



*Better health through
laboratory medicine.*

Compliance Issues in Off-Label Use of Blood Glucose Monitors



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Disclosures

I have nothing to disclose



Learning Objectives

- Discuss the CLIA requirements for waived tests and nonwaived tests
- Understand what is meant by modification of a laboratory test
- Describe compliance issues related to off-label testing and blood glucose meters



Waived Tests

- 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.
- Minimum CLIA requirements for Waived testing – follow manufacturer's instructions and meet the requirements in Subpart B, Certificate of Waiver



Nonwaived Tests

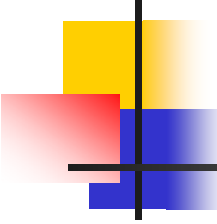
- Moderate complexity and high complexity tests
- The laboratory must follow:
 - All manufacturer's instructions and
 - Applicable CLIA regulations or those of their contracted accreditation organization(AO).
- State requirements (ex. Maryland, New York)

When in doubt, always follow the most stringent requirements



Why Waived Tests are so popular

- Allows for testing in any environment
 - Physician's office, Emergency services, Hospitals
- Performed at or near the patient
- Small sample used for testing
- Provider can make an immediate clinical management decision
- Permits the transfer(communication) of test result to the patient's medical record



Modification or “off-label” use of a laboratory test

A “test system modification” of a laboratory test means any

- change in intended use,
- adjustments to the precautions,
- limitations
- changes to manufacturer’s instructions
...that could affect test system performance specifications for; sensitivity, specificity, accuracy and precision.



Test Modification

- The laboratory modifies an FDA-cleared or approved test system
- Test is classified as “high complexity”
- All CLIA high complexity test regulations will apply
- This is not a new CLIA regulation



Blood Glucose Meters (BGM)

- Provide glucose results quickly
- Majority of meters approved and cleared for monitoring, not diagnosis (per the intended use in the manufacturer's package insert)
- Limitations and interferences i.e. contraindication for use, are stated in the package insert
 - Examples: Hematocrit, interactions with maltose, icodextrin

Compliance issue #1

Manufacturer's Instructions

- Used on virtually every patient, regardless of medical conditions or limitations specified in package insert
- Staff performing testing may or may not be aware of patient conditions that can interfere with the glucose tests
- Alternative test site – Earlobe or forearm specimen, fingerstick only



Current BGM issues

- Problems exacerbated by constant turnover of employees
- Providers want to make timely clinical decisions regardless of the potential inaccuracies of the meters when used off-label
- Test system is used per manufacturer's instructions (as a waived test) and off-label (as a high complexity test)

Compliance issues

Modification/off-label use

- CLIA high complexity test regulations will apply
 - Ensure correct CLIA certificate to perform testing
 - Certificate of Waiver upgraded to Certificate of Compliance or Certificate of Accreditation
 - Establish performance specifications
 - Perform proficiency testing
 - Quality systems requirements
 - Meet personnel qualifications and responsibilities
 - Quality assessment



CLIA certificate

- Certificate of Waiver (CW) laboratory upgrades to a Certificate of Compliance or Certificate of Accreditation, i.e. physician's office, community clinic
- CW laboratory supported by a CoC or a CoA laboratory
 - CoC or CoA has carved out waived tests
- CoC or CoA that performs waived tests



Establish Performance Specifications

- **accuracy** (whether the test produces correct results)
- **precision** (whether the test result is reproducible when repeated),
- **reference range** (whether the normal range of results is based on the laboratory's specific patient population)



Performance Specifications

- **reportable range** (the lower and higher limits that the test can accurately report)
- **analytic sensitivity** (lowest concentration or amount of the analyte which must be present to be measured)
- **analytic specificity** (the extent to which the test measures the analyte for which it is reporting results), this includes interfering substances
- Any other performance characteristics required for test performance



Personnel qualifications and responsibilities

Subpart M: Personnel for Nonwaived Testing

- High complexity CLIA requirements
 - Laboratory Director
 - Technical Supervisor
 - Clinical Consultant
 - General Supervisor
 - Testing Personnel



Personnel qualifications

- Who are the testing personnel performing waived testing?
 - Nurses, Medical assistants, clinical nurse assistants
- Can those testing personnel meet the qualifications and experience required to perform high complexity testing?
- What alternative testing personnel are available to perform high complexity testing?



Laboratory Options for Blood Glucose Testing

- Use POC test systems that meet the intended use needs of the laboratory and do not have the same limitations and interferences as blood glucose meters
- Send glucose tests to main laboratory
 - Presents patient care issues due to volume of blood required, need for frequent testing & timeliness of test results
- Follow the manufacturer's instructions



Performance Specification Resources

- 42 CFR §493.1253 of the CLIA Interpretive Guidelines (IG)
- CLIA Brochure #2, “Verification of Performance Specifications” on the CLIA/CMS website
- Both resources are available on the CLIA website
 - www.cms.hhs.gov/CLIA

READY, SET, TEST

**READY?
SET?
TEST!**

**PATIENT TESTING
IS IMPORTANT.**

Get the right results.

<http://www.cdc.gov/dls/waivedtests>

Office of Surveillance, Epidemiology, and Laboratory Services
Laboratory Science, Policy, and Practice Program Office



PATIENT TESTING IS IMPORTANT.

Get the right results.

- READY?
SET?
TEST!**
- Have the latest instructions for ALL of your tests.
 - Know how to do tests the right way.
 - Know how and when to do quality control.
 - Make sure you do the right test on the right patient.
 - Make sure the patient has prepared for the test.
 - Collect and label the sample the right way.
 - Follow instructions for quality control and patient tests.
 - Keep records for all patient and quality control tests.
 - Follow rules for discarding test materials.
 - Report all test results to the doctor.

<http://www.cdc.gov/dls/waivedtests>





Questions?

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Thank you for attending!

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