

Division of Laboratory Systems

Protecting America's Health by Strengthening
Clinical and Public Health Laboratories

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems
June 27, 2017

CDC's Division of Laboratory Systems

Excellent Laboratories, Outstanding Health

Mission

Strengthen the nation's clinical and public health laboratory system by continually improving quality and safety, informatics and data science, and workforce competency

Our Work



QUALITY AND SAFETY SYSTEMS

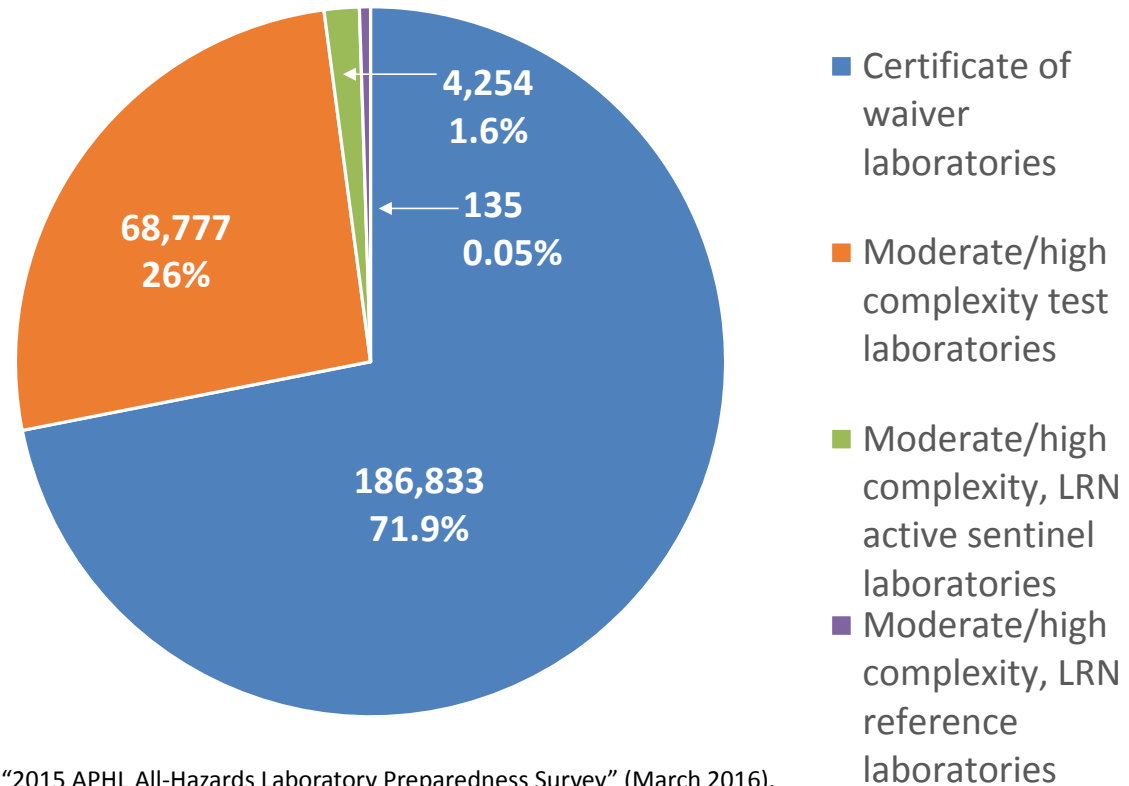


INFORMATICS AND DATA SCIENCE



TRAINING AND WORKFORCE DEVELOPMENT

259,999 CLIA Certified Laboratories in the United States



Data obtained from CMS QIES database, 5/31/2017, and "2015 APHL All-Hazards Laboratory Preparedness Survey" (March 2016). Includes laboratories in CLIA-exempt states of NY and WA. Data does not include CLIA Certificate of Registration laboratories.



