

## FINAL 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 CCR Section 1230 that sets standards for approval of facilities that perform screening tests for the presence of 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, amendments shall be made to Title 17 CCR Section 1230 to:

- Repeal the requirement that laboratories that screen for HIV be licensed blood banks, clinical laboratories, public health laboratories or serology laboratories.
- Repeal the proficiency testing requirement.
- Repeal the requirement that all laboratories performing HIV antibody testing be approved by the Department.
- Amend the requirement that all laboratories performing HIV testing use only an FDA-approved test kit used in strict accordance with manufacturer's instructions.
- Amend the confirmation requirements for all screened reactive HIV results, including the requirement that all indeterminate HIV results be confirmed.
- Repeal the requirement that all laboratories submit monthly or quarterly reports on number of HIV tests performed and results.
- Add quality assurance procedures for laboratories performing waived HIV tests.
- Repeal the provision that approval to test for HIV antibodies is terminated for failure to comply with these standards.

### 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 (3, 4, 6-9). 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 amend Title 17 CCR 1230 which sets standards for clinical laboratories performing screening tests for HIV.

## **AUTHORITY**

H&S Code Section 100275 and 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 131200 transfers the authority to enact regulations from the Department of Health Services to the Department of Public Health. H&S Code Section 1603.3(e) 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 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 (3). 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. Title 17 CCR 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 (6-9). 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 amendments to Title 17 CCR Section 1230 that shall provide safeguards for quality while easing access to rapid HIV testing. In California, this access has been restricted due to Title 17 CCR 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 CFR 493.1 to 493.2001) and state law (B&P Code Chapter 3, Sections 1200 to 1320 and H&S Code 101160.) Compliance is verified by Laboratory Field Services (LFS) in the Department. In addition, Title 17 CCR Section 1230 requires a laboratory seeking approval to perform HIV antibody testing to screen for HIV to gain another approval from LFS 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 are in place to assure quality of testing. The Department is committed to assuring accurate HIV testing since the CDC has determined that HIV antibody testing is a proven HIV prevention method.

## AMENDMENTS

The Department proposes to amend 17 CCR Section 1230 by repealing the current regulation language and amending Section 1230 with more updated regulatory language.

## REPEAL OF EXISTING SECTION 1230

The Department proposes to repeal all of Title 17 CCR Section 1230, as follows:

- Repeal the title, Section 1230. "Approval of Laboratories for Use of HIV Antibody Test." The new title shall be "HIV Screening Testing by Laboratories."
- 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 production of biologics in accordance with chapter 4, division 2 of the Health and Safety Code."

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. These standards and state law, require a biologics production facility to assure that its blood supply is free of HIV and infectious disease (H&S) Code 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. Currently there are about 190 biologics facilities in California and few perform HIV testing onsite. The Department is proposing that this subsection be repealed as 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."

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 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 of Title 17 CCR 1230 became redundant with later law. The Department is now proposing that this subsection be repealed as unnecessary and superseded by Senate Bill 113 in 1996.

- 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 Title 17 CCR 1230 regulations were enacted, public health laboratories, although regulated by the H&S Code, were not specifically

exempted from B&P Code so were required to obtain approval to perform HIV antibody testing. Public health laboratories are subject to federal CLIA regulations and must be certified. These laboratories are required to comply with federal quality standards adopted into state law in 1996 (via SB 113), so this subsection 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 to 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, 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 implemented in 1992 and to state law (Senate Bill 113) in 1996 when amended and expanded by the California legislature. Now this specific reference is redundant and unnecessary. California laboratory law at B&P Code 1265 requires licensure of all laboratories performing infectious disease testing, so this is 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 Senate Bill 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. This is included in the adopted regulation in subsection (a).

- 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.”

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.”

The language of the requirement in this paragraph will be modified and included in the adopted regulation in subsection (a).

- 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.”

The language of the requirement in this paragraph will be modified and included in the adopted regulation in subsection (a).

- Repeal Section (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.”

The language of the requirement in this paragraph will be modified and included in the adopted regulation in subsection (a).

- 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 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 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 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 1320. The Department proposes to no longer give specific authority for laboratories to perform HIV screening.

