CLIA and Point-of-Care Testing

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Objectives

- Overview of CLIA
- Guidance on regulations regarding point-of-care testing/test complexity
- Review Top Five "POCT" deficiencies from Accrediting Organizations (AO's) and CLIA
- CLIA CoW Site Visits

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What is this thing called “CLIA”?

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

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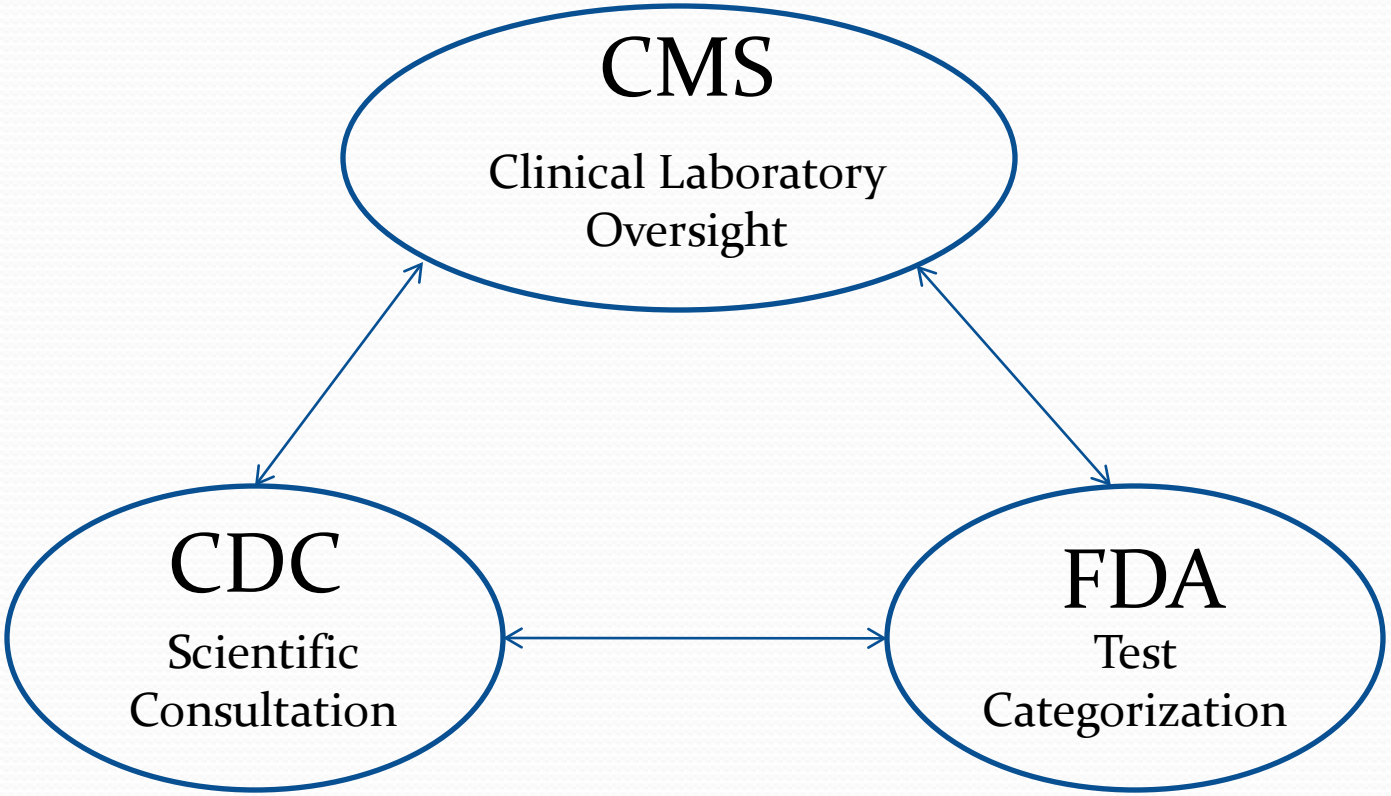
CLIA Program Responsibilities



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Laboratory (as defined by CLIA)

- 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

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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

Laboratories are certified at the highest level of testing performed

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CLIA Certificate Types

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

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Current Enrollment Statistics

- Total Number of Laboratories: 221,793
  - Compliance Labs: 19,404
  - Accredited Labs: 15,864
  - Waived Labs: 141,994
  - PPM Labs: 37,795