QUALITY AND SAFETY SYSTEMS

Clinical Laboratory Improvement Amendments (CLIA)

DLS works to advance the quality and safety of clinical laboratory testing and laboratory medicine nationwide



- DLS partners with the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA) by providing scientific and technical expertise for the CLIA program

Clinical Laboratory Improvement Advisory Committee

2017 CLIAC meeting dates

- ~~April 12-13, 2017~~ Postponed
- November 1-2, 2017

Draft agenda topics for next CLIAC meeting

- Agency updates
- Implementation of next generation sequencing in clinical laboratories
- Laboratory testing in the era of telemedicine
- Institute of Medicine CLIAC workgroup report

www.cdc.gov/cliac/



Hot Topics in Laboratory Quality

- Next Generation Sequencing (NGS)
 - Working with CMS and FDA to identify NGS quality and regulatory challenges and develop a validation guide for both wet and dry lab processes
- Culture Independent Diagnostic Tests (CIDTs)
 - Managing CIDT regulatory workgroup that includes FDA, ASM, APHL, AdvaMed
- Antimicrobial Resistance (AR)
 - Supporting Antibiotic Resistance Laboratory Network and the National Antimicrobial Resistance Surveillance Task Force (with APHL, CSTE)



Clinical Laboratory Integration into Healthcare Collaborative (CLIHC™)

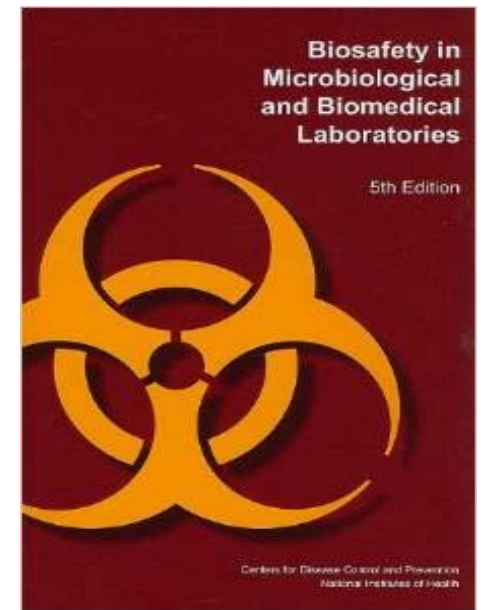
Workgroup of clinical laboratory and medical professionals to develop solutions that optimize the effective use of laboratory services for better patient care



- **“Diagnostic Error and the Need for Better Diagnostic Testing”**
(<http://www.medscape.com/viewarticle/855381>)
- **“Opportunities to Enhance Laboratory Professionals Role On the Diagnostic Team”**
(<https://ascpcdn.s3.amazonaws.com/media/podcasts/Integrating-lab-pros-Taylor>)

New Clinical Laboratory Biosafety Chapter in Development for BMBL 6th Edition

- DLS experts responsible for a new chapter on clinical laboratory biosafety
- Clinical and public health laboratory representation as technical reviewers
- Risk assessment emphasis rather than pathogen-based BSL assignment





INFORMATICS AND DATA SCIENCE

Informatics Self-Assessment Tool

The screenshot displays the Informatics Self-Assessment Tool interface. At the top, the URL is `rasoftware.com/CapabilityArea/Index/c4d10f61-6e44-42be-a734-a8fb595d66d1`. The user is logged in as `lab1admin`. The main header features the APHL logo and the title "Informatics Self-Assessment Tool". Below the header, there are navigation buttons for "Manage Assessments", "Data Visualization", and "Reports".

The main content area is titled "Capability Area: 1" and "Laboratory Test Request and Sample Receiving". It includes a map of the United States with several states highlighted in green. The map has a filter set to "Attribute" and "Select".

