CLIA and Point of Care Testing

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Objectives

- General overview of CLIA
- Guidance on regulations regarding point of care testing
- CLIA updates

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What is CLIA?

- **C**linical **L**aboratory **I**mprovement **A**mendments
- Minimum federal standards laboratories must follow

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CLIA History

- Public Law 100-578 CLIA ’88 signed by President on October 31, 1988
- CLIA final rules 42 CFR part 493 (administrative processes and quality standards) published on February 28, 1992
- CLIA final rules effective on September 1, 1992
- Uniform standards to ensure accuracy, reliability and timeliness

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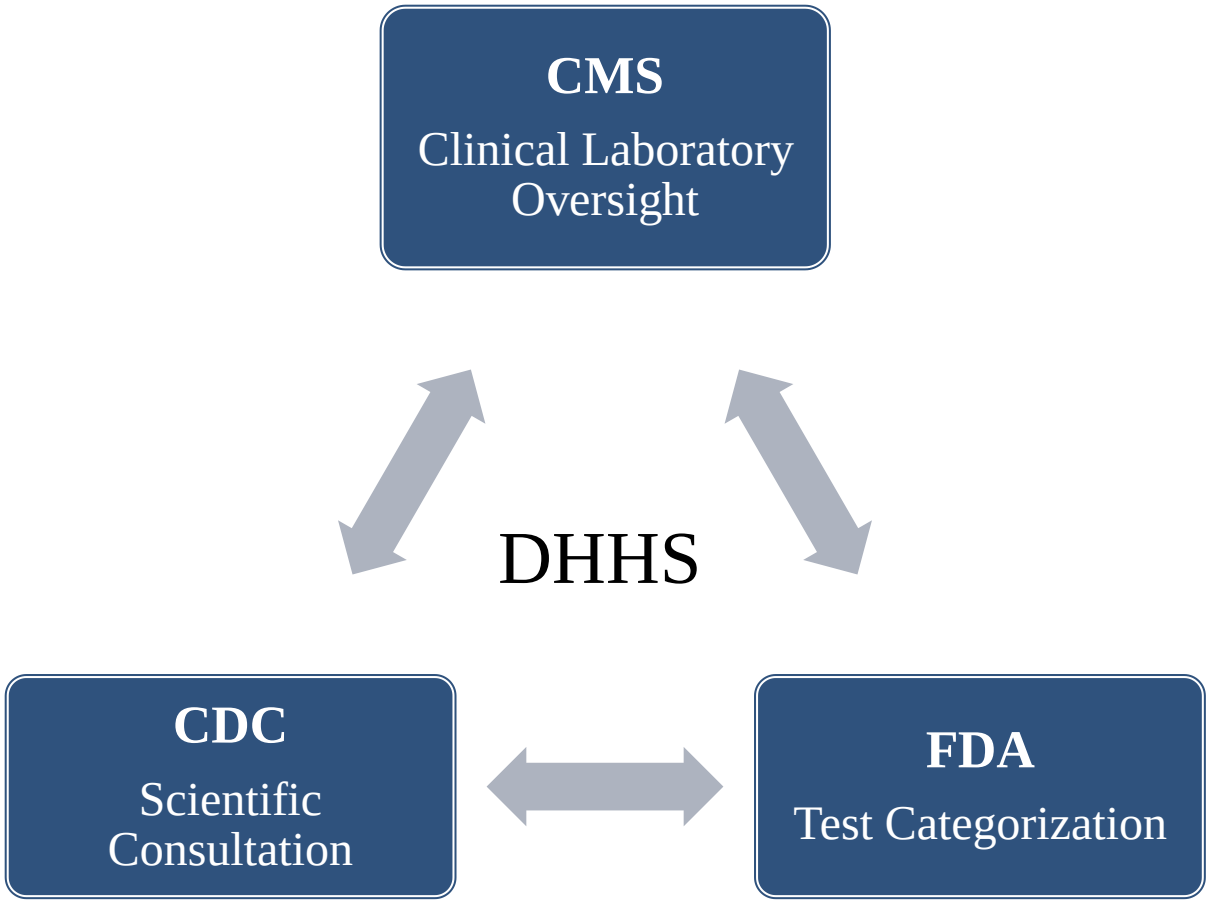
CLIA Program Responsibilities



