

CLIA and Point of Care Testing

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Objectives

- Explain an overview of CLIA
- Outline guidance on regulations; test complexity
- Describe Top Five deficiencies found in CW laboratories
- Analyze challenges for POCT Programs
- Discuss off-label Testing

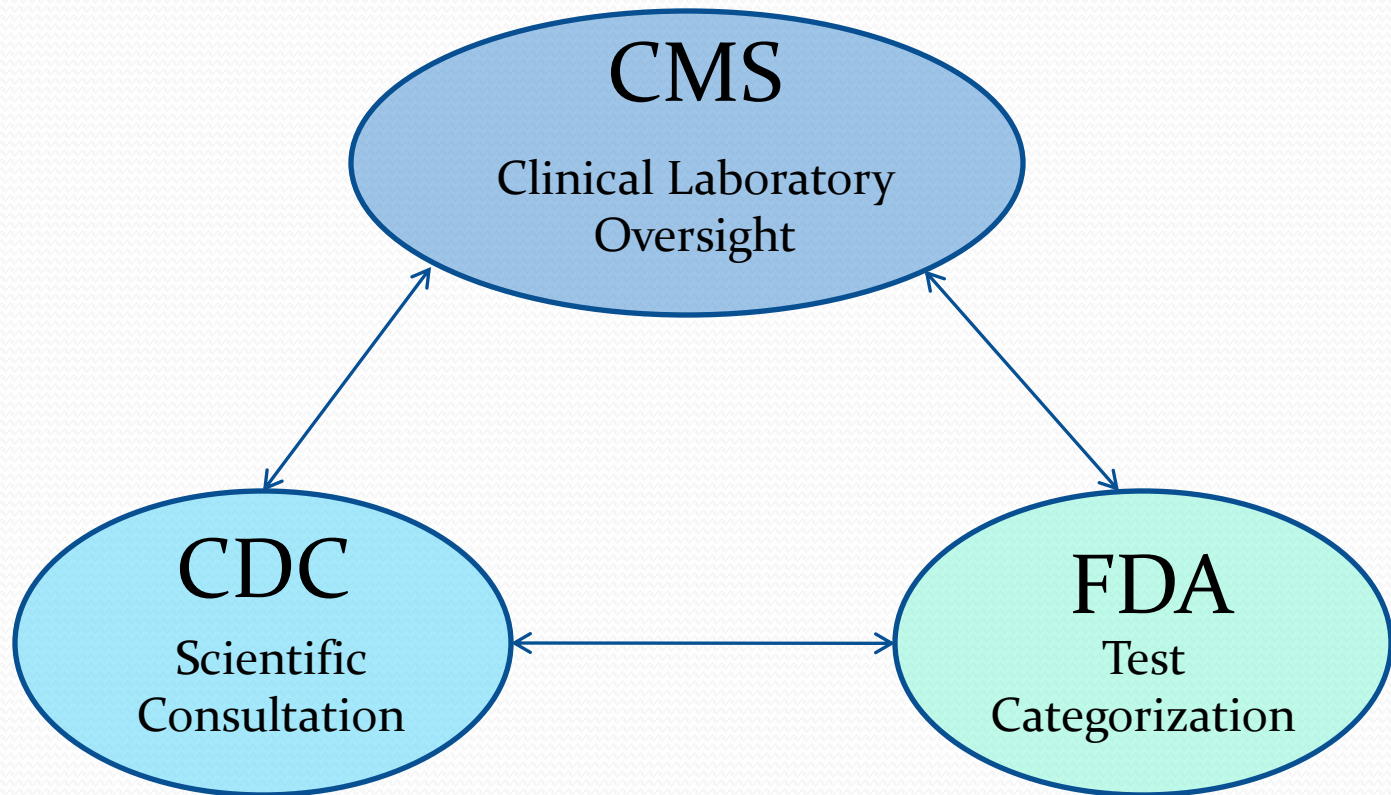
What is “CLIA”?

- Clinical Laboratory Improvement Amendments
- Federal program that establishes quality laboratory standards to protect patient safety and improve health care

The CLIA regulations.....

