

Strep confirmation

Strep culture

Strep pneumoniae confirmation

Strontium

Strontium 90

Sulfate

Sulfide

Sulfite

Sulfur

Swine influenza A

SYNTHETIC CANNABINOID

Tannin and Lignin

TB confirmation

TB Culture

TB culture test group

TB drug panel

TB drug panel Ethambutol

TB drug panel Isoniazid

TB drug panel Pyrazinamide

TB drug panel Rifampin

TB smear

Test Group-E.Coli MPN

Test Group-Total Coliform PA

Test Performed By

Thallium

Thorium

Thorium, Isotopic

Thorium-228

Thorium-230

Thorium-232

Tin

Titanium

Titer

Total Coliform MPN

Total coliforms PA

Total Coliforms, MTF

Total Organic Carbon (TOC)

Total Solids

TOXIC VAPOR

TRAMADOL SCREEN

trans-1,2-Dichloroehtylene

Treponema pallidum Particle Agglutination (TP PA)

Trichomonas vaginalis culture/ID

Trihalomethanes

Tritium

Tungsten

Turbidity

Uranium

Uranium-233

Uranium-234

Uranium-235

Uranium-238

UV@254

Vaccinia Virus PCR human-testing

Vancomycin MIC

Varicella-Zoster Virus PCR human-testing

Variola PCR human-testing

VDRL, CSF

Vibrio confirmation

Vibrio Culture

Virus Indentification

Volatile Organic Compounds (VOC)

Water Activity

West nile virus antibody, IgG

West nile virus antibody, IgM

West nile virus diagnostic panel, human testing

West nile virus, RT-PCR

Western equine encephalitis virus RT-PCR

Western equine encephalitis virus RT-PCR, human testing

Yersinia confirmation

Yersinia culture

Yersinia pestis antigen, DFA

Yersinia pestis confirmation

Yersinia pestis PCR

Yersinia pestis PCR human-testing

Zinc

Zirconium - XRF

ZOLPIDEM SCREEN