What information should I provide when reporting a complaint?

Please provide as much of the following information as possible when reporting a complaint:

- name and address of the laboratory,
- who has been involved or affected,
- a complete description of your concern,
- date(s) and time(s) of the incident(s),
- your view of the frequency and pervasiveness of the issue,
- names of any other agency you have contacted,
- your name, address, and telephone number (optional), and
- any other details or documentation that will verify the problem.

Am I required to provide my contact information?

You may choose not to provide your name and/or contact information. However, the investigating entity will not be able to contact you to gather any further necessary information or to inform you of the outcome of the investigation.

Will I remain anonymous if I provide my contact information?

If you provide your name and contact information, the investigating entity will make every attempt to maintain your anonymity as permitted by Federal or State laws.

You can be assured of the privacy and anonymity of your complaint. A complainant's identity is disclosed only to those individuals who are acting in an official capacity to investigate the complaint.

What happens after I report a complaint?

Every complaint is investigated and documented. If you have provided contact information, you will receive a written acknowledgement that the complaint is being investigated. Once the investigation is complete, you will be notified of the outcome.

Complaints that are not related to CLIA regulatory compliance will be referred to the appropriate entity, whenever possible.

Where can I find additional information about CLIA?

For more information and resources regarding the CLIA program, please visit the CMS/CLIA website at:

www.cms.hhs.gov/clia

NOTE: Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 establishing quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. The final CLIA regulations were published in the Federal Register on February 28, 1992. The requirements are based on the complexity of the test and not the type of laboratory where the testing is performed. On January 24, 2003, the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS) published final CLIA Quality Systems laboratory regulations that became effective April, 24, 2003.

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DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Clinical Laboratory Improvement Amendments (CLIA)

COMPLAINTS

Do You Have a Concern About a Laboratory's Operation?

How to Report a Complaint About a Laboratory's Operation

What is a complaint?

A complaint is any concern that you may have about a laboratory's operation. Examples include the following:

- quality of testing,
- unlabeled specimens,
- unethical practices; e.g., record falsification, proficiency testing cheating,
- confidentiality of patient information, and
- laboratory personnel qualification or responsibility issues.

This is not a comprehensive list and only includes examples of some of the most common types of complaints.

Who can report a complaint?

Anyone can report a complaint. Your complaint is important. Complaints can be reported by, but not limited to, patients, patients' relatives, the public, physicians and any personnel working in a laboratory.

Who do I contact for reporting a complaint?

You may contact the Centers for Medicare & Medicaid Services (CMS) Central Office, Division of Laboratory Services (CLIA), in Baltimore, Maryland at **410-786-3531** locally or at **1-877-267-2323** (toll free) extension **63531**.

Are there additional contacts for reporting a complaint?

You may also call, write or e-mail your complaint to any of the following:

- directly to the laboratory management,
- CMS Regional Office,
- the State Agency (SA) or State Department of Health where the laboratory is located,
- the laboratory's accreditation organization, if applicable or known, or
- the laboratory's exempt State office or State licensure program, if applicable or known.

Where do I find contact information for the following?

- CMS Regional Offices CLIA Contact List, http://www.cms.hhs.gov/CLIA/downloads/CLIA.RO.pdf
- State Survey Agencies CLIA Contact List, http://www.cms.hhs.gov/CLIA/downloads/CLIA.SA.pdf

  There may also be a section in your phone book that lists State offices, as most States have a 1-800 line for complaint submission.

- List of Approved Accreditation Organizations Under CLIA, http://www.cms.hhs.gov/CLIA/downloads/AO.List.pdf
- List of Exempt States Under CLIA, http://www.cms.hhs.gov/CLIA/downloads/Exempt.States.List.pdf

You may also visit your local library to obtain Internet access.