

INTERNATIONAL LABORATORY CLIA CERTIFICATION PROCESS

The following provides basic information about CLIA for international laboratories seeking CLIA certification. This includes instructions for international laboratories on obtaining and completing required forms and other important information. Additional information is also found on the CLIA website at www.cms.hhs.gov/clia.

The Division of Laboratory Services (DLS) in the Central Office (CO) of the Centers for Medicare & Medicaid Services (CMS) of the U.S. Department of Health and Human Services (HHS) is the primary contact for international laboratories seeking CLIA certification. Contact CLIA-IOIntake@cms.hhs.gov, if you have any questions.

The address for DLS is:

Centers for Medicare & Medicaid Services
Survey and Certification Group
Division of Laboratory Services
7500 Security Blvd. (Mailstop: 02-21-16)
Baltimore, Maryland 21244-1850
FAX: 410-786-9643

Applicability of CLIA to International Laboratories

42 CFR 493.2 defines a laboratory as a facility that examines materials “derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.”

For CLIA purposes, an international laboratory is a facility outside the U.S. or its territories that performs laboratory tests for the assessment of the health of human beings when such tests are referred by, and the results are returned to, a facility or authorized person in the U.S. or its territories.

Any testing of materials from human specimens collected in the United States and its territories is subject to CLIA regulations. If specimens are transported outside of the United States and its territories for testing by international laboratories, then these laboratories are also subject to the CLIA regulations.

CLIA regulations are applicable only to those tests that are performed on human specimens collected from the United States and its territories. A laboratory may have an array of different tests but performs only molecular genetics testing on specimens from the United States. In this case, only those specimens tested for molecular genetics are subject to CLIA regulations.

International laboratories may also be subject to additional State laboratory requirements. The CLIA website has a listing of contacts in all State Agencies.

CLIA Certification and or Accreditation

International laboratories may seek CLIA certification through CMS-approved accreditation organizations.

International laboratories that do not seek CLIA certification through CMS-approved accreditation organizations should apply for the level of CLIA certification appropriate for the testing being performed.