



Clinical Laboratory Improvement Amendments (CLIA) Toolkit

Continuous Quality Improvement in Public Health Laboratories

Georgia Department of Public Health

CLIA Toolkit: Continuous Quality Improvement in Public Health Laboratories

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Acknowledgements

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We are grateful for to the nursing leadership in Health District 3-1 Cobb/Douglas for sharing the reference documents listed as appendices for the CLIA Pre-Inspection Checklist. These resources are the foundation of the Checklist and may be adapted for each district.

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DPH CLIA Recommendation Committee (in alphabetical order):

Jamie Ashe, BSN, RN, Marietta Public Health Center Supervisor

Kay Davis, RN, MSN Assistant Clinical Coordinator, Southeast Health District (9-2)

Christi Florence, RN, Deputy Director of Clinical Services, Cobb & Douglas Public Health (3-1)

Donna Goskowsky, MT, ASCP

Laura Layne, MSN, MPH, RN, Deputy Chief Nurse, QI

Meshell McCloud, RN, MS, APRN, WHNP-BC, Chief Nurse

Bill Scott, Director of Audits

Tom Wade, Consultant

DPH State Laboratory Partners:

Dr. Elizabeth Franko, Dr. Tonia Parrott and James Hearn

Georgia Public Health Laboratory

1749 Clairmont Ave

Decatur, GA 30033

404-327-7900

Waycross Regional Laboratory

1751 Gus Karle Parkway

Waycross, GA 31503

912-338-7050

Department of Community Health Partners:

Christel Benn Griffith, MT (ASCP), Diagnostics Program Director, State of Georgia, Department of Community Health, Healthcare Facility Regulation Division

Gwendolyn Williams, Clinical Laboratory Consultant, Division of Survey and Certification, Centers for Medicare & Medicaid Services

Foreword

The CLIA Toolkit is based on a statewide laboratory infrastructure assessment conducted November – December 2018. The results of the infrastructure assessment provided the basis for understanding the structure and processes of DPH laboratories. A Pre-inspection Checklist is also included in the Toolkit to facilitate internal assessments of laboratory processes. The Checklist outlines required laboratory standards with links to example documents in the appendices. We conducted a pilot in Dalton, Rome and Fulton Counties during their DCH inspection in March and April 2019 and revised the Checklist based on lessons learned. The final product is included in this Toolkit and example documents may be adapted locally. Other examples are available through the Office of Nursing.

Purpose

The purpose of the DPH Clinical Laboratory Improvement Amendments Toolkit (CLIA Toolkit) is to provide a preparation checklist, resources and other relevant information for DPH Laboratory Directors as well as lab supervisors and/or District Nursing and Clinical Directors. It offers guidance related to the standards, requirements and processes involved in being and staying in compliance with Centers for Medicare & Medicaid Services (CMS), CLIA Rules and Regulations. The CLIA Toolkit provides a framework for health districts to conduct ongoing internal lab assessments to ensure accuracy and reliability of patient’s test results.

About CLIA

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. For more information, refer to [CLIA overview](#). CMS regulates all laboratory testing (except research) performed on humans in the United States through CLIA.

- State Operations Manual: Appendix C - Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf
- Electronic Code of Federal Regulations (“Rules and Regulations”): <https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5>
- Interpretive Guidelines for Laboratories https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html

To ensure CLIA compliance, it is important to read and review the CLIA rules and regulations and the State Operations Manual Appendix C linked above. The Interpretive Guidelines are a good reference for more detailed explanation of a given regulation.

CLIA Types of Certificates

Each laboratory must be either CLIA-exempt or possess one of the CLIA certificates listed below. All DPH laboratories either possess a Certificate of Compliance or a Certificate for Provider Performed Microscopy. Both are defined in [Subpart A section 493.2 of Laboratory Requirements Code of Federal Regulations](#).

