

FINDING OF EMERGENCY

The director of the California Department of Public Health (CDPH) finds an emergency exists and that the proposed emergency regulatory amendments are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety or general welfare in accordance with Government Code sections 11346.1(b)(1) and 11342.545.

As required by Government Code Section 11346.1(a)(2), CDPH must, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law (OAL), provide a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with CDPH. After submission of the proposed emergency action to OAL, OAL shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code Section 11349.6.

INTRODUCTION

CDPH proposes emergency regulatory amendments to the California Code of Regulations (CCR), Title 17, Sections 1230 and 2641.57. These amendments would immediately allow a newly developed Human Immunodeficiency Virus (HIV) testing algorithm to be used by licensed laboratories in California. These amendments would also permit the immediate use of future developed protocols if they are recommended by the Centers for Disease Control and Prevention (CDC), the Clinical and Laboratory Standards Institute (CLSI), the Association of Public Health Laboratories (APHL) or the U.S. Department of Health and Human Services (DHHS). The proposed emergency regulatory action deletes the existing language in Sections 1230 and 2641.57 that requires recommended CDC protocols be published in the *Morbidity and Mortality Weekly Report* (MMWR) prior to use by a California licensed laboratory or approved public health laboratory.

AUTHORITY

CDPH is authorized to adopt and enforce regulations pursuant to California Health and Safety (H&S) Code sections 131056 and 131200 for the execution of its duties. CDPH's, Office of AIDS has been delegated the statutory authority to coordinate HIV/AIDS-related programs and HIV reporting in California pursuant to H&S Code sections 121022, 131019, and 131051. H&S Code section 1603.1(f) gives CDPH the authority to adopt regulations governing the procedures as it deems necessary to protect the public health and safety regarding reporting HIV infections, and H&S Code section 120895 authorizes CDPH to establish HIV testing methods for anonymous HIV testing and blood plasma supply testing. Business and Professions Code, Article 2, section 1224 gives CDPH authority to adopt, amend or repeal any Business and Professions regulations necessary for the administration of laboratories.

SPECIFIC FACTS SHOWING THE NEED FOR IMMEDIATE ACTION

CDPH expressly finds that the situation these proposed amendments are intended to address is a factual emergency, meaning a situation that calls for immediate action to avoid serious harm. These amendments will allow laboratories to use a newly developed HIV testing algorithm that can identify positive HIV test results within 14 days of infection, as many as 31 days earlier than the existing HIV algorithm. This will allow for earlier notification of HIV test results to the patient, provide more rapid referrals for appropriate HIV treatment, and it will save lives.

California laboratories must be able to implement the use of this superior algorithm immediately in order to significantly decrease the number of Californians becoming infected with HIV. Current estimates indicate that approximately 15 to 16 Californians each day are infected with HIV, and research suggests that people with acute infection may account for up to half of those newly infected. Half of new cases of HIV infection are also related to people who are unaware of their HIV positive status and are at an early and acute infectious stage. Early identification of acute HIV infection saves lives by lowering the transmission of HIV to non-infected members of the public and by more quickly addressing medical needs of those who test positive for HIV. Earlier detection also dramatically reduces the costs of treating HIV-positive patients. At the end of 2012, 117,695 Californians were reported to be living with HIV/AIDS. It is estimated that another 27,000 Californians have HIV but are unaware of their status. CDPH estimates that each year another 5,000 to 6,000 Californians become infected with HIV. While people infected with HIV may live a normal life span, they spend their lives battling a chronic illness that takes its toll on their livelihoods and families.

CDPH finds that these facts demonstrate the substantial evidence necessary pursuant to Government Code section 11346.1(b)(2) to support this emergency regulatory action. Without this newly developed and superior HIV testing algorithm, more Californians each day will continue to be infected with HIV than would happen utilizing the new HIV testing algorithm. This specific emergency regulatory action will avoid serious harm to people with acute HIV infection by identifying their acute infection earlier so treatment can begin earlier. This emergency regulatory action will also reduce the number of HIV transmission cases to uninfected individuals, thus avoiding serious harm to public health and safety. Permitting laboratories in California to use test protocols recommended by CDC, CLSI, APHL or DHHS will make newly developed HIV test protocols immediately available to Californians in the future. This emergency regulatory action is narrowly tailored so licensed laboratories can immediately utilize newly developed laboratory protocols that will more quickly identify acute HIV infections and thereby save lives and avoid serious harm to others.

