

INITIAL STATEMENT OF REASONS

SUMMARY OF PROPOSAL

The Department (California Department of Public Health, formerly the California Department of Health Services) proposes to amend Title 17 California Code of Regulations (CCR) Section 1230 that sets standards for approval of facilities that perform screening tests for the presence of human immunodeficiency virus (HIV). The purpose of these amendments is to accommodate changes in technology and to remove redundancies that have arisen with changes in legislation enacted since these standards were implemented in 1986.

Currently all laboratories in the state are required to comply with standards which are unique to HIV screening tests. These standards are already stricter and more specific than standards in state law and federal regulations for other tests because of concern for accuracy of testing. Since 1986, the Department has required all laboratories to submit documentation to verify compliance with these standards before being allowed to initiate testing. At this time about 1,300 laboratories have been approved. However, some of the standards are now unnecessary and redundant, and are burdensome both to laboratories and the Department. Other standards shall be retained, but amended. Therefore, the Department is proposing that these standards be amended.

Specifically, the following revisions shall be made to Section 1230 to:

- Repeal the requirement that all laboratories, blood banks, public health laboratories, and serology laboratories be licensed or registered by the Department because this is redundant and unnecessary.
- Repeal the requirement that all HIV screening facilities participate in proficiency testing as this is redundant and unnecessary.
- Repeal the requirement that all laboratories be approved by the Department before testing for HIV antibodies.
- Repeal the requirement for use of a federal Food and Drug Administration (FDA) approved HIV screening kit. The new Section 1230 contains a subsection based on this requirement.
- Repeal the requirement for confirmation of screened positive HIV results. The new Section 1230 contains a subsection based on this requirement.
- Repeal the requirement that all indeterminate HIV results be re-tested. The new Section 1230 contains a subsection based on this requirement.
- Repeal the requirement that all HIV-testing laboratories maintain confidential records as this is redundant and unnecessary.
- Repeal the requirement that all laboratories performing HIV antibody screening submit monthly reports to the Department on number of tests performed and results.
- Repeal the requirement that approval for laboratories performing HIV screening be denied or terminated for failure to comply with these standards

- to specify that sanctions shall be imposed for failure to comply. A subsection in the new Section 1230 is based on this requirement.
- Adopt quality assurance procedures for laboratories performing waived HIV tests.

NECESSITY

In 1985 the Legislature determined that it was in the best interest of the public's health and safety to require laboratories performing HIV testing to be reviewed and approved by the Department prior to performing tests on patient samples. At that time the only tests available were HIV antibody tests. Therefore, the current regulation is restricted to HIV antibody tests with confirmation by other HIV antibody tests. However, since 1985 there have been many changes in technology, including development of more specific and sensitive HIV confirmation tests, HIV antigen tests and simple waived and rapid HIV antibody tests. These regulations shall impact any HIV test that is used to screen for evidence of HIV infection.

Since implementation of the current regulation in 1986, there have also been significant changes in both state law and federal regulations. The result is that the current regulation contains many requirements that duplicate current state law. In addition, the current regulation references obsolete federal regulations, the federal Clinical Laboratory Improvement Act of 1967. For these reasons it is necessary to revise Section 1230 which sets standards for clinical laboratories performing screening tests for HIV.

AUTHORITY

Health and Safety (H&S) Code Sections 100275 and 131200, and Business and Professions Code (B&P) Code Section 1224 give general authority for the Department to adopt and enforce regulations for the execution of its duties. H&S Code Section 131050 transfers the authority to enact regulations from the Department of Health Services to the Department of Public Health. H&S Code Section 1603.3(f) specifically authorizes the Department to promulgate any additional regulations it deems necessary to enhance the safety of donated blood and blood components and to safeguard the consistency and accuracy of HIV test results. Using this authority and the combined expertise of the Department's Laboratory Field Services (LFS) and Office of AIDS, these proposed amendments have been developed.

BACKGROUND

HIV AND AIDS

HIV is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). HIV is an infectious agent that invades and disables a person's immune system, the body's natural defense against disease. The only way a person can become infected with HIV is through exposure to HIV-infected blood or other body fluids, including semen, vaginal fluids and

mother's milk. HIV is primarily transmitted through unprotected sex (sex without a condom or other barrier use) and injection drug use (sharing of contaminated syringes and other injection equipment). Children born to infected mothers, health care workers caring for HIV-infected patients, and rarely, recipients of blood transfusions or organ donations can also be at risk. There is no cure for HIV infection. HIV-infected persons who do not receive appropriate medical care may become ill and be diagnosed with an AIDS-defining condition.

