What You Need to Know About Waived Testing

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Objectives

- CLIA Basics
- Certificate of Waiver (CoW) laboratories
- Triagency responsibilities
- FDA draft guidance for glucose meters
- CMS S&C 15-11-CLIA
- Regulations for waived testing
- CLIA survey process

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What is "CLIA"?

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

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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.

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CLIA Definition of Laboratory

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

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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

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CLIA Certificate Types

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

Current Enrollment Statistics

- Total Number of Laboratories: **250,367**
  - Compliance Labs: 19,793
  - Accredited Labs: 16,588
  - Waived Labs: **177,104**
  - PPM Labs: 36,882

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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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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**

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CoW Personnel Requirements

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

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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

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CDC Educational Materials

- 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".

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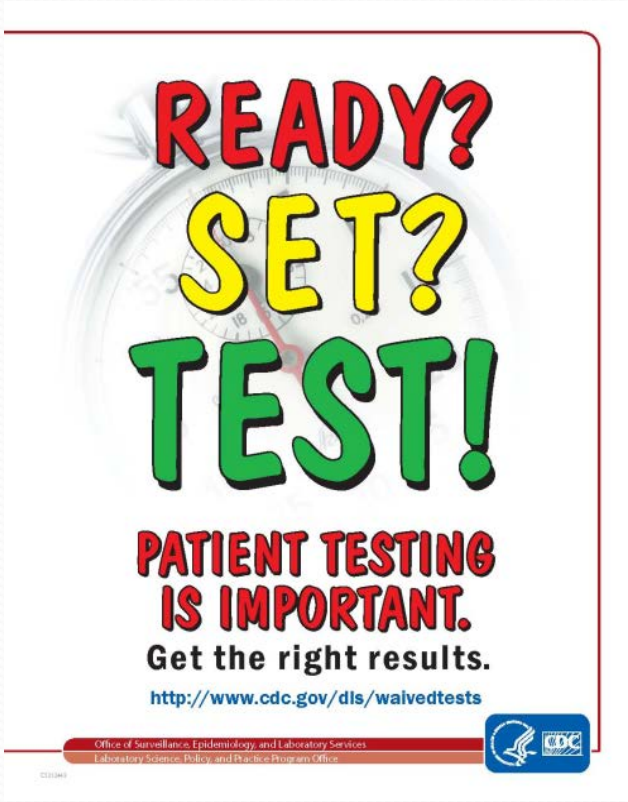
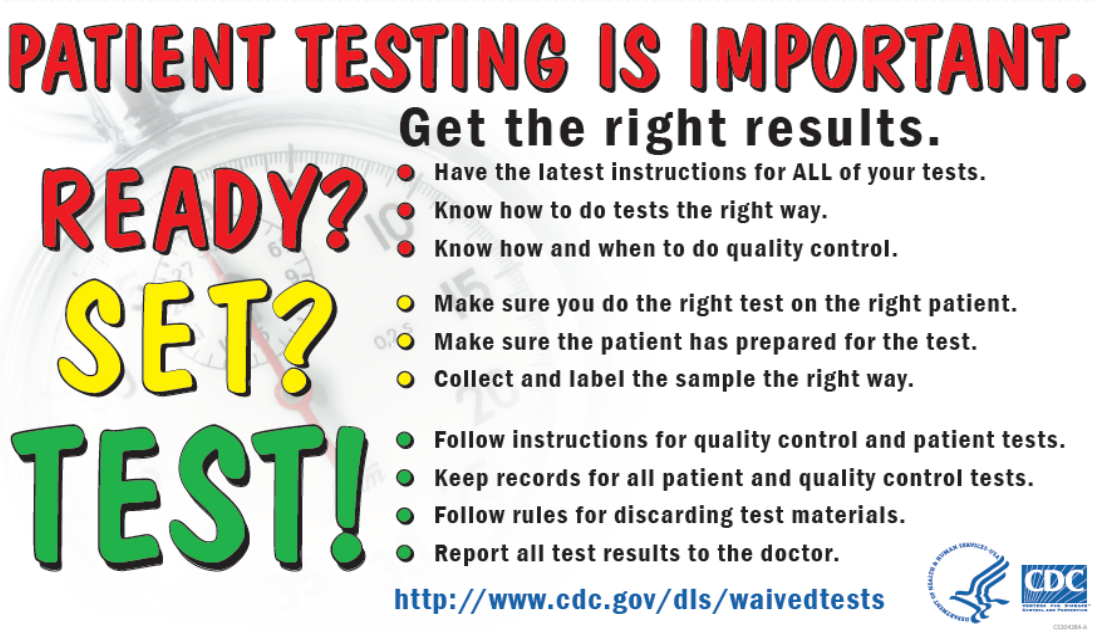
Ready, Set, Test



Educational booklet with job aids



Poster and postcards

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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 provisions and shares responsibility for determining which tests are waived vs. non-waived.
- CDC provides the scientific and research branch of the Tri-Agency

FDA Draft Guidance for Manufacturers

On January 7, 2014, the FDA published two detailed draft guidance documents for *manufacturers*, to advise them on how to conduct the appropriate studies and apply for clearance of their BGMS devices.

Why two separate draft guidance documents?

- Different use settings create distinct intended use populations with unique characteristics and device design requirements.
- Patients in professional healthcare settings are often fundamentally different than a "lay-user" at home.

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FDA Draft Guidance for Manufacturers

Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use

Describes studies/criteria to be used by manufacturers when submitting premarket notifications for self-monitoring blood glucose tests systems

Specific to over-the counter meters used by lay-persons.

