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TO: ALL INTERESTED PARTIES

SUBJECT: GUIDANCE FOR HIV CONFIRMATION TESTING IN HIV TESTING VENUES

With this guidance the California Department of Public Health, Center for Infectious Diseases, Office of AIDS (OA) seeks to clarify current statute and regulation related to HIV confirmation testing in consideration of advances in HIV testing technology.

*Background*

Diagnosis of HIV is regulated by Title 17, California Code of Regulations (CCR), Section 1230. This regulation states that reactive Food and Drug Administration-approved screening tests must be confirmed using confirmation protocols recommended by the Centers for Disease Control and Prevention (CDC) as published in the Mortality and Morbidity Weekly Report (MMWR). The MMWR has published two articles related to the confirmation of an HIV diagnosis:

CDC. *Interpretation and Use of the Western Blot Assay for Serodiagnosis of Human Immunodeficiency Virus Type 1 Infections*. MMWR Supplements July 21, 1989, 38(s-7); 1-7.

CDC. *Update: HIV Counseling and Testing Using Rapid Test – United States, 1995*. MMWR, March 27, 1998; 47(11); 211-15.

These articles describe best practices for providing HIV screening, confirmation testing, and diagnosis. With regard to conventional HIV testing processed at a reference lab, a client's or patient's specimen is screened with one enzyme immunoassay (EIA). If that EIA is reactive, another EIA is performed. If that EIA is reactive, a Western Blot or immunofluorescent assay is performed. If that is reactive the patient is given a confirmed HIV diagnosis. This entire process can take up to one week.

With the introduction of rapid HIV testing, clients and patients can receive HIV screening results immediately after the test is processed, usually within 20 minutes. If the rapid

HIV test is non-reactive a client or patient is told that their HIV test is negative, informed about the window period and referred for future HIV testing if appropriate.

If the HIV screening result is reactive, the client or patient is told they have a preliminary HIV-positive result and further testing is needed to confirm an HIV-positive result. Usually the HIV testing site, such as an emergency department or the HIV counseling, testing, and referral site as referred to in California Health and Safety Code Section 120917, will obtain a specimen for a reference laboratory to process an HIV confirmation test. Clients and patients typically must return to that venue a week later for results.

Advances in HIV testing diagnostics technology allows for clients and patients receiving a preliminary HIV-positive test result to be linked directly to HIV care and treatment and receive their HIV confirmation test at that site. HIV care sites must confirm a patient's HIV status before providing HIV treatment. The procedure would eliminate the cost of the HIV confirmation test at the HIV testing venue, thereby freeing up funding for more HIV screening and allowing test sites to concentrate efforts on ensuring that patients become engaged in follow-up care.

A thorough review of statute and regulation indicates that this procedure can be followed in California at all HIV testing venues if they choose to do so.

There are distinct advantages and challenges for HIV testing venues pursuing this method of HIV confirmation testing that should be carefully considered before employing this strategy.

#### *Advantages*

Clients and patients are linked more quickly to HIV care and treatment. This allows them to establish the relationships necessary to fully engage in HIV care and treatment.

Repetition of the HIV confirmatory test, first at the testing venue and then at the care venue, is avoided, thereby saving scarce resources.

HIV testing venues can use funding allocated for HIV confirmation testing to provide increased HIV screening.

*Challenges*

CCR only provides for reporting of confirmed HIV-positive tests by health care providers to the local health officer (Title 17, CCR, Section 2643.5) and only permits the local health officer to report confirmed HIV-positive tests to OA for the purpose of HIV surveillance (Title 17, CCR, Section 2643.15). A patient with a preliminary HIV-positive test result cannot be reported to the local health officer or OA for the purpose of HIV surveillance. Therefore, if a patient is referred to HIV care but does not go, the patient will not be reported to the surveillance system as HIV infected. A solid linkage-to-care protocol is necessary for the deferral of HIV confirmation testing to succeed in identifying patients with HIV, confirming their HIV infection, and quickly linking them to HIV care and treatment.

OA can provide technical assistance and support as HIV testing venues determine if referring patients with a preliminary HIV-positive diagnosis directly to HIV care and treatment is an appropriate policy. Please contact Kama Brockmann, of my staff, at (916) 449-5964 or e-mail at: [kama.brockmann@cdph.ca.gov](mailto:kama.brockmann@cdph.ca.gov) with further questions.



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