CDC's Division of Laboratory Systems Update

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems

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Excellent Laboratories, Outstanding Health

About DLS

Excellent Laboratories, Outstanding Health
Vision
Exemplary laboratory science and practice across clinical care and population health

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

PREPAREDNESS

QUALITY AND SAFETY SYSTEMS

WAIVED TESTING SOLUTIONS

Home | PT | Resources | Media Gallery | Courses | Links | Self Assessment

Welcome

This website is focused on providing important information and tools for CLIA waived laboratories.

What are CLIA Waived Tests?

Waived tests are laboratory tests that:

- **Are simple to use**
- **Have easy to follow procedures**
- **Provide accurate results**

The Food and Drug Administration (FDA) determines which tests are approved as waived.
The list of waived tests continues to grow as new tests are developed and approved.

Can Anyone Perform CLIA Waived Tests?

http://www.cola.org/education-resources/clia-waived-tests/

Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)

- **Laboratory test selection and ordering**
  - First expert consultation with pathology informaticists held (Atlanta, Sept 2017)

- **Diagnostic management**
  - Increasing collaborations between laboratory professionals and healthcare delivery teams to improve diagnostic medicine and patient health outcomes

- **Clinical decision support tools**
  - Completed evaluation of *PTT Advisor* mobile application
  - *Anticoagulation Manager* mobile application is in the beta testing phase

Next Generation Sequencing (NGS)

- **CDC, FDA, and CMS meeting in May 2017**
  - Defined current landscape of NGS testing
  - Identified NGS quality and regulatory challenges
- **Some questions to consider**
  - What steps can HHS take to facilitate development and implementation of NGS-based clinical tests?
  - What guidance do laboratories that perform NGS need to address critical steps in the testing process?
  - Should HHS clarify the requirements that impact NGS?
  - What are clinicians' and healthcare providers' concerns / issues with NGS?
- **Coordinated engagement with many external stakeholders needed to address action items**