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Laboratory (as defined by CLIA)

A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

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All Clinical Laboratories…

That perform testing on patient specimens must:

- Apply for a CLIA certificate;
- Pay appropriate fees; and
- Follow applicable CLIA requirements

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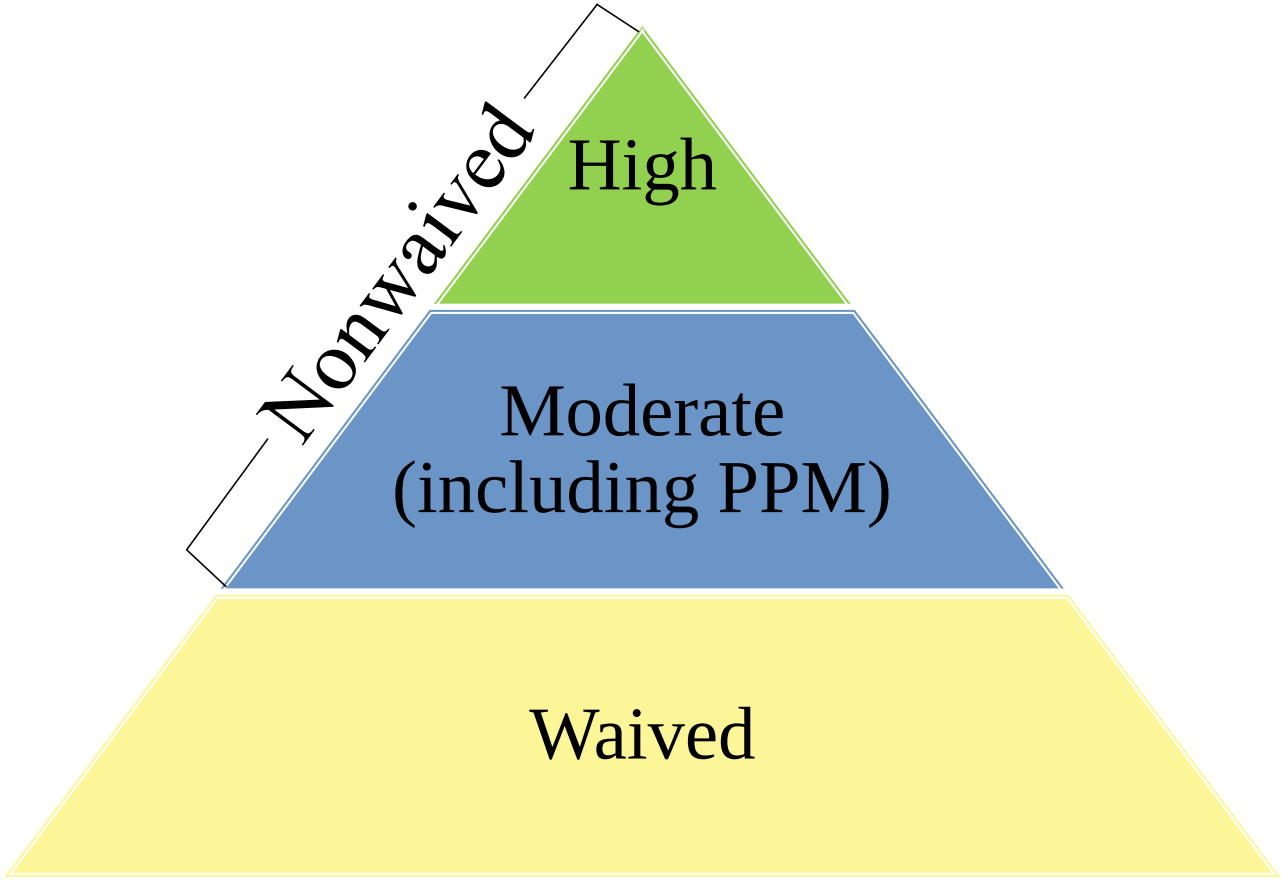
Test Complexity



CLIA Certificate Types

- Certificate of Compliance (CoC)
- Certificate of Accreditation (CoA)
- Certificate for Provider-performed Microscopy (PPM) Procedures
- Certificate of Waiver (CoW)