Established uniform quality standards for all laboratory testing to ensure accuracy, reliability and timeliness of patient test results regardless of where the test was performed.

CLIA Program Responsibilities



Tri-agency Responsibilities

- CMS, FDA and CDC have very distinct and complementary responsibilities
- CMS provides regulatory oversight and ensures that laboratories provide accurate, reliable and timely testing.

Tri-agency Responsibilities

- FDA has authority to implement the CLIA test complexity categorization which includes which tests are waived vs. nonwaived.
- CDC provides the education, scientific and research branch of the Tri-Agency

CLIA Definition of Laboratory

§ 493.2

Any facility that examines human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings

All clinical laboratories.....

- that perform testing on patient specimens must:
 - apply for a CLIA certificate
 - pay appropriate fees and
 - follow applicable CLIA requirements

Test Complexity

- Waived
- Moderate complexity including the subcategory of Provider Performed Microscopy (PPM)
- High complexity

Laboratories are certified at the highest level of testing performed

CLIA Certificate Types

- Certificate of Compliance (COC)
- Certificate of Accreditation (COA)
- Certificate for PPM (PPM)
- Certificate of Waiver (CoW)

Point-of-Care Testing (POCT)

- CLIA does not have a category for “POCT”.
- POCT are typically performed at the patient’s bedside and/or outside the walls of a traditional lab.
- Depending on the facility, a POCT program can include complexity levels.....
 - Waived
 - Nonwaived – Moderate and/or High complexity

CLIA focuses on test complexity

Current Enrollment Statistics

- Total Number of Laboratories: **245,977**
 - Compliance Labs: 18,157
 - Accredited Labs: 16,365
 - Waived Labs: 177,972
 - PPM Labs: 33,483

January 2017

Current Enrollment Statistics

	As of 01/2012	As of 01/2017	% change
Total Number of Laboratories (NE)	229,815	245,977	7%
Compliance Labs	19,387	18,157	-6%
Accredited Labs	15,697	16,365	4%
Waived Labs	150,256	177,972	21%
PPM Labs	37,559	33,483	-11%

Waived Tests

- Simple laboratory examinations and procedures
- Cleared by FDA for home use;
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Waived Testing regulations

- §493.15 Laboratories performing waived tests
 - §493.15(e) Laboratories eligible for a certificate of waiver must-
 - (1) Follow manufacturers' instructions for performing the test; and
 - (2) Meet the requirements in subpart B, Certificate of Waiver, of this part

Certificate of Waiver (CoW)

- Enroll in the CLIA program & pay fees
- Only perform tests categorized as waived
- Not subject to routine inspections
- **Must follow manufacturer's instructions**

CoW Personnel Requirements

- Must have a Laboratory Director
 - There are no educational and experiential requirements for LD
- There are no other personnel requirements.

Nonwaived Tests

- Includes moderate and high complexity tests
- Must follow:
 - All manufacturer's instructions and
 - Applicable CLIA requirements
 - AO requirements
 - State requirements (ex. Maryland, New York)

When in doubt, always follow the most stringent requirements

Nonwaived Tests

- More complex tests require more stringent requirements
- Subpart H - Proficiency Testing (PT)
- Subpart J – Facility Administration

Nonwaived Tests

- Subpart K –
 - General Laboratory
 - Preanalytical
 - Analytical
 - Postanalytical
 - Quality Assessment (QA) Required

Nonwaived Testing

- Must perform the appropriate quality control as defined by the manufacturer, CLIA or the AO (whichever is the most stringent)
- Subpart M - Personnel qualifications and responsibilities for ALL personnel
 - ✓ Qualified / Experienced
 - ✓ Trained / Competent
 - ✓ Accurate / Proficiently
 - ✓ Compliant with regulations