AIDS is a syndrome, or collection of signs and symptoms, that is attributed to the natural course of HIV infection. The federal Centers for Disease Control and Prevention (CDC) has classified a total of 27 different diagnoses and conditions as AIDS-defining illnesses. Once diagnosed with AIDS, many people can subsequently begin, resume, or modify HIV treatment regimens and maintain or return to productive, relatively healthy lifestyles.

HIV TESTING

HIV testing technology has evolved from highly complex tests requiring significant technical oversight in traditional laboratory settings to simple point-of-care (rapid) HIV tests suitable for use in a variety of medical and non-medical settings. Section 1230 was enacted in 1986 before tests were classified by complexity. As HIV testing technology has evolved to encompass simple tests designed for point-of-care use, the number of laboratories capable of conducting HIV testing has increased from a few hundred laboratories to thousands of potential point-of-care settings, including emergency rooms, labor and delivery settings, urgent care clinics, physician offices, public health clinics, and other mobile testing sites. While this technological improvement has resulted in increased access to rapid HIV testing for at-risk individuals, there is also concern that the quality of HIV testing should be maintained. The Department is proposing adoption of a new Section 1230 that will provide safeguards for quality while easing access to rapid HIV testing. In California this access has been restricted due to current Section 1230 which requires special approval for any laboratory to conduct HIV antibody screening. The Department has not been able to keep up with the demand for approval of facilities wanting to perform rapid HIV testing.

REQUIREMENTS TO PERFORM HIV TESTING

When a laboratory wants to perform HIV testing, it must first comply with all state and federal testing requirements. That means the laboratory must have a federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate and a state license or registration appropriate to the complexity of testing. These extensive requirements are found in federal regulations [42 Code of Federal Regulations (CFR) Sections 493.1 to 493.2001] and state law (B&P Code Chapter 3, Sections 1200 through 1320 and H&S Code Section 101160). Compliance is verified by LFS in the Department. In addition, Section 1230 requires a laboratory seeking approval to perform HIV antibody testing to screen for HIV to gain another approval from the Department to verify that they comply with the stricter HIV-testing requirements. HIV antibody testing is the only clinical

laboratory test or examination that requires special approval. It is felt that this level of oversight is no longer necessary as licensure and certification standards B&P Code Chapter 3 ensure quality of testing. The Department is committed to ensuring accurate HIV testing since the CDC has determined that HIV antibody testing is a proven HIV prevention method.

AMENDMENTS

The Department proposes to revise Section 1230 by repealing the current regulation language and adopting a new Section 1230 with more updated regulatory language.

REPEAL OF EXISTING SECTION 1230

The Department proposes to repeal existing Section 1230 as follows:

- Repeal the title, Section 1230. “Approval of Laboratories for Use of HIV Antibody Test.”
- Repeal Subparagraph (a)(1)(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 licensed or certified to engage in the production of biologics in accordance with chapter 4, division 2 of the Health and Safety Code, or”

This requirement is unnecessary as all facilities that engage in the production of biologics must be licensed by the Department as complying with standards adopted by the American Association of Blood Banks pursuant to H&S Code Section 1602.5. These standards and state law, require a biologics production facility to ensure that its blood supply is free of HIV and infectious disease (H&S Code Section 1603.1). The testing does not need to be done onsite, but if it were, that site would need to be licensed or registered as a clinical laboratory and must comply with all state and federal requirements [42 Code of Federal Regulations (CFR) Sections 493.1 to 493.2001] and state law (B&P Code Chapter 3, Sections 1200 through 1320). Currently there are about 190 biologics facilities in California and few perform HIV testing onsite. The Department is proposing that this subparagraph be repealed as it is unnecessary and redundant.

- Repeal Subparagraph (a)(1)(B). “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 licensed or certified as a clinical laboratory in accordance with chapter 3, division 2 of the Business and Professions Code, or”

This requirement was enacted in 1986 before all clinical laboratories in California, and those outside California doing testing on California residents, needed to be

licensed, registered or certified. (Note that in this section, “certified” referred to public health laboratory certification, not CLIA certification which had not been implemented yet.) Because not all laboratories were licensed, it was necessary to require this of HIV testing laboratories in 1986. In 1992, federal CLIA regulations were implemented in the United States and all laboratories were required to be CLIA certified. In 1996 Senate Bill (SB) 113 (Chapter 510, Statutes of 1995) enacted B&P Code Section 1265 which required all laboratories to be licensed or registered (the latter, if doing waived or provider performed microscopy testing), and CLIA certified. Therefore, after 1996 this subsection became redundant with later law. The Department is now proposing that this subsection be repealed as unnecessary and superseded by B&P Code Section 1265, as enacted by SB 113 (Chapter 510, Statutes of 1995).

