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 New York Regional Office (NYRO) 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. Contacts are:

Joseph Cialdella, MT(ASCP)
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Email address: joseph.cialdella@cms.hhs.gov

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The NYRO address is:

U.S. Department of Health & Human Services
Centers for Medicare & Medicaid
Attn: CLIA Program
26 Federal Plaza, Room 37-130
New York, NY 10278-0063
FAX: 212-312-8616

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.

CMS Forms

CLIA Registration Form, CMS-116: CLIA Application for Certification

This form is available at http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf.

An international laboratory seeking accreditation or certification must first register via the form, CMS-116, CLIA Application for Certification. Instructions for completing this form are on the CMS CLIA website. International laboratories are reminded to include only the test volume of specimens coming from the United States and it territories.

The signed application form and a Curriculum Vita for the Laboratory Director must be sent to the CMS NYRO address noted above. For efficient communication, include the name and, if available, e-mail address of an English-speaking contact.

The CMS-116 and the Curriculum Vita may be sent by email or fax. Please note that you cannot save data typed into the PDF form. You should print the form, have the Laboratory Director sign the form and then email or fax the CMS-116 and Curriculum Vita to Debra Stone at debra.stone@hhs.cms.gov or 212-312-8616.

CMS-209: Laboratory Personnel Report (CLIA)

This form is available at http://www.cms.hhs.gov/cmsforms/downloads/CMS209.pdf.

Instructions are on the form. To complete the form, the laboratory must identify the appropriate categorization of its test system(s). Refer to the FDA test complexity database for the categorization of a test system. This form must be signed by the laboratory director.

A test system categorized as moderate complexity is subject to the personnel requirements at 42 CFR 493.1403 through 1425. A laboratory performing moderate complexity testing requires a Laboratory Director, Clinical Consultant, Technical Consultant, and Testing personnel.

A test system categorized as high complexity is subject to the personnel requirements at 42 CFR 493.1441 through 1495. A laboratory performing high complexity testing requires a Laboratory Director, Clinical Consultant, Technical Supervisor, General Supervisor, and Testing personnel.

In both instances, laboratory personnel may assume multiple responsibilities. For example, a laboratory director may perform the duties of a clinical consultant and a technical supervisor may also perform the responsibilities of the general supervisor.

Specify only those individuals performing testing and reporting test results. Laboratory personnel performing only specimen preparation and accessioning are not considered testing personnel.

CMS-1557: Survey Report Form (CLIA)
This form is available at http://www.cms.hhs.gov/cmsforms/downloads/cms1557.pdf .

Note:

1. Some sections, such as State/County and Region codes, under the General Information may not be applicable to international laboratories.

2. Under the Personnel section, consideration must be given on the complexity level of the laboratory's test system (moderate or high complexity). Indicate the number of qualified personnel for each chosen category.

3. Under the Specialties/Subspecialties section, select the appropriate CLIA specialty/subspecialty based on the test system(s) used. Provide estimates of the yearly test volume for each specimen collected from the United States and its territories.