QUIDEL®
CORPORATION

Technical Bulletin

How to Apply for a CLIA Certificate From CMS-116

If an entity performs tests for the purposes of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings, it is considered under CLIA to be a laboratory and must register with the CLIA program. This includes all entities that perform even one test, including waived tests. These entities will be required to meet certain Federal requirements.

The CLIA application collects information about a laboratory's operation, which is necessary to determine the type of certificate to be issued and the fees to be assessed.

CMS has made available the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Application for Certification, Form CMS-116 (http://www.cms.hhs.gov/CLIA/06_How_to_Apply_for_a_CLIA_Certificate_International_Laboratories.asp). **This form should be mailed to the address of the local State Agency (link from the CLIA site) for the State in which your laboratory resides**. Since some states require that additional forms be filed, **you should contact your State agency to ensure that you have filed all the necessary forms to complete the registration process.**

Please call Technical Support at 800-874-1517 if you have any questions regarding this procedure or any Quidel test. Our hours of operation are Monday-Friday, 7:00 am-5:00 pm Pacific Time.

You may also visit our website at www.quidel.com for information on Quidel's line of Rapid Diagnostics, Bone Health and Autoimmune & Complement product lines. Other information available on our website: CPT codes, NCCLS, MSDS and package inserts.