CLIA '88

What is CLIA?

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) are a series of federal laws regulating laboratory testing. They were enacted to ensure high quality, reliable, safe and accurate testing in laboratories of all types and sizes throughout the United States. The majority of the CLIA '88 standards went into effect in September, 1992 but the implementation continues to be an ongoing, dynamic process.

Who Is Responsible for CLIA?

Three government agencies are responsible for CLIA regulations:

Health Care Financing Administration (HCFA)

- Establishes and collects user fees
- Enforces CLIA standards
- Approves proficiency testing programs and CLIA-exempt state programs
- Recognizes private accreditation organizations

Centers for Disease Control and Prevention (CDC)

- Is the primary technical and scientific authority in setting performance standards
- Issues final decisions on test categories and test complexity

Food and Drug Administration (FDA)

- Reviews manufacturer's submissions for new tests, 510(k), and determines test complexity
- Approves QC instructions developed by manufacturers
- Effective early in 2000, the FDA will assume responsibility for test categorization.

How Are Laboratory Tests Classified?

Some laboratory tests are simple and easy to perform, others are more difficult. CLIA regulations were developed taking into account the *complexity* of testing performed by each lab. Three categories of testing complexity were developed: waived, moderate complexity (including the subcategory of provider-performed microscopy) and high complexity.

Waived Tests Certain tests which are so simple and accurate that the likelihood of erroneous results is negligible. The site must have a director but there are no requirements for director or testing personnel.

Moderate Complexity Tests These are tests which are more complex than waived tests. Much of the testing performed in clinical laboratories falls into this category. There are requirements for quality control, quality assurance, proficiency testing and limited personnel requirements. This category includes the subcategory of **Provider-performed microscopy (PPM)**. This category applies to certain tests commonly performed in the physician's office using a microscope. Sites performing PPM tests are subject to the same requirements as moderately complex laboratories, except that they will not be inspected and need only do proficiency testing if programs are available.

High Complexity Tests These are tests that are most difficult to perform or are most subject to error. They are usually performed only by large clinical laboratories. There are requirements for quality control, quality assurance, proficiency testing and tighter personnel requirements.

A test is classified as either moderately or highly complex based on the cumulative score after ranking seven (7) different criteria by difficulty. If the score is <12 the test is moderately complex. If it is >12, it is highly complex.

Waived Status Approved for the Cholestech LDX®

In January 1996, the Cholestech LDX System received approval for waived status from the Centers for Disease Control and Prevention (CDC). It was the first multianalyte chemistry analyzer to be approved for waived status. The Cholestech LDX System provides accurate, precise results in an easy to use format and can be operated without many of the expensive and stringent CLIA requirements. The Cholestech LDX System is only waived for the testing of capillary or venous whole blood. If you test serum on the LDX you will be classified as moderately complex.

Even though the Cholestech LDX System is classified as "waived", users of waived tests are still required to register with HCFA and obtain a CLIA Certificate of Waiver.

Registration and Certification

Anyone providing laboratory services, testing on human specimens, for the purpose of providing information for

the diagnosis, prevention or treatment of disease, is considered a laboratory under CLIA and is required to register with the Health Care Financing Administration (HCFA). CLIA registration is required even if a testing facility is not going to file for reimbursement.

- If you already have a Certificate of Waiver you may start testing on the Cholestech LDX without any further action.

- If you are performing testing in the moderate complexity or high complexity categories you may run the Cholestech LDX as a waived test without any further action.

- If you have a certificate for moderate or high complexity testing and will only be performing waived testing call your state department of health for instructions on how to change your current certificate to a Certificate of Waiver.

- If you have a Certificate of Accreditation or are in a state which has its own licensing program contact the organization or the state to verify that it recognizes the Cholestech LDX as a waived test.

Several states have applied to HCFA for "exempt (deemed) status" or equivalency with the CLIA '88 standards. So far HCFA has exempted three states from the CLIA requirements: The State of New York (for hospitals and commercial labs), the State of Oregon, and the State of Washington. California and Florida have applied for exemption and been approved. Georgia's application for exemption is going through the approval process. If you are testing in one of these states you should apply directly to the state for certification.

Several organizations have also been granted "deemed status":

COLA
Commission on Office Laboratory Accreditation, a voluntary nonprofit accreditation and education program for physician office laboratories. The COLA program began in 1988 and is sponsored by the American Academy of Family Physicians (AAFP), the American Medical Association (AMA), The American Society of Internal Medicine (ASIM) and the College of American Pathologists (CAP).

