OneLab™

A Unified Response to Training Needs

Overview of LDU Resources for Testing Personnel Qualifications in Moderate and High Complexity Laboratories

June 10, 2026

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- Overview of LDU Resources for Testing Personnel Qualifications in Moderate and High Complexity Laboratories
- Q&A
- Upcoming Events

OneLab™ is a registered trademarks of HHS

Participant Rules of Engagement for the Webinar Chat

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.
- **Remain on Topic.** Ensure your comments are relevant to the topic.
- **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.

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

This course helps learners:

- Ensure testing personnel are properly trained to safely and accurately perform CLIA-waived patient testing
- Ensure accurate and timely results and minimize the risk of inaccurate testing

Disclaimer

Subject matter experts and presenters wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Disclaimer

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

Today's Presenter

Cheryl Dobbe, MLT/MT (ASCP)

Technical Advisor
Division of Clinical Laboratory Improvement & Quality
Centers for Medicare & Medicaid Services

Overview of LDU Resources for Testing Personnel Qualifications in Moderate and High Complexity Laboratories

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

Laboratory Director University

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.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

CDC™
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Objectives

Laboratory Director University

1. Identify the CLIA-required personnel positions involved in the clinical laboratory testing process for laboratories that perform moderate and high complexity testing.

2. Summarize the purpose and scope of the CLIA Personnel Qualifications and Responsibilities: Moderate Complexity Testing and CLIA Personnel Qualifications and Responsibilities: High Complexity Testing courses.

LDU: The Product

Laboratory Director University offers **free** and **focused eLearning** for **current and aspiring laboratory directors** whose job will include overseeing CLIA-certified laboratories, as well as CLIA-designated personnel, and other laboratory professionals.

Built by Experts. Backed by Compliance. Designed for You.

Laboratory Director University | OneLab REACH

Continuing Medical Education (CME) credits available for each course

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

Clinical Laboratory Improvement Amendments (CLIA) Personnel Qualifications

Moderate and High Complexity Testing

Course Offerings

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

This course targets individuals involved in moderate complexity clinical laboratory testing across various specialties and subspecialties. It is suitable for laboratory directors, laboratory personnel, and anyone engaged in or supporting clinical laboratory testing.

Clinical Laboratory Improvement Amendments (CLIA) Personnel Qualifications and Responsibilities: High Complexity Testing

This course targets individuals involved in high complexity clinical laboratory testing across various specialties and subspecialties, and those working with tests that the Food and Drug Administration (FDA) has not classified into a specific specialty or subspecialty. It is suitable for laboratory directors, laboratory personnel, and anyone engaged in or supporting clinical laboratory testing.

CLIA Overview

Any laboratory or facility performing testing on specimen derived from the human body that provide information for diagnosis, prevention or treatment of disease MUST be CLIA-certified

Tests performed under CLIA are either waived or nonwaived, depending on the level of complexity.

Moderate Complexity Tests

- Clinical laboratory tests that require more technical skill than waived tests but are less complex than high complexity tests
- Examples include:
  - Rapid antigen tests for infectious diseases
  - Certain immunoassays
  - Some microscopy procedures

High Complexity Tests

- Clinical laboratory tests that require advanced technical expertise including specialized scientific and technical knowledge, as well as extensive training and experience to perform accurately.
- Examples include:
  - Molecular diagnostics
  - Cytogenetics
  - Flow cytometry
  - Immunohematology for transfusion

CLIA Requirements

Moderate Complexity and High Complexity Testing

- Each person filling a CLIA-required position must meet the qualifications for that position in a CLIA-certified laboratory.
- Depending on the position, different combinations of education, training, and/or experience may satisfy CLIA qualification requirements.
- Training or experience must be obtained in a CLIA-certified laboratory.

CLIA Required Personnel Positions

Moderate Complexity Testing

High Complexity Testing

Moderate and High Complexity Testing

- Designed for CLIA laboratory directors and other clinical laboratory personnel who are involved in clinical laboratory testing.
- Includes progressive scenarios that introduce personnel engaged in moderate and high complexity testing in a CLIA-certified laboratory.

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

This course targets individuals involved in moderate complexity clinical laboratory testing across various specialties. It is suitable for laboratory directors, laboratory personnel, and anyone engaged in or supporting clinical laboratory testing.

