Division of Laboratory Systems

OneLab™

A Unified Response to Training Needs

CLIA Proficiency Testing (PT) Final Rule, CMS-3355-F

Penny Keller

September 7, 2023

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- Proficiency Testing (PT) Final Rule, CMS-3355-F
- Q&A
- Upcoming Events

OneLab **REACH™**

NEW

Fundamentals of Laboratory Safety

In this basic-level online course, you will learn the hazards you may encounter while working in a clinical or public health laboratory, ways to mitigate risks, and the proper response to incidents.

P.A.C.E.® credit
1.5 Hour(s)

Register for course on
OneLab REACH™

REGISTER NOW

OneLab **REACH™**

NEW

Fundamentals of Methylene Chloride Safety

This basic-level course provides information on the chemical properties and adverse health effects associated with the use of methylene chloride, or dichloromethane (DCM), in clinical and public health laboratories.

P.A.C.E.® credit
1 Hour(s)

REGISTER NOW

Register for course on OneLab REACH™

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Presenter

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Proficiency Testing (PT) Final Rule, CMS-3355-F

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Centers for Medicare & Medicaid Services/
Division of Clinical Laboratory

Improvement and Quality

Disclaimer

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This publication is a general summary that explains certain aspects of the Clinical Laboratory Improvement Amendments (CLIA) Program, but is not a legal document. The official CLIA Program provisions are contained in the relevant laws, regulations, and rulings. Links to the source documents have been provided within the document for your reference.

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Objectives

After the presentation, you will be able to:

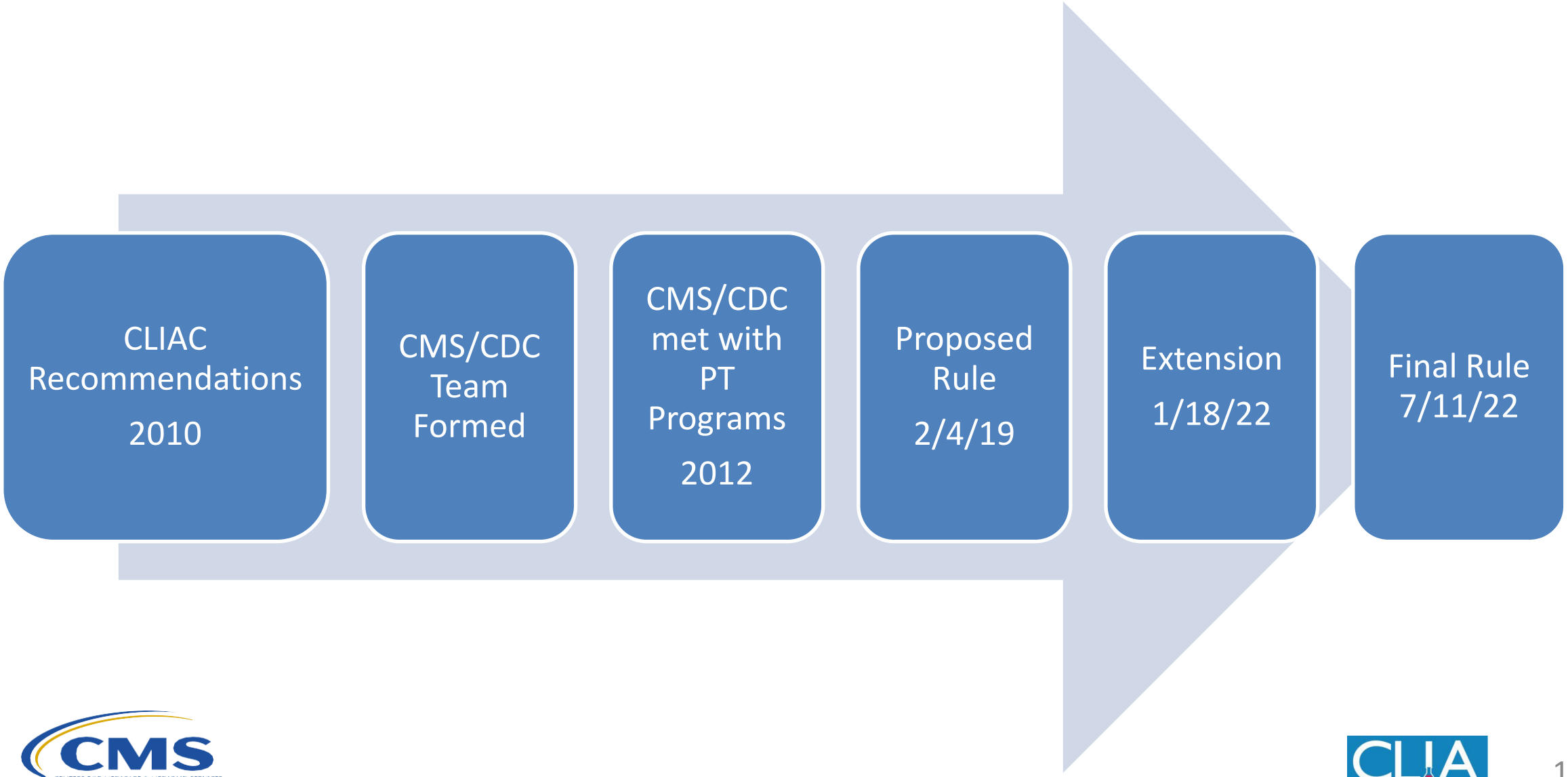
- State the effective dates of the PT Final Rule provisions
- Describe the finalized requirements, including:
  - Microbiology changes
  - Non-Microbiology changes
  - Testing of samples, PT referral for waived tests changes
  - PT Program changes