CAP
College of American Pathologists

JCAHO
Joint Commission on Accreditation of Health Care Organizations

AABB
American Association of Blood Banks

Moderate or high complexity labs may apply for a Certificate of Accreditation and be inspected by one of these organizations instead of by their state inspectors.

How Do I Get a CLIA Certificate of Waiver?

- Call the Department of Health in your state and ask for a CLIA application, form HCFA-116. Cholestech Technical Service can give you the address and phone number of your state department of health and can assist you in filling out the application. The state will also let you know about any additional state requirements.

- Fill out the application and mail it back to the state department of health. Do not send a check with your application.

- The state department of health will put the information into the HCFA computer and this will generate a coupon for the fee. As of January 1998 the fee is $150 for 2 years. The coupon will have your CLIA ID number on it.

- When you receive the coupon with the CLIA ID number you may start testing.

- Mail in the fee. If the fee is not paid your CLIA Certificate of Waiver will not be valid and you will not be able to obtain Medicare reimbursement for the tests you run.

- Every two years you will need to re-register and a new certificate will be issued.

What Are the Requirements For a Waived Laboratory?

- Must only run tests which have received "waived" status from the CDC.

- Follow manufacturers' instructions for performing the test.

- If there is more than one laboratory location, each location must have a separate Certificate of Waiver. The exceptions to this requirement are laboratories that move from one site to another providing screening services. This type of facility may be covered under one Certificate of Waiver issued to the designated primary site.

What Are the Requirements for Running the Cholestech LDX as a Waived Test?

- You must have ROM (software) Version 1.4 or higher. To determine which ROM version you have, unplug the power cord from the LDX and turn it over. On the bottom, in the upper left hand corner is the ROM pack held in place by a metal clip. Without removing the metal clip or the ROM pack, gently slide the metal clip to the left. The ROM version is in the lower right hand corner of the ROM pack, "VER. 1.x".

- Follow Cholestech instructions for running the LDX. Complete instructions can be found in the Cholestech LDX User Manual.

- Follow Cholestech recommendations for quality control. Quality control material should be run:

- On each new shipment of cassettes.

- On each lot of cassettes received.

- If you think the cassettes may not have been stored properly.

- If you are not running the Cholestech LDX under CLIA waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control should be performed in compliance with those regulations.

- Run the Optics Check Cassette each day of patient testing.

- Record all quality control and optics check readings on the appropriate logs.

- Proficiency testing and calibration verification are optional under waived status. If you want to run proficiency testing or calibration verification call Cholestech Technical Service for information.

Note: Some states do not recognize the Cholestech LDX System as waived and may have more stringent regulations for personnel and testing. There may be state or local requirements that quality control be run each day of patient testing. They may also require procedure manuals, documentation of training and participation in proficiency testing. If you are in a state which does not recognize the Cholestech LDX System as waived and would like assistance in complying with these regulations, call Cholestech Technical Service, 800-733-0404.

As of January 1, 1998 you must have your Certificate of Waiver, or other CLIA certificate number, on your claim for Medicare reimbursement or reimbursement will be denied. Cholestech can provide you with the current Medicare CPT codes and reimbursement information. Make sure you have the **QW** modifier after the appropriate CPT code. This indicates that the test(s) for which you are requesting reimbursement is a waived test. If you have a CLIA Certificate of Waiver number and do not include the QW modifier you will be denied reimbursement.

CLIAC

The Clinical Laboratory Improvement Advisory Committee (CLIAC) is comprised of members with various medical and laboratory backgrounds. The function of CLIAC is to advise the various government agencies involved with implementing CLIA about certain aspects of and changes to the regulations. It is up to the Department of Health and Human Services (HHS), however, to make final decisions about interpretation of and changes to the regulation, including changes in test classification. The CDC recommends appointments to and oversees CLIAC.

Resources

If you have CLIA '88 questions, please call:

HCFA, CLIA Program
410-786-3531

Cholestech Technical Service can also provide you with the telephone numbers of the contacts in your state for CLIA information.

Cholestech is committed to superior customer support and service. If you have any additional questions or concerns about the CLIA '88 regulation, please feel free to call Cholestech Technical Service:

Cholestech Corporation
Technical Service
1-800-733-0404
Fax: 510-732-7227

http://www.cholestech.com

http://www.cdc.gov

http://www.hcfa.gov

To assist you with any further questions, please call Technical Service: 800-733-0404

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