

Research Testing and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) were established to strengthen federal oversight of clinical laboratories to ensure the accuracy and reliability of patient test results. CLIA applies to **all laboratories** that examine “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.” (see 42 U.S.C. § 263a(a)).

CLIA regulatory requirements vary according to the kind of test(s) each laboratory conducts. Tests are categorized as waived, moderate complexity or high complexity.

With respect to CLIA applicability, the CLIA regulations do not differentiate between facilities performing provider-ordered testing and those performing non-provider-ordered testing. All facilities that meet the definition of a “laboratory” under the CLIA statute and regulations must obtain an appropriate CLIA certificate prior to conducting patient testing. Whether a test service is billed to Medicare has no bearing on CLIA applicability.

How does CLIA define a “laboratory”?

The CLIA regulations define a laboratory to be “a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body 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. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body” (42 C.F.R. § 493.2 (definition of “laboratory”).

How does the Centers for Medicare & Medicaid Services (CMS) determine CLIA applicability?

CLIA applicability is determined using the regulatory definition of “laboratory” quoted above. Specifically, CLIA applies when: (1) patient-specific results are reported from the laboratory to another entity; **AND** (2) the results are made available “for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.” As stated above, whether a test service is billed to Medicare has no bearing on CLIA applicability. Therefore, if a facility performs tests for the above-stated purposes, it is considered a laboratory under CLIA and must obtain a certificate from the CLIA program that corresponds to the highest complexity of tests performed.

What facilities need to have a CLIA certificate?

CLIA requires **all** facilities that perform even one test, including waived tests, on “materials derived from the human body 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” to obtain a CLIA certificate and meet CLIA regulatory requirements.

What facilities are exempt from needing a CLIA certificate?

Facilities that only perform testing for forensic purposes are excepted from the CLIA regulatory scheme.

Depending on the circumstances, research testing can be either excepted from CLIA or subject to CLIA. Specifically, testing facilities may qualify to be excepted from CLIA certification if they meet the description of “research laboratories” provided by the CLIA regulations at 42 C.F.R. § 493.3(b)(2). In accordance with that regulation, only those facilities performing research testing on human specimens that **do not report patient-specific results** may qualify to be excepted from CLIA certification. An example of a non-patient-specific result would be “10 out of 30 participants were positive for gene X.” The result in this example is a summary of the group data, and is not indicative of an individual’s health. An example of a patient-specific result would be “participant A was positive for gene X” in which the result is specific to participant A.

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.

What if the research testing has Institutional Review Board (IRB) approval?

IRBs do not generally assess whether or not CLIA would apply to a given testing situation, and they do not have authority to determine CLIA applicability on behalf of the CLIA program. The Federal regulations that govern human research subject protection are unrelated to the CLIA requirements, and the IRBs that consider human research subject protection considerations would not be expected to consider the applicability of the CLIA regulations. And, even if they did, IRBs would have no authority to authoritatively opine on the applicability of those CLIA provisions.

What CLIA requirements apply to research testing?

As stated above, CLIA regulatory requirements vary according to the kind of test(s) each laboratory conducts, and whether the results are made available in such a way as to make that testing facility a “laboratory” under the CLIA regulations.

Tests are categorized as waived, moderate complexity or high complexity. If a laboratory test system, assay or examination does not appear on the lists of tests in the Federal Register notices, it is considered to be a test of high complexity until such time as the test system is reviewed and assigned a categorization in accordance with the CLIA regulations (for more information, see <http://www.cms.gov/Regulations-and->

[Guidance/Legislation/CLIA/Categorization_of_Tests.html](#)). Thus, if a research testing system is not categorized, and test results will be reported out, it would be considered a high complexity test system that is subject to the CLIA regulations for laboratories performing high complexity tests.