Clinical Laboratory Improvement Amendments (CLIA) Personnel Qualifications and Responsibilities: High Complexity Testing

This course targets individuals involved in high complexity clinical laboratory testing across various specialties , and those working with tests that the Food and Drug Administration (FDA) has not classified into a specific specialty or subspecialty. It is suitable for laboratory directors, laboratory personnel, and anyone engaged in or supporting clinical laboratory testing.

Moderate Complexity Testing

Required Personnel Qualifications and Responsibilities

Laboratory Director

- Must be qualified to manage and direct the laboratory personnel and performance of moderate complexity tests.
- Responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately , and proficiently, and for assuring compliance with all applicable regulations.

Technical Consultant

- Must be qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures.
- Responsible for the technical and scientific oversight of the laboratory and must be available to the laboratory to provide consultation.

Clinical Consultant

- Must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care.
- Provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

Testing Personnel

- Must be qualified to perform moderate complexity testing.
- Responsible for test performance and reporting test results.

Poll 1

Which position(s) are required in a CLIA laboratory that performs moderate complexity testing?

- ❑ General supervisor
- ❑ Medical director
- ❑ Technical consultant
- ❑ Phlebotomist
- ❑ Technical supervisor

OneLab REACH™

CLIA Personnel Qualifications and Responsibilities: Moderate Complexity Testing

Learners will receive an overview of the requirements, duties, and credentials of personnel who perform or oversee moderate complexity testing subject to Clinical Laboratory Improvement Amendments (CLIA) regulations.

CME: 1.0 AMA PRA Category 1 Credits™

reach.cdc.gov/course/clia-personnel-qualifications-and-responsibilities-moderate-complexity-testing

High Complexity Testing

Required Personnel Responsibilities

Laboratory Director

- Must be qualified to manage and direct the laboratory personnel and performance of high complexity tests.
- Responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately , and proficiently, and for assuring compliance with all applicable regulations.

Technical Supervisor

- Must be qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures.
- Responsible for the technical and scientific oversight of the laboratory and must be available to the laboratory to provide supervision.

Clinical Consultant

- Must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care.
- Provides consultation regarding the appropriateness of the testing ordered and interpretation of test results.

General Supervisor

- Must be qualified to provide supervision of personnel performing high complexity testing.
- Responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing high complexity testing and reporting test results.

High Complexity Testing

Required Personnel Responsibilities (continued)

Testing Personnel

- Must be qualified to perform high complexity testing.
- Responsible for test performance and reporting test results.

Cytology Technical Supervisor

- Must be qualified by education and either training or experience to provide technical supervision for the subspecialty of cytology.
- Responsible for the establishment and reassessment of the workload limit for each individual examining slides, ensuring successful PT participation and confirming the interpretation of each gynecologic slide preparation.

Cytology General Supervisor

- Must be qualified to supervise cytology services.
- Responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting cytology test results including documenting the slide interpretation results, total number of slides examined, and number of hours spent examining slides.

Cytotechnologist

- Must be qualified to examining cytology slide preparations.
- Responsible for documenting the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed, the total number of slides examined or reviewed, and number of hours spent examining slides.

Poll 2

Which positions are required in a CLIA laboratory that performs high complexity testing?

- ❑ General supervisor
- ❑ Medical director
- ❑ Technical consultant
- ❑ Phlebotomist
- ❑ Technical supervisor

OneLab **REACH™**

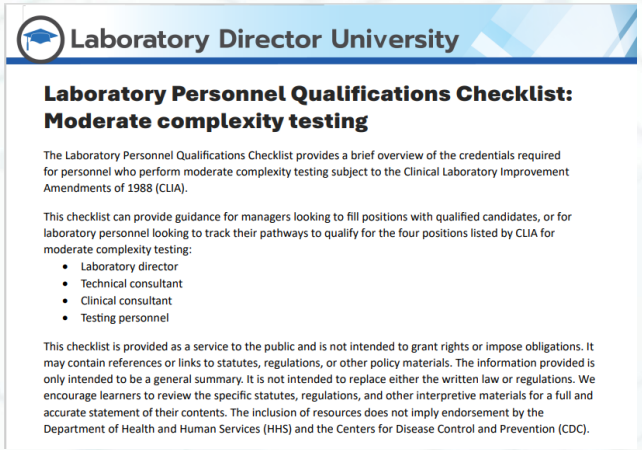
CLIA Personnel Qualifications and Responsibilities: High Complexity Testing

This course provides an overview of the qualifications and responsibilities of laboratory personnel who perform or oversee high complexity testing subject to CLIA regulations.

