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California Department of Public Health



EDMUND G. BROWN JR.
Governor

July 29, 2015 (updated October 03, 2017)

TO: ALL LABORATORIES THAT PERFORM HIV TESTS FOR SAMPLES
ORIGINATING FROM CALIFORNIA

SUBJECT: REPORTING HIV TEST RESULTS TO CALIFORNIA LOCAL HEALTH
OFFICERS

The purpose of this letter is to inform and remind all in-state and out-of-state laboratories conducting HIV tests on biological samples originating in California about the statutory and regulatory reporting requirements.

California HIV Reporting Laws for Laboratories

All laboratories licensed to test biological samples that originate in California—regardless of whether or not the laboratories are actually located within California—are required to report confirmed HIV test results to the health officer of the California local health jurisdiction (LHJ) where the ordering health care provider facility is located. Even though the reporting is redundant, originating laboratories that initially receive the specimens, as well as reference laboratories that process the specimens, are both required to follow HIV reporting laws. A directory of California LHJ HIV Surveillance Coordinators, the individuals at LHJs who can receive HIV laboratory reports, is available. To obtain the most current copy of the directory, you may wish to contact Emily Phillips, Chief of the HIV Surveillance Quality Management Unit at (916) 322-6804 or emily.phillips@cdph.ca.gov.

Electronic Laboratory Reporting (ELR)

Reporting HIV test results through California's Electronic Laboratory Reporting (ELR) system will satisfy the statutory and regulatory reporting requirements for HIV laboratory reporting. The California Department of Public Health, Office of AIDS initiated the reporting of HIV test results through ELR during 2015.

Office of AIDS, MS 7700, P.O. Box 997426, Sacramento, CA 95899-7426

Telephone: (916) 449-5900 / Fax: (916) 449-5909

[Internet address \(https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAmain.aspx\)](https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OAmain.aspx)

California Statutes and Regulations

California Health and Safety Code (HSC) Section [121022\(a\)](#) requires laboratories to report confirmed cases of HIV infection to the local health officer. For HIV reporting purposes, a “laboratory” is defined in California Code of Regulations (CCR), Title 17, Section [2641.60](#) as “a ‘clinical laboratory,’ a ‘physician office laboratory,’ or a ‘public health laboratory,’ as defined in Business and Professions Code (BPC), Section [1206](#), that is authorized to perform clinical laboratory tests or examinations in California, or a clinical laboratory located outside of the State of California that is licensed pursuant to BPC Section [1241\(a\)](#) and that tests specimens originating in California.”

Confirmed HIV test results must be reported within 7 days by laboratories to the health officer for the local health jurisdiction where the ordering health care provider facility is located, 17 CCR Section [2643.10\(a\)](#). The information that must be included in these reports is detailed in this same section.

Laboratories are required to confirm all reactive or indeterminate HIV test results per 17 CCR Section [1230](#). A “confirmed HIV test” is defined broadly in 17 CCR Section [2641.30](#) as “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 . . . all tests used to monitor HIV infection, including HIV nucleic acid detection.” All CD4+ T-Cell test results related to HIV infection are specifically required to be reported per HSC Section [121023](#).

How to Comply with California HIV Reporting Laws for Laboratories

In order to be in compliance with California’s HIV reporting laws for laboratories, please report all confirmed HIV test results for samples originating from California laboratories or health care providers to the health officer for the local health jurisdiction in California where the ordering health care provider facility is located. For those entities licensed pursuant to BPC Section [1241](#), please note that penalties may apply for non-compliance with applicable clinical laboratory licensing laws, per BPC Section [1310](#).

Effective surveillance of the California HIV/AIDS epidemic requires complete, timely, and accurate reporting of all HIV test results. Thank you for your efforts toward helping us achieve this goal. As of April 25, 2017, please contact Deanna Sykes, Ph.D., HIV Surveillance Section Chief at the California Office of AIDS, at (916) 449-5835 or Deanna.Sykes@cdph.ca.gov for further assistance.

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Sincerely,



Karen Mark, M.D., Ph.D.