The CLIA program grants five types of laboratory certificates (from least to most complex):

1. Certificate of Waiver (CoW)
2. Certificate for Provider-Performed Microscopy Procedures (PPMP)
3. Certificate of Registration (COR)
4. Certificate of Compliance (COC)
5. Certificate of Accreditation (COA)

Quality Assurance Based on Test Complexity

[FDA categorizes diagnostic tests](#) by complexity. From the least to the most complex: waived tests, moderate complexity tests, and high complexity tests.

Waived testing

Waived tests are simple and there is little chance these tests will provide wrong information or cause harm if done incorrectly. If the test is cleared by the FDA for home or over-the-counter use it is automatically in the waived category.



The waived category requires the least regulation. The minimum requirement for anyone performing waived testing is to follow the manufacturers' directions for quality control (QC), and if no directions are included, to follow [good laboratory practices](#). Good laboratory practices would dictate that controls be run and results documented and reviewed for correctness before reporting patient results.

The FDA categorization database, also cited in the CLIA Rules and Regulations, is used to find a list of specific waived tests with CPT code, test name, and manufacturer. The most current information on [FDA-approved waived tests](#) is available on their website.

Laboratories with a CLIA Waived Certificate are not subject to a routine survey or inspection although a surveyor from the state agency may visit at any time. A [Self-Assessment tool](#) is available on the CDCs website to continue to ensure accuracy of results.

Moderate Complexity Testing

The requirements for a quality system for non-waived testing are identified and defined in [Subpart K— Quality System for Non-waived Testing](#). The introduction in [section §493.1200](#) defines the overall standards in (a-c) below:

- (a) Each laboratory that performs non-waived testing must establish and maintain written policies and procedures that implement and monitor a quality system for all phases of the total testing process (that is, preanalytic, analytic, and postanalytic) as well as general laboratory systems.
- (b) The laboratory's quality systems must include a quality assessment component that ensures continuous improvement of the laboratory's performance and services through ongoing monitoring that identifies, evaluates and resolves problems.
- (c) The various components of the laboratory's quality system are used to meet the requirements in this part and must be appropriate for the specialties and subspecialties of testing the laboratory performs, services it offers, and clients it serves.

The standards are outlined in [Subpart K](#) under the following sub-sections (493-):

- General laboratory systems (.1230-.1239)
- Preanalytic systems (.1240-.1249)
- Analytic systems (.1250 - .1289)
- Postanalytic systems (.1290-.1299).

There are also standards by testing category under analytic systems (493-):

- Bacteriology (.1261)
- Mycobacteriology (.1262)
- Mycology (.1263)
- Parasitology (.1264)
- Other tests (.1269 - .1278)

Moderate complexity testing includes two types of certificates - Provider Performed Microscopy and Certificate of Compliance.

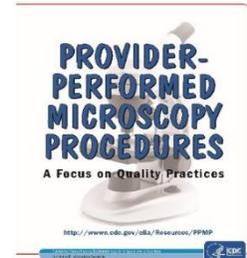
Provider Performed Microscopy Procedures

The PPMP category is a subset of moderate complexity testing. The PPMP Certificate is basically a Certificate of Waiver plus the nine tests below. A biennial inspection is not required but the lab performing PPM Procedures must meet CLIA quality standards for moderate complexity testing. Under this type of certificate only physicians, dentists, nurse practitioners, midwives, and physician assistants may perform the nine tests specified below. The testing must be performed during the patient's visit on a specimen that quickly deteriorates or not able to transport and obtained from his or her own patient.

When these tests are provided, the practitioners are expected to follow the manufacturers' directions for QC or follow [good laboratory practices](#). The primary instrument for performing the test(s) is the microscope. The PPM category includes nine tests (listed below) in addition to waived tests.