#### ADOPTION ON NEW TITLE OF SECTION 1230

Section 1230 (Title). “HIV Screening Testing by Laboratories”

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

ADOPTION of 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”. The Department is amending Title 17 CCR 1230 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 (Senate Bill 113, Chapter 510, Statutes of 1995, B&P Code Section 1265), so secondary approval to perform HIV testing is not necessary.

- “That perform waived, moderate or high complexity tests or examinations”. The Department is amending Title 17 CCR 1230 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.
- “Screen for 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 (3, 4).

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.

ADOPTION OF NEW PARAGRAPH 1230 (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 § 493.1253.

- “Utilize US Food and Drug Administration approved kits...” The US Food and Drug Administration (FDA) is charged with evaluating in vitro diagnostic (IVD) kits in the United States (2). 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. For IVD products this is unique since there is generally no contact

between the kit and the patient as there is with most FDA products (as cosmetics). For IVD kits, safety relates to the impact on patient health of the kit's performance in delivering false negative or false positive results. 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.

- "In accordance with manufacturer's instructions." 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 specification pursuant to 42 Code of Federal Regulations §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 (42 Code of Federal Regulations (CFR) Section 493.1253.

Subpart K (Quality Control) of federal regulations was incorporated into state law at Business and Professions (B&P) Code 1220 (d)(2)(B) with Senate Bill 113 (Chapter 510, Statutes of 1995) in 1996. 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 would 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 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 42CFR 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 assure 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.

ADOPTION OF NEW PARAGRAPH 1230 (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 reactive test results" 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.
- “Confirmation protocols recommended by the federal CDC.” The CDC has published protocols for confirmation of HIV in the Mortality and Morbidity Weekly Report. The March 14, 2004 “Protocol for Confirmation of Reactive Rapid HIV Tests” recommends that all reactive (rapid) HIV test results have confirmatory testing (3). The Department shall incorporate this recommendation 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 incorporating this requirement for HIV screening tests into regulation and shall use its enforcement authority (see below) to sanction laboratories out of compliance with this requirement.

The regulation text proposed to be repealed at Title 17 CCR 1230 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.

ADOPTION OF NEW PARAGRAPH 1230 (a)(3): “Optimize the accuracy of waived HIV test results using quality assurance procedures established by the laboratory, including..”

- “Optimize the accuracy of waived HIV test results.” 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 US 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 assure accuracy of test results.

- “Quality assurance procedures established by the laboratory”. Laboratories performing non-waived testing are subject to extensive quality control and quality assurance requirements in state and federal law. Waived laboratories are not (1). These proposed regulations would require the laboratory performing waived HIV tests to establish additional procedures to assure 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.

ADOPTION OF SUBPARAGRAPH (a)(3)(A). “Assuring competency of testing personnel by direct observation, training, and competency testing, and”

- “Assuring competency of testing personnel”. B&P Code 1206.5 (a) lists those persons who can perform waived testing under the overall administration of a laboratory director. One of the key responsibilities of a laboratory director, as given in B&P Code 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.

Commenter 1A recommended that the testing competency of persons performing waived HIV tests be the same as that for persons performing moderate or high complexity HIV tests, that is, prior to testing, after six months and then annually. The Department has incorporated this requirement for all laboratories performing HIV screening, including waived, as indicated by the title of this subsection.

- “Direct observation of testing personnel”. 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.

ADOPTION OF SUBPARAGRAPH (a)(3)(B). “Assessment 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.”

Comments received during the 45-day comment period expressed concern about the accuracy of HIV tests. Commenter 1B urged the adoption of alternative quality assessment procedures for all HIV screening laboratories. He recommended that procedures as submission of blind retested samples, previously analyzed samples or external proficiency testing samples be required at least twice yearly, and that this be monitored by the laboratory director. Commenter 3H urged that the accuracy of HIV tests be evaluated. In response to these comments, the Department added alternative

quality assessment procedures and specified that these be performed at least twice a year

- “Assessment of test performance”. A test that is performing acceptably would be expected to produce accurate and reproducible results. The US 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 assure accuracy and reproducibility of HIV results.
- “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.

The Department is specifying three alternatives for quality assessment of HIV testing, and proficiency testing is one of the three. A laboratory performing non-waived HIV is already required by law to perform proficiency testing as well as other quality assurance procedures. A laboratory performing waived HIV testing may select one or more of the three, including proficiency testing.