FDA Draft Guidance for Manufacturers

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

Guide manufacturers in conducting appropriate performance studies and prep of premarket notifications for these devices

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NOTE:

The FDA Draft Guidance was not intended for use by CLIA-certified laboratories.

Blood Glucose Monitoring Systems (BGMS)

- CMS became aware of laboratory, health care provider and health care facility confusion and concern in regards to the FDA Guidance on BGMS.
- CMS concern in regards to waived meters being used in settings or on a population different from the intended use as specified in manufacturers instructions/pkg insert
- Risk of patient harm when BGMS used in situations that the manufacturer has not evaluated.

CMS S&C:15-11-CLIA

- Directions on the Off-Label Use of Waived Blood Glucose Monitoring Systems (BGMS)-issued November 21,2014
- Issued to help clarify regulatory requirements and address concerns/questions from laboratories and advocacy groups. These concerns including:
  - Not allowing the use of the glucose meters
  - Not defining the term "critically ill"
  - What can facilities do in order to continue to use the BGMS.

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Glucose Meters-Update

S&C Memorandum 15-11, which was previously issued on November 21, 2014, was withdrawn and reissued in draft-only form in order to:

- Obtain more feedback regarding the use of waived BGMS, the environments in which BGMS are currently used, and any issues that hospitals and other providers have identified with such use
- Promote added education regarding the current CLIA requirements

Reissued S&C 15-11-CLIA

- Areas of clarification in the reissued memo
  - Regulatory background
  - Manufacturer's instructions
  - Off-Label Use or Test Modification
  - Issues identified on Survey
  - Laboratory options for CLIA Compliance

Section 353 Public Health Service Act-CLIA Law

- Subpart 2 – Clinical Laboratories
  - (2) Requirements for Certificate of Waiver
  - (3) Examinations and Procedures
    - ….laboratory examinations and procedures that have been approved by the Food &Drug Administration for home use of that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that-
    - (A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or
    - (B) the Secretary has determined pose no unreasonable risk of harm to the patient of performed incorrectly.

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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

Follow manufacturers instructions

There are three CLIA regulations that deal specifically with following the manufacturer's instructions.

- §493.15(e) and (e)(1) states: Laboratories eligible for a certificate of waiver must— Follow manufacturers' instructions for performing the test…

Follow manufacturers instructions

- §493.1252(a) states: Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253.

Follow manufacturers instructions

- §493.1252(b) states: The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test reporting. The criteria must be consistent with the manufacturer's instructions, if provided…

Manufacturer's Package inserts

Facilities performing blood glucose testing are held to the intended use, limitations and precautions in the package insert

Manufacturer's Package Inserts

- If the BGMS is used according to the manufacturer's intended use, limitations and precautions, the meter retains its' waived status.

Glucose Meters

When manufacturer's instructions contain limitations indicating blood glucose monitoring systems (BGMS) have not been evaluated or cleared for use in specific patient populations, use of systems on these patients is considered "off-label" use.

Off-label use

- Using a test outside of FDA approved/cleared intended use, limitations or precautions as indicated in manufacturer's instructions is considered "off-label" use.
- "Off-label use" means the test (whether waived or non-waived) is considered modified and defaults to High Complexity under CLIA

"Off-label" Use

"Off-label" use of a waived test is not prohibited however.....

If the laboratory chooses to use the test "off label", CLIA regulations at §493.1253(b)(2) require establishment of performance specifications for that test

Performance Specifications

- §493.1253(b)(2) Establishment of performance specifications

  Each laboratory that modifies an FDA-cleared or approved test system…..must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics as applicable…

Performance Specifications

- Accuracy
- Precision
- Analytical Sensitivity/Specificity
- Reportable range
- Reference intervals (normal values)
- Any other performance characteristic required for test performance

CLIA Survey Process

- CMS is not "targeting" BGMS
- CMS following its Outcome Oriented Survey process for CLIA surveys

Outcome –Oriented Survey Process

- Focus: Effect (or outcome) of the laboratory's practices on patient test results and/or patient care
- Assessment of the overall functioning of the laboratory and the laboratory's ability to perform quality testing
- Emphasis placed on the laboratory's quality system and processes through entire testing process that contribute to quality test results.
- Survey for compliance with CLIA regulations

Glucose Meter issues identified on Survey

- If CLIA surveyors note use of BGMS in a facility, they will evaluate if the system is being used per the manufacturer's instructions or "off-label"
- If any non-compliance is identified, a written statement of deficiencies will be issued to the laboratory following the Outcome Oriented Survey Process (OOSP)

Citations on CLIA Surveys

- Form CMS-2567 issued to the laboratory
- Laboratories receiving standard level citation will have a reasonable timeframe (up to 12 months) to obtain a Certificate of Compliance (CoC) or Certificate of Accreditation (CoA)

Laboratory Options for CLIA Compliance

- Lab must meet the additional CLIA requirements for high complexity testing (performance specs, personnel, proficiency testing) and any applicable State regulations

Other Laboratory Options for Compliance

- Identify and use a point-of-care glucose device without the critically ill patient limitations
- For patients whose clinical conditions do not meet those described in the manufacturer's instructions, send samples to a CLIA-certified/accredited laboratory

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Accrediting Organization (AO) Surveys

- Laboratories accredited by a CMS approved accrediting organization must follow the AO's standards which can be equivalent to or more stringent than the CLIA requirements.

Lab Excellence Mailbox

- LabExcellence@cms.hhs.gov
- Still accepting comments/questions on S&C:15-11-CLIA

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