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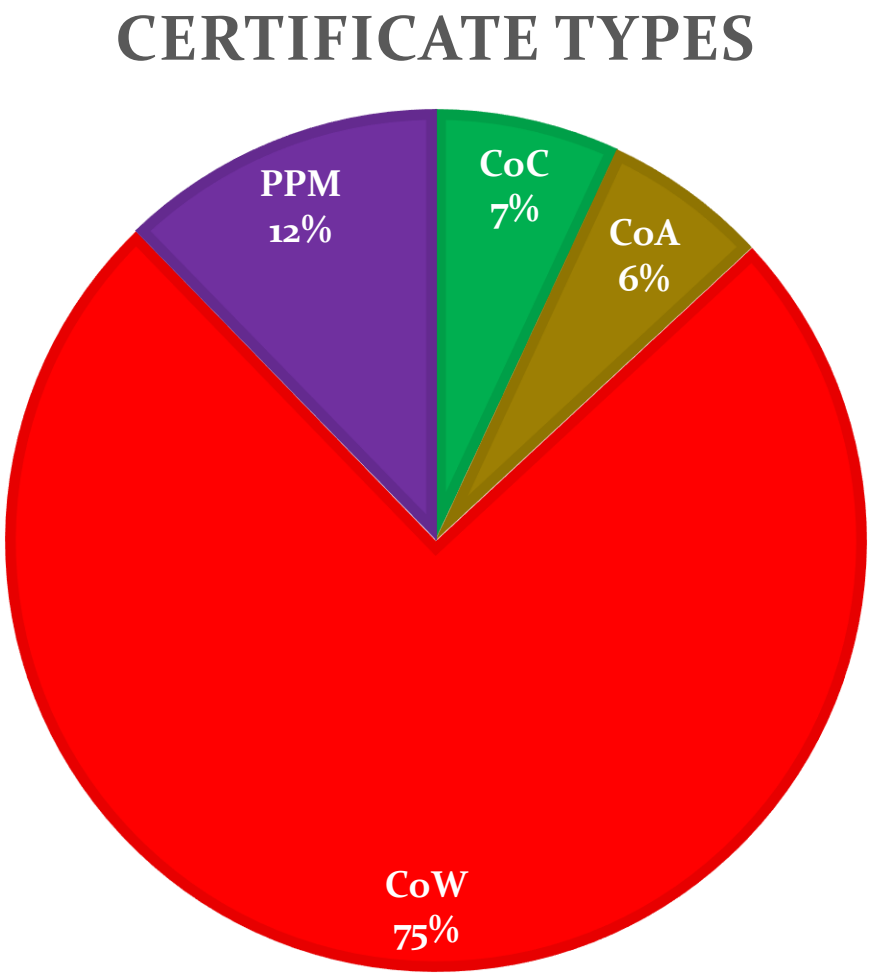
Current Enrollment Statistics



Source: CMS CLIA Database, April 2019

Continuous Laboratory Oversight

- CLIA (State Agencies/Regional Office)
- Accreditation Organizations (AO)

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Certificate of Compliance

- Surveyed for compliance with the CLIA regulations
- Can perform waived, moderate and high complexity testing
- Pay biennial certificate fees
- Routinely surveyed every two years by State Agencies

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Certificate of Accreditation

- Laboratory selects Accrediting Organization at time of CLIA application
- Can perform waived, moderate and high complexity testing
- Pay biennial certificate fees
- Routinely surveyed every two years by AO survey team

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CMS Approved AOs

- AABB
- American Association for Laboratory Accreditation (A2LA)
- Accreditation Association for Hospitals and Health Systems/ Healthcare Facilities Accreditation Program (AAHHS/HFAP)
- American Society for Histocompatibility and Immunogenetics (ASHI)
- COLA
- College of American Pathologists (CAP)
- The Joint Commission

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Certificate for Provider-performed Microscopy (PPM) Procedures

- Pay biennial certificate fees
- Not subject to routine surveys
- Can perform PPM procedures and waived testing
- Examples of PPM include:
  - KOH preparations
  - Fern tests
  - Urine sediment examinations

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Knowledge Check

Which test is not a PPM procedure?