PT Final Rule Published!

The PT final rule (CMS-3355-F) was published in the Federal Register on July 11, 2022

- General *Federal Register* link: Federal Register
- Direct link to PT Final Rule: CMS-3355-F (PT Final Rule)
- Fact Sheet: PT FR Fact Sheet
- QSO Memo: QSO-22-21-CLIA, Final Rule - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing - Analytes and Acceptable Performance Final Rule (CMS-3355-F)

History at a Glance



Effective Dates

- Regulations §§ 493.2 and 493.801 through 493.959 are effective two years after publication in the *Federal Register* - **July 11, 2024**
- Amended regulations at §§ 493.20 and 493.25 are effective **August 10, 2022**
  - Related to laboratories performing tests of moderate and high complexity testing that also perform waived testing

Finalized Requirements

- Microbiology PT changes
- Non-Microbiology PT changes
  - Definitions
  - Addition/Deletion of Analytes
  - Criteria for Acceptable Performance
- Testing of Samples, PT Referral for Waived Tests
- Other changes, PT Programs

Microbiology PT Changes, General

- Types of services listed for each microbiology subspecialty were removed; more general list of organisms was added
- Evaluation of a laboratory's performance updated
- PT programs must attempt to grade using both participant and referee laboratories before determining that the sample is ungradable to achieve consensus
- Mixed culture requirement has been lowered from 50% to 25% for bacteriology, mycobacteriology, and mycology.
- Laboratories must report PT results for microbiology organism identification to the highest level that they report results on patient specimens (493.801(3))

Microbiology PT Changes, Bacteriology (§ 493.911)

- The annual program content must include representatives of the following major groups of medically important aerobic and anaerobic bacteria if appropriate for the sample sources: Gram negative bacilli; Gram positive bacilli; Gram negative cocci; and Gram positive cocci.
- Gram stains includes both stain reaction and morphology

Microbiology PT Changes, Bacteriology (§ 493.911) cont.

- Require at least two PT samples per event for susceptibility or resistance testing, including one Gram positive and one Gram negative organism with a predetermined pattern of susceptibility or resistance to common antimicrobial agents.
- removed references to “resistance testing” in the requirement for antimicrobial susceptibility testing of select bacteria

Microbiology PT Changes, Mycobacteriology (§ 493.913)

- The annual program content must include *Mycobacterium tuberculosis* complex and *Mycobacterium* other than tuberculosis (MOTT), if appropriate for the sample sources.
- Require at least two PT samples per event for susceptibility or resistance testing, including mycobacteria that have a predetermined pattern of susceptibility or resistance to common antimycobacterial agents.

Microbiology PT Changes, Mycology (§ 493.915)

- The annual program content must include the following major groups of medically important fungi and aerobic actinomycetes if appropriate for the sample sources: yeast or yeast-like organisms; molds that include dematiaceous fungi, dermatophytes, dimorphic fungi, hyaline hyphomycetes, and mucormycetes; and aerobic actinomycetes.
- Requires direct antigen testing

Microbiology PT Changes, Parasitology (§ 493.917)

- The annual program content must include intestinal parasites and blood and tissue parasites, if appropriate for the sample sources.
- Requires direct antigen testing

Microbiology PT Changes, Virology (§ 493.919)

- The annual program content must include respiratory viruses, herpes viruses, enterovirus, and intestinal viruses, if appropriate for the sample sources.
- Requires direct antigen testing

Non-Microbiology PT Changes

- Hematology
  - Units of reporting for prothrombin time includes seconds and INR; laboratories must report prothrombin time in the same manner as they report patient results
  - Laboratories performing both cell counts and differentials must enroll and participate in PT for both
  - Criteria for acceptable performance for “cell identification” changed from 90% to 80%

Non-Microbiology PT Changes

- Toxicology
  - PT programs must provide samples that cover the full range of samples that could occur in patient specimens
- Immunohematology
  - criteria for acceptable performance for unexpected antibody detection revised from 80% to 100%

Non-Microbiology PT Changes, Definitions

Additions:

- Acceptance Limit
- Peer Group

Revision:

- Target Value

Non-Microbiology PT Changes, Definitions

Acceptance limit means the symmetrical tolerance (plus and minus) around the target value.