- “...at least twice yearly and monitored by the laboratory director.” In response to comments received during the 45-day public comment period, the Department has specified that one or more of the alternative quality assurance procedures be performed at least twice yearly. This activity is the responsibility of the laboratory director who must monitor that it is successfully completed.

ADOPTION OF NEW SECTION 1230 (b). “Failure to comply with the requirements of this section shall subject the laboratory to sanction pursuant to Business and Professions Code 1320.”

- “Comply with regulations 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 they would be subject to sanctions.
- “Subject to sanctions.” B&P Code 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 1310 subjects licensed laboratories to alternative sanctions of directed plans of correction, civil money penalties, or onsite monitoring. Department regulations at Title 17 CCR 1065 to 1067.15 specify enforcement actions that can be taken.

## STATEMENT OF DETERMINATIONS

### A. ALTERNATIVES DETERMINATION:

The Department has determined that no reasonable alternative considered by the Department, or that has otherwise been identified and brought to the attention of the Department, would be more effective and less burdensome to affected private persons than the proposed action.

### B. LOCAL MANDATE DETERMINATION:

The Department has determined that the proposed regulations would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code, nor are there other non-discretionary costs imposed.

### C. ECONOMIC IMPACT ON SMALL BUSINESS:

The Department has determined that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

**PUBLIC COMMENT LETTERS AND E-MAILS**

Three comments were received during 45-day comment period,  
September 5, 2008 to October 22, 2008.

No comments were received during 15-day comment period,  
March 18, 2009 to April 1, 2009

**Comments received during 45-day comment period:**

Commenter #1: James Ottosen, e-mail received September 26, 2008.

Commenter #2: Michael Arnold and Richard Nicholson, California Clinical Laboratory Association, letter dated October 15, 2008.

Commenter #3: Mimi Lachica, California Association of Public Health Laboratory Directors, e-mail dated October 22, 2008.

Commenter 1  
Page 1 of 1

**From:** Ottosen, Jim E [Jim.E.Ottosen@questdiagnostics.com]  
**Sent:** Friday, September 26, 2008 12:32 PM  
**To:** CDPH Ofc of Regulations  
**Subject:** DPH-07-010  
Hello,

I would like to comment on two sections of the new regulations:

1. Subparagraph (a)(3)(A): Although competency testing is included in the text there is no mention of the frequency required. I would suggest that it be in accord with competency testing frequency for other laboratory personnel. Thus it should be stated in the regulation that competency be assessed upon first performance of the test by that person, six months later, and yearly thereafter as long as their performance on the procedure remains acceptable by other measurements as Proficiency Testing, blind repeat testing, and quality control results. Retraining would be necessary if performance measured by competency testing, or one or more of the other factors previously mentioned, indicated that it was necessary. 1A

2. Subparagraph (a)(3)(B): Although the phrase "each time it is used" is noted in the text, there is no requirement in the regulation about the frequency of the assessment of test performance. At a minimum, a test of this importance should be assessed for proper performance at least each day it is used. Without external control samples being tested there is no way to assure that the test is performing properly. Proficiency test samples do not fill the bill because they are run only three or four times a year. Previously analyzed specimens also do not fill the bill unless there was documentation that the test was performing properly on the day the previously analyzed samples were originally analyzed. External controls of known value provide a timely assessment of test performance and are available commercially. 1B

Thank You for considering these comments.

Jim Ottosen, CLS  
2118 Canterbury Ln.  
Glendora, CA 91741

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*Commenter 2*



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October 15, 2008

Mark Horton, Director  
California Department of Public Health  
MS 0507, PO Box 997377  
Sacramento, CA 95899-7377

Re: DPH-07-010

Dear Director Horton:

I write on behalf of the California Clinical Laboratory Association (CCLA) to show support for the California Department of Public Health's (CDPH) adoption of HIV screening regulations (DPH-07-010).

CCLA recognizes the changes in technology and standards and agrees with CDPH's adoption of a new Section 1230. 27

We look forward to CHPH implementing these new changes and to working with the Department's high standards of testing.