POCT Programs

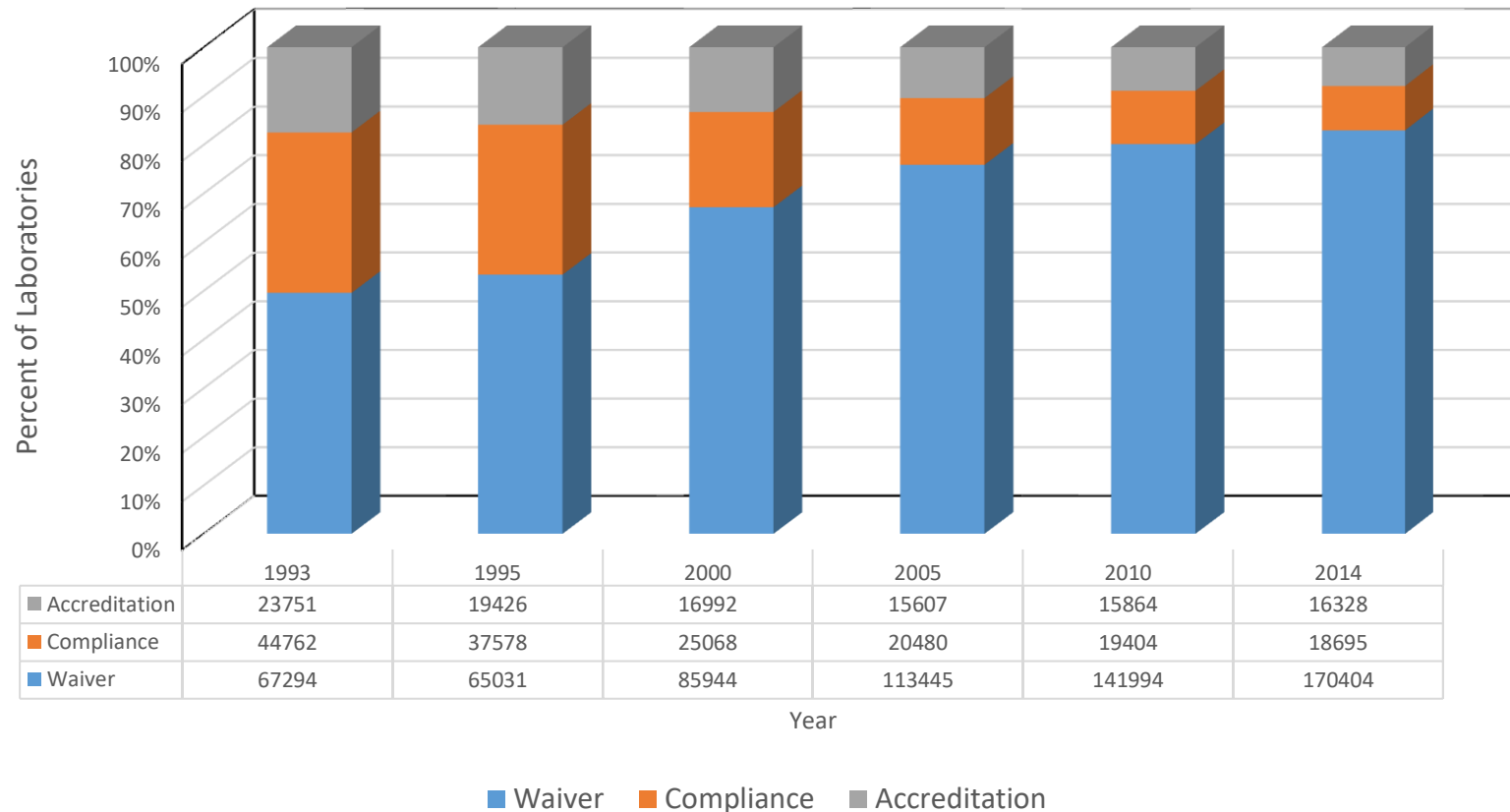
- POCT programs may incorporate different levels of test complexity.
- Operational structure of healthcare facilities can vary greatly.
- Facilities can hold multiple CLIA certificates in support of their testing programs; clinics, patient floors, operating rooms, emergency rooms, etc.

