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 https://www.cms.gov/regulations-and-guidance/legislation/clia.

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

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.

In general, 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.

What types of research testing are subject to CLIA?

In most cases, research testing where patient-specific results are reported from the laboratory, and those results will be or could be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are presumed to be subject to CLIA absent evidence to the contrary.

In cases where patient-specific test results are maintained by a statistical research center for possible use by investigators in which the results are not reported out as patient-specific and could not be used "for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings," CLIA would not apply. For more information on research testing, please refer to Research Testing and Clinical Laboratory Improvement Amendments of 1988.

CLIA regulations are applicable only to those tests that are performed on human specimens collected from the United States and its territories. For example, 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.