SCOPE OF WORK OF LABORATORY DIRECTOR

The contractor shall be responsible for providing Laboratory Director Services in designated CCHCS institutions. The Laboratory Director shall be a duly licensed physician and surgeon, who is licensed to direct a clinical laboratory or who substantially meets the laboratory director qualifications under Clinical Laboratory Improvement Act (CLIA) for the type and complexity of tests being offered by the laboratory.

1. The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall ensure that a sufficient number of laboratory personnel with the appropriate education, Licensure/Certification, and either experience or training are employed to provide services as described in CLIA.

2. Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.

3. As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the State of California – Department of Public Health regulation that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel. As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

    a. Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the

minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

b. Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

c. Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

4. Shall review and approve the supervising licensed clinical laboratory scientist personnel at the institution; and shall delegate some of his/her responsibilities to the supervising senior clinical laboratory technician when he/she is not onsite pursuant to CCHCS Allied Health Services Laboratory Services policy aligned with CLIA 42 CFR 493.1407. The supervising clinical laboratory technician shall perform daily review of all laboratory quality control and equipment records, and laboratory director shall review monthly records pursuant to CLIA laws.

5. The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

   The procedures for evaluating the competency of the staff shall include, but are not limited to all of the following:

a. Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

b. Monitoring the recording and reporting of test results.

c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

d. Direct observation of performance of instrument maintenance and function checks.

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

f. Assessment of problem solving skills.

6. Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year for individual tests of biological specimen. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

7. The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

a. If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under Title 22 may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high quality service.

b. If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist available.

c. As used in this subdivision, a qualified pathologist is a

physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.