On the left side, there is a "CS List" with the following items:

- Capability Statement 1.1
- Capability Statement 1.2
- Capability Statement 1.3
- Capability Statement 1.4
- Capability Statement 1.5
- Capability Statement 1.6
- Capability Statement 1.7a
- Capability Statement 1.7b
- Capability Statement 1.7c
- Capability Statement 1.7d
- Capability Statement 1.7e
- Capability Statement 1.7f

The selected item, "Capability Statement 1.1", is expanded to show the following text:

Guidance ▼

The laboratory is able to receive an electronic submission for all tests.

Level 3 The laboratory is able to receive an electronic submission for all tests.

Level 2 The laboratory is able to receive an electronic submission for all tests based on requisitions for other tests.

Level 1 The laboratory is able to receive only paper-based submissions for all tests.

N/A Not applicable to this laboratory.

Comments

Public Health Laboratory System Database

BROWSE PAGE PUBLISH

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES

Welcome to the Public Health Laboratory System Database

Home

Database Sections

- General Lab Information
- Personnel
- Clinical Tests
- Environmental Tests
- Newborn Screening
- Equipment

Reports

- Log of Issues
- Admin Report

Tools

EDIT LINKS

APHL's Public Health Laboratory System Database (PHLSD) is a tool that enables your public health laboratory to manage your own data on infrastructure, regulatory compliance, test services and equipment. You can use the PHLSD for developing annual reports, documentation for regulatory inspection, preparing grant applications, and more. Finally (or more importantly), the PHLSD will enhance the public health laboratory system as a whole by enabling information sharing on critical capacities of your partners.

Database Access Data Security System Requirements Resources Help Desk

Sections

- General Lab Information: data about lab location, LIMS, CLIA, regulatory and quality systems, staff count and education levels
- Personnel: information about supervisory and higher level personnel
- Clinical Tests: detailed information about clinical tests conducted at your lab
- Environmental Tests: detailed information about environmental tests conducted at your lab
- Equipment: detailed information about equipment at your lab

2017 'soft' launch underway

15 PHLs contributing to database and 4 in process

Enhancing Clinical Laboratory Preparedness

- Improve relationships with clinical laboratory professional organizations on laboratory preparedness
- Engagement with ACLA and commercial labs to formalize relationships and address challenges for surge support
- Market research to identify other large laboratory systems that may provide additional capacity during response
- Enhance communications with clinical laboratories (in addition to sentinel LRN Laboratories) through LOCS (LOCS@cdc.gov)

Improving Deployment and Implementation of EUA Assays

- Workgroup (CDC, FDA, and CMS) formed for early coordination and continued communication
- Short-term action Items
 - Update EUA documents for clarification of test limitations and sample acceptance/rejection criteria
 - Review and clarify CLIA requirements for verification of the test procedure
 - Prioritize EUA assay laboratory equipment selection
 - Consider CLIA exemptions to allow for more rapid implementation of EUA assay





TRAINING AND WORKFORCE DEVELOPMENT

CDC Laboratory Training

The screenshot shows the CDC Laboratory Training website. At the top left is the CDC logo with the text "Centers for Disease Control and Prevention" and "CDC 24/7 Saving Lives. Protecting People™". To the right is a search bar. Below the logo is a navigation menu with "CDC-A-Z INDEX" and "CDC Laboratory Training". The main banner features a blue background with illustrations of laboratory equipment (microscope, pipette, beaker, laptop, tablet) and a globe. The text reads "CDC Laboratory Training" and "Live and archived laboratory training online and in-person for FREE!". Below the banner are social media icons for Facebook, Twitter, and a plus sign. The page is divided into four columns: "Register for Live Training" with a registration form and a countdown timer; "24/7 Online Training" with a list of courses; "External Training Links" with a globe icon; and "Help/FAQs" with a "connecting worldwide" graphic. Each column has a corresponding "All" button at the bottom.