1. All direct wet mount preparations (suspended in saline or water) for the presence or absence of bacteria, fungi, parasites, and human cellular elements
2. KOH preps
3. Pinworm exams
4. Fern tests
5. Post-coital direct qualitative exams of vaginal or cervical mucous
6. Urine sediment exams
7. Nasal smears for granulocytes
8. Fecal leukocyte exams
9. Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

The [PPM Procedure booklet](#) describes recommended practices and an overview of the regulatory requirements, resources including forms and examples, and an overview with images of common microscopic findings for the nine specific microscopic examinations that may be performed under a Certificate of PPM Procedures for physicians, dentists, APRNs and PAs.



Certificate of Compliance

The Certificate of Compliance (COC) is the certificate that allows the laboratory to conduct moderate and/or high complexity testing. Laboratories receive a COC after an on-site survey finds they comply with all applicable CLIA regulations. These surveys occur every 2 years. Under the COC, employees will need to be trained on each test they perform before beginning patient testing. After training, employees will need to be periodically assessed on their ability to perform quality testing. Examples of a training checklist, training evaluation form and performance assessment are available in Appendix C through E in [CDC, To Test Or Not To Test?](#)

Competency Assessment

Regular competency assessment assures that all personnel are capable of performing their laboratory duties correctly. The laboratory must have policies and procedures to assess competency for individuals fulfilling the following positions on the Laboratory Personnel Report (Form CMS-209): clinical consultant (CC), technical consultant (TC), technical supervisor (TS), and general supervisor (GS). The qualifications and responsibilities for these positions are listed in [subpart M](#). This is required at least semiannually during the first year the individual tests patient specimens and at least annually thereafter unless test methodology or instrumentation changes. In that case, the individual's

performance must be reevaluated using the new test methodology or instrumentation prior to reporting patient test results.

It is the responsibility of the TC to evaluate and assure the competency of all testing personnel for each test they perform. The competency of the staff must include, but are not limited to the following 6 steps as outlined in [§ 493.1413 Standard; Technical consultant responsibilities](#)

1. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
2. Monitoring the recording and reporting of test results;
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. Direct observation of performance of instrument maintenance and function checks;
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Assessment of problem-solving skills;

If any problems with competency assessment are noted they should be documented and corrected through the laboratory's QA process.

Proficiency Testing

Proficiency testing, or PT, is the testing of unknown samples sent to a laboratory by an HHS-approved PT program. Most sets of PT samples are sent to participating laboratories on a scheduled basis (usually three times per year). After testing, the laboratory reports its sample results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory their scores. CMS and accreditation organizations routinely monitor their laboratories' performance. For additional information, guidance and FAQs about PT and PT referral refer to the [CLIA Proficiency Testing and PT Referral Dos and Don'ts Booklet](#).

A list of non-waived tests for which PT is required is available in [Attachment 2](#).

Resources and Helpful Links

1. Lab Directors: [CLIA Lab Director Responsibilities Brochure](#)
2. For a Lab Director change: Complete Section 1 General Information on the first page of the [Application for Certification CMS-116](#) . Mark “Other Changes” and specify “lab director change” as the reason. Lab Directors must meet specific education, training and experience requirements. Email/fax proof of the new lab directors qualifications with form [CMS-116](#) (see below in the CLIA Pre-Inspection Checklist) to DCH, Healthcare Facility Regulation Division.
3. Proficiency Testing: [PT and PT Referral Dos and Don'ts Booklet](#)
4. Waived testing, CDC resources: [CLIA Waived Tests](#)
5. “READY? SET? TEST!”
 - [“READY? SET? TEST!” On-demand, online training](#) provides scenario based training on recommended practices for waived testing and offers continuing education credit. Register through [the CDC Train website](#).
 - The [“READY? SET? TEST!” booklet](#) describes recommended practices for patient testing under a CLIA Certificate of Waiver.
6. CLIA, CMS [Quick Reference Brochures](#): performance specifications; calibration; lab director responsibilities; proficiency testing; assessing personnel competency; individualized quality control plan.
7. [CLIA Frequently Asked Questions](#)
8. Questions regarding a CLIA certificate or fees: The point of contact for specific questions related to CLIA fees or payment, CMS-116 applications, demographic updates, certificate status or upgrades, and/or Laboratory Director changes is Christel Benn-Griffith. Her contact information is below or accessed via the [State Survey Agency Contacts](#).



