

Clinical laboratories are facilities for the examination of materials derived from the human body to provide information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings. The definition includes specimen collection stations and blood banks which provide through their ownership or operation a system for the collection, processing, or storage of human blood and its component parts as well as tissue banks which procure, store, or process human or animal tissues designed to be used for medical purposes in human beings.

Exemptions:

- Clinical laboratories operated by medical schools in Georgia
- Clinical laboratories operated by the federal government
- Clinical laboratories operated and maintained exclusively for research and teaching purposes involving no patient or public health service
- Clinical laboratories operated by licensed physicians exclusively in connection with the diagnosis and treatment of their own patients
- Certain capillary testing performed by pharmacists

Type Regulation

State: Certain facilities must obtain licenses. (Hospital laboratories are also licensed).

Federal: All laboratories, including laboratories in physicians' offices, with certain exceptions are regulated pursuant to the federal Clinical Laboratory Improvement Amendments (CLIA) of the Public Health Act. Federal law requires any facility performing certain categories of clinical laboratory testing to obtain CLIA certificates.

Legal Authority:

O.C.G.A. § 31-7-1 Definitions

O.C.G.A. § 31-22-1 et seq. Clinical Laboratories, Definitions

O.C.G.A. § 31-24-1 et seq. Blood Labeling
[Official Code of Georgia Annotated](#)

Rules:

State:

- [Licensure of Clinical Laboratories](#), Chapter 290-9-8, effective December 26, 2001. Last revised- January 29, 2007
- [Rules and Regulations for Blood Labeling](#), Chapter 290-5-34, effective October 13, 1977.
- [Enforcement of Licensing Requirements](#), Chapter 290-1-6, effective August 16, 1993

Federal:

[CLIA Regulations \(Clinical Laboratory Improvement Amendments\)](#), CFR Title 42, Chapter IV, Part 493 (for those facilities that require it). [Clinical Labs \(CLIA\) Center](#) To obtain more information about certification and general information on federally certified Clinical Laboratories, visit the CMS (Center for Medicare and Medicaid Services) website.

Fees:

- Permit: Charge. See application packet for schedule of fees.