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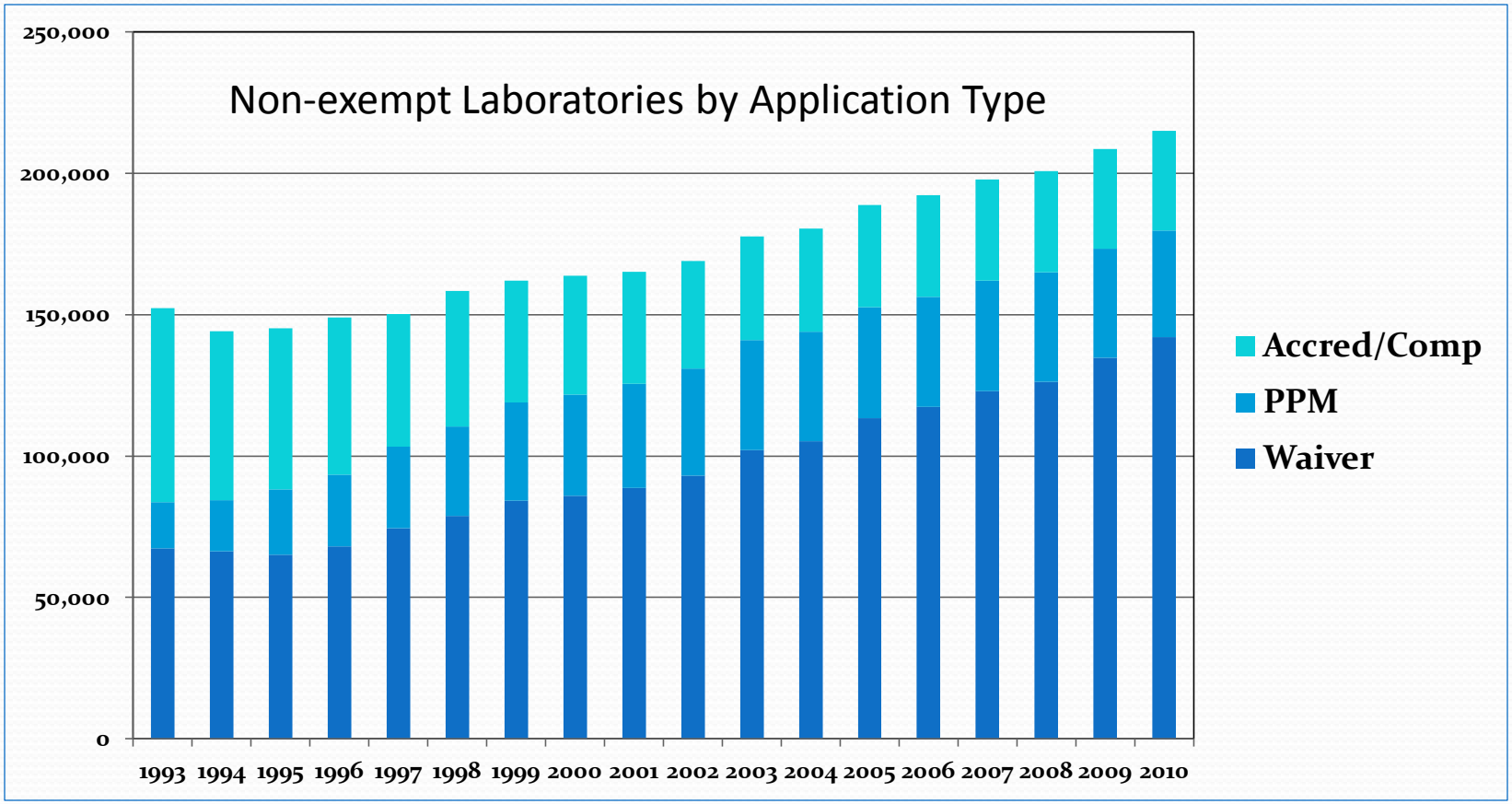
CMS Waived Project --Waived Laboratory Growth



Point-of-Care Testing (POCT)

Depending on the facility, a POCT program can include any or all of the following test complexity levels.....

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

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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.

