

**TITLE 17, CALIFORNIA CODE OF REGULATIONS
SECTION 1230**

(1) Repeal Section 1230 as follows:

~~Section 1230. Approval of Laboratories for Use of HIV Antibody Test.~~

~~(a) No person or entity shall perform tests to detect antibodies to HIV in California, or on specimens originating in California, unless that person or entity is~~

~~(1) licensed or certified:—~~

~~(A) to engage in the production of biologics in accordance with chapter 4, division 2 of the Health and Safety Code, or~~

~~(B) as a clinical laboratory in accordance with chapter 3, division 2 of the Business and Professions Code, or~~

~~(C) as a public health laboratory in accordance with chapter 7, part 2, division 1 of the Health and Safety Code, or~~

~~(D) as a blood bank by the United States Food and Drug Administration in accordance with 42 U.S.C., section 262(a), or~~

~~(E) as a clinical laboratory licensed in serology to engage in interstate commerce in accordance with the Clinical Laboratory Improvement Act of 1967 (CLIA-67), 42 U.S.C. section 263a. and~~

~~(2) Enrolled in a proficiency testing program approved by the Department in accordance with Title 17, section 1051 of the California Code of Regulations for each HIV screening and confirmatory procedure offered by the laboratory.~~

~~(b) An application for approval shall be submitted for each separate location where tests are performed using forms provided by the Department and providing information as required by the Department. Within 15 days of receipt of an application, the Department shall notify the applicant in writing that the application is complete or shall specifically identify what additional information is required. Within 60 days from the receipt of a completed application, the Department shall notify the applicant that the application is either approved or disapproved.~~

~~(c) An approved laboratory shall perform screening for evidence of human immunodeficiency virus (HIV) antibody utilizing only Food and Drug Administration (USFDA) approved kits. In addition, screening assays shall be performed in strict accordance with a kit's package insert and any other manufacturers' instructions or guidelines.~~

~~(d) A specimen shall not be reported as positive on the basis of a screening result. Approved laboratories shall perform confirmatory testing on all specimens tested which give a repeatedly reactive HIV screening result using an additional more specific test prior to reporting the result.~~

~~(e) Whenever a confirmatory test gives an indeterminate result, the specimen giving such an indeterminate result shall be evaluated further, either by additional local testing or by referral to another laboratory. If, upon further evaluation the specimen continues to give an indeterminate result, the laboratory shall notify the submitter of the specimen that the result is inconclusive.~~

~~(f) An approved laboratory shall maintain records of tests and test results in a manner to ensure the patient's confidentiality.~~

~~(g) Approved laboratories which are blood banks or plasma centers shall report to the Department at the conclusion of each month and all other approved laboratories shall report to the Department at the conclusion of each quarter the number and results of the tests performed.~~

~~(h) Approval for performing the tests to detect antibodies to HIV may be denied or terminated for failure to comply with the requirements of this section or with requirements set forth in regulations, or for conduct inimical to the public health, morals, welfare, or safety of the people of the State of California in the maintenance and operation of the facility or services for which approval is granted.~~

Note: Authority cited: Sections 208 and 1603.1(h), Health and Safety Code.

Reference: Section 5, Statutes of 1985, Chapter 23; and Sections 1603.1 and 1632, Health and Safety Code.

(2) Adopt new Section 1230 to read as follows:

§ 1230. HIV Screening Testing by Laboratories.

(a) All clinical laboratories that perform waived, moderate or high complexity tests or examinations to screen for human immunodeficiency virus (HIV) shall do all of the following:

(1) Utilize United States Food and Drug Administration (FDA) approved test systems in accordance with the manufacturers' instructions. Any laboratory that modifies a non-waived FDA-approved kit shall establish and verify the performance specifications pursuant to 42 Code of Federal Regulations Section 493.1253.

(2) Confirm all reactive or indeterminate HIV test results by following the HIV confirmation protocols recommended by the federal Centers for Disease Control and Prevention as published in the Mortality and Morbidity Weekly Report prior to reporting the result as positive.

(3) Establish and maintain a quality assurance program that includes all of the following:

(A) Evaluation and documentation of testing personnel by direct observation, training, and competency testing to ensure tests are accurately performed and reported. This shall be done prior to testing, six months later and then yearly as long as assessment of test performance is acceptable. If the testing personnel fail any assessment of test performance given in subpart (B), the testing personnel shall be removed from testing, retrained and their competency re-evaluated.

(B) Assessment and documentation of test performance by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples at least twice yearly and monitored by the laboratory director.

(b) Failure to comply with all the requirements of this section shall subject the laboratory to sanctions pursuant to Business and Professions Code Section 1320.

Authority cited: Sections 1603.1(f), 100275, 131050, and 131200, Health and Safety Code; and Section 1224, Business and Professions Code.

Reference: Sections 1220 and 1265, Business and Professions Code; and Sections 1603.1 101160, 120895, 131050, 131051 and 131052, Health and Safety Code.