

## COMPARISON OF PROVIDED SERVICES

The following lists outline services that are provided by the SLPH and those services the contract county health department provides. The local health department is responsible for providing all items on both lists if the contract is terminated by either party.

### SLPH PROVIDES

1. Qualified personnel:
  - a. Laboratory director
  - b. Technical consultant
2. Qualified technical consultation  
By phone 5 days per week, 52 weeks per year;  
On site-minimum of 2x per year
3. Certificate/inspection administered
4. Proficiency testing enrollment
5. Access to continuing education resources
6. CLIA inspection assistance
  - a. Preparation
  - b. *Consultant on site during inspection*
  - c. Consultative follow-up for any deficiencies noted
7. Competency assessment program for all moderate complexity testing personnel
8. Model forms and plans

### LHD PROVIDES

1. Qualified personnel:
  - a. Clinical consultant
  - b. Lab manager
  - c. Phlebotomy coordinator
  - d. Testing personnel
2. Quality control materials
3. Preventive maintenance and repair of laboratory equipment
4. *Time and expenses for lab-related CE for testing personnel:*
  - a. Moderate complexity testing: 6.0 hours per year per person
  - b. Moderate complexity testing (one test only; no waived tests): 4.0 hours per year per person
  - c. Waived testing only: 3.0 hours per year per person
5. Organization and storage of required records
6. \$230 annual contract fee
7. Clerical/administrative support
8. Lab computer and printer with Internet and e-mail access for designated lab manager, according to the SLPH Agreement Addendum
9. Copies of CLSI standards, H3 and H4, or an approved phlebotomy text based on current CLSI standards

## LAB DIRECTOR RESPONSIBILITIES

1. Laboratory director is responsible for the overall operation and administration of the laboratory.
2. Laboratory director must:
  - a. Ensure testing systems developed and used provide quality lab services for all phases of test performance (preanalytic, analytic, and postanalytic.)
  - b. Ensure that the physical plant and environmental conditions are appropriate and employees are protected from physical, chemical, and biologic hazards.
3. Laboratory director shall make sure sufficient personnel are employed and specify in writing the responsibilities and duties of each consultant and testing personnel. It shall include tests each individual can perform and any conditions particular to the individual's testing (supervision, reporting, review, etc.)
4. Laboratory director shall delegate to the technical consultants the following duties:
  - a. Ensure that test methods are appropriate and personnel are performing them as required.
  - b. Enroll the laboratory in a CMS-approved proficiency testing program and ensure that all components under subpart H of 42 CFR 493 are met. Technical consultants may sign the proficiency test report forms.
  - c. Establish appropriate quality control and quality assessment programs for the laboratory.
  - d. Ensure acceptable levels of analytical performance for each test system.
  - e. Ensure remedial action is taken and documented when necessary.
  - f. Ensure that testing personnel have appropriate education, experience, and training for the tests performed and that they have demonstrated competency in their testing.
  - g. Ensure that policies and procedures are established to monitor testing personnel. Identify needs for remedial training or continuing education to improve or enhance their skills.
  - h. Ensure that a procedure manual is current and available to all testing personnel. Technical consultant may sign the procedure manual.
5. Laboratory director shall delegate the following duties to the clinical consultant:
  - a. Ensure that reports include pertinent information required for interpretation.
  - b. Ensure that consultation is available to the laboratory's patients.