CME: 1.0 AMA PRA Category 1 Credits™

reach.cdc.gov/course/clia-personnel-qualifications-and-responsibilities-high-complexity-testing

Laboratory Personnel Qualifications Checklists



Laboratory Director University

Laboratory Personnel Qualifications Checklist: Moderate complexity testing

The Laboratory Personnel Qualifications Checklist provides a brief overview of the credentials required for personnel who perform moderate complexity testing subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

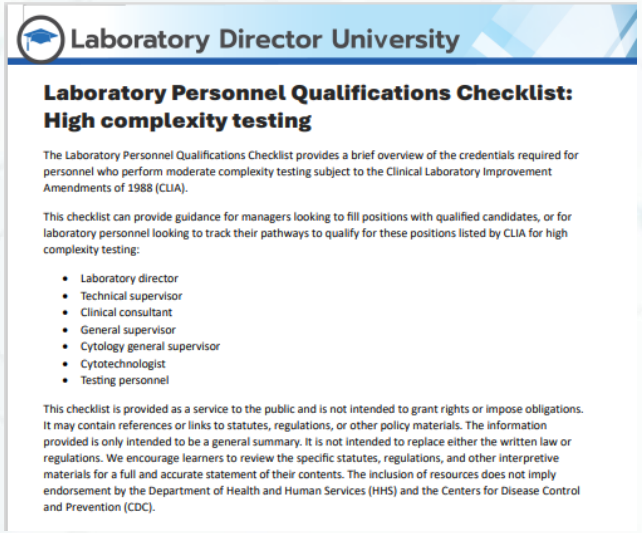
This checklist can provide guidance for managers looking to fill positions with qualified candidates, or for laboratory personnel looking to track their pathways to qualify for the four positions listed by CLIA for moderate complexity testing:

- Laboratory director
- Technical consultant
- Clinical consultant
- Testing personnel

This checklist is provided as a service to the public and is not intended to grant rights or impose obligations. It may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to replace either the written law or regulations. We encourage learners to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents. The inclusion of resources does not imply endorsement by the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC).

Laboratory Personnel Qualifications Checklist: Moderate Complexity Testing

This checklist is designed for laboratory directors and other individuals involved in moderate complexity testing across various specialties and subspecialties.



Laboratory Director University

Laboratory Personnel Qualifications Checklist: High complexity testing

The Laboratory Personnel Qualifications Checklist provides a brief overview of the credentials required for personnel who perform moderate complexity testing subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

This checklist can provide guidance for managers looking to fill positions with qualified candidates, or for laboratory personnel looking to track their pathways to qualify for these positions listed by CLIA for high complexity testing:

- Laboratory director
- Technical supervisor
- Clinical consultant
- General supervisor
- Cytology general supervisor
- Cytotechnologist
- Testing personnel

This checklist is provided as a service to the public and is not intended to grant rights or impose obligations. It may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to replace either the written law or regulations. We encourage learners to review the specific statutes, regulations, and other interpretive materials for a full and accurate statement of their contents. The inclusion of resources does not imply endorsement by the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC).

Laboratory Personnel Qualifications Checklist: High Complexity Testing

This checklist is designed for laboratory directors and other individuals involved in high complexity testing across various specialties and subspecialties.

Qualifications Checklist: Moderate Complexity Testing

Laboratory Name:	Laboratory A	**Personnel Name:**	Jenny Smith
Laboratory Address:	123 Park Dr., Atlanta, GA 30329	**Reviewer Name:**	Aaron Griffin
Laboratory CLIA Number:	12D12345678	**Date Reviewed:**	02/18/2026

The Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Subpart M—Personnel for Nonwaived Testing
Laboratories Performing High Complexity Testing

§ 493.1423 Testing personnel qualifications

☐ (a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required **and**

The testing personnel must meet the CLIA qualification requirements outlined in one of the pathways below:

☐ **Pathway 1: § 493.1423(b)**
- ☐ (1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located.

☐ **Pathway 2: § 493.1423(b)**
- ☐ (2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution.

☐ **Pathway 3: § 493.1423(b)**
- ☐ (3) Meet the requirements in § 493.1405(b)(3)(i)(B) which state
  - ☐ Hold an earned doctoral degree **and**
  - ☐ Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS).