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Non-waived Testing

- 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

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Non-waived Testing - QC

- Must perform the appropriate quality control as defined by the manufacturer, CLIA or the AO (**whichever is the most stringent**)
- Minimum two levels of control each day of testing
- EQC
  - If use EQC, need to have plan on how you will re-assess previously tested patients if problems arise
  - Additional information on EQC can be found in the CLIA Interpretive Guidelines

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Non-waived Testing

- Proficiency Testing (PT)Required
- Quality Assessment (QA)Required
- Personnel qualifications and responsibilities for ALL personnel

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POCT and CLIA

- CLIA does not have a category for "POCT".
- CLIA looks at test complexity levels
- Minimum CLIA requirements for Waived testing – must have LD and follow manufacturer's instructions

In General……

- POCT programs often incorporate different levels of test complexity.
- Non-waived testing has more stringent requirements that will need to be incorporated.
- AO's can have more specific/stringent requirements than CLIA.

"POCT" Deficiencies

- CLIA and AO's strive to ensure consistency when citing deficiencies during surveys
- AO's meet minimum CLIA requirements
- 2010 data collected from AO's and CLIA regarding most frequently cited "POCT" deficiencies.

Top Five "POCT" Deficiencies

- Not following manufacturer's instructions (25%)
- Procedures and Policies (16%)
- Documentation/records (15%)
- Competency assessment/training (14%)
- QC data (10%)

Not Following Directions

- Manufacturer's provide specific directions in package inserts, however….
- 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

What gets Cited:

- Manufacturer may make change to package insert procedure but change is not picked up and reflected in the POCT procedure - staff continue to perform test unaware of change that may affect test performance, limitations, interferences etc.

- Staff may discard the package insert and only use the picture diagram to perform the test.
- Staff do not perform QC as required by Manufacturer

Procedures/Policies (P&P)

- Staff not following established policies/procedures (taking “shortcuts”)
- Written P&P not comprehensive (does not include all information from pkg insert)
- Written P&P doesn’t include facility specific information (using pkg insert result ranges vs. lab determined)

Procedures/Policies

- Test not being used correctly (ex. Test used for diagnostic purposes when manufacturer specifies test is for screening only)

Documentation/Records

- Results not documented as required by lab or manufacturer (ex. “+” rather than “positive” or “Pos”)
- Not having most current package insert available/not retaining package insert
- Kit lot numbers/expiration dates not recorded

Competency/Training

- New staff not properly trained
- Competency to perform test is not assessed at appropriate intervals
- Competency not assessed using required elements
- **Competency assessment confused with training**

Quality Control(QC)

- Quality control not performed as required by manufacturer and lab policy (ex. frequency of QC)
- QC performed but not documented as required or not documented
- QC not performed **at all**

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 lab

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Findings from CoW Visits

- Fail to have current manufacturer's instructions
- Fail to perform Quality Control as required by the manufacturer
- Fail to follow manufacturer's Instructions
- Performing non-waived testing

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CoW Visit

- Complaint to CMS - Company performing HbA1C as diagnostic test for diabetes in grocery store chain
  - Package insert: test is for screening only
  - Investigation by CMS revealed complaint was substantiated
  - Found moderate complexity testing also being performed (ABO/RH by Eldon Card)
  - Company performing tests notified to stop performing ABO/RH and stop using A1C test as diagnostic test

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CoW visit: worse-case scenario

- Lab used all waived instruments
- QC for A1C not performed as per manufacturer's instructions
- User manual for A1C still wrapped in plastic
- **Testing Personnel (TP) could NOT identify an invalid test on rapid strep or urine HCG test**
- **TP was "self-taught"**

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Waived Test Challenges

- Manufacturer's continue to develop new waived test methods
- Providers want results quickly so look at waived testing to fill the need
- More and more testing being done at point-of-care with non-laboratory staff

Next Steps for Waived Testing…..

- Number of CW labs increasing exponentially
- Congress never anticipated this growth
- Education is effective, but resources are lacking
- A CMS “Issue” paper with multi-faceted recommendations for agency management was approved
- CMS collaborating with stakeholders to complete long and short term plans

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CMS' Plan Waived Project

- Short Term
  - Continue CoW project indefinitely
  - Educate with every opportunity
  - Initiate test menu collection with application
  - Collaborate with Partners/CDC/FDA
  - Enlist support of professional and patient advocacy organizations
  - Evaluate data from AO/ES with CoW standards
  - Publish comprehensive report

CMS' Plan Waived Project

- Long term
  - Under consideration by CMS…changes to the CLIA law to improve oversight