Thank you,

*Richard*  
Richard Nicholson  
CCLA President

*Michael*  
Michael J. Arnold  
CCLA Legislative Advocate

Page 1 of 5  
Commenter 3

**Nickel, Karen (CDPH-LFS)**

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**From:** CDPH Ofc of Regulations  
**Sent:** Saturday, October 25, 2008 6:33 PM  
**To:** Miyamura, Maureen (CDPH-EXEC-OLS)  
**Subject:** FW: DPH-07-010 Testing Standards For Laboratories Performing HIV Screening  
**Attachments:** DPH-07-010\_REG\_CAPHLD\_ML.pdf

Comments on DPH-07-010

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**From:** Mimi Lachica [mailto:Mimi\_Lachica@longbeach.gov]  
**Sent:** Wednesday, October 22, 2008 3:31 PM  
**To:** CDPH Ofc of Regulations  
**Subject:** DPH-07-010 Testing Standards For Laboratories Performing HIV Screening

On behalf of the California Association of Public Health Laboratory Directors, please see attached comments and suggestions on the proposed 1230 regulation. Comments and suggestions are those highlighted in yellow.

Mimi Lachica, MA  
CAPHLD President



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TITLE 17. PUBLIC HEALTH

Page 2 of 5  
Comments 3

(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.~~

Page 5 of 7  
Commenter 3

~~(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 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.~~

~~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.~~

Adopt Section 1230 to read:

Section 1230. HIV Screening Testing by Laboratories.

Makes no mention of the requirement of a certificate of waiver for labs performing waived testing, or reference to other B&P Code sections requiring CLIA compliance for waived testing labs. 3A

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

By including "moderate and high complexity" labs in this regulation, it is implied that such labs are only required to comply with this section, which is in many ways contradictory with the B&P Code. 3C

Some testing centers might not recognize themselves as "Clinical laboratories" unless they read section B&P Code section 1206(a)(7). 3B

(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.

Does not address the prohibitions on modification of a waived test. 3D

(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. 3E

Reporting to whom? The local health jurisdiction? The patient?

Interesting. Proposed 1230 requires conformance with a CDC "recommendation." Page 4 of 5 Comment 3

Waived testing labs would not necessarily be "confirming" reactive or indeterminate specimens. The wording should be changed to clarify that all reactive or indeterminate specimens shall be confirmed according to the HIV confirmation protocols recommended by the CDC, etc., or continue to use the language in "old" 1230 (d) and (e). 3F

(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 annual competency testing to ensure tests are accurately performed and reported.

What's the frequency of this evaluation? New employees? Yearly? 3G

(B) Evaluate accuracy of HIV results by aAssessment of test performance by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

Frequency? Documentation of results? (It's mentioned in (A) above.)

3I

This might be acceptable for performance of waived tests, but this section implies that labs performing moderate or high complexity HIV screening tests have a choice of test performance assessment. This seems contradictory with CLIA regs which require proficiency testing, and contradictory with sections in the B&P code which require CLIA compliance (and use of proficiency tests.)

3H

3J

(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.

Summary: If this proposed reg is solely intended for waived HIV testing, then that's what this reg should be about. It seems that this proposed 1230 is more directed toward establishing minimal waived testing. If so, a better approach would be to get the point across in different subsections, e.g., 1230(a) and (b) would cover waived requirements, (c) and (d) would cover moderate/high complexity test, and (e) would cover the penalties for non-compliance, etc. Additionally, it was stated that, "The Department is proposing adoption of a new Section 1230 that will provide *safeguards for quality*." If that is the case, this regulation re-write should include more "good laboratory practices" for waived testing. CAPHLD believes and agrees with doing away with the Department approval prior to performing waived HIV testing. There shouldn't be a registration requirement for performance of one type of waived test but not for another. It's very possible that there could be a problem with a proliferation of unknown labs testing for a reportable disease, unless these labs are clued into the fact that they must have a certificate of waiver before engaging in waived HIV testing. These labs in whatever form they take are still required to report confirmed positives once they receive the report back from a reference lab. Whether they will or not is another matter. Perhaps language can be included in this reg that reminds ALL labs of the reporting requirements included in Title 17.

3K

3L

3M

3N

Page 5 of 5  
Commenter 3

This brings up another point: NDGHA testing sites cannot test for HIV, B&P Code, Section 1244 (a)(3). Perhaps some language should be included to remind NDGHA sites that they cannot offer HIV testing. However, this is confused with Title 17 Section 1053.5, which adds waived HIV testing to B&P Code Section 1246.5. Does this mean NDGHAs can test for HIV, pursuant to 1053.5/1246.5 or not, pursuant to 1244(a)(3). This needs clarification.