Tests often used at the Point of Care

TEST SYSTEM	<u>WAIVED</u>	<u>NONWAIVED</u>
Cholesterol Screens	Capillary finger-stick	Capillary finger-stick
Blood Glucose- whole blood	Reagent strip meters	Portable bench –top analyzers
Pregnancy (hCG)	Pregnancy tests- Urine	Pregnancy tests- Serum
Prothrombin time (PT)	Home use/Professional use	Hand held analyzers
Respiratory viruses	Nasopharyngeal swabs	Nasopharyngeal swabs
Streptococcus group A	Throat swabs	Throat swabs
Urinalysis	Dip-stick methods	Microscopic urine exam
Urine Drug Screen	Multi-panel drug screen	Multi-panel drug screen

CMS -Waived Laboratory Growth

CLIA Laboratories by Certificate Type



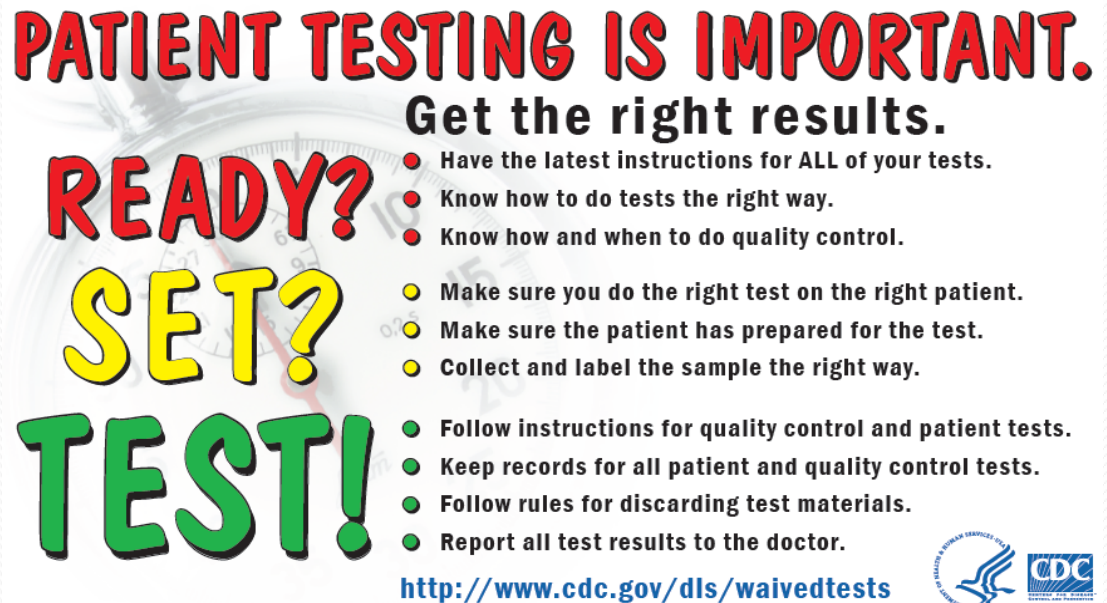
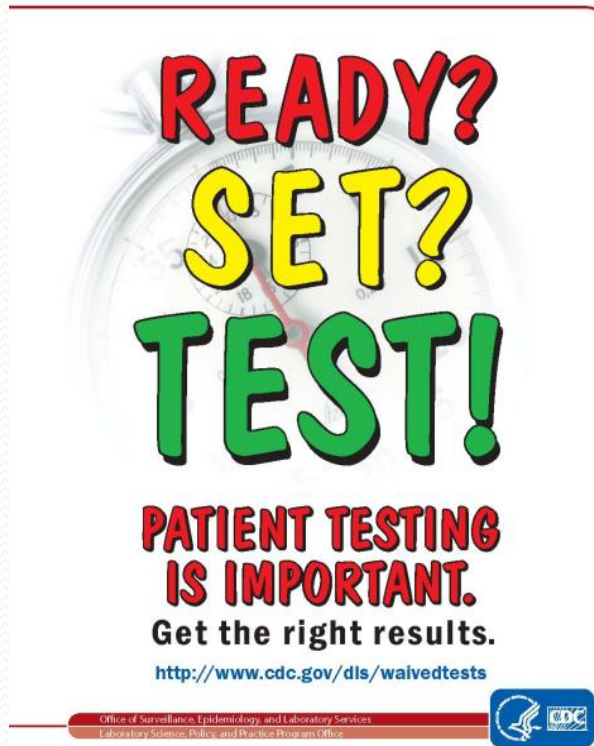
Certificate of Waiver Project

