

**CLIA
CERTIFICATE OF WAIVER (COW)
GOOD LABORATORY
PRACTICES**



RECOMMENDATIONS FROM CMS

The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). In total, CLIA covers approximately 200,000 laboratory entities.

The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Medicaid and State Operations (CMSO) has the responsibility for implementing the CLIA Program.

The objective of the CLIA program is to ensure quality laboratory testing. Although all clinical laboratories must be properly certified to receive Medicare or Medicaid payments, CLIA has no direct Medicare or Medicaid program responsibilities.

For the following information, refer to the downloads/links listed below:

- ◆ For additional information about a particular laboratory, contact the appropriate State Agency or Regional Office CLIA contact (refer to State Agency or Regional Office CLIA link found on the left-hand navigation plane);
- ◆ CMS initiatives to improve quality of laboratory testing under the CLIA program;
- ◆ Updated FYI CLIA information is contained in the Current CLIA News download;
- ◆ Information about direct access testing (DAT) and the CLIA regulations is included in the Direct Access Testing download;
- ◆ OIG reports relating to CLIA;

- ◆ Guidance for Coordination of CLIA Activities Among CMS Central Office, CMS Regional Offices, State Agencies (including State with Licensure Requirements), Accreditation Organizations and States with CMS Approved State Laboratory Programs is contained in the Partners in Laboratory Oversight download;
- ◆ Quality control (QC) highlights from the regulations published in the Federal Register on January 24, 2003 are listed under the QC Highlights download;
- ◆ Micro sample pipetting information for laboratories;
- ◆ CLIA presentation at NIAID/CMCR Workshop on the FDA Pre-Market Regulatory Process: Applications to Technologies for Radiation Biodosimetry After a Large-Scale Radiological Incident, March 27th, 2006, Bethesda, MD;
- ◆ Information on alternative (non-traditional) laboratory is contained in the Special Alert download;
- ◆ Survey and Certification memorandum entitled "Doctors of Optometry Serving as Directors and/or Technical Consultants for Laboratories Performing Moderate Complexity Testing";
- ◆ Identifying Best Practices in Laboratory Medicine - a Battelle Project for the Centers for Disease Control and Prevention (CDC); and
- ◆ Survey and Certification memorandum entitled "Clinical Laboratory Improvement Amendments (CLIA) -- Impact of A/H1N1 Swine Flu on CLIA Operations."



Good Laboratory Practices – Advice from CMS for COWs



- 1) Keep the manufacturer's product insert for the laboratory test in use and be sure it is available to the testing personnel. Use the manufacturer's product insert for the kit currently in use; do not use old product inserts.
- 2) Follow the manufacturer's instructions for specimen collection and handling.
 - a) Are specimens stored at the proper temperature?
 - b) Are the appropriate collection containers used?

- 3) Be sure to properly identify the patient.
 - a) Does the name on the test requisition (or prescription) match the patient's name?
 - b) Does the name on the patient's chart match the name on the patient's identification?
 - c) If more than one patient is present with the same first and last name, how do you determine which one is the test patient? (Look for possible gender differences, social security number, patient identification number, birthdates, different middle name, and relevance of the test to the patient's history).
- 4) Be sure to label the patient's specimen for testing with an identifier unique to each patient.
- 5) Inform the patient of any test preparation such as fasting, clean catch urines, etc.
- 6) Read the product insert prior to performing a test.
 - a) Become familiar with the test procedure.
 - b) Study each step and perform them in the proper order.
 - c) Know the time required for performing the test and achieving the optimal result.
 - d) Be sure to have all of the required reagents and equipment ready before actually performing the test.
 - e) Be able to recognize when the test is finished – e.g. will there be a blue plus or minus sign against a white background?
 - f) Follow the manufacturer's instructions and when a new kit is opened, perform the quality control to be sure that the kit works prior to testing patient samples.
- 7) Follow the storage requirements for the test kit. If the kit can be stored at room temperature but this changes the expiration date, write the new expiration date on the kit.
- 8) Do not mix components of different kits!
- 9) Record the patients' test results in the proper place, such as the patient's chart or the laboratory test log, but not on unidentified post-it notes or pieces of scrap paper that can be misplaced.
 - a) Record the results according to the instructions in the manufacturer's product insert.
 - b) If it's a qualitative test, spell out positive/negative or pos/neg because symbolic representations can be altered (the – can be altered to a +).

- c) Include the name of the test, the date the test was performed, and the initials of the testing personnel in the test record. Include the calendar year in the date.
 - d) If the same test is performed on a patient multiple times in one day, include the time of each test.
- 10) Perform any instrument maintenance as directed by the manufacturer.

