The San Diego Public Health Laboratory is closely regulated by federal law and regulation under the Clinical Laboratory Improvement Amendments (CLIA) 1988, and by California law and regulations based on CLIA 88. These laws and regulations describe strict performance standards for all covered laboratories, and describe in detail standards, requirements, conditions, and consequences of failure to follow the law and regulations. Foremost among these provisions is that all covered laboratories must have a qualified Laboratory Director; that the Laboratory Director is responsible for operation, administration, and compliance to CLIA regulations; and that specific responsibilities cannot be delegated to other parties. The Laboratory Director, as well as the laboratory itself, may be held responsible for compliance failures, including loss of licensure and sanctions. The primary if not the sole role of the Laboratory Director is to ensure compliance with the extensive and detailed CLIA law and regulations.

Apart from regulatory compliance requirements, the Association of Public Health Laboratories(APHL) in cooperation with the Centers for Disease Control and Prevention (CDC), has published a report titled "The Core Functions of State Public Health Laboratories", latest edition, 2010. This reports list and details of 11 core functions of state public health laboratories has also been used extensively as a template to define core functions for local public health laboratories. These core functions, while not mandated by regulation, clearly represent standards of performance for public health laboratories, and represent concrete performance goals for Laboratory Directors at any level.

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

Responsibilities required and described under CLIA for Laboratory Director (LD) which may not be delegated to an Assistant Laboratory Director or anyone else.

Chief, Public Health Laboratory (LD)
LD must demonstrate active involvement in the laboratory's operation and be available to the laboratory staff, as needed.
LD is responsible for the overall operation and administration of the laboratory, including the employment of competent qualified personnel. Even though LD may delegate some of the responsibilities, LD remains ultimately responsible and must ensure that all the duties are properly performed and applicable CLIA regulations are met.
LD is responsible for ensuring the laboratory develops and uses a quality system approach to laboratory testing that provides accurate and reliable patient test results.
testing systems in the laboratory provide quality services in all aspects of test performance, i.e., the preanalytic, analytic, and postanalytic phases of testing and are appropriate for your patient population
physical and environmental conditions of the laboratory are adequate and appropriate for the testing performed;
the environment for employees is safe from physical, chemical, and biological hazards and safety and biohazard requirements are followed
a general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results as well as provide on-site supervision for specific minimally qualified testing personnel when they are performing high complexity testing

sufficient numbers of appropriately educated, experienced, and/or trained personnel who provide appropriate consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by you, are employed by the laboratory
new test procedures are reviewed, included in the procedure manual and followed by personnel
each employee's responsibilities and duties are specified in writing

Responsibilities required and described under CLIA for Laboratory Director (LD) which may be delegated.

Chief, Public Health Laboratory (LD) responsible for ensuring:
appropriate test method selection
adequate method verification in order to determine the accuracy and precision of the test
enrollment of the laboratory in a CMS-approved proficiency testing (PT) program for the test performed
PT samples are tested in accordance with the CLIA requirements
PT results are returned within the time frames established by the PT program
PT reports are reviewed by the appropriate staff
corrective action plans are followed when PT results are found to be unacceptable or unsatisfactory
quality assessment and quality control programs are established and maintained
acceptable analytical test performance are established and maintained for each test system
remedial actions are taken and documented when significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly
personnel have been appropriately trained and demonstrate competency prior to testing patient specimens
policies and procedures are established for monitoring personnel competency in all phases (preanalytic, analytic, and postanalytic) of testing to assure the ongoing competency of all individuals who perform testing
remedial training or continuing education needs are identified and training provided
an approved procedure manual is available to all personnel

Responsibilities not required under CLIA for Laboratory Director (LD), but which are essential for ensuring delegated duties are performed appropriately.

Chief, Public Health Laboratory (LD)
Have a mechanism in place for effective communication among management and all personnel in the laboratory
Routinely review quality control and quality assessment activities to assure problems occurring within the laboratory are identified and corrected and the corrections are monitored for effectiveness and timeliness
If there are no apparent problems identified through the quality control or quality assessment programs for lengthy periods of time, investigate the possible need for more stringent or sensitive programs, as the current programs may not be appropriately identifying errors.

