

**State of California  
Office of Administrative Law**

**In re:**

**Department of Public Health**

**Regulatory Action:**

**Title 17, California Code of Regulations**

**Adopt sections:**

**Amend sections: 1230, 2641.57**

**Repeal sections:**

**NOTICE OF APPROVAL OF CERTIFICATE OF  
COMPLIANCE**

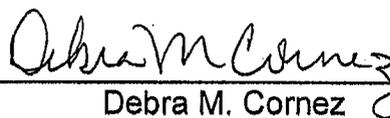
**Government Code Section 11349.1 and  
11349.6(d)**

**OAL File No. 2014-0314-03 C**

This certificate of compliance makes permanent the Department's prior emergency regulatory actions (OAL file nos. 2013-1210-03EE and 2013-0617-01E) that amended the current HIV screening testing protocols to allow a newly developed HIV testing algorithm developed by federal public health agencies and national HIV laboratory associations, as well as the Centers for Disease Control and Prevention, to be used by licensed California laboratories for laboratory screening testing for HIV.

OAL approves this regulatory action pursuant to section 11349.6(d) of the Government Code.

**Date: 4/16/2014**



**Debra M. Cornez  
Director**

**Original: Dr. Ron Chapman, MD, MPH  
Copy: Elizabeth Reyes**



(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

<b>OAL FILE NUMBERS</b>	<b>NOTICE FILE NUMBER</b> Z-2013-1121-01	<b>REGULATORY ACTION NUMBER</b> 2014-0314-03C	<b>EMERGENCY NUMBER</b>
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**ENDORSED FILED**  
IN THE OFFICE OF

2014 APR 16 PM 2:09

*Debra Bowen*  
DEBRA BOWEN  
SECRETARY OF STATE

For use by Office of Administrative Law (OAL) only	
NOTICE	REGULATIONS

2014 MAR 14 PM 4:02  
OFFICE OF  
ADMINISTRATIVE LAW

<b>AGENCY WITH RULEMAKING AUTHORITY</b> Department of Public Health	<b>AGENCY FILE NUMBER (if any)</b> DPH-13-007E
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**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
<b>OAL USE ONLY</b> <input checked="" type="checkbox"/> Approved, as Submitted	<input type="checkbox"/> Approved, as Modified	<input type="checkbox"/> Disapproved/Withdrawn	<b>NOTICE REGISTER NUMBER</b> 2013 492
			<b>PUBLICATION DATE</b> 12/6/2013

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S) HIV Screening Testing by Laboratories	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2013-0617-01E, 2013-1210-03EE
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	
<b>SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)</b>	ADOPT
	AMEND 1230, 2641.57
TITLE(S) 17	REPEAL

3. TYPE OF FILING

<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input checked="" type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify) _____	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)  
N/A

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input checked="" type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify) _____
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input checked="" type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input checked="" type="checkbox"/> Other (Specify) <i>HSC §131205 Calif. Conference of Local Health Officers per agency rmc 4-16-14</i>		

7. CONTACT PERSON Elizabeth Reyes, Regulations Coordinator	TELEPHONE NUMBER (916) 445-2529	FAX NUMBER (Optional) (916) 319-9821	E-MAIL ADDRESS (Optional) Elizabeth.Reyes@cdph.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Karin S. Schwartz</i>	DATE 3/13/14
TYPED NAME AND TITLE OF SIGNATORY Karin S. Schwartz, Deputy Director and Chief Counsel	

For use by Office of Administrative Law (OAL) only

**ENDORSED APPROVED**

APR 16 2014

Office of Administrative Law

1) Adopt Section 1230 as follows:

**1230. HIV Screening Testing by Laboratories.**

(a) All clinical laboratories that perform waived, moderate or high complexity tests or examinations to screen for human immunodeficiency virus (HIV) shall do all of the following:

(1) Utilize United States Food and Drug Administration (FDA) approved test systems in accordance with the manufacturers' instructions. Any laboratory that modifies a non-waived FDA-approved kit shall establish and verify the performance specifications pursuant to 42 Code of Federal Regulations Section 493.1253.

(2) Confirm all reactive or indeterminate HIV test results by following the HIV diagnostic protocols recommended by the federal Centers for Disease Control and Prevention, the Clinical and Laboratory Standards Institute, the Association of Public Health Laboratories or the U.S. Department of Health and Human Services prior to reporting the result as positive.

(3) Establish and maintain a quality assurance program that includes all of the following:

(A) Evaluation and documentation of testing personnel by direct observation, training, and competency testing to ensure tests are accurately performed and reported. This shall be done prior to testing, six months later and then yearly as long as assessment of test performance is acceptable. If the testing personnel fail any assessment of test performance given in subpart (B), the testing personnel shall be removed from testing, retrained and their competency re-evaluated.

(B) Assessment and documentation of test performance by testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples at least twice yearly and monitored by the laboratory director.

(b) Failure to comply with all the requirements of this section shall subject the laboratory to sanctions pursuant to Business and Professions Code Section 1320.

Note: Authority cited: Sections 1603.1(f), 131050 and 131200, Health and Safety Code; and Section 1224, Business and Professions Code. Reference: Sections 1220 and

1265, Business and Professions Code; and Sections 1603.1, 101160, 120895, 131050, 131051 and 131052, Health and Safety Code.

2) Adopt Section 2641.57 as follows:

**2641.57. HIV Test Algorithm.**

"HIV test algorithm" means any multi-test procedure that determines the presence of HIV infection using diagnostic protocols recommended by the Centers for Disease Control and Prevention, the Clinical and Laboratory Standards Institute, the Association of Public Health Laboratories or the U.S. Department of Health and Human Services.

Note: Authority cited: Sections 120125, 120130, 121022, 131080 and 131200, Health and Safety Code. Reference: Sections 1206 and 1220, Business and Professions Code; and Sections 120917, 121022, 131051, 131052 and 131056, Health and Safety Code.