☐ **Pathway 4: § 493.1423(b)**
- ☐ (3) Meet the requirements in § 493.1405(b)(3)(i)(B) which state
  - ☐ Hold an earned doctoral degree **and**
  - ☐ Have an approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

☐ **Pathway 5: § 493.1423(b)**
- ☐ (3) Meet the requirements in § 493.1405(b)(4)(i)(B) which state
  - ☐ Meet bachelor's degree equivalency **and**
  - ☐ Have at least 16 semester hours of additional graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science.

☐ **Pathway 6: § 493.1423(b)**
- ☐ (3) Meet the requirements in § 493.1405(b)(4)(i)(C) which state
  - ☐ Meet bachelor's degree equivalency **and**
  - ☐ Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, clinical or medical laboratory science and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

☐ **Pathway 7: § 493.1423(b)**
- ☐ (3) Meet the requirements in § 493.1405(b)(5)(i)(B) which state
  - ☐ Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes
    - ☐ Forty-eight (48) semester hours of medical laboratory science or medical laboratory technology courses

☐ **Pathway 8: § 493.1423(b)**
- ☐ (3) Meet the requirements in § 493.1405(b)(5)(i)(B) which state
  - ☐ Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes
    - ☐ Forty-eight (48) semester hours of science courses that include
      - ☐ Twelve (12) semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry **and**
      - ☐ Twelve (12) semester hours of biology, which must include general biology and molecular biology, cell biology or genetics **and**
      - ☐ Twenty-four (24) semester hours of chemistry, biology, or medical laboratory science or medical laboratory technology in any combination.

☑ **Pathway 9: § 493.1423(b)**
- ☑ (4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution.

☐ **Pathway 10: § 493.1423(b)**
- ☐ (5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

Qualifications Checklist: Moderate Complexity Testing

- ☐ **Pathway 11: § 493.1423(b)**
  - ☐ (6)(i) Have earned a high school diploma or equivalent and
  - ☐ (6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has
    - ☐ (A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens **and**
    - ☐ (B) The skills required for implementing all standard laboratory procedures **and**
    - ☐ (C) The skills required for performing each test method and for proper instrument use **and**
    - ☐ (D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed **and**
    - ☐ (E) A working knowledge of reagent stability and storage **and**
    - ☐ (F) The skills required to implement the quality control policies and procedures of the laboratory **and**
    - ☐ (G) An awareness of the factors that influence test results **and**
    - ☐ (H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.
- ☐ **Pathway 12: § 493.1423(b)**
  - ☐ (8) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.
- ☐ **Blood Gas Analysis**
  - ☐ **Pathway 1: § 493.1423(b)(7)**
    - ☐ (i) Be qualified under § 493.1423(b)(1), (2), (3), (4), (5), or (6).
  - ☐ **Pathway 2: § 493.1423(b)(7)**
    - ☐ (ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution **and**
    - ☐ (ii)(B) Have at least 1 year of laboratory training or experience, or both, in blood gas analysis.
  - ☐ **Pathway 3: § 493.1423(b)(7)**
    - ☐ (iii)(A) Have earned an associate degree related to pulmonary function from an accredited institution **and**
    - ☐ (iii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis.

Examples of personnel records that can be used to determine qualifications:

- ☑ Diplomas
- ☐ Board Certification
- ☐ Current licenses
- ☐ Transcript(s) from accredited institution(s)
- ☐ Approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing
- ☐ Earned continuing education (CE) credit hour documentation in laboratory practice
- ☐ CMS Quality, Certification and Oversight Reports (QCOR) site
  - ☐ Utilize the CLIA Laboratory Lookup to search for CLIA certificates and identify the effective dates for laboratory specialties and subspecialties.
- ☐ Training and experience
  - ☐ Letters from training programs or employers
  - ☐ Attestation statements of an individual's training and experience by the LD
  - ☐ Log sheet(s) initialed by the individual indicating attendance at a training session or in-service
  - ☐ Certificates from organizations providing training sessions, workshops, conferences, and specialty courses

Notes:

Diploma confirmed associates degree in medical laboratory technology awarded on June 3, 2025.

