CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA): CONSUMER COMPLAINTS FAQ

WHAT IS CLIA?

The Centers for Medicare & Medicaid Services (CMS) regulates all clinical laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). Congress passed CLIA in 1988 to establish quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results no matter where the test is performed.

WHAT CAN A CLIA COMPLAINT INCLUDE?

CLIA requirements apply specifically to laboratory testing. You can submit a complaint if you have concerns about the quality of laboratory testing.

A CLIA complaint can include any concern about a laboratory's operation, such as:

- Unlabeled specimens
- Record falsification
- Confidentiality of patient information
- Unqualified staff
- Missing or incorrect test results

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

WHO CAN FILE A COMPLAINT?

Anyone, including patients and their families, laboratory personnel, and the general public, can file a complaint.

HOW DO I FILE A COMPLAINT?

Contact the State Agency (SA) for the state where the laboratory is located.

WHAT INFORMATION SHOULD I GIVE WHEN FILING A COMPLAINT?

Please give as much information as possible when filing a complaint:

- Name and address of the laboratory and the CLIA certification number, if you know it
- Individual(s) involved or affected (e.g., patient's name, date of birth, sample identification number, etc.)
- A complete description of your concern (including patient/sample identification numbers, if applicable)
- Date(s) and time(s) of the incident(s)
- Your knowledge of the frequency and severity of the issue
- Names of any other government agencies you have contacted
- Your contact information (name, address, email address and telephone number)
  - — You can also choose to remain anonymous
- Any other details or documentation about the problem (e.g., copy of patient test report)

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DO I HAVE TO GIVE MY CONTACT INFORMATION?

You may choose not to give your name and contact information and have your complaint be anonymous. However, we may not be able to contact you to gather any further necessary information or inform you of the outcome of the investigation.

CAN I STAY ANONYMOUS IF I GIVE MY CONTACT INFORMATION?

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

WHAT HAPPENS AFTER I FILE A COMPLAINT?

Every CLIA-related complaint is documented and evaluated. If you give your contact information, you will get acknowledgment that the complaint is being investigated. Once the investigation is complete, we will contact you regarding the outcome.

Some laboratories are accredited by a CMS-approved laboratory Accreditation Organization (AO). If your complaint is about an accredited laboratory, we may refer your complaint to the laboratory's AO. The State Agency will provide you with contact information for the AO.

WHERE CAN I FIND ADDITIONAL INFORMATION ABOUT CLIA?

For more information and resources about the CLIA program, please visit the CMS CLIA website.
You can also email questions to the CMS CLIA Lab Excellence mailbox.