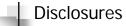


Compliance Issues in Off-Label Use of Blood Glucose Monitors



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I have nothing to disclose

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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

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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.

CLIA

approved test system Test is classified as "high complexity" All CLIA high complexity test regulations will apply This is not a new CLIA regulation

■ The laboratory modifies an FDA-cleared or

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
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Blood Glucose Meters (BGM)

Compliance issue #1 Manufacturer's Instructions

- Used on virtually every patient, regardless of medical conditions or <u>limitations specified in</u> <u>package insert</u>
- 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?





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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





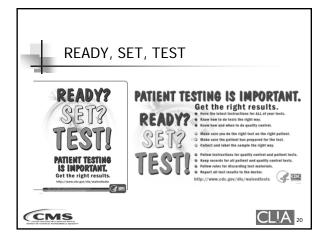


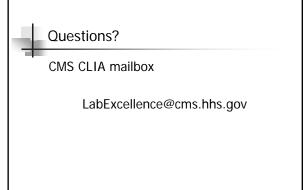
Performance Specification Resources

- 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









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