Qualifications Checklist: High Complexity Testing

Laboratory Name: Laboratory B
Laboratory Address: 123 Lane St., Atlanta, GA 30329
Laboratory CLIA Number: 12D87654321
Personnel Name: Adam Green
Reviewer Name: Stephanie Parks
Date Reviewed: 02/18/2026

The Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Subpart M—Personnel for Nonwaived Testing
Laboratories Performing High Complexity Testing

§ 493.1461 General supervisor qualifications

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

- ☐ (a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required **and**

The general supervisor must meet the CLIA qualification requirements outlined in one of the pathways below:

- ☐ **Pathway 1: § 493.1461(b)**
  - ☐ (1) Be qualified as a laboratory director under § 493.1443.
- ☐ **Pathway 2: § 493.1461(b)**
  - ☐ (2) Be qualified as a technical supervisor under § 493.1449.
- ☐ **Pathway 3: § 493.1461(c)**
  - ☐ (1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution **and**
  - ☐ (1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing.
- ☑ **Pathway 4: § 493.1461(c)**
  - ☑ (2)(i) Qualify as testing personnel under § 493.1489(b)(3) which states
    - ☑ Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution **and**
  - ☑ (2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing.
- ☐ **Pathway 5: § 493.1461(c)**
  - ☐ (2)(i) Qualify as testing personnel under § 493.1489(b)(3) which states
    - ☐ Have education and training equivalent to that specified in § 493.1489(b)(2)(i) that includes
      - ☐ At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes
        - ☐ Twenty-four (24) semester hours of medical laboratory technology courses **and**
      - ☐ Have laboratory training that includes
        - ☐ Completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES) or the Commission on Accreditation of Allied Health Education Programs (CAAHEP). This training may be included in the 60 semester hours listed in § 493.1489(b)(3)(ii)(A).
    - ☐ (2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing.
- ☐ **Pathway 6: § 493.1461(c)**
  - ☐ (2)(i) Qualify as testing personnel under § 493.1489(b)(3) which states
    - ☐ Have education and training equivalent to that specified in § 493.1489(b)(2)(i) that includes
      - ☐ At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes
        - ☐ Twenty-four (24) semester hours of medical laboratory technology courses **and**
      - ☐ Have laboratory training that includes
        - ☐ At least 3 months of documented laboratory training in each specialty in which the individual performs high complexity testing.
  - ☐ (2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing.

Qualifications Checklist: High Complexity Testing

- ☐ **Pathway 7: § 493.1461(c)**
  - ☐ (2)(i) Qualify as testing personnel under § 493.1489(b)(3) which states
    - ☐ Have education and training equivalent to that specified in § 493.1489(b)(2)(i) that includes
      - ☐ At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes
        - ☐ Twenty-four (24) semester hours of science courses that include
          - ☐ Six (6) semester hours of chemistry, **and**
          - ☐ Six (6) semester hours of biology; **and**
          - ☐ Twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination; **and**
      - ☐ Have laboratory training that includes
        - ☐ Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in § 493.1489(b)(3)(ii)(A).
    - ☐ (2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing.
- ☐ **Pathway 8: § 493.1461(c)**
  - ☐ (2)(i) Qualify as testing personnel under § 493.1489(b)(3) which states
    - ☐ Have education and training equivalent to that specified in § 493.1489(b)(2)(i) that includes
      - ☐ At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes
        - ☐ Twenty-four (24) semester hours of science courses that include
          - ☐ Six (6) semester hours of chemistry, **and**
          - ☐ Six (6) semester hours of biology; **and**
          - ☐ Twelve (12) semester hours of chemistry, biology, or medical laboratory technology in any combination; **and**
      - ☐ Have laboratory training that includes
        - ☐ At least 3 months of documented laboratory training in each specialty in which the individual performs high complexity testing.
    - ☐ (2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing.
- ☐ **Pathway 9: § 493.1461(c)**
  - ☐ (3) Meet the laboratory director requirements at § 493.1443(b)(3).
- ☐ **Pathway 10: § 493.1461(c)**
  - ☐ (3) Meet the technical supervisor requirements at § 493.1449(c)(4).
- ☐ **Pathway 11: § 493.1461(c)**
  - ☐ (3) Meet the technical supervisor requirements at § 493.1449(c)(5).
- ☐ **Pathway 12: § 493.1461(c)**
  - ☐ (4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