In 2016

- 98 different courses offered
- 18,918 students completed the courses
- 92% indicated training objectives aligned with training needs
- 77% applied training to their laboratory

<http://www.cdc.gov/labtraining/>

CDC Laboratory Biosafety Training

- Courses developed for CDC laboratory staff
 - 12 in 2016
 - 12 in development in 2017
- 7 courses to date shared with other HHS agencies (i.e., FDA and NIH)
- CDC courses now being updated for public health and clinical laboratory use



Laboratory Workforce Development

- Comprehensive Laboratory Competency Guidelines
- Competency Implementation Toolbox
- CDC Laboratory Fellowships
- APHL/CDC Fellowships



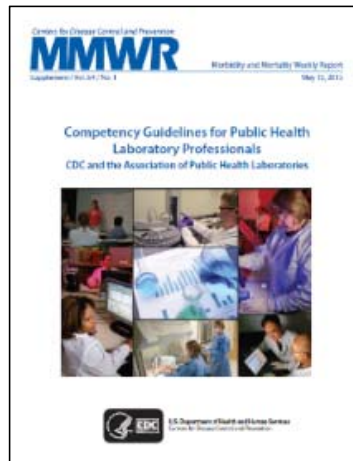
NLTN: Looking Forward

- Strengthen collaboration, branding, governance, and communications for laboratory training
- Address cross-cutting laboratory systems workforce training needs
- Create a national curriculum that is part of broader, competency-based workforce strategy



Public Health and Clinical Laboratory Curriculum Map (Proposed)

Training curriculum based on the Competency Guidelines for Public Health Laboratory Professionals



Laboratory Safety and Security			Quality Management		Leadership
Potential Hazards	Hazard Control		Organizational Structure	Facilities and Safety	
Communication and Training	Administrative Controls		Customer Focus		General Management
	Documents and Records		Laboratory Equipment	Purchasing and Inventory	
Security	Risk Management	Compliance	Process Management	Documents and Records	
Case Studies			Audits and Assessments	Nonconforming Event Management	
			Continual Improvement	Information Management	
			Ethics	Case Studies	
					Financial Management
					HR Management
					General Leadership
					Case Studies

General Laboratory Practices													
Microbiology				Molecular Biology				Chemistry				Research	
Basic Techniques				Basic Science				Basic Analytical Chemistry				Communication	
Virology	Serology	Mycology		Specimen Prep/Extraction				Specimen Prep/Extraction				Workforce Training	
Immunology		AST		PCR	rt-PCR	RT-PCR		Separation Science		Inorganic		Surveillance	
Rule-Out-Or-Refer				Organism Specific Methods				LC	GC	AA/ICP			
Organism Specific Methods				Fundamentals of AMD				Fundamentals of MS					
Identification of Unknowns				NGS	MALDI-TOF			LC-MS	GC-MS	ICP-MS			
Case Studies				Organism Specific Methods				Target Analyte Methods					
				Identification of Unknowns				Identification of Unknowns					
				Case Studies				Case Studies					
Informatics				Bioinformatics				Emergency Response					
Sample Receiving		LIMS		Biology	Computer Science			Incident Command		COOP			
Reports	Test Scheduling			Statistical Methods				Pack and Ship		LRN			
Sample Tracking				Data Analysis				Specimen Transport		Stockpile			
Interoperability				Data Management				Exercise Planning					
Case Studies				Case Studies				Case Studies					

CDC's Division of Laboratory Systems



QUALITY AND SAFETY SYSTEMS



INFORMATICS AND DATA SCIENCE




TRAINING AND WORKFORCE DEVELOPMENT

The background features a stylized globe with various colored dots (yellow, orange, green, blue) and lines connecting them, suggesting a global network or data flow. The globe is centered in the middle of the slide.

If we can assist you...

Contact us at
DLInquiries@cdc.gov



For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Images used in accordance with fair use terms under the federal copyright law, not for distribution.

Use of trade names is for identification only and does not imply endorsement by U.S. Centers for Disease Control and Prevention.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of Centers for Disease Control and Prevention.