- Repeal Subparagraph (a)(1)(C). “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 licensed or certified as a public health laboratory in accordance with chapter 7, part 2, division 1 of the Health and Safety Code, or”

In 1986 when Section 1230 regulations were enacted, public health laboratories, although regulated by the H&S Code, were not specifically exempted from B&P Code so they were required to obtain approval to perform HIV antibody testing. Public health laboratories are subject to federal CLIA regulations (42 CFR 493) and must be certified. These laboratories are required to comply with federal quality standards adopted in 1996 into state law at B&P Code Section 1220, as enacted by SB 113 (Chapter 510, Statutes of 1995), so this subparagraph is unnecessary and should be repealed.

- Repeal Subparagraph (a)(1)(D). “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 licensed or certified as a blood bank by the United States Food and Drug Administration in accordance with 42 U.S.C., section 262(a), or”

Blood banks are licensed by the Department and are subject to standards in H&S Code Sections 1600 through 1611. Of the about 190 licensed blood banks in California, only a few perform HIV testing. Such testing requires a separate license as a clinical laboratory and compliance with state (B&P Code Section 1265) and federal (42 CFR 493) regulations. Most blood banks test for HIV-1, HIV-2, HTLV-1 and HTLV-2 by Nucleic Acid Testing at facilities outside California. Since laboratories outside California are required to be licensed pursuant to B&P Code Section 1241, this subparagraph is redundant and should be repealed.

- Repeal Subparagraph (a)(1)(E). “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 licensed or certified 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”

Laboratories that were certified to perform serology (syphilis) testing by the federal government were thought likely candidates to perform HIV testing. Therefore, these facilities were included in the 1986 regulations among those needing approval to perform HIV testing. These facilities became subject to CLIA when it was implemented in 1992 and to state law (SB 113) in 1996 when amended and expanded by the California legislature. Since California laboratory law at B&P Code Section 1265 requires licensure of all laboratories performing infectious disease testing this reference is redundant and unnecessary.

- Repeal Paragraph (a)(2). “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 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.”

This paragraph is unnecessary and redundant with later legislation enacted with SB 113 (Chapter 510, Statutes of 1995) at B&P Code Sections 1220 and 1272. All laboratories performing non-waived testing are already required to enroll and successfully participate in proficiency testing. The Department has proposed alternative quality assurance procedures, including but not requiring, proficiency testing for waived HIV tests. Paragraph (a)(3) in the new Section 1320 is based on this paragraph.

- Repeal Subsection (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 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.”

This subsection shall be repealed as the Department does not need to specifically review and approve each location where HIV screening tests are performed. Each licensed or registered laboratory is already reviewed and approved for testing pursuant to B&P Code Section 1265 and this requirement is no longer necessary.

- Repeal Subsection (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.”

Paragraph (a)(1) in the new Section 1320 is based on this subsection.

- Repeal Subsection (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.”

Paragraph (a)(2) in the new Section 1320 is based on this subsection.

- Repeal Subsection (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.”

Paragraph (a)(2) in the new Section 1320 is based on this subsection.

- Repeal Subsection (f). “An approved laboratory shall maintain records of tests and test results in a manner to ensure the patient’s confidentiality.”

This subsection shall be repealed as it is unnecessary and redundant with more recent legislation which requires HIV test results, as all laboratory test results, to be maintained in a confidential manner. Health records relating to HIV or AIDS, containing personally identifying information, shall be kept confidential and shall not be disclosed, except as provided by law for public health purposes (H&S Code Section 121025(a)).

- Repeal Subsection (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.”

This subsection shall be repealed as it is unnecessary. All confirmed positive HIV test results are reported by the laboratory to the health officer of the county in which the physician practices. This is done on an ongoing manner and not as specified in this regulation. Negative test results are reported to the ordering physician but not to the health officer. All test results are maintained confidentially by the laboratory.

- Repeal Subsection (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 law, 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.”

This subsection shall be repealed as it is duplicative with state law at B&P Code Section 1320.

