Clinical Laboratory Improvement Amendments (CLIA)

Laboratory Complaints

GENERAL INFORMATION

This brochure includes information about laboratory complaints, including how to file a complaint, details on what to include in a complaint and what to expect after the complaint investigation.

What's CLIA?

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) and its implementing regulations at 42 CFR Part 493 are federal laws and regulations that apply to all U.S. and CLIA-certified international laboratories or sites that test specimens from humans (e.g., blood, tissue, and body fluid) to assess health or to diagnose, prevent, or treat disease. The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Centers for Disease Control (CDC) and the Food & Drug Administration (FDA), support the CLIA program to ensure quality laboratory testing.

Why is CLIA important?

CLIA ensures that applicable laboratories meet standards to conduct accurate, reliable, and timely testing. This is important for patient care because accurate laboratory test results are essential for making correct diagnoses and treatment decisions.

What's a complaint?

A complaint is any concern that you may have about the quality of laboratory testing or a laboratory's operation, including:

- Unlabeled specimens
- Falsified records
- Proficiency testing (PT) issues, like falsifying the process that's used to evaluate a laboratory's performance, or PT referral where a laboratory inappropriately sends PT samples to another laboratory for testing
- Breaches in patient information confidentiality
- Unqualified laboratory personnel
- Incorrect or missing test results

Note: This list only includes examples of the most common types of complaints.

Who can file a complaint?

Anyone, including patients, their relatives, the public, physicians, and laboratory personnel.

How do I file a complaint?

To file a complaint, contact the State Agency (SA) where the laboratory is located.

What information should I include when filing a complaint?

- Laboratory name, address, and CLIA certification number
- Details of those involved or affected (e.g., patient name, date of birth, sample identification number)
- Description of the concern, including patient/sample identification numbers, if applicable
- Date(s) and time(s) of the incident(s)
- Frequency or number of occurrences and severity or damage caused by the occurrence(s)
- Any other government agencies you've contacted regarding the issue
- Any additional details or documentation (e.g., a copy of the patient's test report) that support your complaint
- Your contact information (name, address, email address, and phone number) or indicate if you prefer to remain anonymous

Do I have to provide my contact information, or can I remain anonymous?

You may file an anonymous complaint. However, please note that if you choose to remain anonymous, we may not be able to contact you for further information or update you on the outcome of the investigation.

If you provide your contact information, the investigating entity will make efforts to keep your identity private, as permitted by Federal or State laws.

What happens after I file a complaint?

Every CLIA-related complaint regarding a laboratory is documented and reviewed.

If you provide contact details, you'll receive an acknowledgment that the complaint is being investigated. When the investigation is complete, you'll be informed of the outcome; however, please note that specific details may not always be disclosed due to confidentiality laws.

Some laboratories are accredited by a CMS-approved laboratory Accreditation Organization (AO). If your complaint involves an accredited laboratory, we may forward your complaint to the laboratory's AO for further action. CMS will provide you with the AO's contact information if you wish to follow up.

WHERE CAN I FIND MORE INFORMATION?

For more information and resources about the CLIA program, visit:

Resource	Website
CMS CLIA Website	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
CDC CLIA Website	https://www.cdc.gov/clia/php/about/index.html
FDA CLIA Website	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
CLIA State Agency Contacts	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf
Accreditation Organizations	https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/accreditation-exemptions
CLIA Requirements **42 CFR 493**	https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

You can also email questions to the CMS Lab Excellence mailbox at: LabExcellence@cms.hhs.gov

Note: *This brochure presents information about laboratory complaints. It's not intended to replace or substitute CLIA regulatory requirements. Note that state, local, and accreditation requirements may be more stringent.*

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Congress passed the **Clinical Laboratory Improvement Amendments (CLIA)** in 1988 establishing authority to promulgate standards for certain laboratory testing to ensure the accuracy, reliability, and timeliness of test results regardless of where or by whom the test was performed. The CLIA requirements are based on the complexity of the test and the type of laboratory where the testing is performed. The information provided in this brochure is intended only to be a general informal summary of technical legal standards. It is not intended to take the place of the statutes, regulations, or formal policy guidance upon which it is based. This brochure summarizes current policy and operations as of the date it was published. We encourage readers to refer to the applicable statutes, regulations, and other interpretive materials for complete and current information.