30

3P

Interestingly, requirements for NDGHA testing sites are quite stringent (B&P Code Section 1244 et seq). If this proposed 1230 is adopted, there will be many more requirements for waived cholesterol and glucose tests than there will be for HIV waived testing. Frankly, which of these tests would have greater life-changing implications for the person tested?

3Q

Proposed 1230 says that a positive or indeterminate screening test must be confirmed before it is reported as positive. Who will the report go to - the Health Department under Title 17 Section 2500, or to the client? If the latter, what will the client be told? It is understood that proposed 1230 cannot legislate the counseling session or the interaction between the client and the counselor, but this is too ambiguous. It needs to be more clearly stated.

3R

Unless these things are addressed, 1230 will become just another piece of confusing law that won't be understood and adhered to. And come next session, there will be proposed amendments to the once proposed 1230. And the cycle continues.....

**SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL PUBLIC NOTICE PERIOD OF SEPTEMBER 5, 2008 THROUGH OCTOBER 22, 2008.**

The originally proposed text was made available for public comment for at least 45 days from September 5, 2008 through October 22, 2008. Three written comment emails or letters were received during that period. Pursuant to Government Code section 11346.9(a)(3) and (a)(5), the Department has summarized and responded to those comments as follows:

**Commenter #1: James Ottosen, email received September 26, 2008.**

**Comment 1A: New subsection 1230 (a)(3)(A):** The commenter states that there is no mention of frequency of competency testing for waived HIV. He said it should be the same as the frequency of testing of other lab personnel performing non-waived testing, i.e., before first performance, six months later and yearly thereafter as long as performance on quality assurance procedures is acceptable. He suggested that if a person performing waived HIV fails a quality assurance procedure, then he or she should be retrained before being allowed to resume testing waived HIV.

**Accept:** The suggested additional competency assessment requirement has been added to this section for waived HIV tests.

**Comment 1B: New subsection 1230 (a)(3)(B):** The commenter states that there is no mention of frequency of assessment of test performance. Ideally, he says this should be done daily with quality control samples. He states that external controls should be run daily even with waived HIV tests that do not provide or require controls.

**Accept in part:** The Department does not want to counter the US FDA determination that daily quality control specimens are not required of waived HIV tests. Alternatively, the Department has specified that external quality assessment procedures be performed at least twice yearly and monitored by the laboratory director.

**Commenter #2: Michael Arnold and Richard Nicholson, California Clinical Laboratory Association, letter dated October 15, 2008.**

**Comment 2: New section 1230:** The commenters recognize changes in technology and standards, and agree with the proposed amendments to Section 1230.

**Accept:** The Department appreciates the support of this organization.

**Commenter #3: Mimi Lachica, California Association of Public Health Laboratory Directors, email dated October 22, 2008**

**Comment 3A: Section 1230 (a):** Commenter states these regulations do not specifically mention laboratories performing waived tests or that they need a CLIA certificate of waiver.

**Reject:** The Department notes that the regulations apply to all clinical laboratories, including those performing waived tests, and that currently already requires these facilities to have a certificate of waiver. This need not be included in these standards.

**Comment 3B:** Section 1230 (a): Commenter states that public health laboratories need to be included to those performing HIV testing.

**Reject:** This comment cannot be accepted as public health laboratories are already authorized to perform HIV testing.

**Comment 3C: Section 1230 (a):** Commenter states the reference to laboratories performing moderate or high complexity HIV tests implies that these standards only apply to them.

**Reject:** The Department notes that these standards clearly pertain to all facilities performing HIV tests, waived, moderate or high complexities.

**Comment 3D:** Section 1230 (a)(1): Commenter states that these standards do not *prohibit modifications of waived HIV tests*.

**Reject:** The Department notes that these standards specify that only tests classified by the US FDA as non-waived may be modified, and then are subject to complex test performance verification pursuant to federal CLIA law.

**Comment 3E:** Section 1230 (a)(2): The commenter states that these regulations do not explain to whom HIV results can be reported.

**Reject:** The Department notes that reporting of HIV tests is already specified in other parts of state law and need not be explained here.

**Comment 3F:** Section 1230 (a)(2): The commenter states that the wording should be changed to explain that even waived HIV tests need to be confirmed before reporting.

**Reject:** The Department has specified in these regulations that all positive HIV screening tests must be confirmed before reporting.