ADOPTION ON NEW SECTION 1230

The Department proposes to adopt new Section 1230 as follows:

- Adopt the new title, Section 1230. “HIV Screening Testing by Laboratories”

The Department proposes the adoption of this title to more clearly reflect the content of the section.

- Adopt new Subsection 1230(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:”

“All clinical laboratories . . .” This subsection is adopted to specify that these standards apply for each and every laboratory performing HIV testing. There would be no exemption for inner city clinics, public health programs or research facilities. All laboratories must be approved as complying with state law and federal regulations before licensure or registration [B&P Code Section 1265, as enacted by SB 113 (Chapter 510, Statutes of 1995)], so secondary approval to perform HIV testing is not necessary.

“. . . that perform waived, moderate or high complexity tests or examinations . . .” This subsection is adopted to specify that this requirement applies to all complexities of testing. All types of HIV tests, even the simple waived tests, are subject to these standards.

“. . . to screen for human immunodeficiency virus (HIV) . . .” Screening is an initial test, usually designed to be sensitive, to identify all persons with a given condition or infection. “Screen for HIV” means to use a procedure that will test for presence of HIV. Once a person has been found “positive” by HIV screening and confirmation, he or she would be considered HIV infected. HIV screening tests could be designed to look for the actual virus (such as a virus culture) or a component of the virus. Since viral culture is difficult and not very sensitive, it is not usually used for screening. The most commonly used screening tests for HIV

are HIV antibody tests. These systems screen for the presence or absence of HIV antibody for the purposes of determining infection. New HIV antigen tests detect HIV viral components and they could be used for screening. Other types of HIV testing are used for monitoring treatment and disease progression of AIDS patients, and are not appropriate for screening asymptomatic persons.

Once a person has been found positive by HIV screening and confirmation, further tests would monitor treatment and AIDS disease progression. The tests used for this are typically viral load, CD4 counts and genotyping for drug therapy. Viral load tests are too expensive and are not appropriate for HIV screening. CD4 testing is too nonspecific for HIV infection. HIV genotyping evaluates “resistance/sensitivity” to drug therapy. HIV antibody testing is not usually done on these patients. The provisions of these regulations only impact testing done to screen for presence of HIV antibodies.

- Adopt new Paragraph (a)(1). “Utilize United States Food and Drug Administration (FDA) approved test systems used in accordance with the manufacturers’ instruction. 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.”

“Utilize United States Food and Drug Administration (FDA) approved test systems . . .” The FDA is charged with evaluating in vitro diagnostic (IVD) kits in the United States. Pre-market approval of a kit is based on scientific evidence provided by the manufacturer that the kit is safe and effective for its intended use. The manufacturer must provide the FDA with kit performance specifications (clinical sensitivity and specificity, or agreement “correlation”) with relation to known clinical studies using randomly collected clinical values. When a kit is approved by the FDA, the FDA has verified that the IVD performs according to the manufacturer’s clinical data.

“. . . used in accordance with the manufacturers’ instruction.” A key part of FDA approval is approval of the instructions to use the kit. The instructions tell the user how the kit may be used. Any alterations to the kit procedure invalidate FDA approval and the user becomes responsible for validating kit performance (see below).

“Any laboratory that modifies a non-waived FDA-approved kit . . .” Only non-waived HIV screening tests can be modified from their FDA-approved procedures. A laboratory performing waived HIV screening tests must strictly adhere to the procedure as approved by the FDA.

“. . . shall establish and verify the performance specifications pursuant to 42 Code of Federal Regulations Section 493.1253.” Current Department regulations require a clinical laboratory to use only an FDA-approved kit to screen for HIV.

These regulations propose to amend that requirement to allow HIV screening laboratories using non-waived procedures to modify an FDA-approved kit if they need to, when the laboratory establishes its performance specifications as required in federal regulations at 42 CFR Section 493.1253.

Subpart K (Quality Control), commencing 42 CFR Section 493.1201, was incorporated in 1996 into state law at B&P Code Section 1220(d)(2)(B), enacted by SB 113 (Chapter 510, Statutes of 1995). Laboratories that modify an FDA-approved kit, or that introduce a test not cleared by the FDA, must establish and verify its performance specifications prior to introduction. This is currently required of any modification of any waived or non-waived kit. These regulations authorize a modification of a non-waived FDA-approved kit used to screen for HIV if the laboratory follows the requirements of state law and federal regulations. State law at B&P Code Section 1220(d)(1) specifically requires all waived laboratory tests to be performed in conformity with the manufacturer's instructions.

