Division of Laboratory Systems

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

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CDC's Division of Laboratory Systems

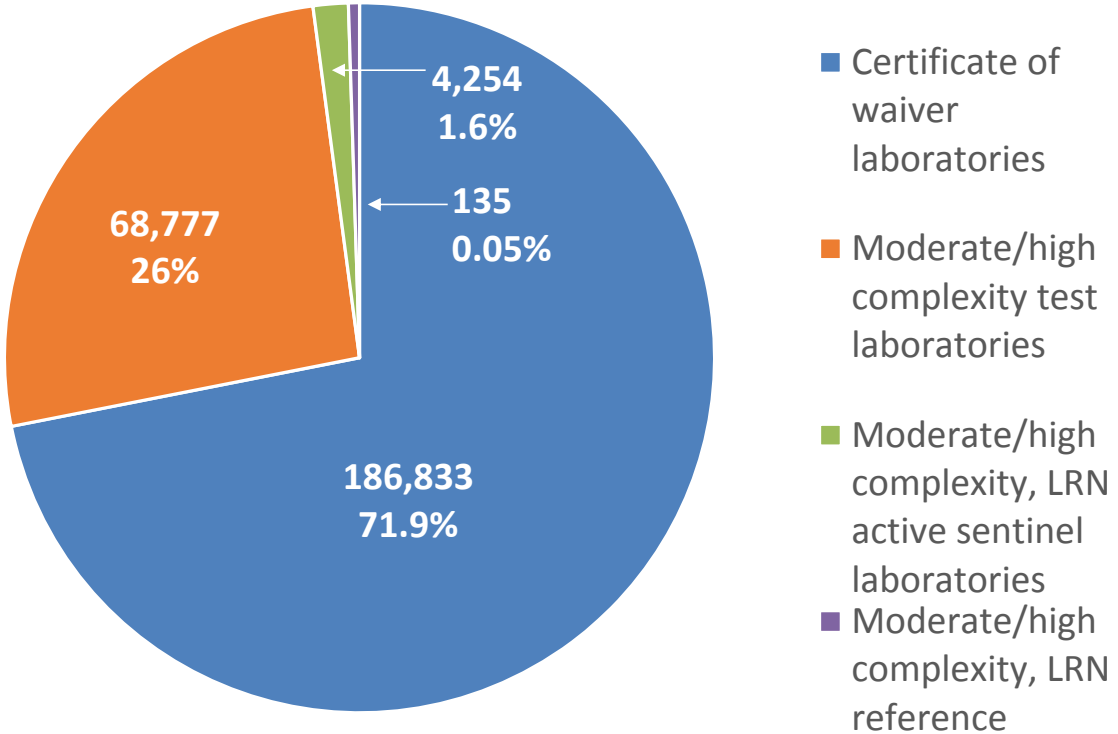
Our Work

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 includes 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

ww.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™)

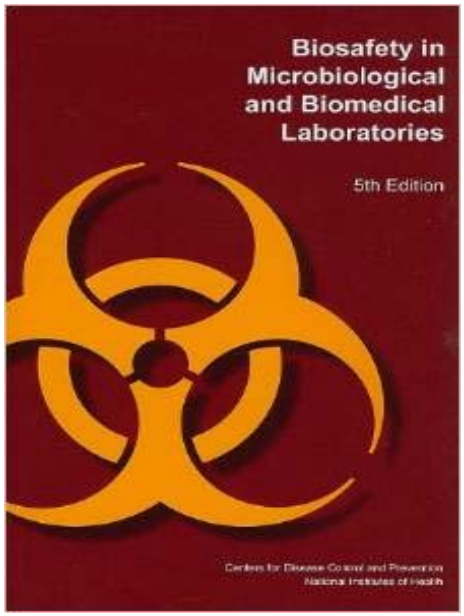
Workgroup of clinical laboratory and medical professionals to develop solutions that optimize the effective use of laboratory services for better patient care