REFERENCE: 42 CFR 493.1407

## TECHNICAL CONSULTANT RESPONSIBILITIES

1. The technical consultant is responsible for the technical and scientific oversight of the laboratory.
2. The technical consultant's responsibilities include:
  - a. Selection of appropriate test methodology.
  - b. Verification of test procedures performed and establishment of performance limits, including precision and accuracy.
  - c. Enrollment and participation in a CMS-approved proficiency testing program.
  - d. Establishment of quality control program, including establishment of acceptable parameters for preanalytic, analytic, and postanalytic steps.
  - e. Resolution of technical problems; ensuring that remedial actions are taken and documented.
  - f. Ensuring that no patient results are reported if test system is not functioning properly.
  - g. Identifying training needs for staff; assuring that staff receives training.
  - h. Evaluating competency of the staff. Procedures must include, but not be limited to:
    - 1) Direct observation of patient testing
    - 2) Monitoring records and reporting of results
    - 3) Review of intermediate test results, QC records, PT records, preventive maintenance records
    - 4) Direct observation of instrument maintenance and function checks
    - 5) Assessment of test performance (ex. - blind test samples, previously analyzed specimens, external PT)
    - 6) Assessment of problem-solving skills
  - i. Evaluation and documentation of staff performance - semiannually the first year that the individual tests specimens, annually thereafter.
3. Other responsibilities as delegated to the technical consultant by the Lab Director.

REFERENCE: 42 CFR 493.1413

**CLINICAL CONSULTANT RESPONSIBILITIES  
Moderate Complexity Labs**

493.1419 - Standard; Clinical Consultant Responsibilities

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must:

- (a) Be available to provide clinical consultation to the laboratory's clients;
  - (b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;
  - (c) Ensure that reports of test results include pertinent information required for specific patient interpretation;
- and
- (d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

REFERENCE: 42 CFR 493.1419

\_\_\_\_\_  
(Clinical Consultant)

\_\_\_\_\_  
(Date)

## **LABORATORY MANAGER RESPONSIBILITIES IN A CLIA CONTRACT HEALTH DEPARTMENT**

- Serves as the primary liaison for all communication between the local laboratory and the SLPH, lab director, and technical consultant.
- Cooperates with the SLPH and the technical consultant in ensuring compliance with applicable federal and state regulations.
- Develops, implements, monitors, and revises laboratory policies and procedures in accordance with local and state policies; obtains signature approval of these policies by the lab director (or designee).
- Establishes, maintains and monitors a comprehensive, effective quality assurance program for laboratory services.
- Monitors and assesses procedural quality control.
- Develops, implements, and monitors safety practices in the laboratory.
- Designs, reviews, and revises technical manuals and protocols, and obtains signature approval by the lab director (or designee).
- Develops, implements and monitors appropriate data collection and information management systems.
- Coordinates the functions of the laboratory to provide needed support for other services and operations of the local department.
- Sets priorities, assigns responsibilities and establishes workflow and personnel schedules.
- Informs local health director, laboratory director and technical consultant about status of or changes in laboratory services.
- Ensures laboratory orientation for all new employees in the local health department.
- Maintains records on all testing personnel to include assignment to pre-analytic, analytic, and post-analytic duties, continuing education, and frequency of testing (for proficiency purposes).
- Informs all testing personnel of continuing education opportunities and deadlines for completion of required continuing education hours.
- Coordinates participation of all testing personnel in competency assessment challenges, and provides reports to the technical consultant.
- Fulfills or assures appropriate delegation of phlebotomy coordinator duties.
- Assesses and recommends appropriate contractual relationships for utilization of external resources, including reference laboratories.
- Develops and maintains effective working relationships within laboratory and with others in the local department.
- Establishes good public relations for the laboratory within the department, with the community, and with representatives of other disciplines and professions.
- Represents the laboratory in interactions with other members of the health care team.
- Promotes an awareness and understanding of laboratory services in relation to patient care, environmental conditions and general public health.
- Ensures that all deadlines as set forth in the contract program are met.