You may find it necessary to make some changes in what you are monitoring. Once you have consistently achieved success with a quality assessment indicator, you may wish to move on to others
Make certain the quality assessment activities include a mechanism for resolution of any complaints received against the laboratory, either from the staff, public or clients of the laboratory
Make certain the quality assessment activities include a mechanism to address any breakdown in communication between the laboratory and persons authorized to order tests and receive test results
Review a sampling of PT results, ensure that PT samples are tested in the same manner as patient specimens and that the cause of PT failures are identified, corrected and documented
Ensure that laboratory staff and management are aware of CLIA requirements that preclude them from referring PT specimens to another laboratory or communicating about the results until after the date by which the laboratory must report PT results to the program for the testing event in which the samples were sent
Review a sampling of results obtained from procedures and their outcomes for verifying the accuracy of tests for which PT is not required
Review policies and procedures for personnel evaluation and a sampling of personnel evaluations
Review a sampling of the analytical performances of test systems for acceptability based on your laboratory's criteria

Duties not specified by CLIA, but derived from APHL "Core Functions and Capabilities of a State Public Health Laboratory", 2010.

Chief, Public Health Laboratory (LD)
Ensure laboratory is appropriately supporting prevention, control, and surveillance of diseases of public health significance including infectious, communicable, genetic and chronic diseases, environmental exposures by providing accurate and precise analytical data in a timely manner in support.
Ensure Integrated Data Management by serving as the conduit for scientific data and information in support of public health programs through capturing laboratory data, application of standardized data formats, participating in statewide disease reporting networks, linking with other national and international networks, collaboration with state and national laboratory systems, and continuously improving laboratory data systems.
Ensure Reference and Specialized Testing is available
Ensure Environmental Health and Protection is supported by providing testing for toxic agents and environmental contaminants, conducting biomonitoring of human specimens in assessment of toxic exposures, testing in support of federal and state regulations, participating in the chemical Laboratory Response Network, and the Environmental Response Laboratory Network.
Ensure Food Safety by testing appropriate samples, characterizing isolates, participating in Food Emergency Response Network.
Ensure ongoing laboratory improvement and regulatory compliance by implementing quality improvement programs, developing programs to ensure reliability of laboratory data, promote laboratory safety, participating in statewide laboratory system improvement programs, and compliance with regulation and law contributing to laboratory improvement.
Ensure a role in policy development by generating scientific evidence that informs public health practice and law, monitoring impact of public health practive on health outcomes, participate in development and evaluation of standards, advocating for sound policy, and engaging in strategic planning.

Ensuring public health preparedness and response by function in laboratory response network, assuring triage procedures for human, environmental, and food samples, ensuring for surge capacity, having a continuity of operations plan.
Participating in public health related research by assessing new technologies, partnering with other organizations, conducting research, working with private sector.
Ensuring ongoing training and education by sponsoring training and education opportunities, leadership and management training, training domestic and international scientists, partnering with academia, and providing ceu ion laboratory practices.
Ensure partnerships and communication by highlighting importance of laboratory contributions, having a strong communications plan, using information technology(Web Site), engaging partners, and coordinating activities.

Assistant Chief, Public Health Laboratory

This is a request to reclassify 1.0 FTE Senior Public Health Microbiologist position to a new classification of Assistant Chief, Public Health Laboratory to address

1) Assist the Chief, PHL in maintaining legal and regulatory compliance under CLIA and state law by ensuring maintenance of and providing supervision of the following programs:
    a. Quality Assurance
    b. Personnel Training and Education
    c. Proficiency Testing
    d. Competency Assessment
    e. Safety
2) Assist the Chief by ensuring
    a. Appropriate test methods are selected, implemented, maintained and a program of verification and validation is implemented
    b. Emergency Preparedness capacity is maintained and exercised
    c. Information technology capacity is fully used to ensure electronic communications for test requesting and test results delivery and to ensure PHL has a functioning and effective website
    d. A program of public health research is maintained
3) Reinforcing concepts of continuity of operations within the laboratory by
    a. Continuity in leadership development, preparing and qualifying an individual as CLIA qualified Laboratory Director to maintain laboratory's legal requirements
    b. Continuity in CLIA law and regulation in case of incapacity or absence of Chief
    c. Redundancy during emergencies and capacity surge situations
4) Provide additional high level expertise which may complement Chief's expertise or fill a gap in specific field of expertise
5) Provide Chief opportunity to focus CLIA responsibilities which may not be delegated, and on larger programs including strategic planning, program development, policy evaluations, budget issues, and community relations.