GLOSSARY OF TERMS

- 1) ***CLIA*** means the Clinical Laboratory Improvement Amendments of 1988.
- 2) ***Certificate of waiver*** (COW) allows a facility to do only waived tests.
- 3) ***PPMP Certificate*** allows qualified providers to do waived testing and certain microscopic examinations during the patients' visit.
- 4) ***Certificate of registration*** or registration certificate means a certificate issued to a laboratory that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined to be in compliance through a survey by the Centers for Medicare and Medicaid Services (CMS) or its agent; or in accordance with Sec. 493.57 to an entity that is accredited by an approved accreditation organization.
- 5) ***HHS*** means the Department of Health and Human Services, or its designee.
- 6) ***Kit*** means all components of a test that are packaged together.
- 7) ***Laboratory*** means a facility for the examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.
- 8) ***MedWatch***: FDA service for health care facilities to voluntarily report a serious adverse event or product problem that the user suspects is associated with a drug or medical device used, prescribed, or dispensed. Online: www.fda.gov/medwatch/report/hcp.htm Phone: 1-800-FDA-1088
- 9) A ***pipet/pipette*** is a narrow, usually calibrated glass or plastic tube into which small amounts of liquid are suctioned for transfer or measurement.

- 10) **Plasma** is the usually clear, yellowish fluid portion of blood, lymph, or intramuscular fluid in which cells are suspended. It is the fluid produced when a blood specimen is collected in a vacuum tube with anticoagulant.
- 11) **Serum** is the usually clear yellowish fluid obtained upon separating whole blood into its solid and liquid components after it has been allowed to clot. Also called blood serum.
- 12) A **reagent** is a substance or material or ingredient used in a lab test to detect, measure, examine, or produce other substances.
- 13) **Controls** are materials with known values of the substance measured that help the laboratory achieve accurate and reliable testing by checking if the test system is working. Controls, also known as quality control material, are external or internal. External controls are usually a liquid and are processed or tested in the same manner as a patient specimen. Internal or procedural controls are indicators that the test procedure was performed in the proper order.
- 14) **Quality Control (QC) procedures** help to ensure the excellence of the patient testing. If the QC results are not within the prescribed range or the expected pattern, then the laboratory cannot be sure that the patients test results are accurate and reliable. See Controls above.
- 15) **Quality Assurance (QA)** is the laboratory's self-examination of the specimen collection, testing, and test reporting processes. What does the laboratory do to assure accurate results? Ten recommended QA questions to ask are:
 - ◆ Are the patients and specimens properly identified?
 - ◆ Are the patients' charts up-to-date with the proper patient test information?
 - ◆ Is the quality control performed and documented?
 - ◆ Did the laboratory get the right answers for the quality control?
 - ◆ Do the waived test results correlate with the patients' history or symptoms?
 - ◆ Are there any complaints about the laboratory testing?
 - ◆ Are the testing personnel trained prior to performing laboratory testing?
 - ◆ Are there periodic discussions about laboratory concerns?
- 16) **Screening tests** – initial tests to determine if a disease or medical condition exists.
- 17) **Diagnostic tests** – tests to identify a disease or medical condition that exists in a patient.
- 18) **Monitoring tests** – once a patient is diagnosed with a disease or medical condition, these tests help the clinician keep track of the patient's specific medical condition or response to treatment on a periodic basis.
- 19) **Routine order** of draw (when the laboratory collects more than one tube of blood at a time on a patient):

- ◆ Blood culture tube
- ◆ Non-additive serum tube
- ◆ Citrate tube
- ◆ SST (serum separator tube), plastic serum tube
- ◆ Heparin tube
- ◆ EDTA tube
- ◆ Glycolytic inhibitor tube Please consult with the reference laboratory for specific specimen collection requirements.

20) **Package Insert** – Instructions included by the manufacturer in the kit or test package. Read these carefully each time a new kit is opened to check for changes in procedures or quality control. Retain the current package insert for reference. The language used to convey the instructions is important. Words like ‘always’, ‘shall’, ‘must’, and ‘required’ mean the instruction is regulatory and must be performed. ‘Should’ or ‘recommend’ mean the action is not regulatory, but it is good laboratory practice to perform those actions.

NOTE: THIS DOCUMENT IS INTENDED AS A PRELIMINARY EDUCATION TOOL FOR LABORATORIES THAT HAVE A CLIA CERTIFICATE OF WAIVER. THE STATEMENTS ARE RECOMMENDATIONS THAT MAY HELP TO IMPROVE THE QUALITY OF LABORATORY TESTING. ADHERENCE TO THIS DOCUMENT IS VOLUNTARY AND IS NOT CONSIDERED TO BE ALL INCLUSIVE.

CLIA INFORMATION IS AVAILABLE ON THE INTERNET AT
<http://www.cms.hhs.gov/clia>

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