Peer group means a group of laboratories whose testing process utilizes similar instruments, methodologies, and/or reagent systems and is not to be assigned using the reagent lot number level.

Non-Microbiology PT Changes, Definitions cont.

Target value for quantitative tests means:
(1) If the peer group consists of 10 participants or greater:
(i) The mean of all participant responses after removal of outliers (that is, those responses greater than three standard deviations from the original mean, as applicable);
(ii) The mean established by a definitive method or reference methods; or
(iii) If a definitive method or reference methods are not available, the mean of a peer group; or
(2) If the peer group consists of fewer than 10 participants, the mean of all participant responses after removal of outliers (as defined in paragraph (1) of this definition) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

Non-Microbiology PT Changes, Added/Deleted Analytes

Criteria used:

- Current availability of PT materials and the number of PT programs offering PT
- Volume of patient testing performed nationwide
- Impact on patient health and/or public health
- Cost and feasibility of implementation

Non-Microbiology PT Changes, Added Analytes

General Immunology **§ 493.927**	**Anti-HBs** **Anti-HCV** **C-reactive protein (high sensitivity)**
Routine Chemistry **§ 493.931**	**B-natriuretic peptide (BNP)** **ProBNP** **Cancer antigen (CA) 125** **Carbon dioxide** **Carcinoembryonic antigen** **Cholesterol, low density lipoprotein, direct measurement** **Ferritin** **Gamma glutamyl transferase** **Hemoglobin A1c** **Phosphorus** **Prostate specific antigen, total** **Total iron binding capacity (TIBC), direct measurement** **Troponin I** **Troponin T**

Non-Microbiology PT Changes, Added Analytes cont.

Endocrinology **§ 493.933**	**Estradiol** **Folate, serum** **Follicle stimulating hormone** **Luteinizing hormone** **Progesterone** **Prolactin** **Parathyroid hormone** **Testosterone** **Vitamin B12**
Toxicology **§ 493.937**	**Acetaminophen, serum** **Salicylate** **Vancomycin**

Non-Microbiology PT Changes, Deleted Analytes

§493.931

- LDH isoenzymes

§493.93

- Ethosuximide
- Quinidine
- Primidone
- Procainamide (and its metabolite, N-acetyl procainamide)

Criteria for Acceptable Performance

- Most limits changed from standard deviations to percentage-based limits
- Fixed Concentration Units added to Fixed Percentage Units to address lower concentrations, for example:
  - Bilirubin, total - ±20% or ±0.4 mg/dL
  - Thyroid-stimulating hormone - ±20% or ±0.2 mIU/L
  - Lithium - ±15% or ±0.3 mmol/L

Testing of Samples, PT Referral for Waived Tests

- Aligns the CLIA statute (law) with the regulations
- Moderate and high complexity laboratories that also perform waived tests:
  - Are not required to enroll in PT for waived tests
  - Are held to requirements for testing of PT samples if enrolled for waived tests
  - Does not exclude waived tests from PT referral

Other Changes, PT Programs

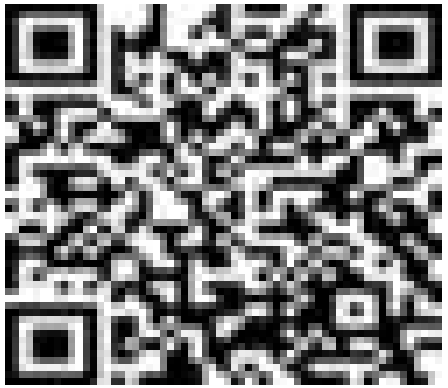
- Require a minimum of 10 laboratory participants for each specialty, subspecialty, and analyte or test when seeking reapproval
- Technical and scientific responsibilities must be a private nonprofit organization or a Federal or State agency, or an entity acting as a designated agent for the Federal or State agency.
- May require on-site visits for all PT program, initial applications for approval or when problems are encountered for previously HHS approved proficiency testing programs

Other Changes, PT Programs

- HHS may require a proficiency testing program to reapply for approval using the process for initial applications if significant problems are encountered during the reapproval process.
- CMS will notify the program of its withdrawal of approval in certain cases:
  - PT program fails to meet any PT criteria
  - PT program provides false or misleading information with respect to any information that is necessary to meet any criteria

How To Reach Us

- Email address: LabExcellence@cms.hhs.gov
- CLIA website: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
- CLIA Communications ListServ: https://public.govdelivery.com/accounts/USCMS/subscriber/new?topic_id=USCMS_12461
- QR code to CLIA website:



Questions?

