ATTENTION: Copies may be made of this document, but the original (ivory-color paper) must be maintained on file with the laboratory. Changes are italicized.

NORTH CAROLINA STATE LABORATORY OF PUBLIC HEALTH
CLIA CONTRACT PROGRAM
2016

INTRODUCTION:

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 and the CLIA Final Rule set forth federal standards designed to improve quality in all phases of clinical laboratory testing. Since 1993, approximately one-half of North Carolina's local health departments (LHDs) have subscribed to the State Laboratory of Public Health (SLPH) CLIA Contract Program in order to meet the mandates of CLIA. The CLIA Contract program falls under the federally defined category of "limited public health testing" which allows a 15-test maximum of waived and moderately complex tests per certificate.

OVERSIGHT:

The Centers for Medicare and Medicaid Services (CMS) is the federal oversight agency, with the NC Division of Health Service Regulation administering the regulations in North Carolina.

GUIDELINES:

The guidelines that must be followed by each laboratory include all components of the CLIA '88 Final Rule (42 CFR Part 493) as published 1/24/2003. These guidelines encompass all phases of laboratory analysis including pre- and post-analytic activities. Since the CLIA rules set a minimum standard, the Program also includes acknowledged laboratory practice standards for areas not specified by CLIA (ex. - waived testing.) Inclusion in the Program is voluntary on the part of each LHD; however, participants must follow all aspects of the Program as established. Every effort will be made to resolve problems, but it must be noted that failure of an individual LHD to comply with the guidelines could jeopardize testing in all other LHDs in that contract group. Unresolved failure to comply can result in suspension of testing in that facility or removal from the Program. (See Sanctions, p.7.) This must be done to protect the interests of every LHD in the Program. The specific components of the Program are described below. Because of the CMS definition of "limited public health testing," this program is only for those laboratories that are classified as "moderately complex." Current subscribers will have their test menus reviewed annually to confirm eligibility. Laboratories performing only waived testing, high complexity testing or only moderately-complex testing listed as Provider Performed Microscopy Procedures must apply for CLIA certification on their own. Re-categorization of test methodologies by the federal government may necessitate changes in this program, but participating LHDs will be notified as soon as any changes are identified.

CERTIFICATES:

The Contract Program provides separate certificates from CMS for the four (4) contract areas. An organizational chart for the certificates is found in Appendix 1. The Area certificates only cover specific fixed sites of the LHDs. **The Area certificates do not cover testing performed at jails, school-based clinics, day care centers, or patients' homes**. The Laboratory Director for these certificates is provided by the NC SLPH. Regional Laboratory Improvement Consultants serve as Technical Consultants, and the Lab Director may delegate certain responsibilities to the Technical Consultants. LHDs are grouped to allow a proportionate distribution to each Technical Consultant. Each LHD must designate a Clinical Consultant (see

Appendix 5) and provide qualified testing personnel (refer to Appendix 7).

The 15-test menu for each contract area is determined by the Laboratory Director based on state program requirements and local needs assessment. Test menus vary slightly from area to area. LHDs must abide by the test menu for their contract area. Individual laboratories may not make changes to the test menu, methods, kits, or procedures without prior approval of the Laboratory Director or designee.

To maintain these certificates, documentation must be provided to the Laboratory Director or his/her designee annually, **and as changes occur**. The annual deadline for submission is January 31. The required documentation includes:

1. Current name and address of all laboratory testing sites for the facility,
2. List of all laboratory tests performed at any of those sites, along with test methodology, quality control products and CPT codes used,
3. List of testing personnel and assigned tests for each facility,
4. Name of the Clinical Consultant for each facility,
5. Annual report of test totals for each *on-site* test performed,
6. Continuing education documentation for all testing personnel.

Immediate notification to the Technical Consultant is required when changes occur in items 1-4.

STANDARDIZATION OF LABORATORY SERVICES:

Once a LHD joins a contract area, all LHDs in that group are dependent on each other, to a certain extent, to maintain uniform standards of quality. For this reason the Program requires participating LHDs to do certain things in a standardized way. Included are:

A. **Quality Assessment** – In the CLIA Final Rule published January 24, 2003, Quality Assurance was renamed Quality Assessment to more clearly reflect the activities performed. QA encompasses all analytic as well as pre- and post-analytic activities that are meant to assess the quality of results and reporting. The laboratory must establish and maintain a written QA plan that provides an on-going mechanism for monitoring and assessing laboratory activities. LHDs with an agency QA team must include laboratory personnel on that team, and if there is no team already in place, the LHD laboratory must establish its own. The laboratory must document assessment activities and review the effectiveness of any corrective action instituted. All items listed under STANDARDIZATION OF LABORATORY SERVICES are components of QA, and the laboratory must monitor each one of these systems at least once per year using the Laboratory Quality Systems Assessment (QSA) Checklist (Appendix 11) provided. **Failure to complete the Checklist will negatively impact the Accreditation/Reaccreditation status report for the laboratory**. The QA Team must meet at least annually and at a minimum review the QSA checklist summaries, all QA studies, yearly competency assessment results, yearly proficiency testing results, if applicable, and any recurring item(s) documented on the Problem Log.