CDC's New Website for Clinical Laboratory Biosafety

https://www.cdc.gov/ophss/csels/dls/index.html

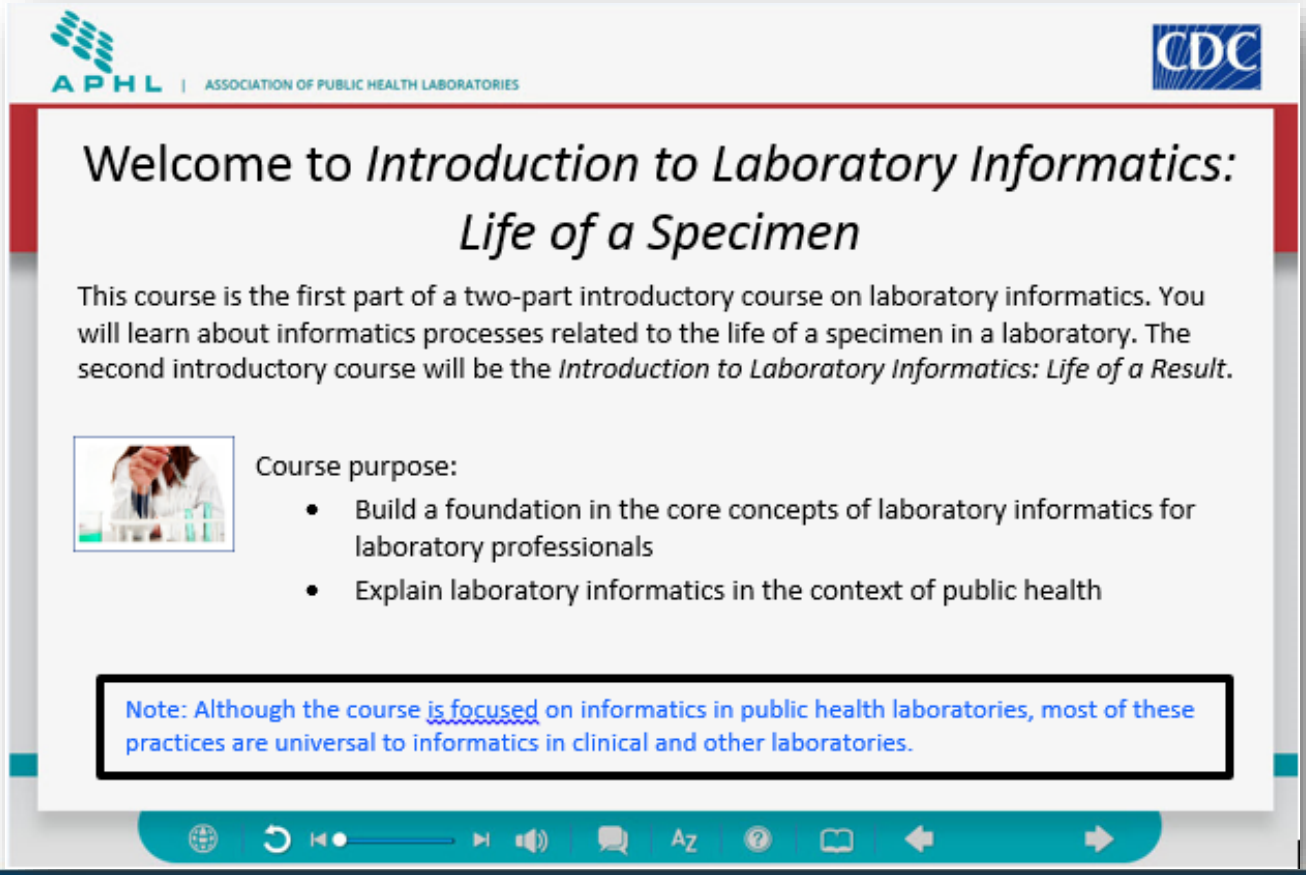
INFORMATICS AND DATA SCIENCE

Semantic Interoperability Taskforce

- Aim to standardize the test ordering codes - Logical Observation Identifiers Names and Codes (LOINC)
- Encouraging instrument manufacturers to provide specific codes for their tests in digital format to the laboratories
- Working to create test names within the codes that will be easily recognizable by clinicians who order the tests

Workforce Development

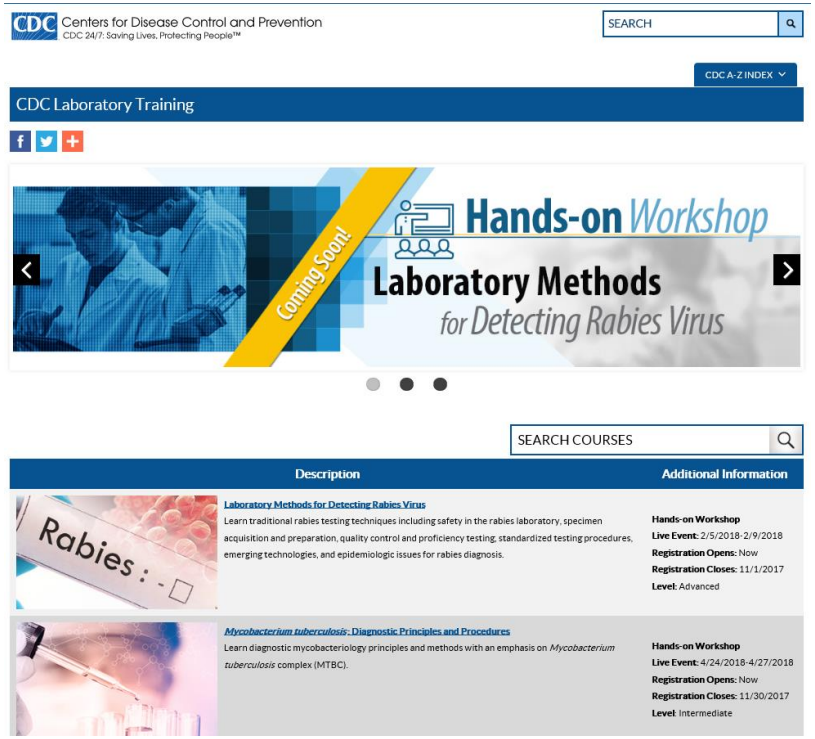
- Collaborating with APHL to develop competency-based training modules and curriculum for laboratory informatics