A. Semen analysis; presence and/or motility
B. Nasal smears for eosinophils
C. Tzanck smear
D. Fecal leukocyte examination

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Certificate of Waiver

- Enroll in the CLIA program
- Pay biennial certificate fees
- Only perform tests categorized as waived
- Not subject to routine surveys
- Must follow manufacturer's instructions

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Waived vs Nonwaived

Subpart of 493 – Laboratory Requirements	Waived	Nonwaived
Subpart A – General Provisions	✓	✓
Subpart B – Certificate of Waiver	✓	
Subpart C – Registration Certificate, Certificate for Provider-performed Microscopy Procedures, and Certificate of Compliance		✓
Subpart D – Certificate of Accreditation		✓
Subpart E – Accreditation by a Private, Nonprofit Accreditation Organization of Exemption Under an Approved State Laboratory Program		✓
Subpart F – General Administration	✓	✓
Subpart H – Participation in Proficiency Testing for Laboratories Performing Nonwaived Testing		✓
Subpart I – Proficiency Testing Programs for Nonwaived Testing		✓
Subpart J – Facility Administration for Nonwaived Testing		✓
Subpart K – Quality System for Nonwaived Testing		✓
Subpart M – Personnel for Nonwaived Testing		✓
Subpart Q – Inspection	✓	✓
Subpart R – Enforcement Procedures	✓	✓

Point of Care Testing

- Waived
- Moderate complexity
- PPM procedures
- High complexity

Nonwaived

Quality Control

Waived:

- Follow manufacturer's instructions

Nonwaived:

- §493.1256(d) Unless CMS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must:
  - Follow additional specialty and subspecialty requirements
  - Perform control procedures using the number and frequency specified by the manufacturer or established by the lab when they meet or exceed performing two levels of QC each day of patient testing [§493.1256(d)(2)]

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When Should You Consider an IQCP?

Waived:

- Not applicable

Nonwaived:

- If manufacturer's instructions are less stringent than CLIA regulations, either follow CLIA control regulations at §493.1256-1278 or perform an IQCP

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IQCP…cont.

- Voluntary, tailored QC plan specific for your testing environment
- Entire testing process: preanalytic, analytic, postanalytic
- Includes:
  - Risk Assessment (RA)
  - Quality Control Plan (QCP)
  - Quality Assessment (QA)
  - LD signature

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Personnel Requirements

- Waived testing
  - Laboratory Director (LD)

Personnel Requirements

- Moderate complexity testing
  - Laboratory Director (LD)
  - Technical Consultant (TC)
  - Clinical Consultant (CC)
  - Testing Personnel (TP)

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Personnel Requirements

- PPM procedures
  - Laboratory Director (LD)
    - Physician (MD, DO, DPM), midlevel practitioner (nurse midwife, nurse practitioner, physician assistant), dentist
  - Testing Personnel (TP)
    - Physician (MD, DO, DPM), midlevel practitioner (nurse midwife, nurse practitioner, physician assistant), dentist

Personnel Requirements

- High complexity testing
  - Laboratory Director (LD)
  - Technical Supervisor (TS)
  - Clinical Consultant (CC)
  - General Supervisor (GS)
  - Testing Personnel (TP)