Chief, Office of AIDS

California Department of Public Health

cc: Local AIDS Directors, all California LHJs
Surveillance Coordinators, all California LHJs
Jessica Brown, HIV Surveillance Laboratory Coordinator, Surveillance Section
Scott Masten, Chief, Surveillance Section
Gary Horpedahl, Chief, Surveillance Quality Management Unit
Valorie Eckert, Chief, Data Management and Analysis Unit
Juliana Grant, Chief, Surveillance, Research & Evaluation Branch

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A description complete with Internet addresses of the references used in this document follow. The Internet addresses were accessed October 03, 2017.

[California Health and Safety Code \(HSC\) Section 121022\(a\)](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=121022&lawCode=HSC)

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=121022&lawCode=HSC

[17 California Code of Regulations \(CCR\) Section 2641.60](https://govt.westlaw.com/calregs/Document/IE12A2630D60511DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))

[https://govt.westlaw.com/calregs/Document/IE12A2630D60511DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/IE12A2630D60511DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))

[Business and Professions Code \(BPC\) Section 1206](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC§ionNum=1206)

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC§ionNum=1206.

[BPC Section 1241](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC§ionNum=1241)

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC§ionNum=1241.

[17 CCR Section 2643.10 \(a\)](https://govt.westlaw.com/calregs/Document/I63266290BA1F11E4B047E81FC17CBBB4?contextData=(sc.Search)&rank=1&originationContext=Search+Result&navigationPath=Search%2fv3%2fsearch%2fresults%2fnavigation%2fi0ad70f700000014de920444d181c8f5b%3fstartIndex%3d1%26Nav%3dREGULATION_PUBLICVIEW%26contextData%3d(sc.Default)&list=REGULATION_PUBLICVIEW&transitionType=SearchItem&listSource=Search&viewType=FullText&t_T1=17&t_T2=2643.10&t_S1=CA+ADC+s)

[https://govt.westlaw.com/calregs/Document/I63266290BA1F11E4B047E81FC17CBBB4?contextData=\(sc.Search\)&rank=1&originationContext=Search+Result&navigationPath=Search%2fv3%2fsearch%2fresults%2fnavigation%2fi0ad70f700000014de920444d181c8f5b%3fstartIndex%3d1%26Nav%3dREGULATION_PUBLICVIEW%26contextData%3d\(sc.Default\)&list=REGULATION_PUBLICVIEW&transitionType=SearchItem&listSource=Search&viewType=FullText&t_T1=17&t_T2=2643.10&t_S1=CA+ADC+s](https://govt.westlaw.com/calregs/Document/I63266290BA1F11E4B047E81FC17CBBB4?contextData=(sc.Search)&rank=1&originationContext=Search+Result&navigationPath=Search%2fv3%2fsearch%2fresults%2fnavigation%2fi0ad70f700000014de920444d181c8f5b%3fstartIndex%3d1%26Nav%3dREGULATION_PUBLICVIEW%26contextData%3d(sc.Default)&list=REGULATION_PUBLICVIEW&transitionType=SearchItem&listSource=Search&viewType=FullText&t_T1=17&t_T2=2643.10&t_S1=CA+ADC+s)

[17 California Code of Regulations \(CCR\) Section 1230](https://govt.westlaw.com/calregs/Document/IEC1FDA10CC2A11E3948B9615BBCB2C0E?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))

[https://govt.westlaw.com/calregs/Document/IEC1FDA10CC2A11E3948B9615BBCB2C0E?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/IEC1FDA10CC2A11E3948B9615BBCB2C0E?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))

[17 CCR Section 2641.30](https://govt.westlaw.com/calregs/Document/IDF4DC510D60511DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))

[https://govt.westlaw.com/calregs/Document/IDF4DC510D60511DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=\(sc.Default\)](https://govt.westlaw.com/calregs/Document/IDF4DC510D60511DE88AEDDE29ED1DC0A?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default))

[HSC Section 121023](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC§ionNum=121023)

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC§ionNum=121023.

[BPC Section 1310](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC§ionNum=1310)

http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=BPC§ionNum=1310.