## TESTING PERSONNEL RESPONSIBILITIES

1. The testing personnel are responsible for specimen processing, test performance and for reporting test results.
2. Each individual performs only those tests that are authorized by the laboratory director (or designee) and require a degree of skill commensurate with the individual's education, training, or experience, and technical abilities.
3. Each individual performing testing must:
  - a. Follow the laboratory's procedure for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;
  - b. Maintain records that demonstrate applicable proficiency testing and/or competency assessment samples are tested to the extent possible, in the same manner as patient samples;
  - c. Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;
  - d. Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;
  - e. Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the laboratory manager, technical consultant, clinical consultant or director;
  - f. Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

REFERENCE: 42 CFR 493.1425

## TESTING PERSONNEL RECORD

Employee name:	Agency:
Diploma on file <i>(documentation required)</i> :	Employment start date:
Certification, registration, or licensure:	<input type="checkbox"/> Full-time <input type="checkbox"/> Part-time <input type="checkbox"/> Per diem
Position title:	Employment end date:

**Training/Degree:**

- |  |   |
|--|---|
| <input type="checkbox"/> Certified Nurse Assistant (CNA)     | <input type="checkbox"/> Medical Laboratory Assistant (MLA)   |
| <input type="checkbox"/> Certified Nurse Midwife (CNW)       | <input type="checkbox"/> Medical Laboratory Technician (MLT)  |
| <input type="checkbox"/> Certified Phlebotomist (CPBT)       | <input type="checkbox"/> Medical Laboratory Technologist (MT) |
| <input type="checkbox"/> Clinical Laboratory Scientist (CLS) | <input type="checkbox"/> Medical Office Assistant (MOA)       |
| <input type="checkbox"/> Family Nurse Practitioner (FNP)     | <input type="checkbox"/> Physician Assistant (PA)             |
| <input type="checkbox"/> Licensed Practical Nurse (LPN)      | <input type="checkbox"/> Registered Nurse (RN)                |
| <input type="checkbox"/> Medical Doctor (MD)                 | <input type="checkbox"/> Other <i>(list)</i> _____            |

Indicate all sources of previous laboratory work experience *(check all that apply)*:

- |  |  |
|--|--|
| <input type="checkbox"/> Local Hospital                      | <input type="checkbox"/> Reference Laboratory      |
| <input type="checkbox"/> Military Hospital/Clinic            | <input type="checkbox"/> Research Laboratory       |
| <input type="checkbox"/> Physician's Office Laboratory (POL) | <input type="checkbox"/> Other <i>(list)</i> _____ |
| <input type="checkbox"/> Public Health Laboratory            | <input type="checkbox"/> Other <i>(list)</i> _____ |

Briefly describe work history as it pertains to laboratory testing:

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Indicate workshops/trainings attended:

**State Laboratory of Public Health**

- Darkfield Examination
- Lab Methods in the Clinical Diagnosis of Gonorrhea
- Microscopy: Viewing & Reviewing
- Packaging & Shipping
- Phlebotomy
- Syphilis Serology
- Urinalysis
- Wet Mount
- Other *(list)* \_\_\_\_\_

**Other Courses/Workshops**

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

**Reviewed by:**

\_\_\_\_\_

**Title:**

\_\_\_\_\_

**Date:**

\_\_\_\_\_





# AREA A

## 2009 Quality Control Requirements

The following quality control requirements are established by the CLIA '88 Final Rule and the NC CLIA Contract Program, in conjunction with manufacturers' instructions.