B. **Policy Manual** - Individual written laboratory policies must be developed and kept current. They must be signed by the Laboratory Director (or designee) when they are implemented, and at the time of any change in the policy. Examples are: policies for unsatisfactory specimens, medical alert (panic) values, specimens referred to other laboratories for testing, general reporting procedures, record retention schedules, and a test systems backup plan, should a kit or instrument become inoperable. The policy

manual must include the statement “All functions of this laboratory are regulated by CLIA ’88 and are to be authorized by the Laboratory Director of record or his/her designee.” Testing performed under standing orders for programs and/or clinics must be stated in nursing policy and readily available to laboratory personnel. The location of these standing orders should be stated in the laboratory policy manual. No testing may be performed on verbal orders. Normal and panic values must be annually reviewed, approved and signed by the Clinical Consultant. Testing personnel will document policy manual review on an annual basis. Discontinued policies will be retained in a separate section of the manual or in lab files for a minimum of two years, with the date of discontinuance noted.

C. **Technical Procedure Manual** – A comprehensive and up-to-date procedure manual must be available to and followed by all testing personnel to ensure reliable and reproducible performance among individuals. Procedures for specimen collection and each test performed must be typewritten and follow an approved guideline for technical procedure manuals established by the Clinical and Laboratory Standards Institute, CLSI (formerly NCCLS; document GP2 or *QMS02*) and kept in a 3-ring binder. A copy of the approved guideline used will be kept in each LHD lab. **Note: An electronic backup for all laboratory procedures is strongly recommended.** The laboratory must have approval from the Technical Consultant before changing any test method. Procedures for new tests or test methods and major revisions of an existing procedure must be in writing and approved by the Laboratory Director prior to use for patient analysis. Testing personnel must document procedure manual review on an annual basis. Discontinued procedures shall be retained in a separate section of the manual or in lab files for a minimum of two years, with the date of discontinuance noted.

D. **Blood Specimen Collection –** Written blood collection procedures must be based upon, and in agreement with, the most current CLSI standards, including H3-A6, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; and H4-A6, Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens.

1. LHDs must purchase and have available in the lab an approved phlebotomy reference that reflects the current standards. Alternatively, LHDs may purchase the two CLSI standards (H3 and H4) referenced.
2. For the safety of their patients, facilities must ensure the availability of phlebotomy chairs for blood collection activities. Chairs should have a safety device to protect against falling in the event a patient becomes faint. It is strongly recommended that the facility’s blood collection area occupy a separate space from specimen processing and/or laboratory testing areas.
3. Each LHD bears ultimate responsibility for the training, competency and supervision of LHD personnel performing blood specimen collection. To assure proper oversight, the LHD must designate at least one individual to serve as the site’s phlebotomy coordinator. Individual requirements include documentation of a one-year minimum of phlebotomy experience, successful demonstration of basic theoretical knowledge of phlebotomy through a written test provided by the Technical Consultant. Meeting these requirements qualifies the individual to serve as phlebotomy coordinator. Responsibilities include a written phlebotomy competency assessment plan, which includes conducting and documenting periodic evaluations of all LHD personnel assigned blood collection duties.

E. **Safety** – As defined in the CLIA Final Rule, Sub Part J - Facility Administration for Non-

waived Testing, 42 CFR 493.1101, LHDs bear responsibility for compliance with all applicable Federal, State and local requirements concerning laboratory safety. LHDs must ensure that adequate safety precautions are in place to provide protection from laboratory hazards. This includes compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, 29 CFR 1910.1030. Facilities are strongly encouraged to ensure compliance with the most current CLSI safety guideline, GP17-A3, Clinical Laboratory Safety; Approved Guideline-Third Edition. In regards to the proper packaging and shipping of specimens, applicable regulations include the U.S. Department of Transportation, 49 CFR Parts 171–178; the Centers for Disease Control and Prevention, 42 CFR Parts 72 –73; and the U.S. Postal Service, 39 CFR Part 111 and related documents.

F. **Quality Control (QC)** - For non-waived laboratories, QC requirements are defined in the CLIA regulations. For each procedure, the Program has established the number of levels of control material that must be used, and the frequency (see Appendix 10). A facility under the contract cannot decide to eliminate QC because of cost. Responsibilities of the LHD for QC will include purchase of appropriate QC materials, designation of personnel to review and monitor QC, daily use of Levy-Jennings charts, and a policy for reporting out-of-range patient values and medical alert (panic) values.