- **"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

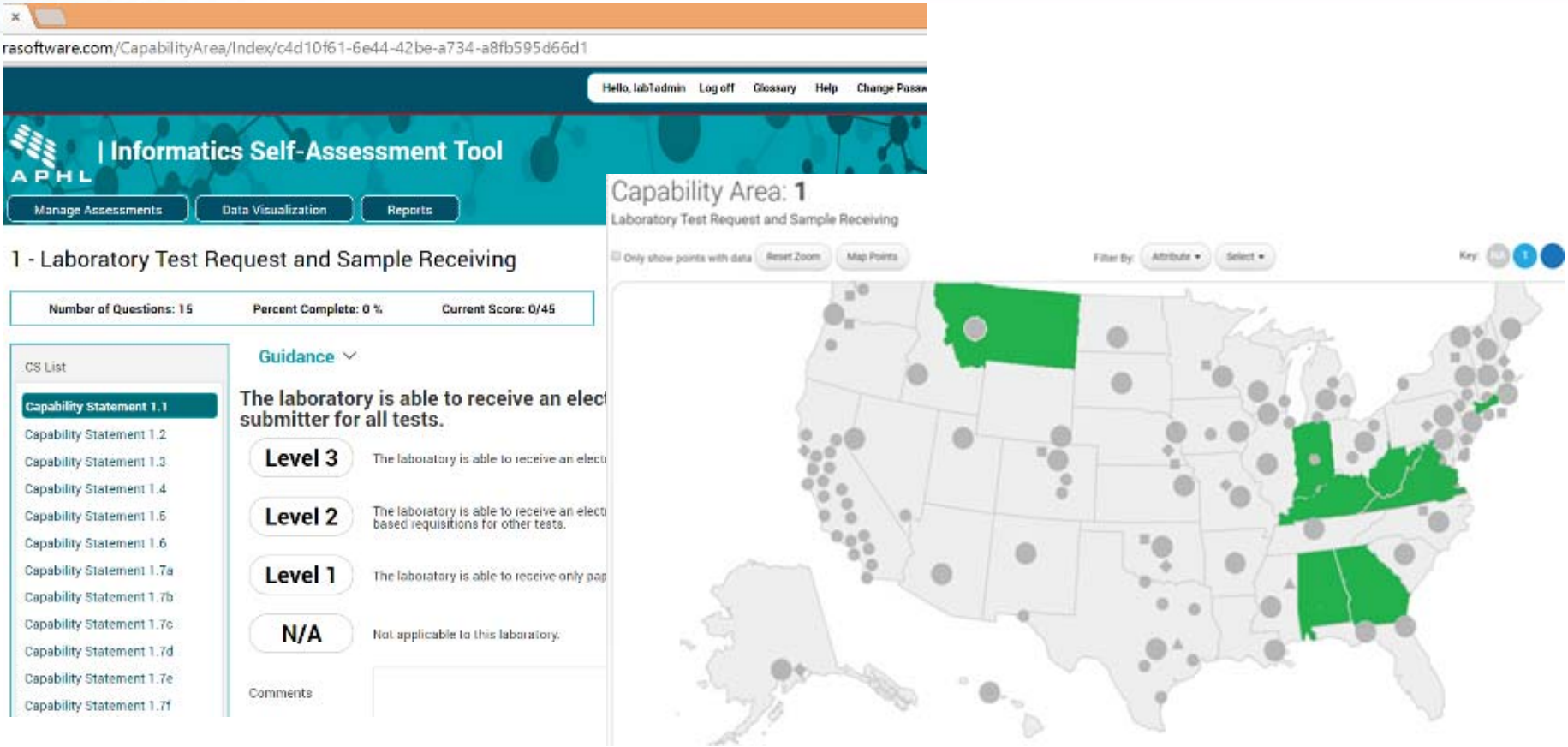
New Clinical Laboratory Biosafety Chapter in Development for BMBL 6th Edition

- 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



Public Health Laboratory System Database

2017 'soft' launch underway

15 PHLs contributing to database and 4 in process

Enhancing Clinical Laboratory Preparedness

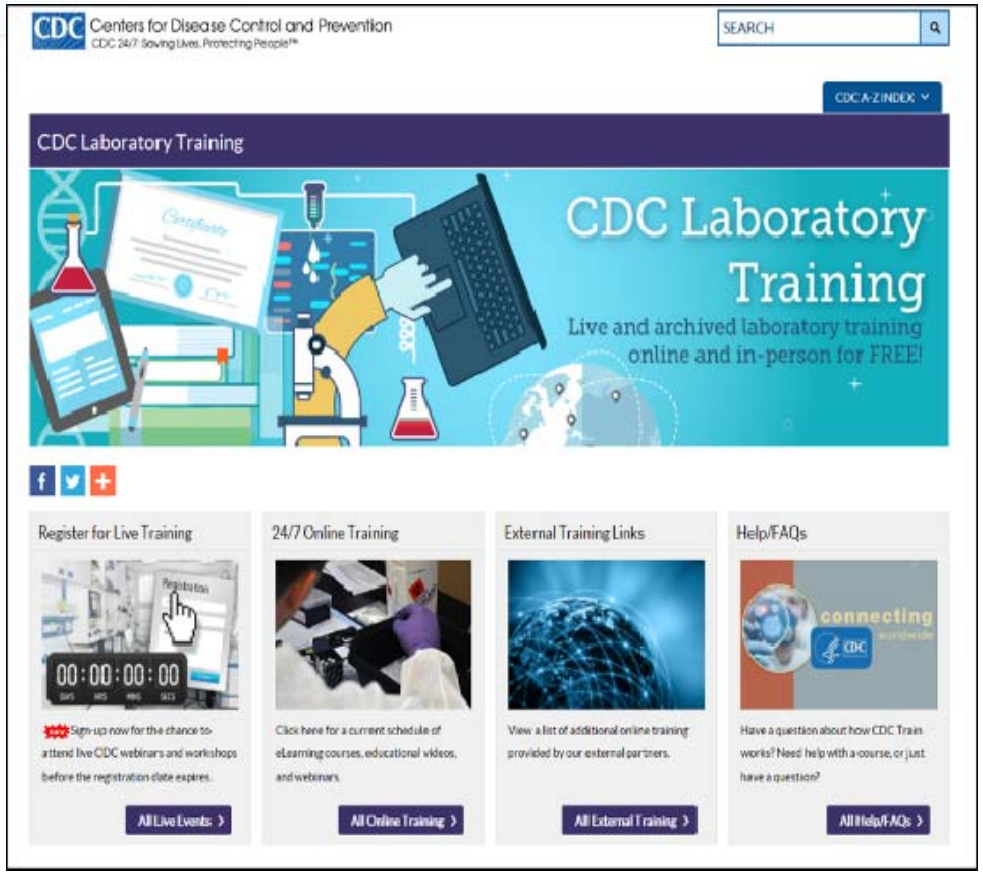
- Improve relationships with clinical laboratory professional organizations on laboratory preparedness
- Engagement with ACLA and commercial labs to formalize relationships and address challenges for surge support
- Market research to identify other large laboratory systems that may provide additional 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
TRAINING AND WORKFORCE DEVELOPMENT

