

Direct Access Testing (DAT) and the Clinical Laboratory Improvement Amendments (CLIA) Regulations

What is CLIA?

The Clinical Laboratory Improvement Amendments (CLIA) was established to strengthen federal oversight of clinical laboratories to ensure the accuracy and reliability of patient test results. A laboratory is defined to be a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention, or treatment of any disease or impairment of a human being; or the assessment of the health of a human being; or procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in a human body (42 C.F.R. sec. 493.2.). CLIA's regulatory requirements vary according to the kind of test(s) each laboratory conducts. Tests are categorized as waived, moderate complexity or high complexity. Moderate and high complexity tests are collectively referred to as "non-waived" testing.

What is DAT?

"Direct access testing" (DAT) is generally defined as consumer (as opposed to physician) initiated testing of human specimens. DAT is also known as "direct-to-consumer" or "patient-authorized" testing. Some states do not allow for DAT. Where DAT is permitted, it is commonly ordered by an individual without a prior consultation with a physician or a physician's request for testing.

DAT/CLIA

Interest in DAT-based issues is growing as trends in the direct marketing of laboratory testing to consumers (including web-based solicitation), consumer privacy concerns, convenience, cost savings, and consumer self-empowerment in managing their health are all leading to greater use of DAT. Interest has also grown in how CLIA affects the availability of DAT. CLIA authorizes regulation of laboratories that conduct testing, not the individuals who order the tests or receive test results. State laboratory laws may regulate that issue, and limit the availability of DAT.

The CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider ordered testing. All facilities that meet the definition of "laboratory" under CLIA must obtain an appropriate CLIA certificate prior to conducting patient testing, *including* DAT. These CLIA certificates must be maintained and the CLIA laboratory procedures must be followed throughout all phases of testing.

CLIA affects DAT in the same manner in which it affects provider ordered laboratory testing. DAT testing using waived test systems are subject to the CLIA provisions on waived testing. DAT testing using moderate or high complexity test systems are subject to the CLIA provisions on non-waived tests. The following regulatory excerpts are a

selection of the CLIA provisions on waived and non-waived testing that should be of particular interest to laboratories providing DAT.

For waived-testing:

493.15 Laboratories performing waived tests.

- (e) Laboratories eligible for a certificate of waiver must –
 - (1) Follow manufacturer's instructions for performing the test; and
 - (2) Meet the requirements in subpart B, Certificate of Waiver, of this part (42 C.F.R. secs. 493.35-493.39).

For non-waived testing:

493.1241 Standard: Test request.

- (a) The laboratory must have a written or electronic request for patient testing [with data elements that satisfy those required at 42 C.F.R. sec. 493.1241(c)] from an authorized person. [An authorized person is defined at 42 C.F.R. sec. 493.2 to be an individual authorized under State law to order tests or receive test results, or both. 42 C.F.R. sec. 493.2.]

493.1291 Standard: Test report.

- (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the test and, if applicable, the individual responsible for using the test results.

- (f) Except as provided in § 493.1291(l), test results must be released only to authorized persons and, if applicable, the persons responsible for using the test results and the laboratory that initially requested the test.

- (g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminent life-threatening condition, or panic or alert values.

- (h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing.

- (l) Upon request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those persons specified under 45 CFR 164.524(c)(3)(ii), as applicable, with access to completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient.

In summary...

Under CLIA, a laboratory performing DAT must have an appropriate CLIA certificate and satisfy the requirements for the types of testing offered.