This emergency regulation proposal by CDPH is not based upon expediency, convenience, best interest, general public need or speculation. The situation was not known to exist by CDPH in sufficient time to have addressed it through nonemergency regulations. (See Government Code, section 11346.1(b)(2); Title 1, CCR, section

52(b)(2)). When this new HIV testing algorithm became available, CDPH understood that CDC would urgently recommend and publish the new algorithm by the end of 2012. However, in December 2012, CDC staff informed CDPH that it would be late 2013 or 2014 before CDC would complete the steps necessary to formally recommend the new algorithm. CDPH staff was also told at that time that CDC will not publish the new algorithm in CDC's MMWR as was CDC's practice in the past. Instead, CDC will publish the new algorithm and all subsequent recommendations on the website www.AIDSinfo.gov. CDPH reacted to this news quickly by proposing this emergency regulatory action to delete and amend existing restrictions in Title 17 that limit licensed California laboratories from using the most current recommended HIV testing algorithms.

Authority and Reference Citations:

Authority: Sections 1603.1(f), 120125, 120130, 120895, 121022, 131019, 131050, 131080, 131056, and 131200, Health and Safety Code and Section 1224, Business and Professions Code.

Reference: Sections 1603.1, 101160, 120895, 120917, 121022, 131050, 131051, 131052 and 131056, Health and Safety Code and Sections 1206, 1220, and 1265, Business and Professions Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Background:

The first cases of AIDS were first identified in 1981, and testing for HIV became available in 1985. In 1986, California enacted Title 17, section 1230 that mirrored the recommendation from CDC and APHL to use a sequential two-test algorithm to diagnose HIV-1. This laboratory protocol identifies positive HIV test results within approximately 45 days of infection.

Since then, HIV research, treatment, and testing protocols have improved dramatically. Today, California is the one of the only states with high HIV prevalence that is not able to use a newly recommended HIV testing protocol or algorithm that can detect acute HIV infection within 14 days of infection, as many as 31 days earlier than the existing HIV algorithm. In addition, the existing HIV algorithm can take 7 to 10 days to process and return test results. Since the existing HIV algorithm confirmation test takes a long time to process, these tests are often run in batches two or three times a week rather than every day. In comparison, the new HIV test algorithm can be processed with results back within 1 to 3 days. Combined with the time saving of earlier detection, the new HIV test algorithm reduces the time for diagnosing acute HIV infection from between 52 and 55 days down to 15 to 17 days.

The use of this new HIV testing algorithm is supported by the California Association of Public Health Laboratory Directors¹ and the California Conference of Local Health Officers. CLSI² has recommended the use of this new HIV testing algorithm for supplemental testing after a reactive HIV screening test. The CDC and the APHL have also proposed the use of this new algorithm. Importantly for California, the new HIV testing algorithm identifies *acute* HIV infection, a critical feature that the existing algorithm is unable to do. In a side-by-side comparison of the existing and new algorithm over an 18-month period, the San Diego Public Health Laboratory found 14 acute HIV infections that would not have been detected using the existing laboratory algorithm.³ The San Francisco Public Health Laboratory also ran a side-by-side comparison of the existing and new algorithm and found 19 acute HIV infections in 2012. These early acute HIV infection cases were not detected using the existing HIV algorithm.

Early detection of HIV is essential to decreasing the transmission of HIV to non-infected individuals. Research and public health studies show that people with acute HIV infection are more likely to transmit HIV than those with established infections.⁴ CDC also found that people with early infection are more likely to transmit than those with established infections due to high viral load and viral variants more able to cause infection.⁵

Phylogenetic analysis of viral gene sequences has shown that people with early infection may account for between 24 and 50 percent of new transmissions of HIV infection.⁶ In addition, a 2005 meta-analysis of eight studies showed that people who knew their HIV positive status were 68 percent less likely to engage in risky sexual behaviors with people of unknown HIV status than people who did not know their HIV

¹ California Association of Public Health Laboratory Directors' letter of support, dated February 6, 2013.

