

1) Adopt Section 1230 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 diagnostic protocols recommended by the federal Centers for Disease Control and Prevention, the Clinical and Laboratory Standards Institute, the Association of Public Health Laboratories or the U.S. Department of Health and Human Services 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.

Note: Authority cited: Sections 1603.1(f), 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.

2) Adopt Section 2641.57 as follows:

2641.57. HIV Test Algorithm.

“HIV test algorithm” means any multi-test procedure that determines the presence of HIV infection using diagnostic protocols recommended by the Centers for Disease Control and Prevention, the Clinical and Laboratory Standards Institute, the Association of Public Health Laboratories or the U.S. Department of Health and Human Services.

Note: Authority cited: Sections 120125, 120130, 121022, 131080 and 131200, Health and Safety Code. Reference: Sections 1206 and 1220, Business and Professions Code; and Sections 120917, 121022, 131051, 131052 and 131056, Health and Safety Code.