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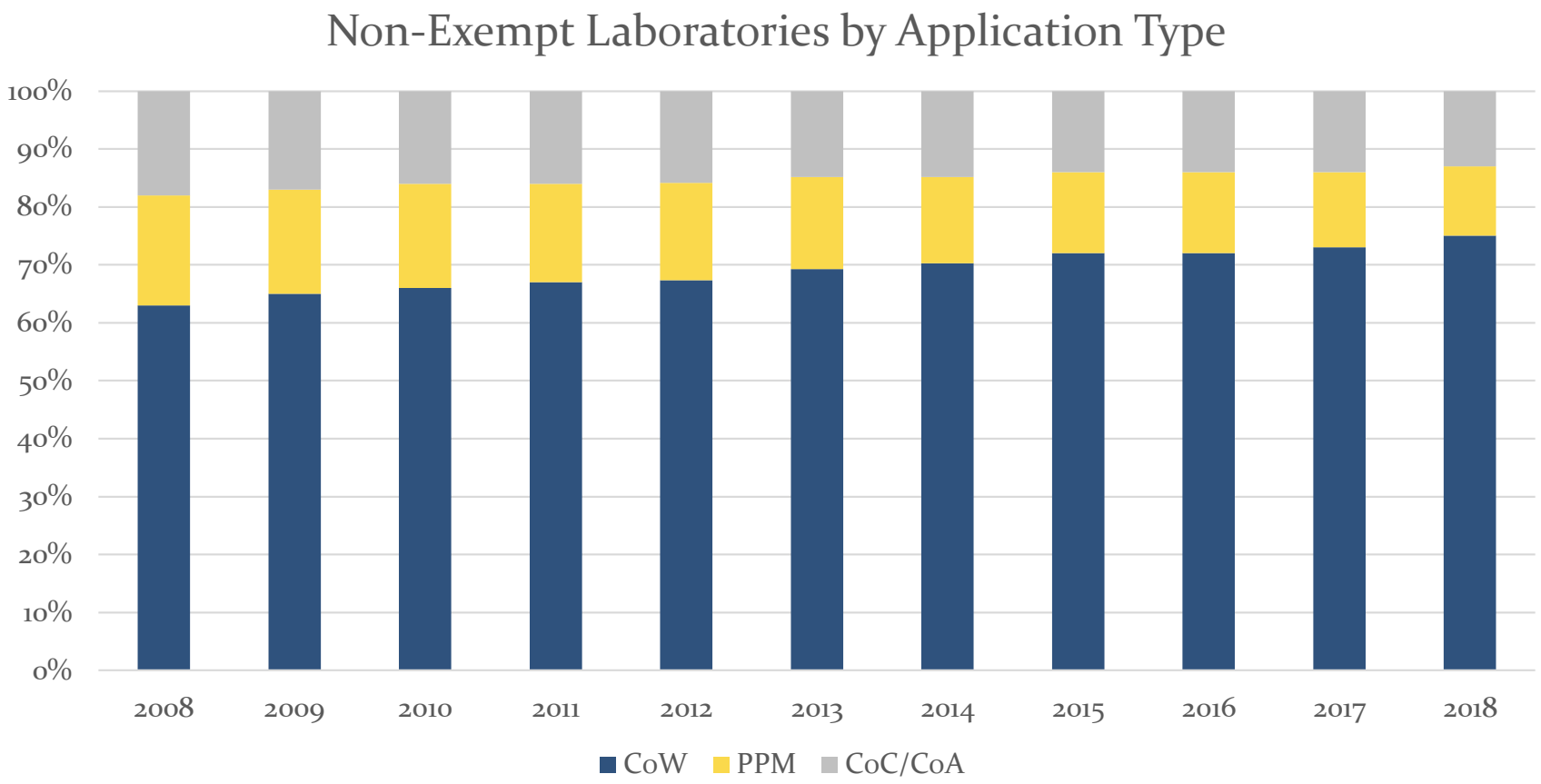
Laboratory Growth Nationwide



Source: CMS CLIA Database, April 2019

Certificate of Waiver (CoW) Project

- CMS surveyed a percentage of CoW laboratories nationwide
- Announced surveys geared towards education
- Surveyors determined:
  - Patient safety
  - Regulatory compliance
  - Waived tests only

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Findings from CoW Project

- Failed to have current manufacturer's instructions
- Failed to perform quality control per manufacturer's instructions
- Failed to follow manufacturer's instructions
- Performed nonwaived testing

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Why is this Important?

- Can lead to misdiagnosis
- Confirms complaints from the public
- Most important… PATIENT SAFETY

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What Did We Do?

- Initiated test menu collection with CLIA application
- Created educational booklets in collaboration with the CDC
- Enlisted support of professional and patient advocacy organizations

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CLIA Updates

Federal Register:

1/9/2018, Request for Information **CMS-3326-NC**: Revisions to Personnel Regulations, PT Referral, Histocompatibility Regs and Fee Regs.

2/4/2019, Proposed Rule **CMS-3355-P**: CLIA PT Regulations Related to Analytes and Acceptable Performance

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Resources

Name	Hyperlink
CMS CLIA website	https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/
MLN Fact Sheet	https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/CLIABrochure.pdf
CDC CLIA website	https://wwwn.cdc.gov/CLIA/Default.aspx
FDA CLIA website	https://www.fda.gov/medical-devices/ivd-regulatory-assistance/clinical-laboratory-improvement-amendments-clia
FDA CLIA Database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm

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QUESTIONS?

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