



MARK B HORTON, MD, MSPH
Director

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



ARNOLD SCHWARZENEGGER
Governor

December 19, 2008

TO: DIRECTORS, CALIFORNIA CLINICAL AND PUBLIC HEALTH
LABORATORIES PERFORMING CD4+ TESTING

SUBJECT: NEW CALIFORNIA LAW REQUIRING CD4 REPORTING

This letter is to announce that Governor Arnold Schwarzenegger signed into law Senate Bill (SB) 1184 (Kuehl, Chapter 347, Statutes of 2008), which requires each clinical laboratory to report all CD4+ T-cell tests to the local health officer (LHO) within seven days of the completion of a CD4+ T-cell test. The new reporting requirements took effect immediately upon the Governor's signature on September 26, 2008.

The Office of AIDS (OA) and local health department staff are available to assist laboratories in implementing the requirements of the new law. SB 1184 requires:

- Each clinical laboratory to report CD4+ T-cell test results to LHO for the local health jurisdiction where the health care provider facility is located within seven days of completion of the CD4+ T-cell test.
- Laboratories to include specific patient information when reporting CD4+ T-cell test results if that information is provided by the ordering health care provider.
 - The patient's name, date of birth, and gender.
 - The name, telephone number, and address of the local health care provider that ordered the test.
- Laboratories to include specific clinical and laboratory-related information when reporting CD4+ T-cell test results.
 - CD4+ T-Cell test results shall be expressed as an absolute count (the number of lymphocytes containing the CD4 epitope per cubic millimeter) and, if available, the relative count (the number of lymphocytes expressing the CD4 epitope as a percentage of total lymphocytes).
 - The type of laboratory test performed; the date the laboratory test was performed; the name, telephone number, and address of the clinical laboratory that performed the test; the Clinical Laboratory Improvement Amendment number and the laboratory report number.
- LHOs to determine if the CD4+ T-cell test report is related to a case of HIV infection.

Directors, California Clinical and Public Health
Laboratories Performing CD4+ Testing

Page 2

December 19, 2008

- LHOs to destroy any CD4+ T-cell test reports that are not related to a case of HIV infection.
- LHOs to report the case of HIV infection or AIDS, as appropriate, to OA within 45 days of receipt of the laboratory report.
- CD4+ T-cell test reports shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding.
- CD4+ T-cell test reports to be considered confidential public health records.

In California, active HIV surveillance is facilitated by laboratory reporting of confirmed positive HIV antibody and viral load tests to LHOs. CD4+ T-cell tests are the primary laboratory test used to document immune status and progression to an AIDS diagnosis. Requiring CD4+ T-cell test results to be reported to LHOs will facilitate active surveillance of AIDS and will help capture additional unreported cases of HIV infection. Note that OA has been receiving CD4 counts from some LHOs for years as part of the HIV/AIDS surveillance system, but this was not a requirement before SB 1184.

In order to evaluate whether CD4+ T-cell test results are being reported, OA will review the completeness of CD4+ T-cell test result data in the HIV/AIDS Reporting System before and after the effective date of SB 1184. In addition, OA will evaluate trends in HIV/AIDS case reporting to assess if SB 1184 may have increased case reporting. OA will consult with the California Conference of Local Health Officers and the California Conference of Local AIDS Directors regarding further development of the evaluation strategy.

CD4+ T-cell reporting will increase California's HIV/AIDS case counts, which ensures that OA as well as California's Ryan White Program-eligible local health jurisdictions remain competitive for federal funding. Reported HIV and AIDS cases are used in the federal funding formula utilized by the Health Resources and Services Administration, which administers the Ryan White HIV/AIDS Treatment Modernization Act of 2006.

For further assistance, please contact Ms. Teresa Lauchaire, Acting Chief, HIV/AIDS Case Registry Section, at (916) 449-5954 or the HIV/AIDS surveillance coordinator at your local health jurisdiction. Please feel free to share this information with other interested parties. The full text of SB 1184 and its specific reporting requirements is available online at <http://www.leginfo.ca.gov/> under "Bill Information." OA has also posted "SB 1184 Talking Points" on the OA Web site <http://www.cdph.ca.gov/programs/AIDS>.



Michelle Roland, MD, Chief
Office of AIDS

cc: See Next Page

Directors, California Clinical and Public Health
Laboratories Performing CD4+ Testing

Page 3

December 19, 2008

cc: California Conference of Local Health Officers

California Conference of Local AIDS Directors

HIV/AIDS Surveillance Coordinators

Mark Damesyn, Dr.P.H.
Acting Chief
HIV/AIDS Case Registry Section
Office of AIDS
California Department of Public Health
MS 7700
P.O. Box 997426
Sacramento, CA 95899-7426