Contact: Christel Benn Griffith

Email: christel.benn-griffith@dch.ga.gov

(404) 657-5700 FAX: (404) 463-4398

Georgia DCH, Healthcare Facility Regulation Division Diagnostic Services Unit 2

Peachtree Street, N.W. Suite 31-447 Atlanta, GA 30303-3142

Conclusion

The CLIA Toolkit is part of DPH's continuous quality improvement efforts to strengthen our laboratory processes to provide the highest quality laboratory care for the citizens of Georgia. The best way to assess overall compliance with CLIA regulations is to continually assess lab processes using the CLIA Toolkit and specifically the [CLIA Pre-Inspection Checklist \(Attachment 1\)](#) and accompanying [appendices \(Attachment 2\)](#) and conduct mock inspections.

Attachment 1: CLIA Pre-Inspection Checklist

The CLIA Pre-Inspection Checklist is a list of standards and required laboratory practices and documents. It provides a framework to conduct an internal lab assessment and prepare for inspection. This is designed for laboratories performing non-waived testing but may be used for quality assurance in any laboratory. Please note that additional documents may be required by the surveyor.

CLIA Pre-Inspection Checklist

ADMINISTRATION	Yes	No	N/A
Inspection Package Instructions Reviewed? Appendix A and links below to federal documents			
CMS-116 Application – Section VIII (Past Year) Annual Test Volume per specialty completed? For Lab Director change complete Section 1 General Information and email/fax with qualifications			
CMS- 116 Application – All areas completed and Signed by the Lab Director?			
CMS- 209 Laboratory Personnel completed? Note: only include moderate testing personnel			
Disclosure of Ownership and Control Interest Statement completed?			
Previous CLIA Inspection reviewed at district Level?			
LABORATORY PERSONNEL	Yes	No	N/A
Lab Director qualifying documents on file? Refer to Lab Director Responsibilities Guidance			
Moderate Complexity lab – Technical Consultant & Clinical Consultant documents, on file? Refer to Technical Consultant 493.1409 and Clinical Consultant 493.1415			
Laboratory Testing Duties & Responsibilities? See Appendix B			
Testing Personnel Qualifying Academics on file (GED, High School, AA, BS, MS, PhD, MD, etc.)? See Appendix C, pages 3 & 4			
Testing Personnel Job Description and Test Authorization on file? See Appendix B and D			
Testing Personnel Training records on file? See Appendix E			
New Testing Personnel Semi-annual (twice-first year) Competency assessments on file? See Appendix F and refer to 493.1413			
Testing Personnel Yearly Competency assessments on file and signed by Lab Director? See Appendix F			

LABORATORY WRITTEN POLICIES PROCEDURES AND RECORDS	Yes	No	N/A
List of laboratory tests performed available? See Appendix G			
Laboratory Policies and Test procedure manuals available? District Level			
Equipment Manufacturer manuals available? Keep directions by instrument for troubleshooting and in a manual			
Manufacturer kits or reagent inserts available? District Level			
Laboratory Safety Manual available? See Appendix H			
QUALITY ASSESSMENT/QUALITY ASSURANCE	Yes	No	N/A
Quality Assurance manual available? See Appendix I			
Quality Assurance plan monitored, and corrective actions documented on QA Checklist? See Appendix J and needs to be reviewed and signed by the Technical Consultant			
PROFICIENCY TESTING (PT) RECORDS	Yes	No	N/A
Laboratory is enrolled in a CLIA Approved PT program for every non-waived test it performs patient testing? See Appendix K			
Investigation and Corrective Actions Documented for unsuccessful PT performances for submitting site and self-assessment sites? See Appendix L			
Review PT results against the PT provider participant's summary results for non-consensus scores on file? Would be reported by PT provider.			
Documented review of all PT events regardless of score and submit to the Lab Director for review and signature.			
Review of patient test results to ensure that no tests results were affected during the failed PT?			
Documented records of all testing personnel participating in PT events? See Appendix M and needs to be reviewed and signed by Lab Director			
LABORATORY SYSTEMS CALIBRATIONS AND VERIFICATIONS	Yes	No	N/A
Calibration Guidelines available? See Appendix N			
System Calibration records (bi-annual) or more frequently if required? See Appendix O			