The establishment of method performance specifications is a difficult process, and not easily done. Any modification must not change the manufacturer's intended use of the kit. The laboratory is responsible for establishing that the FDA-modified method produces correct results and must assess day-to-day, run-to-run and within-run variation, as well as operator variance, pursuant to 42 CFR 493.1253. The laboratory is responsible for establishing that the accuracy, precision, sensitivity, specificity and reporting criterion are acceptable. Typical modifications would include:

- 1) Any change in specimen type or specimen handling conditions.
- 2) Any change in any aspect of the test procedure, as incubation time, addition of reagents.
- 3) Any change in reporting criterion.

The Department has proposed to make this change in non-waived HIV screening requirements because of changing technologies, to give laboratories more flexibility in testing and to ensure access to quality HIV screening. There is increasing pressure to give all persons access to HIV screening. At the same time, laboratories that have the expertise to develop their own "in-house" screening tests or to modify FDA-approved tests and meet federal requirements, should be allowed to do so. With increasing pressure to provide HIV testing to all persons, accommodations must be made to ease testing requirements while maintaining quality.

- Adopt new Paragraph (a)(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."

“Confirm all reactive . . .” An HIV screening test found “reactive” must not be reported until the test result is confirmed by another method. A confirmatory test is a highly specific test designed to confirm the results of an earlier screening test. For HIV testing, a Western blot or an immunofluorescent assay (IFA) is used for confirmation. Other tests include an RNA test using nucleic acid amplification. When the initially reactive test result is confirmed by a highly specific method, the result may be reported as “positive.”

“. . . indeterminate HIV test results . . .” In certain situations an indeterminate HIV test result is obtained as in a recent HIV infection or a false-positive due to interferences. In these situations, the test result must be confirmed using the CDC protocol and reported as positive, or indeterminate with follow up repeat testing recommended. An indeterminate result is always problematic since it provides an indefinite diagnosis for the clinician. A patient with a confirmed indeterminate HIV result would be retested at a later date.

HIV kit manufacturers usually specify how an indeterminate test should be reported and when it should be repeated. These actions are approved by the FDA as part of the kit approval. Users of the kit are required to follow the kit insert for testing and reporting. These regulations would put further restrictions on how HIV can be reported in California. Any screened positive or indeterminate test must be confirmed prior to reporting, even if the kit manufacturer does not require it. This requirement ensures that false positive results are not reported.

“. . . HIV confirmation protocols . . .” An HIV screening test must be confirmed before reporting, but there are a variety of other tests available for confirmation. Protocols have been developed to guide the laboratory in how best to confirm a positive or indeterminate screening test.

“. . . recommended by the federal Centers for Disease Control and Prevention as published in the Mortality and Morbidity Weekly Report . . .” The CDC has published protocols for confirmation of HIV in the Mortality and Morbidity Weekly Report (MMWR). The March 14, 2004 “Protocol for Confirmation of Reactive Rapid HIV Tests” recommends that all reactive (rapid) HIV test results have confirmatory testing. The Department shall require this confirmation protocol for all screened HIV tests in California, waived or non-waived. The current CDC recommendation is that all reactive HIV test results be confirmed either with Western blot or IFA testing.

Confirmation protocols recommended by the CDC are not enforceable on their own. The Department is requiring the MMWR confirmation protocol for HIV screening tests.

The regulation text proposed to be repealed at Section 1230(d) requires that confirmation be done by a “more specific test.” The proposed regulation text requires confirmation following protocols recommended by the CDC. These protocols may change as technologies change, and the Department shall rely on their recommendation ongoing.

“. . . prior to reporting the result as positive.” A screened initially reactive HIV test result cannot be reported as positive. It must be confirmed using the more specific CDC recommended protocol and then reported as positive (or negative) for HIV.

- Adopt new Paragraph (a)(3): “Establish and maintain a quality assurance program that includes all of the following:”

The Department is concerned about the deleterious impact of inaccurate HIV screening test results, particularly false negative results. Waived tests have few quality control procedures except those approved by the FDA. Waived laboratories are not subject to routine inspections or proficiency testing. Waived HIV tests, in particular, may be performed from mobile vans, inner city clinics or emergency rooms where quality control is particularly difficult. The Department proposes to require that additional steps be taken by facilities performing waived HIV screening to ensure accuracy of test results.

