

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

## **NORTH CAROLINA STATE LABORATORY OF PUBLIC HEALTH CLIA CONTRACT PROGRAM 2026**

### **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, more than *half* of North Carolina's local health departments (LHDs) have subscribed to the State Laboratory of Public Health (SLPH) CLIA Contract Program 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 (e.g., waived testing).

*While participation in the program is voluntary for each LHD, all participants must fully comply with its established guidelines. Every effort will be made to resolve issues that arise. However, it is crucial to understand that an individual LHD's failure to comply could jeopardize testing in all LHDs in that contract group. Unresolved non-compliance may lead to the suspension of testing at that facility or its removal from the program (see Sanctions, p.7), which is*

*necessary to protect the interests of all participating LHDs.*

*This program is exclusively for laboratories classified as “moderately complex” due to CMS’s definition of “limited public health testing”. The test menus of current participants will be reviewed annually to confirm their eligibility. Laboratories that perform only waived testing, high complexity testing, or only moderately complex testing classified as Provider Performed Microscopy Procedures must obtain their own CLIA certification independently. Any re-categorization of test methodologies by the federal government may necessitate changes to this program and participating LHDs will be notified promptly if such changes occur.*

### **CERTIFICATES:**

The Contract Program provides separate certificates from CMS for the five (5) contract areas. An organizational chart for the certificates is found in Appendix 1. These certificates only cover specific fixed LHD sites and do not extend to testing performed at day care centers, *mobile clinics*, or patients’ homes. Jails and school-based clinics are covered only when the site is staffed with health department employees and considered satellite sites of the LHD.

*The NCSLPH provides the Laboratory Director for these certificates. Regional Laboratory Consultants serve as Technical Consultants to whom the Laboratory Director may delegate certain responsibilities. LHDs are grouped to allow a proportionate distribution among the Technical Consultants. 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 *cannot* make changes to the test menu, methods, kits, or procedures without prior approval of the Laboratory Director or their designee.

*To maintain these certificates, laboratories must submit annual documentation to the Laboratory Director or their designee by January 31. This documentation is also required whenever changes occur in certain areas. 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 an LHD joins a contract area, all LHDs in that group are mutually dependent on each other to maintain uniform standards of quality. Therefore, the Program *mandates that the participating LHDs standardize practices.*

#### **A. Quality Assessment**

The CLIA Final Rule published January 24, 2003, renamed Quality Assurance to Quality Assessment to better reflect the activities involved. QA encompasses all phases of the total testing process (pre-analytic, post-analytic, analytic, and general laboratory systems). Each 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 *components* listed under STANDARDIZATION OF LABORATORY SERVICES are *integral to QA*. The laboratory must monitor each one of these systems at least once per year using the *Laboratory Quality Systems Review Schedule* (Appendix 11) provided. Failing to complete the *activities* will negatively impact the Accreditation/Reaccreditation status report for the laboratory. The QA Team must meet at least annually to review the *QA activity summaries*, all QA studies, yearly competency assessment results, yearly proficiency testing results (if

applicable) and any recurring *issue(s)* documented on the Problem Log.

**B. Policy Manual**

Individual written laboratory policies must be developed and kept current. *These policies require approval by the Laboratory Director (or designee) upon implementation and whenever changes are made.* Examples include 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, if a kit or instrument becomes 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 a nursing policy readily available to laboratory personnel. *The laboratory policy manual should specify the location of these standing orders.* No testing may be performed on verbal orders. Normal and panic values must be reviewed, approved, and signed by the Clinical Consultant annually and as changes occur. Testing personnel must document review of *the policy manual* annually and as changes occur. Discontinued policies must be retained in a separate section of the manual or in laboratory files for a minimum of two years, with the date of discontinuance noted.

**C. Technical Procedure Manual**

A comprehensive and up-to-date *technical* procedure manual must be available to and followed by all testing personnel to ensure *consistent* and reproducible performance. Procedures for specimen collection and each test performed must be typewritten and *adhere to the Clinical and Laboratory Standards Institute, (CLSI) guideline for technical procedure manuals (CLSI document QMS02-A6)* and kept in a 3-ring binder. *Alternatively, an electronic document control system is acceptable.*

The laboratory must *obtain* 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 *their* review annually and as changes occur *in the procedure manual*. Discontinued procedures must be retained in a separate section of the manual or in laboratory 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 align with, the most current CLSI standards, including *PRE02*, Collection of Diagnostic Venous Blood Specimens; and *GP42-Ed7*, Collection of Capillary Blood Specimens.