**Comment 3G:** Section 1230 (a)(3)(A): The commenter states that evaluation of a testing person's competency should be done annually.

**Accept in part:** The Department amended the regulations to increase frequency of competency testing.

**Comment 3H, I: Section 1230 (a)(3)(B):** The commenter suggested that there should be an evaluation of the accuracy of HIV test performance, and that this should be documented.

**Accept in part:** The Department added that quality assessment must be performed and documented at least twice yearly.

**Comment 3J: Section 1230 (a)(3):** The commenter asked whether quality assessment replaces mandatory proficiency testing, contrary to CLIA.

**Response:** The Department has explained in the Statement of Reasons (SOR) that proficiency testing is included as one of three alternative quality tools for waived HIV tests. These procedures are not required in federal CLIA law and are unique to state laboratory law, but only for waived HIV tests. Laboratories performing non-waived HIV tests already are required to perform quality assessment procedures.

**Comment 3K: Section 1230(a)(3):** The commenter asked whether this subsection is geared only for waived HIV tests.

**Response:** The Department has explained in the SOR that the quality assessment

procedures impact all laboratories in these standards. However, it shall impact waived laboratories performing HIV in California more in that these procedures are not required of any other waived test.

**Comment 3L: Old Section 1230 (b):** The commenter said eliminating specific approval to perform HIV testing is a good idea.

**Accept:** The Department appreciates the support for this action.

**Comment 3M:** The commenter states that these regulations should specify that all laboratories performing waived HIV should have a certificate of waived from CLIA.

**Reject:** The Department notes that this is already required in state law and need not be specified here.

**Comment 3N:** The commenter states that regulatory language should be added to remind laboratories that HIV is a reportable disease.

**Reject:** The Department notes that this is already stated in Department regulations and need not be added here.

**Comment 3O:** The commenter states that regulatory language should be added to remind non-diagnostic general health assessment (NGHA) programs that they are not authorized to perform HIV.

**Reject:** The Department notes that this is already stated in statute and need not be added here.

**Comment 3P:** The commenter asks that if an HIV test kit is approved by the US FDA as an over-the-counter HIV test kit, can an NGHA program perform waived HIV?

**Response:** The Department notes that state law prohibits NGHA from performing any type of HIV test.

**Comment 3Q:** The commenter feels there are more requirements for non-HIV tests performed at NGHA programs than for HIV tests performed by waived laboratories. She urges stricter standards for HIV tests because of the health implications.

**Accept:** The Department has specified stricter standards for laboratories performing waived HIV tests by requiring competency testing of personnel and quality assurance procedures.

**Comment 3R: Section 1230 (a)(2):** The commenter asks to whom HIV results shall be reported and whether counseling is provided.

**Response:** The Department notes that reporting of HIV results and counseling provided the patient is already required and specified in Department regulations and need not be reiterated here.

**COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC.** The modified text was made available to the public for a 15-day comment period from March 18, 2009 to April 1, 2009. No additional comments to these proposed standards were received during that time.

## DOCUMENTS RELIED UPON

The following documents were relied upon for formulating the reasoning behind the proposed amendments to CCR, Title 17, Section 1230

- (1) Title 42 Code of Federal Regulations 493 Federal Register Volume 68, Number 16, January 24, 2003, Rules and Regulations.
- (2) 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>.
- (3) 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.
- (4) Guidelines for Laboratory Test Result Reporting of Human Immunodeficiency Virus Type 1 Ribonucleic Acid Determination, Mortality and Morbidity Weekly 50-11/16/2001, page 1-12..
- (5) FDA's Role in HIV/AIDS, U.S. Food and Drug Administration Notice, August 2006, <http://www.fda.gov/oashi/aids/fdarole.html>
- (6) Rapid HIV-1 Diagnostic Algorithms for Use in HIV Infection Screening, E. Calero et al, Walter Reed Army Institute of Research. Presented at XIV International AIDS Conference, July 7-12, 2002, Barcelona, Spain.
- (7) Point-of-Care Rapid Tests for HIV Antibodies, B.M.Branson, J Lab Med 2003: 27(7/8) 288-295.
- (8) 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>; Last Modified: November 20, 2007.
- (9) A Rapid Review of Rapid HIV Antibody Tests, J. L. Greenwald, et al, Current Infectious Disease Reports 2006, 8:125-131.