QC requirements:

- The laboratory must perform and document quality control.
- Acceptable ranges for control products must be verified prior to use.
- Corrective action must be taken and documented when QC failures occur.
- QC results must be within acceptable limits prior to performing patient testing.
- Quality control and calibration data, including manufacturers' assay sheets with expected ranges, must be retained a minimum of two years.
- Quality control records, as established for each certificate and facility, must be available to the Technical Consultant for review.
- Laboratory environmental conditions that could affect reagent storage and test system operation must be monitored and documented.
    1. Facility requirements:
        - Room temperature check must be performed daily.
        - Humidity check, as required, must be performed daily.
    2. Equipment - Data on instruments and equipment must be recorded and retained according to CLIA regulations. This data includes preventive maintenance, equipment logs and charts, function checks, and facility monitoring.
        - For qualified analyzers, calibration and calibration verification must be performed according to the manufacturer's directions or at least every six months. All calibration activities must be documented.
        - Each laboratory must have a preventive maintenance schedule for all instruments, refrigerators, incubators, centrifuges, and other lab equipment that is currently being used for testing.
        - All maintenance and function checks must be performed as scheduled and documented.
        - All appropriate temperature checks must be performed daily.
        - Instrument printouts must be kept for at least two years.
        - For laboratories that perform the same test using different methodologies or instruments, or perform the same test at multiple sites, the lab must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

G. **Proficiency Testing (PT)** - Each contract area must perform testing on unknown samples provided by a CMS-approved agency for each non-waived test on the certificate. CLIA regulations mandate the frequency and number of challenges required for each test each calendar year. LHDs are selected from each contract area to perform this mandated PT on behalf of all the other participating LHDs in that area. All counties on each certificate are eligible to be selected to perform PT. If a designated LHD fails PT for an analyte, specialty, or subspecialty, testing at all sites on that certificate would be affected. (Example: Designated LHD fails syphilis PT two out of three challenges. Syphilis testing may be suspended at all sites on that certificate.)

H. **Patient Test Management** – The laboratory must ensure confidentiality and compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in regards to patient information throughout all phases of the total testing process that is under the laboratory's control. Contract laboratories are required to use a requisition system or lab information system for reporting patient results. **Transition to any computerized laboratory information management system must include thorough documentation of system validation and approval by the Laboratory Director (or designee).** The test report must bear the facility name and street address. All parts of the system, whether paper or electronic, must meet CLIA regulations and are subject to the review and approval of the Technical Consultant. The laboratory must employ and maintain a system that provides for appropriate patient preparation, proper specimen collection and processing, with **accurate and retrievable result reporting**. This system must ensure optimum specimen integrity and identification throughout the entire process. The laboratory must document all results of intermediate testing. Instrument printouts must have a patient ID that is traceable to the log and/or report. The laboratory must maintain a record of referred testing.

I. **Testing Personnel** – Per federal regulations, each individual may perform only those tests that are authorized by the Laboratory Director. The laboratory must first complete a separate Testing Personnel Record (see Appendix 8) for each individual. Individual training records for those tests assigned must also be kept on file by the laboratory and are subject to review by the Laboratory Director or designee prior to approval. To obtain authorization to conduct testing, the Laboratory Director (or designee) must document his/her approval of the completed Testing Personnel Record, prior to the individual reporting patient test results. LHDs must assure sufficient laboratory coverage by authorized testing personnel (see Appendix 3) during all hours of operation. In instances of laboratory personnel shortages, an acceptable contingency plan must be implemented by the LHD and immediately communicated to the Technical Consultant or Laboratory Director. Failure to provide sufficient staffing of authorized testing personnel negatively impacts laboratory operations and may result in a LHD's removal from the program.

All position/job descriptions must be current for each lab position (< five years). **The Technical Consultant must be notified immediately regarding a change in laboratory manager** and within 10 working days regarding any other change in testing personnel or Clinical Consultant.

The Technical Consultant must review and approve the application and/or qualifications of prospective new laboratory personnel <u>prior</u> to an offer of hire being extended.

1. **Qualifications** - CLIA has set forth the minimum qualifications for testing personnel.
   a) Those performing only waived tests must:
      - provide proof of education (high school diploma, GED or higher),
      - document that they have read all the procedures and manufacturers' instructions associated with the tests, and
      - document successful testing of QC materials and previously analyzed patient samples.
   b) Those performing non-waived tests, in addition to the requirements listed above for waived testing personnel, may be required to attend specific training workshops and mentoring sessions at other facilities.
   c) Each LHD must designate a "laboratory manager." This is the primary liaison between the LHD lab and the Technical Consultant, and is most often the person in the LHD who can best perform the administrative laboratory functions. In the event of a vacancy in the laboratory manager position, a qualified replacement must be named within 10 working days, or the vacancy must be advertised with necessary qualifications within 10 working days. Because of the technical nature of these functions, it is highly recommended that the laboratory manager have a minimum of an associate degree in medical laboratory technology and two years of experience, or a bachelor degree in medical technology and one year of experience (see Appendix 6).