Laboratories performing non-waived testing are subject to extensive quality control and quality assurance requirements in state and federal law. Waived laboratories are not. These proposed regulations would require the laboratory performing waived HIV tests to establish additional procedures to ensure the accuracy of its test results. The laboratory may establish any other procedures it deems appropriate, but the Department proposes to require the two that follow.

- Adopt new Subparagraph (a)(3)(A). “Evaluation and documentation of testing personnel by direct observation, training, and competency testing to ensure tests are accurately performed and reported.”

One of the key responsibilities of a laboratory director, as given in B&P Code Section 1209(e), is assessing the competency and performance of testing staff performing non-waived tests. The Department considers this very important in the performance of waived HIV tests, also.

The competency of testing personnel can best be assessed by personal observation of their testing. They must be capable of performing the procedure in strict adherence to the manufacturer’s instructions, including specimen collection, reagent storage, test performance and interpretation. Testing personnel should be trained or retrained as necessary and their competency should be documented.

- Adopt new Subparagraph (a)(3)(B). “Assessment of test performance by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.”

“Assessment of test performance . . .” A test that is performing acceptably would be expected to produce accurate and reproducible results. The FDA approves waived HIV kits with varying quality control requirements. Some have internal controls while others have external controls that must be run when there is a change in kit or testing personnel. Without controls, it is difficult to evaluate whether a procedure is giving accurate results each time it is used. Therefore, the Department is proposing that the facility be required to set up other mechanisms to ensure accuracy and reproducibility of HIV results.

“. . . by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.” Inter-run variation of test performance can be assessed by testing samples previously analyzed or by testing samples of known HIV levels. Enrolling in a proficiency testing program for waived HIV would be a recommended, but not required, method of evaluating accuracy of HIV results.

- Adopt new Subsection (b). “Failure to comply with the requirements of this section shall subject the laboratory to sanctions pursuant to Business and Professions Code Section 1320.”

“Failure to comply with the requirements of this section . . .” All laboratories are subject to state and federal law, plus those laboratories screening for HIV are subject to these regulations. In several areas, the HIV screening requirements are stricter than those for non-HIV testing. A laboratory may comply with all state law and federal regulations, but if they violate the HIV testing requirements when performing HIV screens the laboratory would be subject to sanctions.

“. . . shall subject the laboratory to sanctions pursuant to Business and Professions Code Section 1320 . . .” B&P Code Section 1320 authorizes the Department to proceed with revocation or suspension of a laboratory license or registration for failure to comply with conditions of licensure or registration. B&P Code Section 1310 subjects licensed laboratories to alternative sanctions of directed plans of correction, civil money penalties, or onsite monitoring. Department regulations at Title 17 CCR Sections 1065 through 1067.15 specify enforcement actions that can be taken.

DOCUMENTS RELIED UPON

The following documents were relied upon for formulating the reasoning behind the adoption of the new Section 1230

Title 42 Code of Federal Regulations 493, Federal Register Volume 68, Number 16, January 24, 2003, Rules and Regulations.

Office of In Vitro Diagnostic Device Evaluation and Safety, Overview of IVD Regulations, U.S. Food and Drug Administration Center for Devices and Radiological Health, <http://www.fda.gov/cdrh/oivd.html>.

Protocols for Confirmation of Reactive Rapid HIV Tests, Center for Disease Control and Prevention, Mortality and Morbidity Weekly Report, March 19, 2004, 53(10), 221-222.

Guidelines for Laboratory Test Result Reporting of Human Immunodeficiency Virus Type 1 Ribonucleic Acid Determination, Mortality and Morbidity Weekly 50

FDA's Role in HIV/AIDS, U.S. Food and Drug Administration Notice, August 2006, <http://www.fda.gov/oashi/aids/fdarole.html>

Rapid HIV-1 Diagnostic Algorithms for Use in HIV Infection Screening, E. Calero et al, Walter Reed Army Institute of Research.

Point-of-Care Rapid Tests for HIV Antibodies, B.M.Branson, J Lab Med 2003: 27(7/8) 288.

General and Laboratory Considerations: Rapid HIV Tests Currently Available in the United States, Centers for Disease Control and Prevention, <http://www.cdc.gov/hiv/topics/testing/resources/factsheets/rt-lab.htm>

A Rapid Review of Rapid HIV Antibody Tests, J. L. Greenwald, et al, Current Infectious Disease Reports 2006, 8:125.