TRAINING AND WORKFORCE DEVELOPMENT

CDC Laboratory Training

- **In FY2017**
  - 54 eLearning courses
    - > 16,000 students completed the courses
  - 84 in-person workshops
  - Topics included
    - Parasitology
    - Infectious Diseases
    - Preparedness
    - Laboratory Safety
    - Microbiology



www.cdc.gov/labtraining

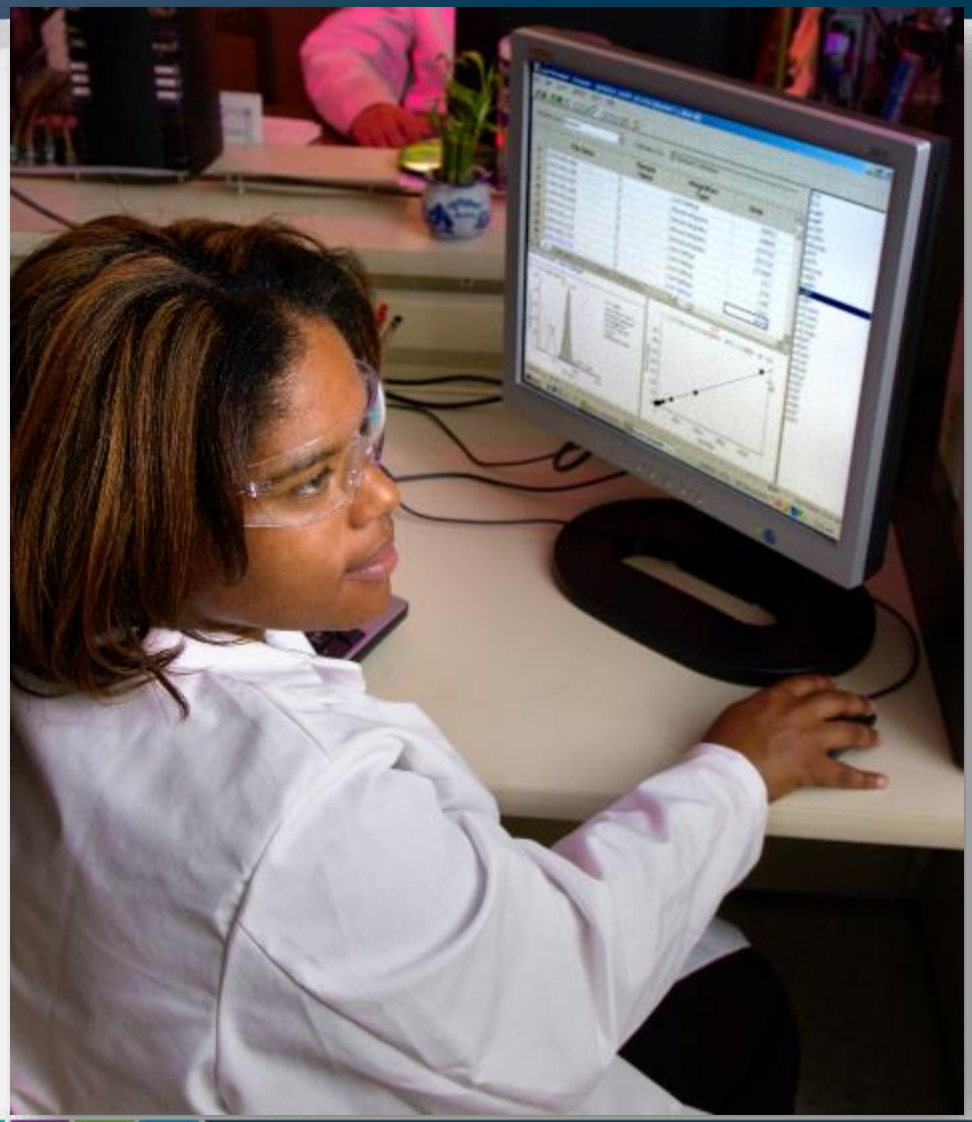
Clinical and Public Health Laboratory Workforce Development

- **New initiative focused on the future of the laboratory workforce**

  - Identify the critical training and workforce development needs
  - Generate feedback on competency guidelines uptake and applicability
  - Collaborate with partners to address gaps/needs in laboratory training and workforce development

PREPAREDNESS

Building Public-Private Laboratory Partnerships



- Meet quarterly with professional associations to address clinical laboratory priorities
- Enhance communications with clinical laboratories through LOCS (LOCS@cdc.gov)
- Augment public health response by strengthening engagement of clinical laboratory community

LOCS
Laboratory Outreach Communication System

Improving Deployment and Implementation of EUA Assays

- **CDC, FDA, and CMS workgroup formed for early coordination and continued communication**

- **Short-term action items**
  - Update EUA documents to clarify test limitations and sample acceptance and rejection criteria
  - Review and clarify CLIA requirements for verification of test procedures
  - Prioritize selection of laboratory equipment for EUA assays
  - Consider CLIA exemptions to allow for more rapid implementation of EUA assays

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

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