<i>MODERATE COMPLEXITY PROCEDURES</i>		
TEST	REQUIREMENTS	FREQUENCY
<b>Glucose</b>	2 levels	Each day of testing
<b>Urine Microscopy</b>	Abnormal	Each week of testing
<b>GC-Lect Media</b>	Observe condition Check sterility	Each plate Each lot & shipment
<b>GC Testing:</b> a. <b>Oxidase Test</b> b. <b>Gram Stain</b> c. <b>Gram Stain (BD kits)</b>	a. Positive & negative b. Positive & negative c. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed c. Each day of testing; at least monthly if no testing is performed
<b>Wet Mount</b>	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
<b>Urine Colony Count Media</b>	Observe condition Check sterility	Each day of use Each lot & shipment
<b>Syphilis Serology*</b>	a. Reactive & non-reactive b. Needle & rotator count c. Room temperature	a. Each day of testing b. Each day of testing c. Each day of testing
<i>WAIVED PROCEDURES</i>		
TEST	REQUIREMENTS	FREQUENCY
<b>Glucose</b>	2 levels	Each day of testing
<b>Hemoglobin</b>	2 levels	Each day of testing
<b>Urine Dipstick:</b>		
a. <b>Visual/Manual Method</b>	a. Abnormal only	a. Weekly, and with each new can of strips
b. <b>Automated</b> (Clinitek 50)	b. Normal & abnormal	b. Daily, and with each new can of strips
c. <b>Automated</b> (Clinitek Status only)	c. Normal & abnormal	c. Weekly, and with each new can of strips
<b>Urine Pregnancy/hCG**</b>	Positive & negative	Weekly, and each new kit/container
<b>Rapid Test, Group A Strep**</b>	Positive & negative	Each week of testing, each new kit, and each operator
<b>Fecal Occult Blood**</b>	Written procedure Proper training	
<b>Amine</b>	Written procedure Proper training	

\*Quantitative results require a reactive control of graded or titered reactivity.

\*\*Internal performance monitor result must be recorded for each patient.

## AREA B

### 2009 Quality Control Requirements

The following quality control requirements are established by the CLIA '88 Final Rule and the NC CLIA Contract Program, in conjunction with manufacturers' instructions.

<b>MODERATE COMPLEXITY PROCEDURES</b>		
<b>TEST</b>	<b>REQUIREMENTS</b>	<b>FREQUENCY</b>
<b>Urine Microscopy</b>	Abnormal	Each week of testing
<b>GC-Lect Media</b>	Observe condition Check sterility	Each plate Each lot & shipment
<b>GC Testing:</b> a. <b>Oxidase Test</b> b. <b>Gram Stain</b> c. <b>Gram Stain (BD kits)</b>	a. Positive & negative b. Positive & negative c. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed c. Each day of testing; at least monthly if no testing is performed
<b>Wet Mount</b>	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
<b>Urine Colony Count Media</b>	Observe condition Check sterility	Each day of use Each lot & shipment
<b>WAIVED PROCEDURES</b>		
<b>TEST</b>	<b>REQUIREMENTS</b>	<b>FREQUENCY</b>
<b>Cholesterol, Total</b>	2 levels	Each day of testing
<b>Glucose</b>	2 levels	Each day of testing
<b>Hemoglobin</b>	2 levels	Each day of testing
<b>Hemoglobin A<sub>1c</sub></b>	2 levels 1 level (alternating)	Each new lot #; New kit; same lot #
<b>Urine Dipstick:</b>		
a. <b>Visual/Manual Method</b>	a. Abnormal only	a. Weekly, and with each new can of strips
b. <b>Automated</b> (Clinitek 50)	b. Normal & abnormal	b. Daily, and with each new can of strips
c. <b>Automated</b> (Clinitek Status only)	c. Normal & abnormal	c. Weekly, and with each new can of strips
<b>Urine Pregnancy/hCG*</b>	Positive & negative	Weekly, and each new kit/container
<b>Rapid Test, Group A Strep*</b>	Positive & negative	Each week of testing, each new kit, and each operator
<b>Fecal Occult Blood*</b>	Written procedure Proper training	
<b>Amine</b>	Written procedure Proper training	

\*Internal performance monitor result must be recorded for each patient.

# AREA C

## 2009 Quality Control Requirements

The following quality control requirements are established by the CLIA '88 Final Rule and the NC CLIA Contract Program, in conjunction with manufacturers' instructions.

