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IMPORTANT NOTICE

LABORATORY FIELD SERVICES (LFS) WRITTEN APPROVAL IS NO LONGER REQUIRED TO PERFORM HIV TESTING. THE REVISED REGULATION IS BELOW WITH AN EFFECTIVE DATE OF **NOVEMBER 14, 2009**

Title 17, California Code of Regulation (CCR), Section 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.