CDC Laboratory Training



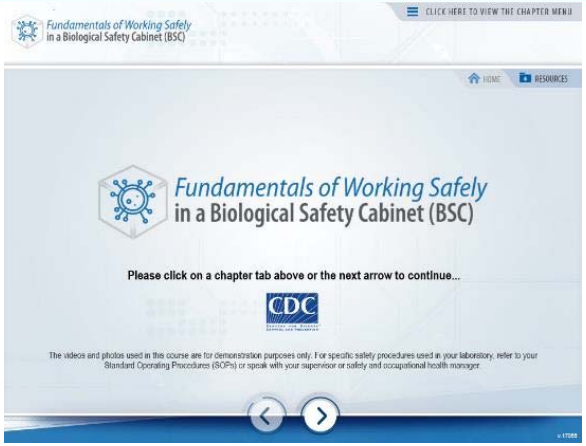
In 2016

- 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

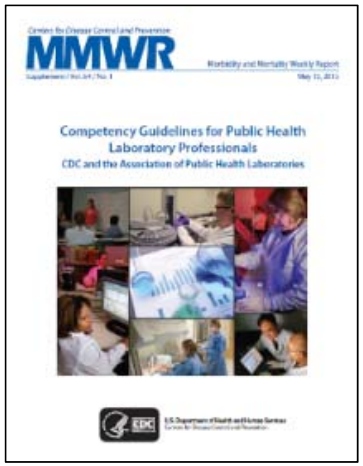
- Comprehensive Laboratory Competency Guidelines
- Competency Implementation Toolbox
- CDC Laboratory Fellowships
- APHL/CDC Fellowships

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		
Potential Hazards	Hazard Control	
Communication and Training	Administrative Controls	
	Documents and Records	
Security	Risk Management	Compliance
Case Studies		

Quality Management	
Organizational Structure	Facilities and Safety
Customer Focus	Workforce Development
Laboratory Equipment	Purchasing and Inventory
Process Management	Documents and Records
Audits and Assessments	Nonconforming Event Management
Continual Improvement	Information Management
Ethics	Case Studies

Leadership
Assessing Competency
General Management
Policy Development
Financial Management
HR Management
General Leadership
Case Studies

General Laboratory Practices

Microbiology		
Basic Techniques		
Virology	Serology	Mycology
Immunology	AST	
Rule-Out-Or-Refer		
Organism Specific Methods		
Identification of Unknowns		
Case Studies		

Molecular Biology		
Basic Science		
Specimen Prep/Extraction		
PCR	rt-PCR	RT-PCR
Organism Specific Methods		
Fundamentals of AMD		
NGS	MALDI-TOF	
Organism Specific Methods		
Identification of Unknowns		
Case Studies		

Chemistry		
Basic Analytical Chemistry		
Specimen Prep/Extraction		
Separation Science		Inorganic
LC	GC	AA/ICP
Fundamentals of MS		
LC-MS	GC-MS	ICP-MS
Target Analyte Methods		
Identification of Unknowns		
Case Studies		

Research
Communication
Workforce Training
Surveillance

Informatics	
Sample Receiving	LIMS
Reports	Test Scheduling
Sample Tracking	
Interoperability	
Case Studies	

Bioinformatics	
Biology	Computer Science
Statistical Methods	
Data Analysis	
Data Management	
Case Studies	

Emergency Response	
Incident Command	COOP
Pack and Ship	LRN
Specimen Transport	Stockpile
Exercise Planning	
Case Studies	

CDC's Division of Laboratory Systems

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INFORMATICS AND DATA SCIENCE

TRAINING AND WORKFORCE DEVELOPMENT

If we can assist you…

Contact us at

DLSinquiries@cdc.gov

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

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.