- CW labs are increasing exponentially
- Congress never anticipated this growth
- Concerns over quality testing arose
- 1999 – Initial Pilot in Colorado and Ohio
- 2000 – Expanded Pilot project to 8 additional States
- 2002 - Pilot expanded to remaining States

CLIA CoW Site Visits

- Announced, designed to help educate on sound laboratory practices
- Surveyors determine:
 - Testing being conducted in manner that protects patient safety
 - Regulatory compliance
 - Performing tests appropriate for a CoW laboratory

Good Laboratory Practices for Waived Testing Sites



Poster and postcards

Educational booklet with job aids

Top Waived Testing Deficiencies

Deficiency	2012	2013	2014
Not performing QC required by manufacturer	17%	16%	13%
Does not have current package insert	10%	9%	7%
Not using proper expiration date for storage method	9%	8%	7%
Not reporting patient test results as required by manufacturer	5%	5%	5%
Not following manufacturer's storage and handling instructions	5%	4%	4%

Following Manufacturer's Instructions

- Wording found in package inserts can be above reading level/comprehension of non-laboratory staff
- Package inserts can be printed with small fonts and not have standardized formats between manufacturer's

Manufacturer's Instructions con't

- Staff not following established instructions (taking “shortcuts” or) use the picture diagram to perform the test.
- Testing restrictions and limitations noted in the package insert may be missed.

Documentation/Records

- Results not documented as required by manufacturer (ex. “+” rather than “positive” or “Pos”)
- Not having most current package insert available
- Testing Kit expiration dates were not changed if stored at room temperature

Quality Control(QC)

- Quality control was not performed if required by manufacturer (ex. frequency of QC)
- QC performed but not documented as required or not documented (ex. Internal control interpretation failure)

Challenges in POCT



Challenges: POCT Testing Programs

- Providers want tests results quickly so look at waived testing to fill the need
- More and more testing being manufactured & introduced to the market are done at point-of-care with non-laboratory staff
- Personnel unknowingly use laboratory tests in a manner not clinically validated by the manufacturer (**off-label use**).

Modification or “off-label”

A “test system modification” of a waived or moderate complexity test system means any

1. change in intended use,
2. adjustments to the precautions, limitations
3. changes to manufacturer’s instructions

that could affect test system performance specifications for; sensitivity, specificity, accuracy and precision.

Test Modification

- CLIA allows for modification of waived or moderate complexity tests.
- If providers decide to modify a waived or moderate test, the test is classified as “high complexity”
- All high complexity test regulations will apply

Regulatory Impact for Providers

- Obtain the appropriate CLIA certificate
- High complexity personnel requirements are met
- The laboratory must establish performance specifications in order to ensure the accuracy and reliability of the test results after the modification of the test system is made.

Performance Specifications

- accuracy
- precision
- reference range
- reportable range
- analytic sensitivity
- analytic specificity

§493.1253(b)(2)

Review “POCT” Programs

- Examine the test menu in the POCT program(s)
- Confirm the test complexity of each test
- Verify that the facility has the correct type of CLIA certificate
- Look closely at the manufacturer’s instructions
- And if test modifications are chosen, that they be performed in compliance with CLIA, State or AO requirements.

Lab Excellence Mailbox

Questions?

- LabExcellence@cms.hhs.gov

Resources:

- CLIA Website
 - <http://www.cms.gov/CLIA>
 - <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>
 - <http://www.cdc.gov/mmwr/pdf/rr/rr5413.pdf>
 - <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html>
- CDC: Ready, Set, Test
 - <http://www.cdc.gov/dls/waivedtests>