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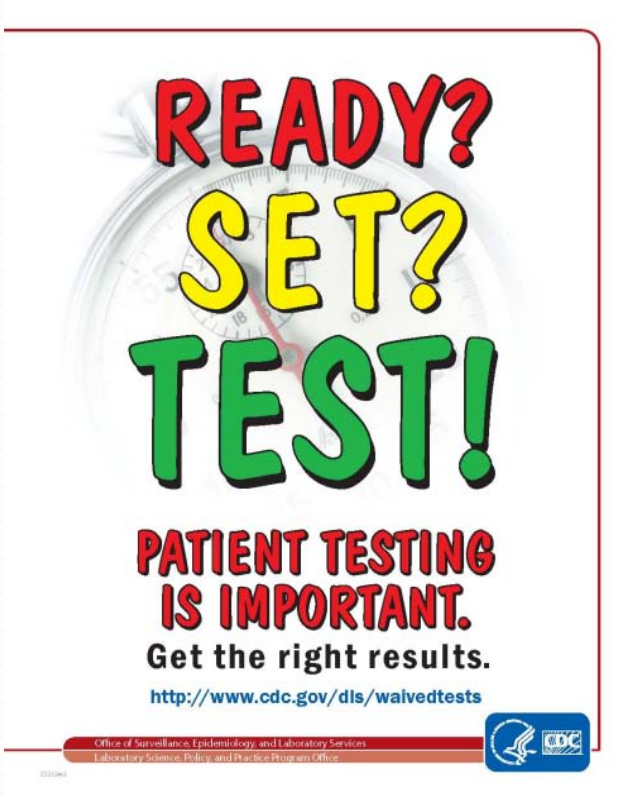
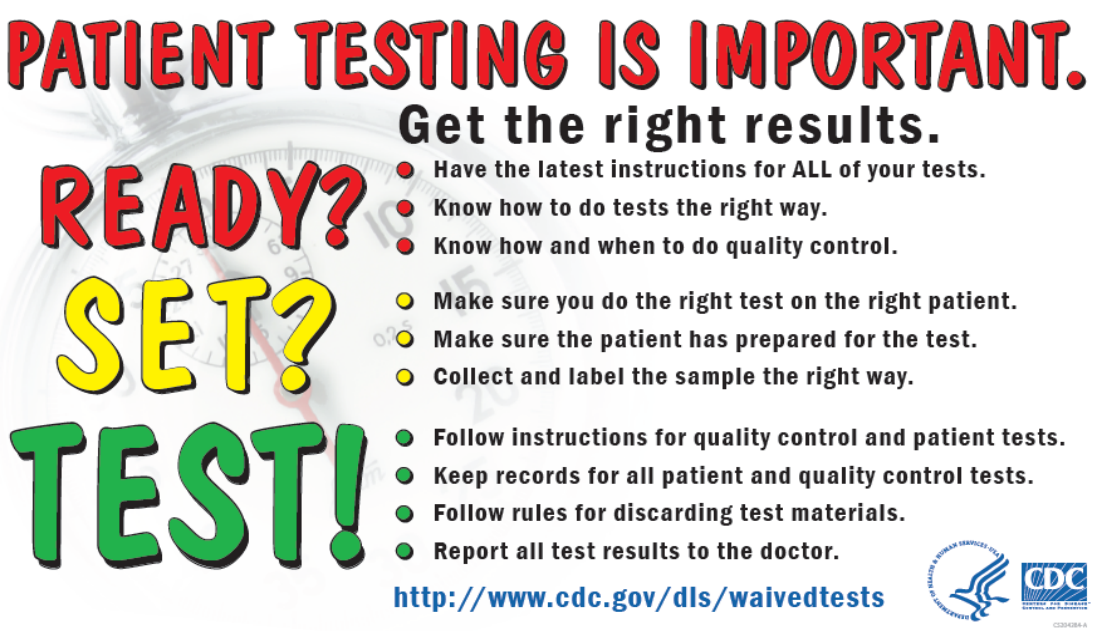
CDC Educational Materials

- In addition to the information found on the CLIA website……
  - CDC has published “Ready, Set, Test” booklet - describes recommended practices for physicians, nurses, medical assistants and others performing patient testing under a CLIA Waiver Certificate
  - CDC also has on-line training course corresponding to the “Ready, Set, Test” book.

Good Laboratory Practices for Waived Testing Sites



Educational booklet with job aids



Poster and postcards

CLSI EP-23

- Published by CLSI on October 25, 2011
- Quality Control based on risk analysis
- The “Right QC” for your lab

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

- CDC: Ready, Set, Test
  - http://www.cdc.gov/dls/waivedtests

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