1. LHDs must purchase and make available in the laboratory an approved phlebotomy reference that reflects the current standards. Alternatively, LHDs may purchase the two CLSI standards referenced.
2. For the safety of their patients, facilities must ensure the availability of phlebotomy chairs *with safety devices to prevent falls*. It is strongly recommended that the blood collection be a separate space from specimen processing and/or laboratory testing areas.
3. Each LHD is ultimately responsible 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. *This individual must have a minimum of one-year of phlebotomy experience and successful demonstration of basic theoretical knowledge through a written test provided by the Technical Consultant. The phlebotomy coordinator's* responsibilities include developing 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 are responsible for complying with all applicable Federal, State and local requirements regarding laboratory safety. LHDs must ensure that adequate safety

precautions are in place to protect against laboratory hazards including 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.

For 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. These regulations require documentation that all personnel involved in packaging and/or shipping human specimens have received facility-specific hands-on training and refresher training every two years as determined by the U.S. Department of Transportation (DOT) and International Civil and Aviation Organization (ICAO).

#### F. **Quality Control (QC)**

For non-waived laboratories, *Quality Control* requirements are defined in the CLIA regulations. *The Program specifies the number of control levels and their frequency* (see Appendix 10). A facility under the contract cannot decide to eliminate QC because of cost.

LHD responsibilities for QC include:

- Purchasing appropriate QC materials
- Designating personnel to review and monitor QC
- Daily use of Ley-Jennings charts
- *Establishing a* policy for reporting out-of-range patient values and medical alert (panic) values

#### **Specific 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 for review by the Technical Consultant.
- Laboratory environmental conditions that could affect reagent storage and test system operation must be monitored and documented.
  1. Facility requirements:
    - Room temperature checks must be performed *and documented each day the facility is open*.
    - Humidity check, as required, must be performed *and documented each day the facility is open*.
  2. Equipment - Data on instruments and equipment must be recorded and retained according to CLIA regulations. This includes preventive maintenance, equipment logs and charts, function checks, and facility monitoring.
    - Each laboratory must have a preventive maintenance schedule for all instruments, refrigerators, incubators, centrifuges, and other laboratory equipment 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, a system *must be in place to evaluate and define* the relationship between test results using the different methodologies, instruments, or testing sites twice a year.

**G. Proficiency Testing (PT)**

Each contract area must perform *Proficiency Testing (PT)* on unknown samples provided by a CMS-approved agency for hemoglobin, glucose, and each non-waived test on the certificate. CLIA regulations mandate the frequency and number of challenges required for each test *annually*.

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 for selection. If a designated LHD fails PT for an analyte, specialty, or subspecialty, *appropriate corrective action will be determined by the Technical Consultant*. Testing at all sites on that certificate would be affected. For example, if 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) regarding patient information throughout all phases of the total testing process under the laboratory's control. Contract laboratories are required to use an electronic record system for reporting patient results. Test reports 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 all referred testing.

***Laboratory staff will not place orders in electronic medical records.***

***This requirement exists to prevent potential errors and inefficiencies that can arise when lab staff manually enter orders from paper requisitions. It ensures:***

- *Minimized Errors: Limiting test ordering to providers or delegated care team members (like nurses or medical assistants) ensures that the individuals with the full clinical context for a patient are making these decisions. This significantly reduces the risk of incorrect tests being ordered.*
- *Record Integrity: The patient's medical record is a legal document. This policy helps maintain the integrity of that record by ensuring all*

- entries, especially test orders, are made by authorized personnel with a clear clinical purpose.*
- *Legal and Liability Protection: Unauthorized order entry can lead to significant legal and liability concerns. An incorrectly ordered test that results in a negative patient outcome could have serious legal repercussions for both the facility and its staff.*
  - *Regulatory Compliance and Fraud Prevention: Restricting who can place orders helps with regulatory compliance and prevents issues that might be flagged during audits. This practice ensures that test utilization is properly managed and helps mitigate potential fraud.*