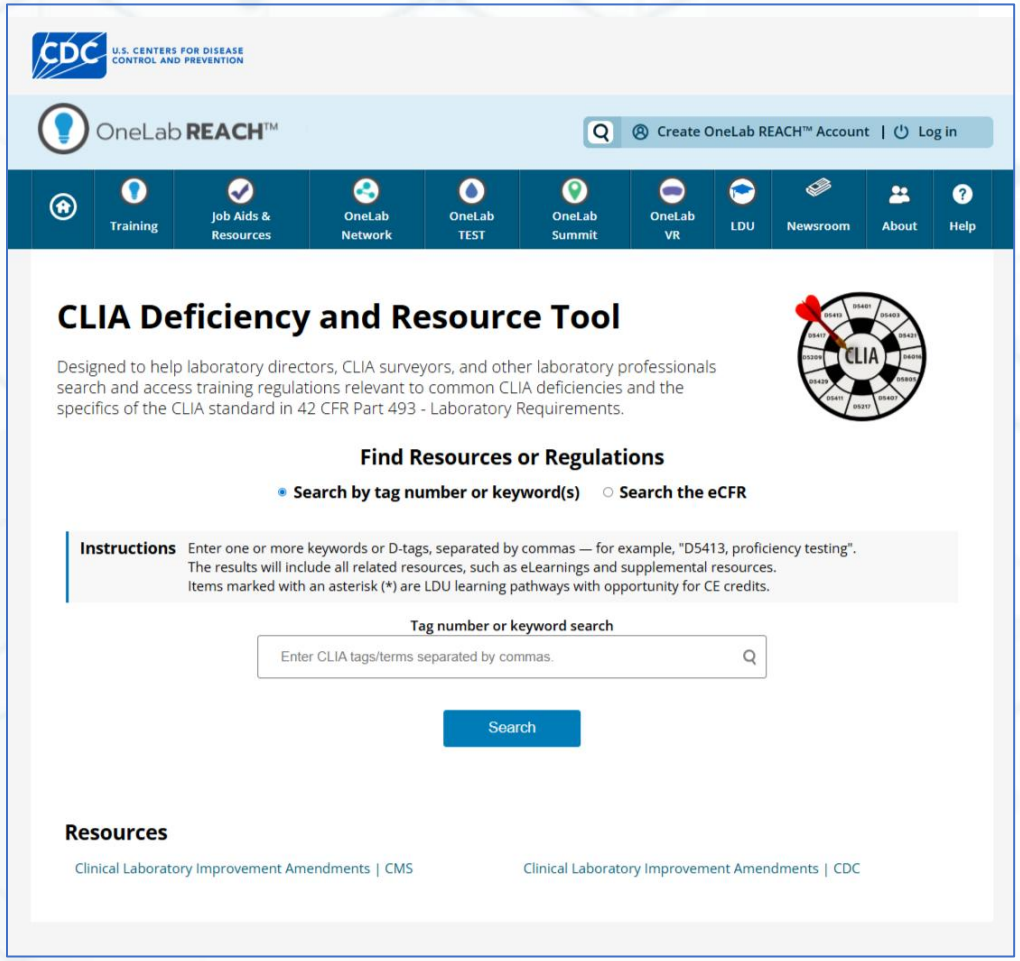
Examples of personnel records that can be used to determine qualifications:

- ☑ Diplomas
- ☐ Board Certification
- ☐ Current licenses
- ☐ Transcript(s) from accredited institution(s)
- ☐ Approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing
- ☐ Earned continuing education (CE) credit hour documentation in laboratory practice
- ☐ CMS Quality, Certification and Oversight Reports (QCOR) site
  - ☐ Utilize the CLIA Laboratory Lookup to search for CLIA certificates and identify the effective dates for laboratory specialties and subspecialties.
- ☐ Training and experience
  - ☑ Letters from training programs or employers
  - ☐ Attestation statements of an individual's training and experience by the laboratory director
  - ☐ Log sheet(s) initialed by the individual indicating attendance at a training session or in-service
  - ☐ Certificates from organizations providing training sessions, workshops, conferences, and specialty courses

Notes:

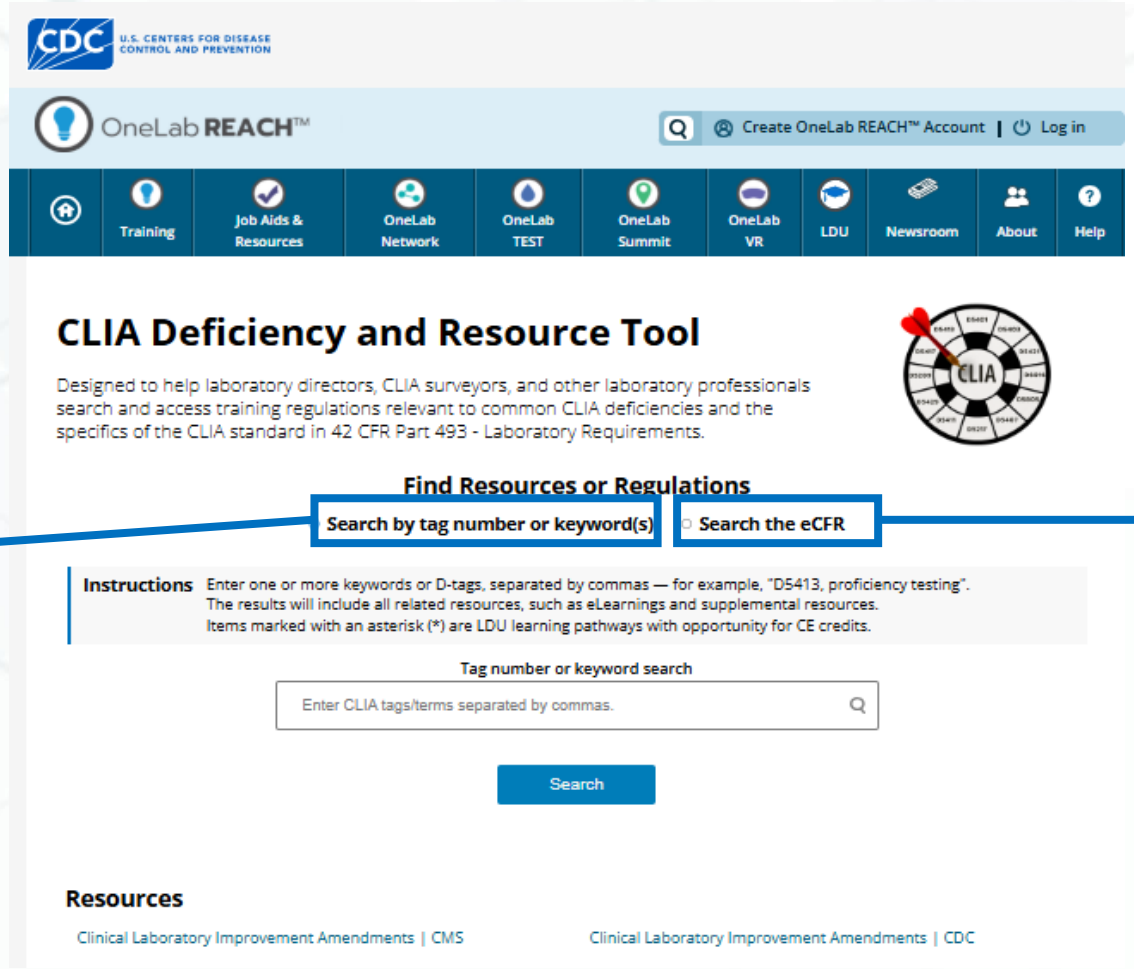
- Diploma confirmed associates degree in medical laboratory technology awarded on June 22, 2023.
- Letters provided from current employer indicating training performed is from a CLIA-certified laboratory.
- Attestation statement from current employer indicating that Mr. Green was on their CLIA certificate for 3 years as testing personnel.

Hit the Bull's-Eye with CDART



LDU's innovative and exclusive CLIA Deficiency and Resource Tool – known as **CDART** – connects laboratory professionals and CMS surveyors with CLIA resources relevant to common CLIA deficiencies.

CLIA Deficiency and Resource Tool (CDART)



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

Search Regulations by keywords

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.

We are continually expanding the resources available in CDART. If your search does not return any results, it may be because the corresponding learning pathways and materials are still in development. Please check back in the coming weeks as new resources are added.

Tag number or keyword search

D5209

Search Reset

Results: 1 resource(s) found for D5209.

D5209

CFR	Interpretive Guideline	Resource Title
493.1235 Standard: Personnel competency assessment policies	The laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency as specified in the personnel	Clinical Laboratory Improvement Amendments (CLIA) Personnel Qualifications and Responsibilities: High Complexity Testing *eLearning* *

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.

Coming Soon

Topic 3: CLIA Personnel Qualifications and Responsibilities: Cytology Testing

Topic 2: The Purpose of the CLIA Survey

Topic 2: Introduction to Laboratory Director Responsibilities (ILDR)

Topic 3: Delegating Responsibilities Practice Example

Built by Experts. Backed by Compliance. Designed for You.

Thank You!