² CLSI. *Criteria for Laboratory Testing and Diagnosis of HIV: Approved Guideline*. CLSI document M53-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011. This guidance is proprietary although all certified laboratories use this document. <http://shopping.netsuite.com/s.nl/c.1253739/it.A/id.250/f>

³ Manlutac, A.M. *Identification of Early HIV Infections Using the Fourth Generation Abbott Architect HIV Ag/Ab Combo Chemiluminescent Microparticle Immunoassay (CIA) in San Diego County*. 2012 HIV Diagnostics Conference Program Book, p. 21.
<https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/b7a7473c5a084eecaa23e146649e3f33.pdf>
<https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/5aed5ead2525484fa1981dedad756cf4.pdf>

⁴ Branson, B., & Mermin, J. *Establishing the Diagnosis of HIV Infection: New Tests and a New Algorithm for the United States*. *Journal of Clinical Virology*, 52S(2011) S3-S4.
[http://www.journalofclinicalvirology.com/article/S1386-6532\(11\)00387-8/fulltext](http://www.journalofclinicalvirology.com/article/S1386-6532(11)00387-8/fulltext)

⁵ *Ibid.*

⁶ Brenner, B.G. et al. *High Rates of Forward Transmission Events after Acute/Early HIV-1 Infection*. *Journal of Infectious Disease*, 2007;195, 951–959 (April 1).
<http://jid.oxfordjournals.org/content/195/7/951.full.pdf+html?sid=1098401a-b005-4098-83a7-f87959b6a47a>

status.⁷ Allowing and encouraging California laboratories to implement use of this superior algorithm will decrease HIV transmission within California.

CDC estimates that prevention efforts in the United States have averted more than 350,000 HIV infections.⁸ In addition to the lives saved from HIV, it is estimated that more than \$125 billion in medical costs have been averted. Yet, HIV continues to be an epidemic in the United States and California. CDC estimates that in 2010, approximately 1,148,200 people in the United States lived with HIV/AIDS. At the end of 2012, 117,695 Californians were reported to be living with HIV/AIDS. It is estimated that another 27,000 Californians have HIV but are unaware of their status. CDPH estimates that each year another 5,000 to 6,000 Californians become infected with HIV. The projected life expectancy of someone from the time of entering HIV care is 24.2 years. Total discounted costs associated with the lifetime care of a person with HIV are estimated at \$385,200.⁹ HIV also decreases personal productivity and the quality of life for all affected Californians. If a person's HIV is undetected and untreated, their HIV disease will most likely progress to an AIDS diagnosis. While HIV care and treatment has improved, people with HIV still have to manage a long-term and chronic illness. This illness takes its toll on their capacity to work, their contributions to society and affects their families. Since research suggests between a quarter and half of all new infections are caused by people with acute HIV infection, widespread use of the new HIV testing algorithm could significantly decrease this number.

On a technical level, this newly developed HIV testing algorithm is more accurate than the existing HIV algorithm because the initial test is a sensitive screening assay that detects HIV-1 and HIV-2 or antibodies to these two viruses. If this initial test is reactive, a supplemental test is performed to differentiate between HIV-1 and HIV-2. If the supplemental test is also reactive, HIV-1 or HIV-2 is established. If the supplemental test is non-reactive or indeterminate, the specimen is further tested for acute HIV infection that neither of the first two tests could determine.