Comparison of Test Results available when performing the same test using different methodology or instruments? Bi-annual applies to non-waived testing only, excluding KOH, wet prep, and gram stain.			
New equipment Installation (correlation verification studies) available? Applies to non-waived testing only, excluding KOH, wet prep, and gram stain.			
LABORATORY QUALITY CONTROLS	Yes	No	N/A
Quality Control records for the past two years (logs, instrument print outs or LIS) available? See Appendix P (one example included)			
Are the assay ranges available on log? See Appendix P (one example included)			
Documented QC reviews by lab director or designee available? See Appendix P (one example included)			
Documented investigations and corrective actions for any QC failures available? See Appendix P (one example included)			
TESTING RECORDS	Yes	No	N/A
Patients test requisitions for 2 years plus current year should be on file			
Normal and Panic test values available? Refer to GDPH Nurse Protocols			
Reference Laboratory log available? Print manifest at District level			
LABORATORY MAINTENANCE RECORDS	Yes	No	N/A
Laboratory equipment and systems maintenance logs available? See Appendix O			
Lab equipment (centrifuges, pipettes, thermometer, timers, hoods, etc.) calibration/verification available? See Appendix O			
All Equipment Repairs documented? See Appendix O			
Test systems repairs, or replacement of parts include documented Calibration Verifications? See Appendix O			
TEMPERATURE CONTROLLED SPACES, EQUIPMENT AND INSTRUMENTS	Yes	No	N/A
Equipment/Instruments monitored for acceptable temperature ranges? See Appendix Q			
Facility space, temperature and humidity logs available? See Appendix Q			
LABORATORY TESTING – AREA, SUPPLIES AND SAFETY	Yes	No	N/A

Reagents monitored for date received, open and expiration dates? See Appendix O			
Expired reagents and test accessories (kits, collect tubes, etc.) discarded?			
Laboratory safety equipment, biohazard waste containers and labels in place?			
Laboratory with adequate space, good ventilation and clean?			

Self-Assessment Conducted by: _____ Date: _____

Reviewed by: _____ Date: _____

Attachment 2: List of Non-Waived Tests Requiring Proficiency Testing

MICROBIOLOGY	
Bacteriology	Aerobic/Anaerobic Culture & Identification Antibiotic Susceptibility Testing Direct Bacterial Antigen Detection Gram Stain
Mycobacteriology	Acid Fast Stain Mycobacteriology Identification Mycobacteriology Susceptibility Testing
Mycology	Culture and Identification
Parasitology	Presence or Absence of Parasites Identification of Parasites
Virology	Direct Viral Antigen Detection Viral Isolation and Identification
DIAGNOSTIC IMMUNOLOGY	
Syphilis Serology General Immunology	Alpha-1 Antitrypsin Alpha Fetoprotein (tumor marker) Antinuclear Antibody Antistreptolysin O Anti-Human Immunodeficiency Virus (Anti-HIV) Complement C3 Complement C4 Hepatitis B Surface Antigen (HBsAg) Hepatitis B Core Antibody (Anti-HBc) Hepatitis Be Antigen (HBeAg) Immunoglobulins, total:IgA, IgG, IgM, IgE Infectious Mononucleosis Rheumatoid Factor Rubella
CHEMISTRY	
Routine Chemistry	Alanine Aminotransferase (ALT/SGPT) Albumin