Laboratory Director University

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

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR CLINICAL STANDARDS & QUALITY

CDC
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

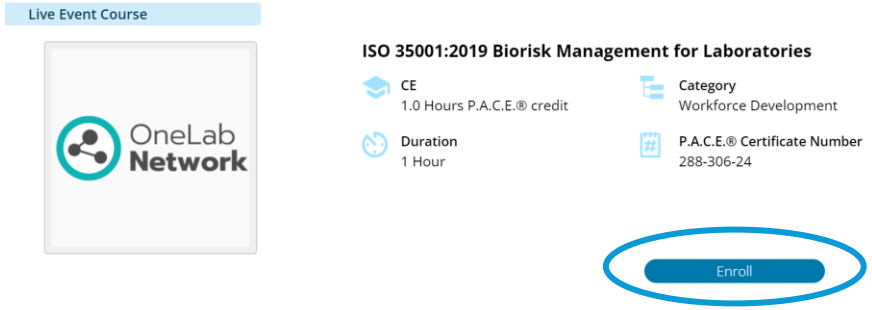
Questions?

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

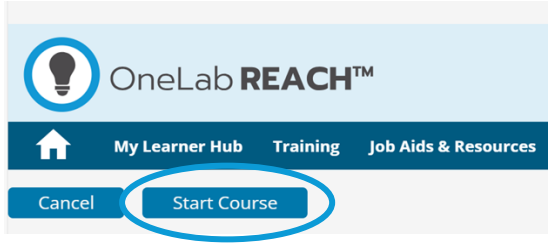
OneLab REACH™ Continuing Education

After participating in today's session, to receive continuing education credits you must:

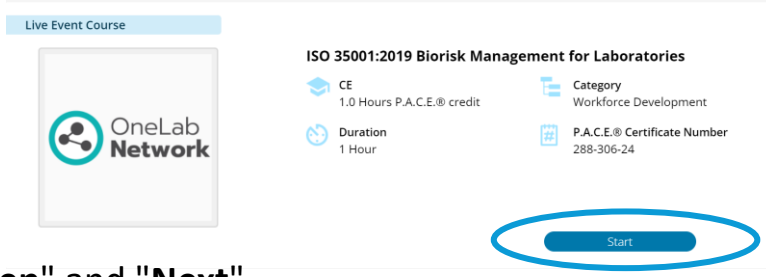
1. Log into your OneLab REACH account. **You must be logged into your REACH account to access the evaluation.**
2. Click on this link to take you to the survey.
3. Enter passcode "**mod26**"
4. Click "**Enroll**"



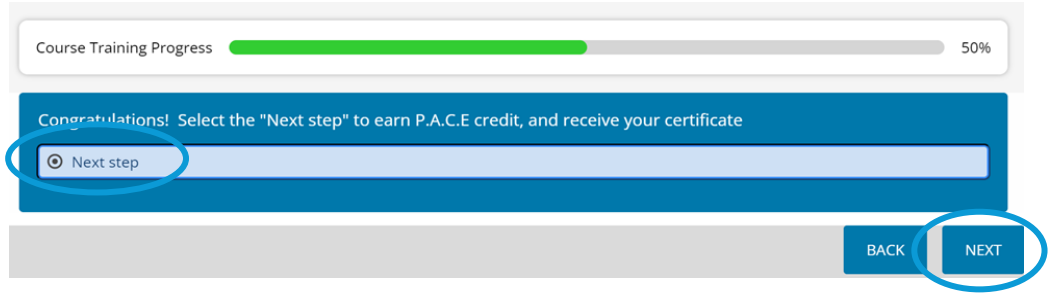
5. Select "**Start Course**".



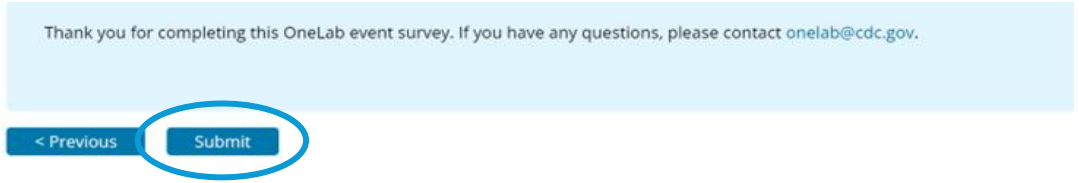
6. Select "**Start**".



7. Select "**Next step**" and "**Next**".



8. Complete the evaluation and click "**Submit**". Receive your P.A.C.E.® certificate in your MyLearnerHub.



OneLab **Assessments**

Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov