CMS Waived Testing Update
CLIAC
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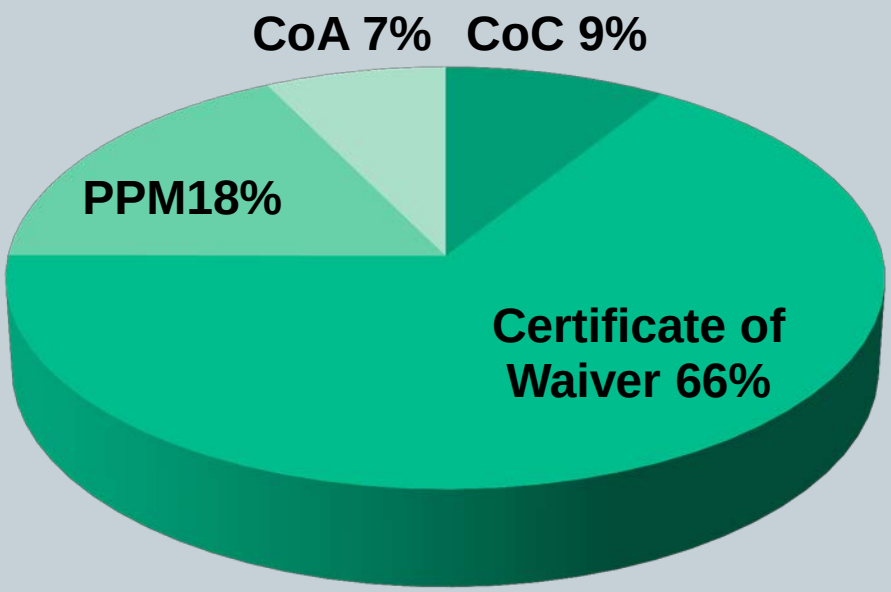
Centers for Medicare & Medicaid Services (CMS)

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.

CLIA Laboratories by Certificate Type



- Certificate of Compliance (CoC)
- Certificate of Waiver (CoW)
- Certificate of Provider Performed Microscopy (PPM)
- Certification of Accreditation (CoA)

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.
- Are not subject to CLIA quality standards

Waived Testing

- Provides for timely, efficient, convenient patient care
- Continues to increase
- Increased testing comes w/ issues:
  - ✓ Testing personnel less-trained; may not ID problems
  - ✓ No routine oversight w/ no funding/resources
  - ✓ Minimal manufacturer recommended QC

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Certificate of Waiver (CoW)

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

CoW Personnel Requirements

- A CoW must have a laboratory director (LD)
- There are no educational and experiential requirements for LD
- There are no other personnel requirements

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Since 1992……

- CLIA-waived tests have increased from 8 to about 100 tests, representing 1000's of test systems
- The number of laboratories issued a CoW has grown exponentially from 20% to 66% of the >235,000 laboratories enrolled

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Certificate of Waiver Project

- 1999 – Initial Pilot in Colorado and Ohio
- 2000 – Expanded Pilot project to 8 additional States
- 2002 - Project expanded to all States

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Expanded Pilot Results

- Quality problems identified in these laboratories:
  - 32% failed to have current manufacturer's instructions
  - 32% didn't perform quality control as required by the manufacturer
  - 16% failed to follow the manufacturer's instructions

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CoW Project

- Based on findings of CMS Pilot, CMS embarked upon the CMS CLIA Certificate of Waiver (CoW) Project
- In April 2002, CMS initiated on-site visits to 2% of the CoW laboratories in all 50 states

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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

Findings from CoW Visits

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

2004 CDC Findings Include…

- High staff turnover in waived testing sites
- Lack of formal laboratory education
- Limited training in test performance & QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ QC instructions (~55-60%)
- CDC & NY studies correspond to CMS’.

(Presentation CLIAC_Waived testing update_Sept 2004.ppt)

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Top Waived Deficiencies

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

Next Steps for Waived Testing…..

- Number of CoW 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' Plans for the 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 CW standards
  - Publish comprehensive report

CMS' Plans for the Waived Project

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

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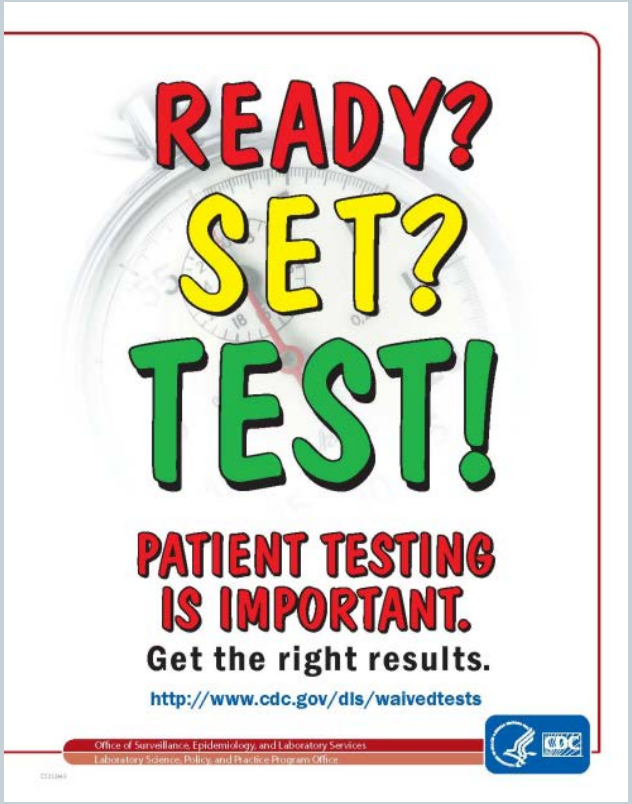
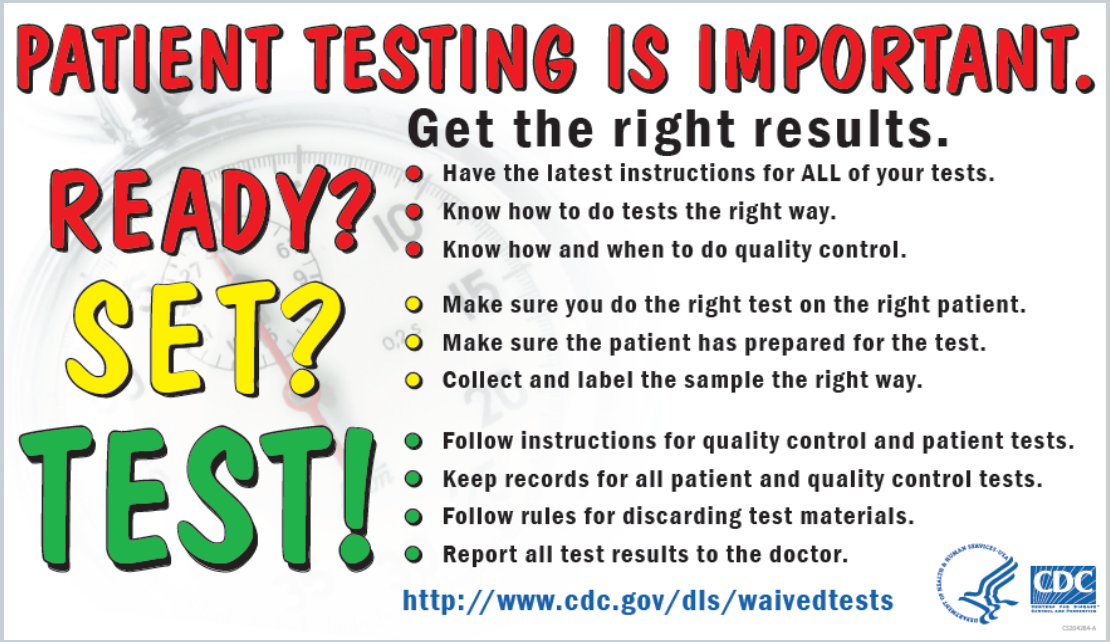
CDC Educational Materials

- 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 offers an on-line training course corresponding to “Ready? Set? Test!”

Ready? Set? Test!

Educational booklet with job aids





Poster and postcards

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Government Performance Review Act (GPRA)

- Goal – improved compliance with CLIA standards
- Measured by- increased percentage of Letters of Congratulations (no problems found) sent to waived (CW) laboratories based on onsite educational visits

GPRA Ready? Set? Test! Waived Lab Project

- Pilot Study – 2 states in each CMS Region
  - Selected CW labs received copy of ‘Ready, Set, Test!’ booklet prior to their CW survey
  - Post survey information collected regarding lab use of booklet to improve lab practices

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GPRA Ready? Set? Test! Waived Lab Project

- 97% - rec'd. the booklet
- 84% - reviewed the booklet
- 95% - found the booklet helpful
- 50% - changed current practices as a result of reading the booklet
- Helpful sections of booklet:
  - QC log instructions
  - Record keeping
  - QC testing

GPRA Ready? Set? Test! Waived Lab Project

2010-2011Baseline – 20% or more received Letters of Congratulations

- Results from 2012 – 44%
- Results from 2013 – 45%

Conclusion – Educational materials like 'Ready, Set, Test' booklet are well-rec'd.; serve as excellent means to improve lab test quality

Blood Glucose Meters (BGMs)

- Two types of BGMs:
  - Devices intended for point-of-care use in a professional healthcare setting
  - Self-monitoring devices intended for OTC (home) use

BGMs

- Provide glucose results quickly
- Intended use for monitoring, not diagnosis (per the intended use in pkg. insert)
- Currently include limitations for use in the package insert
- Examples: Hematocrit, interactions with maltose, icodextrin

CLIA Requirements for BGMs

Follow the manufacturer's instructions

- Key sections:
  - Intended Use – describes test purpose and may indicate if test is for monitoring, screening or diagnosis
  - Limitations – describes conditions affecting test results, interferences, or circumstances for which the test was not intended

Current BGM Issues

- Used on virtually every patient, regardless of medical conditions or limitations specified in pkg. insert
- Staff performing testing may or may not be aware of patient conditions that can interfere with the glucose tests
- Problems exacerbated by constant turnover of employees

Test Modification/Off Label Use

- Devices used outside of the manufacturer's requirements or **intended use** are considered to be **test modification/off label use**
- Modified tests become high complexity tests under CLIA
- High complexity – stringent personnel requirements and quality standards

Facilities Using Meters Off-Label Must:

- Cease the off-label use to maintain waived status, or
- If they want to continue the off-label use, establish performance specifications
- 42 CFR §493.1253(b)(2)

Facilities Using Meters Off Label Must:

- Obtain a CLIA CoC or CoA
- Pay the applicable fees
- Meet the other high complexity requirements (ex. proficiency testing, personnel..)
- Follow the forthcoming guidance in the Survey & Certification memo

Other Laboratory Options

- Use a device other than BGM without the BGM limitations
- Send glucose tests to the main laboratory
  - Presents patient care issues due volume of blood required and the need for frequent and timely results

Performance Specification Resources

- 42 CFR §493.1253 of the CLIA Interpretive Guidelines (IG)
- CLIA Brochure #2, “Verification of Performance Specifications on the CMS/CLIA website
- http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html

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Point-of-Care (POC) or Manual Testing

- There is no POC or manual testing category in CLIA
- Depending upon the test, the complexity can be waived or nonwaived
  - **Nonwaived refers to either moderate or high complexity testing**

Summary

Facilities performing only waived testing:

- ✓Must enroll in CLIA and follow the manufacturer's instructions
- ✓May be visited as part of the CMS CoW Project/GPRA
- ✓Improved with the education provided by CMS/CDC

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