

CDC's Division of Laboratory Systems Update

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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

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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?

www.waivedtestingsolutions.org

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



Clinical Laboratory Biosafety is a Critical Unmet National Need

Learn more about the Division of Laboratory Systems initiatives
to fulfill biosafety demand

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



INFORMATICS AND DATA SCIENCE

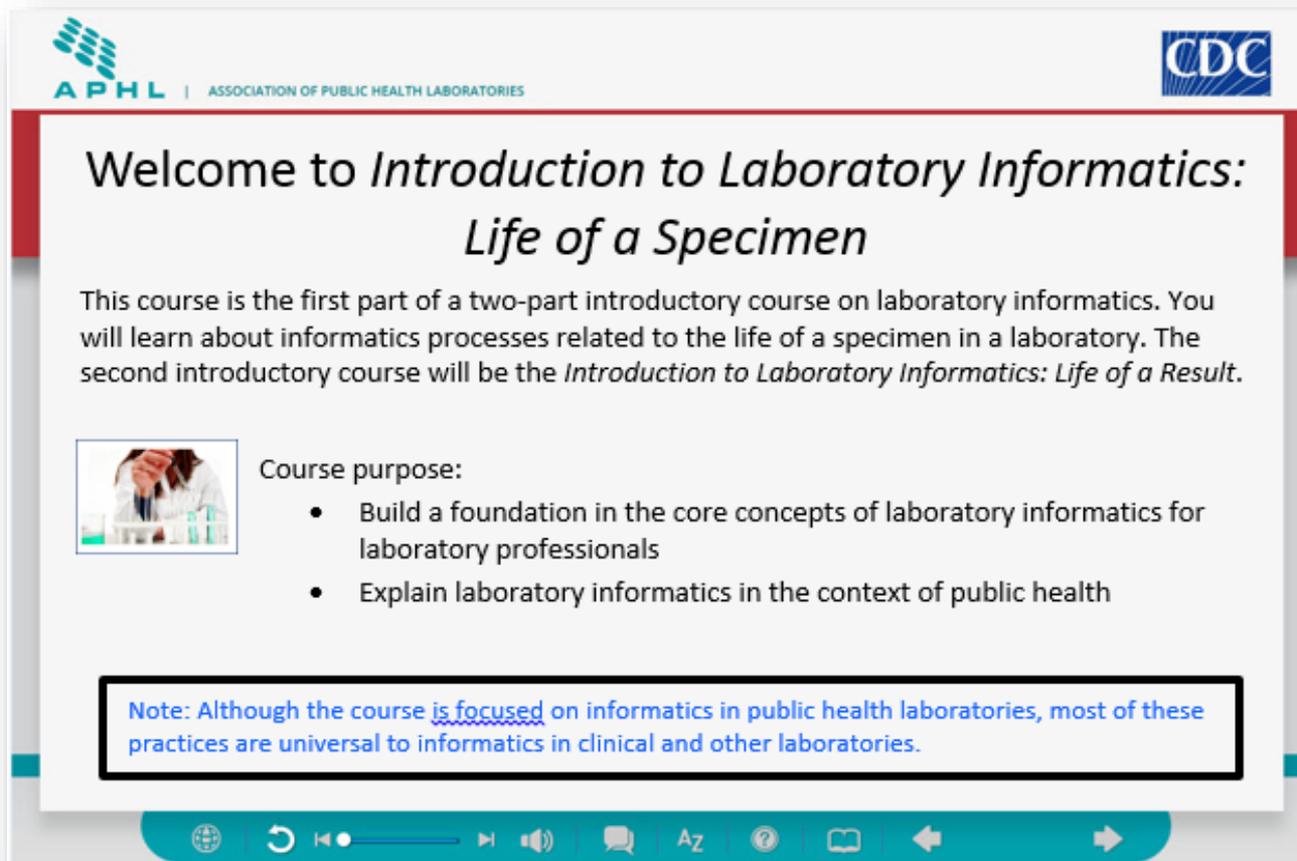
Semantic Interoperability Taskforce

- 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



The screenshot shows a slide from a training module. At the top left is the APHL logo (Association of Public Health Laboratories) and at the top right is the CDC logo. The main title is "Welcome to *Introduction to Laboratory Informatics: Life of a Specimen*". Below the title is a paragraph: "This course is the first part of a two-part introductory course on laboratory informatics. You will learn about informatics processes related to the life of a specimen in a laboratory. The second introductory course will be the *Introduction to Laboratory Informatics: Life of a Result*." To the left of the "Course purpose:" section is a small image of a person in a lab coat. The "Course purpose:" section contains two bullet points: "Build a foundation in the core concepts of laboratory informatics for laboratory professionals" and "Explain laboratory informatics in the context of public health". At the bottom, a note in a black-bordered box states: "Note: Although the course is focused on informatics in public health laboratories, most of these practices are universal to informatics in clinical and other laboratories." A navigation bar at the very bottom contains icons for home, back, forward, search, and other controls.

APHL | ASSOCIATION OF PUBLIC HEALTH LABORATORIES

CDC

Welcome to *Introduction to Laboratory Informatics: Life of a Specimen*

This course is the first part of a two-part introductory course on laboratory informatics. You will learn about informatics processes related to the life of a specimen in a laboratory. The second introductory course will be the *Introduction to Laboratory Informatics: Life of a Result*.