	<p>Alkaline Phosphatase Amylase Aspartate Aminotransferase (AST/SGOT) Bilirubin, total Blood Gases:pH, pCO₂, pO₂ Calcium, total Chloride Cholesterol, total Cholesterol, HDL Creatine Kinase, total Creatine Kinase, Isoenzyme (CK-MB) Creatinine Glucose Iron, total Lactate Dehydrogenase (LDH), total LDH Isoenzymes (LDH₁/LDH₂) Magnesium Potassium Sodium Total Protein Triglycerides Urea Nitrogen Uric Acid</p>
Endocrinology	<p>Cortisol Free Thyroxine Human Chorionic Gonadotropin T₃ Uptake Triiodothyronine Thyroid Stimulating Hormone Thyroxine, total</p>
Toxicology	<p>Blood Alcohol Blood Lead Carbamazepine Digoxin Ethosuximide Gentamicin Lithium Phenobarbital Phenytoin</p>

	<p>Primidone Procainamide and Metabolite Quinidine Theophylline Tobramycin Valproic acid</p>
HEMATOLOGY	<p>Cell Identification WBC Differential Erythrocyte Count Hematocrit Hemoglobin Leukocyte Count Platelet Count Fibrinogen Partial Thromboplastin Time Prothrombin Time</p>
IMMUNOHEMATOLOGY	<p>ABO Group D (Rho) Typing Unexpected Antibody Detection Compatibility Testing Antibody Identification</p>

Attachment 3: Glossary

Quality control: Procedures to monitor the accuracy and precision of the complete testing process. QC consists of the activities used to detect errors that occur due to test system failure, adverse environmental conditions and variance in operator performance. Testing two levels of external control materials daily to monitor the accuracy and precision of the analytic test system components meets the requirement for monitoring test system components, environment, and operator performance.

Quality assessment: Involves the ongoing monitoring of each testing process (preanalytic, analytic, postanalytic) used in the laboratory in order to identify errors or potential problems that could result in errors; taking corrective action; and evaluating the corrective actions taken, to make sure that they were effective and will prevent recurrence.

Quality assurance: The overall program that ensures that the final results reported by the laboratory are as correct and accurate as possible

Proficiency testing (PT): The testing of unknown samples sent to a laboratory by an HHS-approved PT program. Most sets of PT samples are sent to participating laboratories on a scheduled basis (usually three times per year). After testing, the laboratory reports its sample results back to their PT program. The program grades the results using the CLIA grading criteria and sends the laboratory their scores. CMS and accreditation organizations routinely monitor their laboratories' performance.

Five types of CLIA certificates:

Additional information about the types of CLIA certificates and requirements is available [here](#).

1. **Certificate of Waiver (COW):** Issued to a laboratory that performs only waived tests.
2. **Certificate for Provider Performed Microscopy Procedures (PPMP):** Issued to a laboratory in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. A limited list of microscopy procedures is included under this certificate type and these are categorized as moderate complexity.
3. **Certificate of Registration:** Issued to a laboratory to allow the laboratory to conduct nonwaived (moderate and/or high complexity) testing until the laboratory is surveyed (inspected) to determine its compliance with the CLIA regulations. Only laboratories applying for a certificate of compliance or a certificate of accreditation will receive a certificate of registration.
4. **Certificate of Compliance (COC):** Issued to a laboratory once DCH conducts a survey (inspection) and determines that the laboratory is compliant with all applicable CLIA requirements. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.
5. **Certificate of Accreditation:** Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS. This type of certificate is issued to a laboratory that performs nonwaived (moderate and/or high complexity) testing.

Waived tests: In CLIA, waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." The Food and Drug Administration

(FDA) determines the criteria for tests being simple with a low risk of error and approves manufacturer's applications for test system waiver.

Nonwaived tests: Moderate or high complexity examinations and procedures.