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State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

September 1, 2014

TO: LABORATORIES THAT PERFORM HIV GENOTYPE TESTING

SUBJECT: REPORTING OF HIV GENOTYPE SEQUENCE DATA REQUIRED BY CALIFORNIA HEALTH AND SAFETY CODE SECTION 121022

The goal of molecular HIV surveillance (MHS) is to collect HIV genotype sequence data so that local and state public health surveillance systems can monitor and investigate patterns and trends in transmission of HIV drug resistance mutations. The Centers for Disease Control and Prevention (CDC) maintains the National HIV Surveillance System (NHSS) and collects HIV genotype sequence data for national, state, and local HIV program planning and evaluation. Modernization of California's HIV surveillance system through implementation of MHS will provide an innovative approach to describing the molecular epidemiology of HIV. California currently has approximately 120,000 persons living with HIV infection reported in the Enhanced HIV/AIDS Reporting System (eHARS) as of December 2013. MHS can be used to assess prevalence and trends in acquired and transmitted HIV drug resistance; evaluate HIV genetic diversity; and describe HIV transmission patterns. This information is beneficial for the purpose of evaluating the impact of HIV prevention and treatment strategies and enhancing our understanding of the burden of HIV in California.

California Health and Safety Code (HSC) Section [121022](#) requires laboratories to report cases of HIV infection to the local health officer. Laboratories are required to report a confirmed HIV test. The California Code of Regulations (CCR), Title 17, Section [2641.30](#) defines a confirmed HIV test as:

- (a) a procedure which verifies the presence of HIV infection as determined by any clinical laboratory test or HIV Test Algorithm or examination used to detect the presence of HIV, a component of HIV, or antibodies to or antigens of HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), and immunofluorescence antibody tests.
OR
- (b) all tests used to monitor HIV infection, including HIV nucleic acid detection.

Laboratories that Perform HIV Genotype Testing

Page 2

September 1, 2014

Under HSC and CCR, HIV genotyping data, including raw genetic sequence data and reports on drug resistance, are reportable because they are used to monitor HIV infection. Local health jurisdictions (LHJ) and the California Department of Public Health, Center for Infectious Diseases, Office of AIDS (OA), are developing a plan for implementing collection of HIV sequencing data from all laboratories. We will be contacting individual laboratories to make arrangements to receive HIV genotyping sequence data. Therefore, please do not send sequence data until you receive additional instructions from your LHJ or OA.

The security and confidentiality of all data reportable to local and state HIV surveillance programs, including HIV sequence data, are guaranteed by HSC Sections [121022](#) and [121025](#). Surveillance data are exempt from the Health Insurance Portability and Accountability Act (HIPAA). However, surveillance data are covered under the Code of Federal Regulation's [\[45 CFR § 164.512\(b\)\]](#) privacy rule which permits covered entities to disclose protected health information, without authorization, to public health authorities

Information about HIV reporting requirements can be found on the Office of AIDS website <http://www.cdph.ca.gov/PROGRAMS/AIDS/Pages/OAHIVReportingLaws.aspx>). For further assistance, please contact your local health department or Jessica Brown, HIV Surveillance Laboratory Coordinator for the HIV Surveillance Section at OA, at (916) 445-9231 or Jessica.Brown@cdph.ca.gov.

Sincerely,



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Chief, Office of AIDS
California Department of Public Health

cc: Local AIDS Directors, all California LHJs
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