States with high prevalence of HIV/AIDS comparable to California such as New York and Florida¹⁰ are permitted to use this newly developed HIV testing algorithm to identify

⁷ CDC. *Revised Recommendations for HIV Testing of Adult, Adolescents, and Pregnant Women in Health-Care Settings*. *Morbidity and Mortality Weekly Report*. September 22, 2006, Vol. 55, No. RR-14. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>

⁸ CDC. *HIV Prevention in the United States at a Critical Crossroads*. August, 2009. http://www.cdc.gov/hiv/resources/reports/hiv_prev_us.htm

⁹ 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>

¹⁰ 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, p. 42. <https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/b7a7473c5a084eeca23e146649e3f33.pdf>

early HIV/AIDS infections and better protect public health. Both these states have had success identifying acute HIV infection.

Existing Law:

Currently, CCR, Title 17, sections 1230 and 2641.57 define and establish clinical laboratory HIV screening testing protocols and permit only protocols recommended by CDC as published in the MMWR. The current regulatory language restricts licensed California laboratories from using newly developed HIV testing protocols recommended by federal public health agencies and national HIV laboratory associations.

Purpose:

The broad purpose of this emergency regulatory action is to reduce the transmission of HIV during the first months of acute HIV infection by reducing the waiting time for positive HIV test results from 45 days to 14 days from infection and allow for rapid notification of HIV test results to the patient. This emergency regulatory action will reduce the number of newly HIV-infected persons in California and save lives.

The more specific purpose of CDPH's proposed emergency regulatory action is to immediately allow a newly developed HIV testing algorithm to be used by licensed California laboratories to better protect the public health, safety and welfare.

Objectives:

The broad objectives of this proposed regulatory action are to:

- Permit the use of a newly developed HIV testing algorithm by licensed California laboratories to more quickly identify persons with acute HIV infections.
- Reduce the transmission of HIV during the first months of acute infection.
- Reduce the time for HIV test results from 45 days to 14 days from infection and reduce the HIV test processing time from 7 to 10 days down to 1 to 3 days. All combined the time needed to diagnose HIV infection is reduced from 52 to 55 days down to 15 to 17 days.
- Reduce the number of persons newly infected with HIV in California.
- Reduce health care costs by reducing the transmission of HIV to non-infected members of the public in California.

<https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/6eebbfa7fb1b4553b9676161e980b211.pdf>

- Allow superior HIV testing protocols to better protect California's public health and safety.
- Permit use of best laboratory protocols in California so CDPH and California's laboratories continue to be leaders in HIV testing.

Benefits:

Anticipated benefits including nonmonetary benefits to the protection of public health and safety, worker safety, the environment, the prevention of discrimination, or the promotion of fairness or social equity, from this proposed regulatory action are:

- Making a laboratory protocol available to laboratory professionals to determine within 14 days of infection if a person has been infected with HIV, rather than waiting 45 days pursuant to the only protocol currently approved in CCR Title 17.
- Improving health outcomes of newly diagnosed HIV-positive individuals due to earlier diagnosis and linkages to appropriate care and treatment.
- Reducing the transmission of HIV from one infected individual to potentially numerous others during the first months of acute HIV infection.
- Establishing consistency between California's HIV testing protocols and those adopted in other states with high HIV prevalence rates so that California remains a leader in HIV public health.
- Establishing alternative permissive laboratory protocol options rather than prescriptive requirements that meet current and serious concerns of public health officials, laboratory directors and the public.
- Promoting statewide availability of the best laboratory protocol practices that more effectively protect public health and safety.
- Reducing health care costs by reducing the transmission of HIV between members of the public in California.
- Saving lives by reducing the transmission of HIV between members of the public in California.

Pursuant to its authorities, CDPH is proposing to amend CCR Sections 1230 and 2641.57, as follows:

Amend Section 1230: This emergency regulatory proposal would amend Section 1230 to permit licensed laboratories to confirm HIV test results by using a newly developed

HIV testing algorithm or other future diagnostic protocols recommended by CDC, CLSI, APHL or DHHS. This proposal would also delete the requirement that CDC publish its recommended protocols in the MMWR before licensed California laboratories can use CDC recommended protocols.

These amendments are reasonably necessary to permit the immediate use of superior HIV diagnostic protocols recommended by leading HIV researchers and proposed by the federal government. These amendments also provide consistency between California and CDC, eliminate confusion for regulation users and provide clarity for laboratories and the public given CDC no longer publishes its recommended protocols in the MMWR.