Course purpose:

- Build a foundation in the core concepts of laboratory informatics for laboratory professionals
- Explain laboratory informatics in the context of public health

Note: Although the course is focused on informatics in public health laboratories, most of these practices are universal to informatics in clinical and other laboratories.



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

The screenshot shows the CDC Laboratory Training website. At the top, it features the CDC logo and the text 'Centers for Disease Control and Prevention' and 'CDC 24/7: Saving Lives, Protecting People™'. There is a search bar and a 'CDC A-Z INDEX' dropdown menu. Below this is a blue header with 'CDC Laboratory Training' and social media icons for Facebook, Twitter, and a plus sign. A large banner features a photo of two scientists in a lab, with a yellow diagonal banner that says 'Coming Soon!'. The main text on the banner reads 'Hands-on Workshop Laboratory Methods for Detecting Rabies Virus'. Below the banner is a search bar labeled 'SEARCH COURSES'. The main content area is a table with two columns: 'Description' and 'Additional Information'. The first row is for 'Laboratory Methods for Detecting Rabies Virus' and the second row is for 'Mycobacterium tuberculosis: Diagnostic Principles and Procedures'.

Description	Additional Information
Laboratory Methods for Detecting Rabies Virus Learn traditional rabies testing techniques including safety in the rabies laboratory, specimen acquisition and preparation, quality control and proficiency testing, standardized testing procedures, emerging technologies, and epidemiologic issues for rabies diagnosis.	Hands-on Workshop Live Event: 2/5/2018-2/9/2018 Registration Opens: Now Registration Closes: 11/1/2017 Level: Advanced
Mycobacterium tuberculosis: Diagnostic Principles and Procedures Learn diagnostic mycobacteriology principles and methods with an emphasis on <i>Mycobacterium tuberculosis</i> complex (MTBC).	Hands-on Workshop Live Event: 4/24/2018-4/27/2018 Registration Opens: Now Registration Closes: 11/30/2017 Level: Intermediate

www.cdc.gov/labtraining

Clinical and Public Health Laboratory Workforce Development

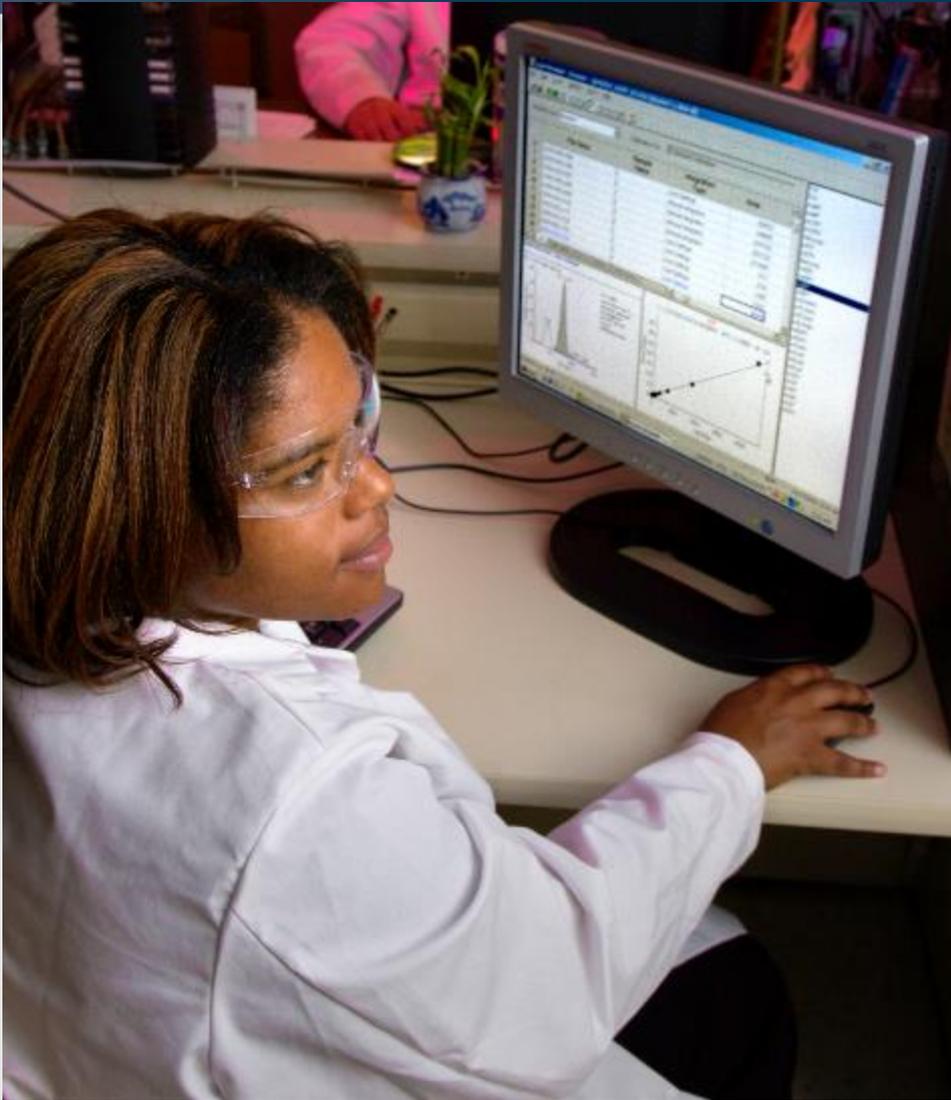
- **New initiative focused on the future of the laboratory workforce**
 - Identify the critical training and workforce development needs
 - Generate feedback on competency guidelines uptake and applicability
 - Collaborate with partners to address gaps/needs in laboratory training and workforce development



PREPAREDNESS



Building Public-Private Laboratory Partnerships

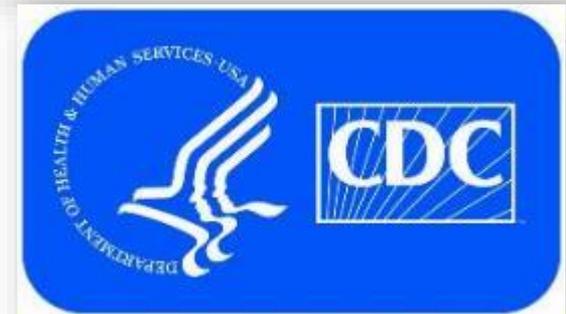


- Meet quarterly with professional associations to address clinical laboratory priorities
- Enhance communications with clinical laboratories through LOCS (LOCS@cdc.gov)
- Augment public health response by strengthening engagement of clinical laboratory community



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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