2. **Continuing Education (CE)** - Persons assigned to perform waived testing only must obtain at least three (3.0) contact hours of lab-related continuing education per calendar year. Persons performing non-waived testing must have six (6.0) contact hours of lab-related continuing education per calendar year. Persons performing only one non-waived test (i.e., wet mount examinations) and no waived tests must have four (4.0) contact hours of lab-related continuing education per calendar year. The main focus of the CE events must be laboratory testing or management, but annual on-site safety updates may be included, up to two (2.0) hours per year. The SLPH provides several opportunities for no-cost or low-cost CE every year. If a non-lab continuing education program has a clinical laboratory component, a detailed agenda of the program must be sent to the Technical Consultant for review and possible inclusion in the acceptable category. Testing personnel CE documentation for each calendar year must be sent to the Technical Consultant by January 31 of the following year (see Appendix 9).

3. **Maintaining Proficient Status** - Individuals who perform laboratory testing infrequently will lose proficiency, so LHDs are strongly encouraged to limit the number of people assigned to perform a given test. Once a person is assigned to perform a test, he/she must perform the test at least once per quarter or be dropped from doing that test. If an individual is performing a test only once per month or less, he/she must perform and document QC for that test each day he/she conducts testing. This policy applies to every test assigned.

4. **Competency Assessment** - A component of the Contract Program is the Competency Assessment (CA) Program for the ongoing evaluation of testing personnel as mandated by CLIA. The CA Program provides photos and unknown samples for evaluation by qualifying testing personnel. The CA Program conducts two (2) challenges per calendar year for each moderately-

complex test included on the Area test menu. All personnel who perform non-waived testing must be assessed annually.

Competency assessment also encompasses the following:

- Direct observation of all phases of testing;
- Monitoring recording and reporting processes;
- Review of intermediate test results or worksheets, QC records, PT records, and preventive maintenance records;
- Direct observation of instrument maintenance and function checks;
- Assessment of test performance through previously analyzed specimens, blind samples, and external PT;
- Evaluation of problem solving skills.

Testing personnel must demonstrate successful performance on CA challenges to continue testing. Failure to do so indicates the need for retraining or other follow-up. Testing personnel who repeatedly fail to properly perform critical tasks will have to cease to perform that particular test.

SANCTIONS:

The sanction process is necessary to protect the mutual interests of all LHDs within a contract area from potential decertification due to one lab's failure to comply. The Technical Consultant will notify the Laboratory Director when there is a repeated failure to correct a noted deficiency or when a time-critical activity or situation is discovered that could place a contract area's certification in jeopardy. Initiation of a sanction will be at the discretion of the Laboratory Director.

NOTE: Any laboratory receiving three (3) sanctions within a two-year period will be automatically removed from the NCSLPH CLIA Contract Program.

Reasons for the issuance of a sanction include, but are not limited to, the following:

- Failure to provide an adequate number of qualified testing personnel.
- Repeated failure to address a noted deficiency.
- Allowing unauthorized personnel to perform testing.
- Performing a procedure not on the 15-test menu.
- Failure to retrain personnel after unsuccessful PT or technical competency assessment. (Retraining must be at the earliest possible course, and the individual may be required to stop testing until training is completed.)
- Failure to send appropriate representative(s) to a mandatory meeting.
- Failure to submit required documentation.
- Falsifying documentation of any kind, including test results.
- Failure to perform, document and/or monitor required quality control.
- Using expired reagents or supplies.
- Three (3) occurrences of a LHD failing to ensure all qualified testers submit competency assessment results.

REFERENCES:

- Centers for Medicare & Medicaid Services. Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications: Final Rule (42 CFR Part 493, et al.). Federal Register; January 24, 2003.
- CLSI. Laboratory Documents: Development and Control; Approved Guideline GP2-A5, Wayne, PA; 2006.
- CLSI. Managing and Validating Laboratory Information Systems; Approved Guideline Auto08-A, Wayne, PA; 2006.
- CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard H3-A6, Wayne, PA; 2007.
- CLSI. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens. Approved Standard H4-A6, Wayne, PA; 2008.
- NCCLS. Clinical Laboratory Safety. Approved Guideline GP17-A2, Wayne, PA; 2004.
- Ernst, D. Applied Phlebotomy. Philadelphia, PA: Lippincott, Williams & Wilkins, 2005.
- US Department of Labor, Occupational Safety and Health Administration (OSHA). Occupational Exposure to Bloodborne Pathogens: Final Rule (29 CFR 1910.1030). Federal Register; 1991.

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