<i>MODERATE COMPLEXITY PROCEDURES</i>		
TEST	REQUIREMENTS	FREQUENCY
<b>Urine Microscopy</b>	Abnormal	Each week of testing
<b>GC-Lect Media</b>	Observe condition Check sterility	Each plate Each lot & shipment
<b>GC Testing:</b> a. <b>Oxidase Test</b> b. <b>Gram Stain</b> c. <b>Gram Stain</b> (BD kits)	a. Positive & negative b. Positive & negative c. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed c. Each day of testing; at least monthly if no testing is performed
<b>Wet Mount</b>	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
<b>Urine Colony Count Media</b>	Observe condition Check sterility	Each day of use Each lot & shipment
<b>Syphilis Serology*</b>	a. Reactive & non-reactive b. Needle & rotator count c. Room temperature	a. Each day of testing b. Each day of testing c. Each day of testing
<i>WAIVED PROCEDURES</i>		
TEST	REQUIREMENTS	FREQUENCY
<b>Glucose</b>	2 levels	Each day of testing
<b>Hemoglobin</b>	2 levels	Each day of testing
<b>Hemoglobin A<sub>1c</sub></b>	2 levels 1 level (alternate)	Each new lot # New kit; same lot
<b>Urine Dipstick:</b>		
<b>a. Visual/Manual Method</b>	a. Abnormal only	a. Weekly, and with each new can of strips
<b>b. Automated</b> (Clinitek 50)	b. Normal & abnormal	b. Daily, and with each new can of strips
<b>c. Automated</b> (Clinitek Status only)	c. Normal & abnormal	c. Weekly, and with each new can of strips
<b>Urine Pregnancy/hCG**</b>	Positive & negative	Weekly, and each new kit/container
<b>Rapid Test, Group A Strep**</b>	Positive & negative	Each week of testing, each new kit, and each operator
<b>Fecal Occult Blood**</b>	Written procedure Proper training	
<b>Amine</b>	<i>Written procedure</i> <i>Proper training</i>	

\*Quantitative results require a reactive control of graded or titered reactivity.

\*\*Internal performance monitor result must be recorded for each patient.

# AREA D

## 2009 Quality Control Requirements

The following quality control requirements are established by the CLIA '88 Final Rule and the NC CLIA Contract Program, in conjunction with manufacturers' instructions.

<i>MODERATE COMPLEXITY PROCEDURES</i>		
TEST	REQUIREMENTS	FREQUENCY
Urine Microscopy	Abnormal	Each week of testing
GC-Lect Media	Observe condition Check sterility	Each plate Each lot & shipment
GC Testing: a. Oxidase Test b. Gram Stain c. Gram Stain (BD kits)	a. Positive & negative b. Positive & negative c. Positive & negative	a. Each day of use b. Each week of testing; at least monthly if no testing is performed c. Each day of testing; at least monthly if no testing is performed
Wet Mount	Written procedure Proper training	Parallel testing with all assigned testing personnel (TP) twice per year
Syphilis Serology*	a. Reactive & non-reactive b. Needle & rotator count c. Room temperature	a. Each day of testing b. Each day of testing c. Each day of testing
<i>WAIVED PROCEDURES</i>		
TEST	REQUIREMENTS	FREQUENCY
Cholesterol	2 levels	Each day of testing
Glucose	2 levels	Each day of testing
Hemoglobin	2 levels	Each day of testing
Hemoglobin A <sub>1c</sub>	2 levels 1 level (alternate)	Each new lot # New kit; same lot
Urine Dipstick:		
a. Visual/Manual Method	a. Abnormal only	a. Weekly, and with each new can of strips
b. Automated (Clinitek 50)	b. Normal & abnormal	b. Daily, and with each new can of strips
c. Automated (Clinitek Status only)	c. Normal & abnormal	c. Weekly, and with each new can of strips
Urine Pregnancy/hCG**	Positive & negative	Weekly, and each new kit/container
Rapid Test, Group A Strep**	Positive & negative	Each week of testing, each new kit, and each operator
Fecal Occult Blood**	Written procedure Proper training	
Amine	Written procedure Proper training	

\*Quantitative results require a reactive control of graded or titered reactivity.

\*\*Internal performance monitor result must be recorded for each patient.