## I. **Testing Personnel**

Per federal regulations, individuals may perform only tests 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 cases of laboratory personnel shortages, *the LDH must implement an acceptable contingency plan and immediately communicate 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 laboratory position (*less than 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 prior**

**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 for 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 for waived testing personnel, they may be required to attend specific training workshops and mentoring sessions at other facilities.

c) Each LHD must designate a "laboratory manager." This *person serves as the* primary liaison between the LHD laboratory and the Technical Consultant and *is typically best suited for administrative laboratory functions. If the laboratory manager position becomes vacant*, a qualified replacement must be named within 10 working days, or the vacancy must be advertised with necessary qualifications within 10 working days. Given the technical nature of these functions, it is highly recommended that the laboratory manager have at least an associate degree in medical laboratory technology and two years of experience, or a bachelor's degree in medical technology and one year of experience (see Appendix 6).

2. **Continuing Education (CE)**

a) *Personnel* assigned to perform **waived testing only** must obtain at least three (3.0) contact hours of lab-related continuing education per calendar year.

b) *Personnel* performing **non-waived testing** must have six (6.0) contact hours of lab-related continuing education per calendar year.

c) *Personnel* 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.

d) The focus of the CE events must be laboratory testing or management. Annual on-site safety updates may be included for 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-laboratory continuing education program has a clinical laboratory component, a detailed agenda of the program must be sent to the Technical Consultant for review and potential 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. Therefore, 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, they must perform the test at least once per quarter or they *will no longer be authorized to perform* that test. If an individual is performing a test only once per month or less, *they* must perform and document QC for that test each day *they* conduct testing. This policy applies to every test assigned.

### **4. Competency Assessment**

A *key* 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 *qualified* 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 not be allowed to perform that specific test.

### **SANCTIONS:**

The sanction process is *crucial for safeguarding* the shared interests of all LHDs within a contract area. *It prevents potential* decertification that could result from one laboratory's non-compliance.

The Technical Consultant will notify the Laboratory Director when there is a repeated failure to correct a noted deficiency or when a critical activity arises that could jeopardize a contract area's certification. *The decision to initiate a sanction rests with 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:

- *Insufficient Qualified Staff*: failure to provide an adequate number of qualified testing personnel.
- *Persistent Deficiencies*: repeatedly failing to correct identified deficiencies.
- *Unauthorized Testing*: allowing unauthorized personnel to perform testing.
- *Exceeding Test Menu*: performing a procedure not on the 15-test menu.
- *Inadequate Retraining*: failure to retrain personnel after unsuccessful PT or technical competency assessment. (Retraining must occur at the earliest possible course and the individual may be required to stop testing until training is completed.)
- *Missed Mandatory Meetings*: failure to send appropriate

representative(s) to a mandatory meeting.

- *Missing Documentation*: failure to submit required documentation.
- *Falsifying Records*: falsifying documentation of any kind, including test results.
- *Quality Control Failures*: failure to perform, document and/or monitor required quality control.
- *Using Expired Materials*: using expired reagents or supplies.
- *Competency Assessment Non-Submission*: 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; August 12, 2024.
- CLSI. Developing and Managing Laboratory Documents; Approved Guideline QMS02-Ed7, Wayne, PA; 2024.
- CLSI. Managing and Validating Laboratory Information Systems; Approved Guideline Auto08-A, Wayne, PA; 2006.
- CLSI. *Collection of Diagnostic Venous Blood Specimens; Approved Standard PRE02*, Wayne, PA; 2025.
- CLSI. Collection of Capillary Blood Specimens. Approved Standard GP42-Ed7, Wayne, PA; 2020.
- CLSI. Clinical Laboratory Safety. Approved Guideline GP17-A3, Wayne, PA; 2012.
- 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; 2004.
- <https://reach.cdc.gov/course/packing-and-shipping-dangerous-goods-what-laboratory-staff-must-know> Accessed 8/4/25.

## **LIST OF APPENDICES:**

1. Organizational Chart
2. Comparison of Provided Services
3. Laboratory Director Responsibilities
4. Technical Consultant Responsibilities
5. Clinical Consultant Responsibilities
6. Laboratory Manager Responsibilities
7. Testing Personnel Responsibilities
8. Testing Personnel Record
9. Training and Continuing Education Record
10. Quality Control Requirements (by Area)
11. Laboratory Quality Systems Assessment Schedule