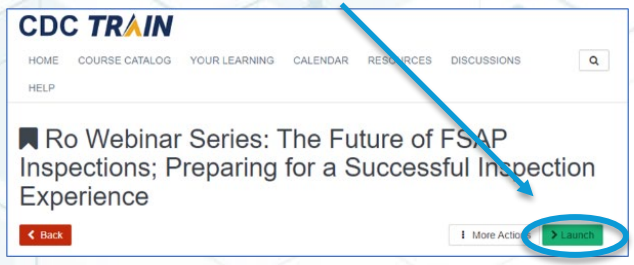
Questions?

Continuing Education

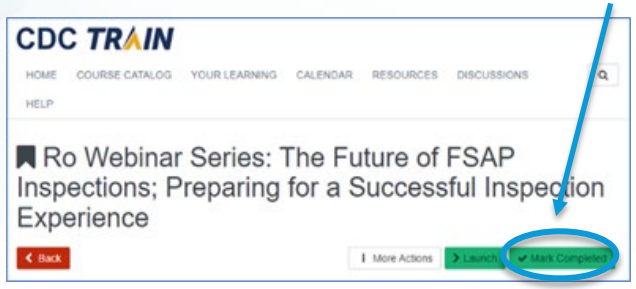
In order to receive continuing education credits, you must:

1. **Attend** entire webinar/**register** for course on TRAIN
   - Register for the course in TRAIN
   - Registration passcode: **F986**
   - Select **"PACE"** credit type

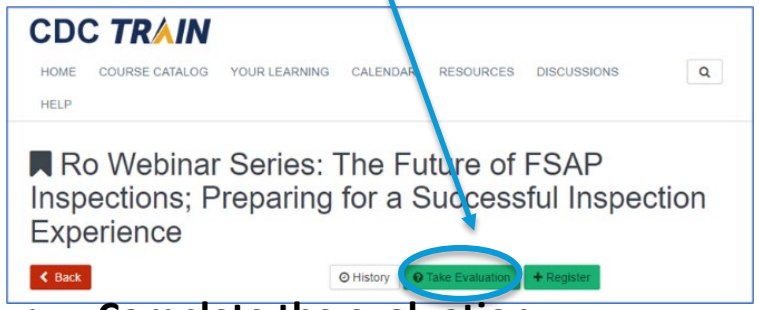
   - Click "**Launch**"



   - Click on green **"Mark Complete"**

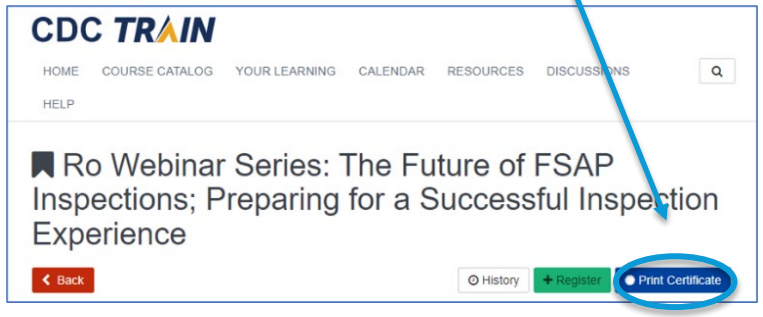


2. **Complete** webinar evaluation
   - Click green **"Take Evaluation"** button



   - **Complete the evaluation**

3. **Obtain** P.A.C.E Certificate
   - Click on the blue **"Print Certificate"** button to download



Upcoming OneLab Network Events

OneLab™
A Unified Response to Training Needs

How to Plan for *B. pseudomallei* Exposure Cases - A Laboratory Perspective

September 26, 2023, at 12 PM ET

Register Now!

OneLab Summit

COMING SOON!

OneLab Summit 2023

Thrive: People. Planning. Preparedness.

OCTOBER 3-5 | A Three-Day Virtual Learning Event

Developed for Laboratory Professionals to:

- Improve their skills through hands-on technologies, learning and development tools, and practices
- Glean insights from the laboratory community's success and resilience
- Collaborate and connect with CDC and laboratory education and training peers

Registration details and agenda available on reach.cdc.gov/onelabsummit/2023