



A Unified Response to Training Needs

Introduction to Laboratory Director University

December 10th, 2025
11:00 am ET

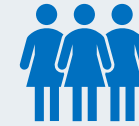
Agenda

- Introduction
 - *Today's Presenters*
- Introduction to Laboratory Director University
- Q&A
- Closing Remarks

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Please keep the following in mind when using the chat feature:

- **Connect with others!** React to what you're hearing, share experiences, and ask questions of your fellow participants!
- **Have a question for the presenter?** Use the Q&A function, *not* the chat.
- **Show Respect and Professionalism.** Inappropriate language, improper conduct, or any form of discrimination may result in removal from the webinar.
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- **Comply with Moderators' Guidance.** If a moderator gives direction regarding chat behavior, please comply accordingly.
- **Report Issues.** Notify moderators if you experience technical difficulties or observe any disruptive behavior.



Today's Presenters

Cheryl Dobbe, MLT/MT (ASCP)

Technical Advisor

Division of Clinical Laboratory Improvement & Quality

Centers for Medicare & Medicaid Services

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Centers for Medicare & Medicaid Services

Introduction to Laboratory Director University (LDU)



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**Centers for Medicare & Medicaid Services (CMS)
Division of Clinical Laboratory Improvement & Quality (DCLIQ)**

**Centers for Disease Control and Prevention (CDC)
Division of Laboratory Systems (DLS)**



Acknowledgements and Disclaimers



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The Centers for Medicare & Medicaid Services (CMS) Division of Clinical Laboratory Improvement & Quality (DCLIQ) has partnered with the Centers for Disease Control and Prevention (CDC) Division of Laboratory Systems (DLS) to develop this program.



Objectives



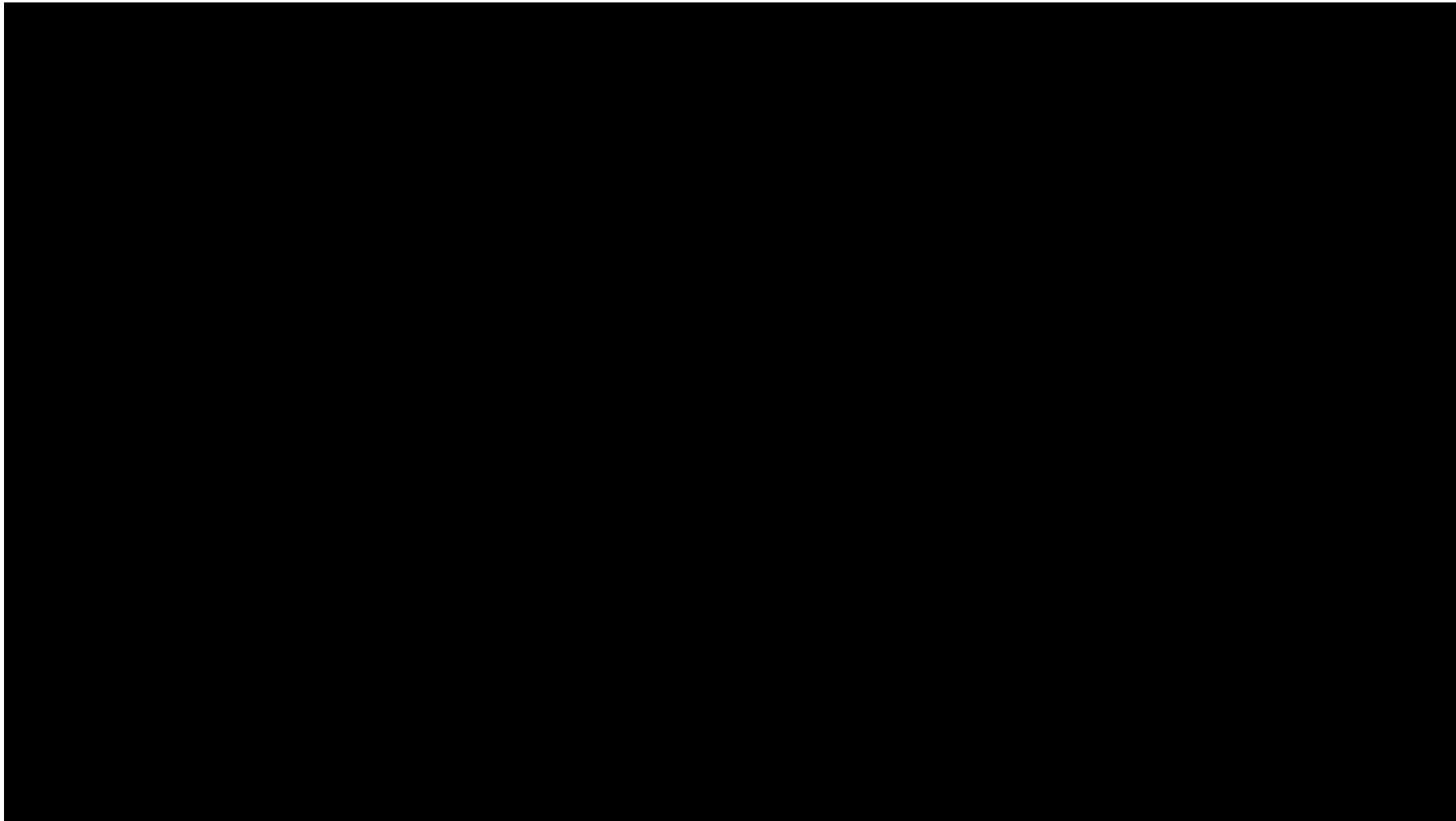
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1. Describe the role and responsibilities of a CLIA Certified Laboratory Director.
2. Summarize the purpose and scope of Laboratory Director University (LDU).

Meeting the Need



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Behind Every Result, There Are Hidden Experts



Laboratory Director Accountability



- The laboratory director must personally oversee and ensure that the testing systems used in the laboratory are appropriate for the patient population and provide quality test performance in all testing phases.
- Laboratory Directors in CLIA-certified laboratories hold ultimate responsibility for the laboratory's compliance with all CLIA regulations. Most importantly, they are responsible for ensuring patients receive accurate, reliable test results every day.
- Poor performance reflects not only on the laboratory but also directly on the laboratory director's leadership and accountability.

Laboratory Director Roles and Responsibilities



Laboratory
Oversight

Quality Assurance
and Performance
Improvement

Personnel
Management

Test Method
Selection

Compliance and
Regulatory
Responsibilities

The Product



Laboratory Director University (LDU) offers free, high-quality content and resources for current and prospective CLIA laboratory directors.



What LDU Offers



- Focused training for current and prospective CLIA laboratory directors
- Interactive tools that connect surveyors to training resources
- Scenario-based learning to reinforce practical application
- Pathways to successful competency assessment
- Reassessment for failed areas

LDU Design



The learning pathway includes high-quality training for current and prospective laboratory directors whose job will include overseeing regulatory compliance in CLIA-certified clinical laboratories.





The CLIA Deficiency and Research Tool (CDART)





This innovative resource lets laboratory directors, CLIA surveyors, and other laboratory professionals search and access training and regulations relevant to common CLIA deficiencies and the specifics of the CLIA standard in 42 CFR Part 493 – Laboratory Requirements.

LDU Supplemental Content



Supplemental


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CLIA Deficiency and Resource Tool

Designed to help laboratory directors, CLIA surveyors, and other laboratory professionals search and access training regulations relevant to common CLIA deficiencies and the specifics of the CLIA standard in 42 CFR Part 493 - Laboratory Requirements.



Find Resources or Regulations

Search by tag number or keyword(s) Search the eCFR

Instructions Enter one or more keywords or D-tags, separated by commas — for example, "D5413, proficiency testing". The results will include all related resources, such as eLearnings and supplemental resources. Items marked with an asterisk (*) are LDU learning pathways with opportunity for CE credits.

Tag number or keyword search

Enter CLIA tags/terms separated by commas.

Resources

[Clinical Laboratory Improvement Amendments | CMS](#) [Clinical Laboratory Improvement Amendments | CDC](#)

Search Resources by Deficiency Tag ("D-tag") or Keywords

Search Regulations by keywords

LDU Helps Maintain CLIA Compliance



LDU's flexible learning environment equips laboratory directors with the high-quality training, tools, and resources they need to maintain CLIA compliance. LDU focuses on improvements in:

- Documentation
- Quality control and quality assurance
- CLIA proficiency testing (PT)
- Unsatisfactory results and unsuccessful performance in PT
- Evaluation of testing systems

More Coming Soon on OneLab REACH™

LDU learning topics



1. Introduction to Laboratory Director University

Summarizes fundamental concepts of CLIA regulations and the basics of waived and nonwaived testing.

2. Laboratory Director Responsibilities

Summarizes laboratory director responsibilities, distinguishing between delegated and nondelegated.

3. Personnel Responsibilities

Covers responsibilities for the laboratory director and delegation of responsibilities to personnel.

4. The Survey Process

Summarizes laboratory director requirements before, during, and after the survey process.

5. Quality Systems for Laboratories Performing Nonwaived Testing

Covers application of quality practices for accurate, reliable testing.

6. Participation in CLIA PT for Laboratories Performing Nonwaived Testing

Covers successful proficiency testing from start to finish.

7. LDU Capstone

Applies LDU concepts to real-world scenarios for learner practice and development.

LDU eLearning Courses for Topic 1



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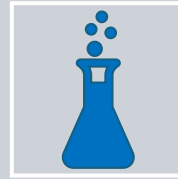
Introduction to LDU
OneLab Network Event



Introduction to Clinical
Laboratory Improvement
Amendments of 1988



Fundamentals of Quality
Practices in CLIA and
Provider Performed
Microscopy Procedures



Ready? Set? Test! Patient
Testing is Important. Get
the Right Results.

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LDU eLearning Course for Topic 3



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CLIA Personnel Qualifications and Responsibilities: High Complexity Testing



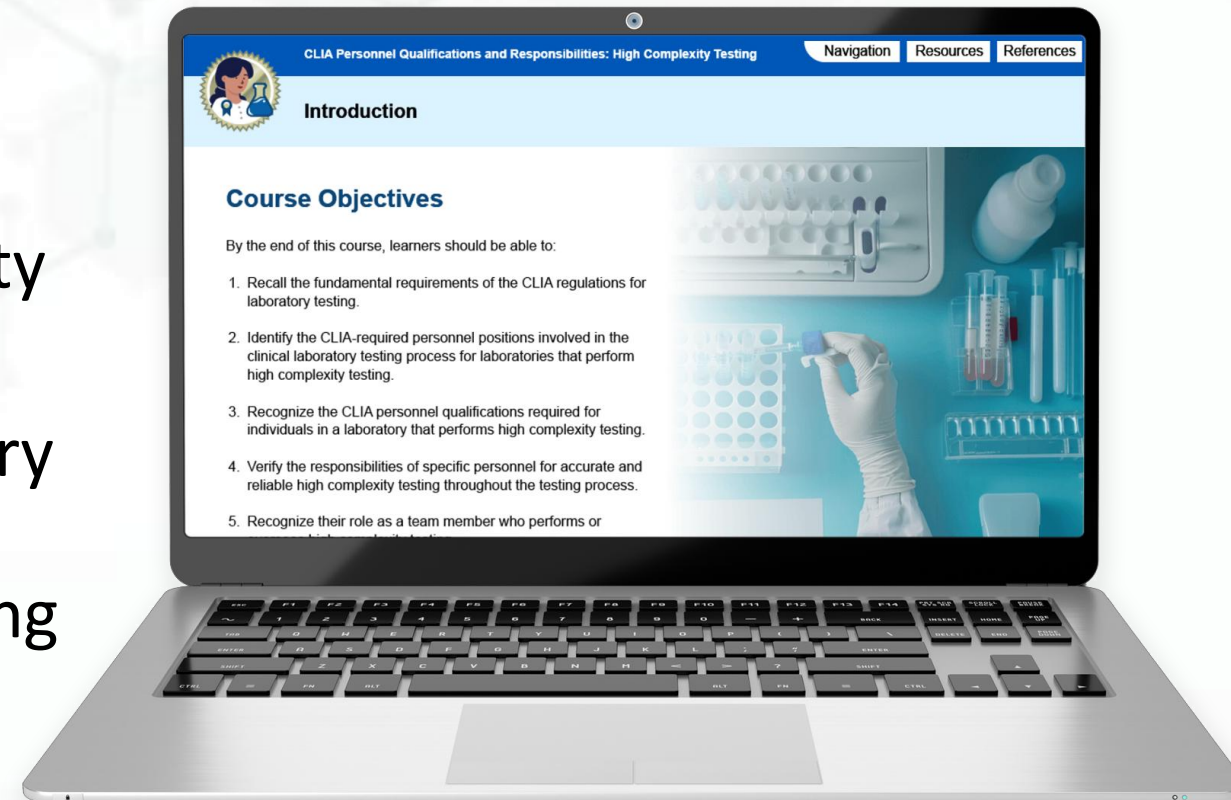
Requirements, duties, and credentials of personnel who perform or oversee high complexity testing



Clinical and public health laboratory staff and others involved in CLIA non-waived, high complexity testing

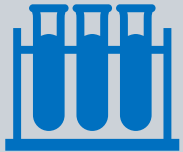


Several types of CE offered



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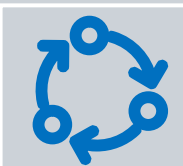
Coming Soon



Topic 3: Clinical Laboratory Improvement Amendments (CLIA) Personnel Qualifications and Responsibilities: Moderate Complexity Testing



Topic 2: The Purpose of the CLIA Survey



Topic 2: Introduction to Laboratory Director Responsibilities (ILDR)



Topic 3: Delegating Responsibilities Practice Example

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LDU Future Courses (1 of 3)



Topic 3: Personnel Responsibilities

- Addressing the Laboratory Director and Laboratory Personnel Qualifications and Responsibilities
- Using the eCFR for Knowledge Reinforcement
- Personnel Competency Assessments



Topic 4: The Survey Process

- The CLIA Survey Process
- Identifying CLIA Inspection Deficiencies
- Completing form CMS-2567

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LDU Future Courses (2 of 3)



Topic 5: Quality Systems for Laboratories Performing Nonwaived Testing

- Laboratory Systems and General Requirements
- Fundamentals of a CLIA Quality System
- Pre-Analytic, Analytic, Post-Analytic Systems
- The Importance of Instrument Maintenance and Function Checks
- Calibration and Calibration Verification
- Verification versus Validation
- Performance Specifications
- Specimen Identification and Integrity
- Quality Assessment

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LDU Future Courses (3 of 3)



Topic 6: Participation in CLIA PT for Laboratories Performing Nonwaived Testing

- The Alternative Assessment (AA) Process
- Introduction to CLIA Proficiency Testing (PT)



Topic 7: LDU Capstone

- Capstone Practice Part 1
- Capstone Practice Part 2

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Thank You!



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We Can't Wait to See What LDU Can Do for You!





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

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Questions?

We will address only the questions that pertain to the event's topic.

For all other inquiries, please contact the CMS Laboratory Excellence team at labexcellence@cms.hhs.gov



OneLab **Assessments**

Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov