

Neuman, D. et. al. *Performance of the new HIV-1/2 Diagnostic Algorithm in Florida's Public Health Testing Population: A Review of the First Five Months of Utilization*. 2012 HIV Diagnostics Conference Program Book, December 12-14, 2012, Atlanta, Georgia. <https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/b7a7473c5a084eeca23e146649e3f33.pdf>, <https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/6eebbfa7fb1b4553b9676161e980b211.pdf>.

Shackman, B.R. et. al. *Lifetime Cost of Current Human Immunodeficiency Virus Care in the United States*. *Medical Care*. Vol. 44, No. 11, November 2006. <http://webserver.rilin.state.ri.us/HIV/Documents/lifetimecostofHIV.pdf>

STATEMENTS OF DETERMINATIONS

LOCAL MANDATE DETERMINATION

CDPH has determined that the regulation 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.

FISCAL IMPACT ESTIMATE

1. Fiscal Impact on Local Government: None. CDPH is not aware of any cost impacts that a local health department laboratory would necessarily incur in reasonable compliance with the proposed action because the new HIV testing algorithm is not required to be used by licensed laboratories. Under this proposed action, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.
2. Fiscal Impact on State Government: None. CDPH is not aware of any cost impacts that a State laboratory would necessarily incur in reasonable compliance with the proposed action because the new HIV testing algorithm is not required to be used by licensed laboratories. Under this proposed action, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.
3. Fiscal Impact on Federal Funding of State Programs: None.
4. Fiscal Impact on Private Persons or Businesses Directly Affected: CDPH is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action because the new HIV testing algorithm is not required to be used by licensed laboratories. CDPH estimates that the costs for existing HIV algorithm is approximately \$4.34 to \$5.34 per patient sample, and utilizing the newly developed HIV test algorithm will cost approximately \$3.44 to \$8.44 depending on the volume of the laboratory and the

number of highly complex diagnostic steps required for a particular patient sample. These cost estimates include rental of laboratory equipment from the test manufacturer (standard laboratory operation cost). Under this proposed action, licensed laboratories are allowed to continue to use the existing HIV test algorithm if they so choose at no increase or decrease in cost.

5. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: There are no known costs or savings imposed on local agencies in connection with this emergency regulatory package.

6. Mandate on Local Agencies or School Districts: None. There are no known mandates on local agencies or school districts.

ALTERNATIVES CONSIDERED

In accordance with Government Code Section 11346.5, subdivision (a)(13), CDPH has determined that no reasonable alternative considered or that has otherwise been identified and brought to the attention of CDPH would be more effective in carrying out the purpose for which this emergency action is proposed, would be as effective and less burdensome to affected private persons than the proposed action or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

ADVISORY GROUP OR OTHER AGENCY COMMENT, CONSULTATION AND/OR APPROVAL, INCLUDING CALIFORNIA CONFERENCE OF LOCAL HEALTH OFFICERS

This proposal is supported by the California Association of Public Health Laboratory Directors.