CCR Section 1230 also uses the term “confirmation” with respect to the HIV test results. CDC has discontinued use of the terms “confirmation” and “confirmatory” because they imply that the HIV test is in some way a definitive determination of HIV infection. Instead, an HIV diagnosis is obtained by screening and supplemental tests that indicate the presence of HIV antigens or antibodies. The deletion of the word “confirmation” and replacement with the word “diagnostic” in Section 1230 is reasonably necessary to more accurately represent the conclusions that can be drawn from HIV testing protocols. This amendment will also reduce confusion for licensed laboratories using these regulations and provide clarity for the public.

Amend Section 2641.57: This emergency regulatory proposal would amend the definition of “HIV test algorithm” to permit the use of HIV test protocols recommended by CDC, CLSI, APHL or DHHS. This amendment is reasonably necessary so the definition of “HIV test algorithm” does not conflict with the proposed amendments to Section 1230. This amendment will provide clarity for regulation users by avoiding conflicts in wording between these regulatory sections.

Section 2641.57 also uses the term “confirmation” with respect to the HIV test results. CDC has discontinued use of the terms “confirmation” and “confirmatory” because they imply that the HIV test is in some way a definitive determination of HIV infection. Instead, an HIV diagnosis is obtained by screening and supplemental tests that indicate the presence of HIV antigens or antibodies. The deletion of the word “confirmation” and replacement with the word “diagnostic” in Section 2641.57 is reasonably necessary to more accurately represent the conclusions that can be drawn from HIV testing protocols. This amendment will also reduce confusion for licensed laboratories using these regulations and provide clarity for the public.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

CDPH has evaluated whether the proposed regulations are inconsistent or incompatible with existing state regulations. This evaluation included a review of CDPH’s laws and specifically those statutes and regulations related to HIV, laboratory practices and

health and safety. CDPH staff also conducted an internet search of other California and federal regulations.

While several state and federal statutes and regulations relate to HIV and AIDS, no statute or regulation was found that conflicts with this emergency regulatory proposal. CDPH also determined that this regulatory proposal is non-duplicative of any other known state or federal statute or regulation.

No other state regulation or statute addressed the same subject matter. Therefore, CDPH has determined that this proposal, if adopted, would not be inconsistent or incompatible with existing state regulations or statutes.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS OR DOCUMENTS RELIED UPON

Branson, B.M., Mermin, J. *Establishing the Diagnosis of HIV Infection: New Tests and a New Algorithm for the United States*. *Journal of Clinical Virology*, 52S(2011) S3-S4. [http://www.journalofclinicalvirology.com/article/S1386-6532\(11\)00387-8/fulltext](http://www.journalofclinicalvirology.com/article/S1386-6532(11)00387-8/fulltext)

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CDC. *Revised Recommendations for HIV Testing of Adult, Adolescents, and Pregnant Women in Health-Care Settings*. *Morbidity and Mortality Weekly Report*. September 22, 2006, Vol. 55, No. RR-14. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>

CLSI. *Criteria for Laboratory Testing and Diagnosis of HIV: Approved Guideline*. CLSI document M53-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2011. Note that this laboratory guidance is proprietary although all certified laboratories use this document. <http://shopping.netsuite.com/s.nl/c.1253739/it.A/id.250/f>

Hutchinson, A., et.al. *Laboratory cost of the APHL/CDC Proposed Algorithm for the Diagnosis of HIV*. 2012 HIV Diagnostics Conference Program Book, p. 69. <https://custom.cvent.com/ADE0EB81B3184D618E2FB8340F1EC28E/files/b7a7473c5a084eecaa23e146649e3f33.pdf>

Manlutac, A.M. *Identification of Early HIV Infections Using the Fourth Generation Abbott Architect HIV Ag/Ab Combo Chemiluminescent Microparticle Immunoassay (CIA) in San Diego County*. 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/5aed5ead2525484fa1981dedad756cf4.pdf>

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.
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.
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).

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.