

HEART HEALTH:

Cardiovascular Guidelines for Community Health Centers



TRAINING PRESENTATION **In-House CLIA Waived Point-of-Care Diagnostic Testing**

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- The contents this training reference manual are solely the responsibility of the authors and do not necessarily represent the official views of CDC



About CHCANYS

- CHCANYS, a 37 year-old organization, is New York's Primary Care Association and the statewide association of community health centers
- CHCANYS works to ensure that all New Yorkers and particularly those living in underserved communities, have access to high quality community based health care services
- CHCANYS' mission is focused on retaining and expanding primary care capacity; investing in primary care health information technology (HIT); implementing primary care home standards; reforming the primary care payment system; and developing the primary care workforce



About Hudson River HealthCare, Inc.

- Hudson River HealthCare, Inc. is network of 16 Community Health Centers in 6 counties located in the Lower Hudson Valley and Long Island in New York State
- Hudson River HealthCare, Inc. is a Federally Qualified Health Center (FQHC) and is Joint Commission accredited for primary care and behavioral health
- Their mission is to increase access to comprehensive primary and preventive health care and to improve the health status of our community, especially for the underserved and vulnerable
- Their practice is based on Care Model (formerly Chronic Care Model)



Overview

- Clinical Laboratory Improvement Amendment (CLIA)
- Surveys of waived testing sites
- CLIA Certificate of Waiver requirements
- JCAHO waived testing requirements
- Competency assessment for waived tests
- Establishing a competency assessment program for waived tests



Objectives

- Discuss CLIA waived tests regulations and requirements
- Identify CLIA waived tests to perform in-house Point of Care (POC) diagnostic test
- Select CLIA waived tests to perform in-house POC diagnostic test
- Establish competency protocol for in-house POC diagnostic test



Clinical Laboratory Improvement Amendment (CLIA)

- Congress enacted CLIA in 1988 to establish “quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient results regardless of where the test was performed.”
- Current law states that all laboratories must be certified under CLIA to perform testing on human specimens.



CLIA (cont'd)

- CLIA regulations define a laboratory as *“a facility for the...examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.*
- Congratulations, you are a laboratory! It is not a specific room or site, but what you are performing and reporting.



Categorization of Waived Tests

- Certificates of Waiver are issued to laboratories that use specific test methods approved by the Food and Drug Administration (FDA) for this category
- Categorized as a Waived Tests if:
 - Approved by FDA for home use
 - Determined to have an insignificant risk of erroneous result, including those that:
 - “Are so simple and accurate as to render the likelihood of erroneous results negligible, or
 - The Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.”



Requirements for Waived Laboratories

- Waived laboratories are exempted from routine site visits under CLIA law, but states may require their own site visits
- State law always super cedes Federal law if the state law is more stringent



Meeting Requirements for Waived Laboratories

- Apply for a certificate of waiver
- Describe the characteristics of the laboratory operation and test procedures performed by the laboratory, including:
 - Qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the test procedures
- Make records available to New York State Department of Health
- Follow manufacturers' instructions for waived tests and to limit testing to methods approved by the FDA as waived



Vulnerability Concerns for Waived Tests

- Failure to follow manufacturers' instructions
- Failure to identify incorrect results
- Testing beyond the laboratory's CLIA certificate
- Untrained staff
- Lack of quality controls
- Poor equipment
- Poor storage of reagents
- Poor record keeping
- Misunderstanding of requirements



Federal (CMS) Project Findings: 2000-2001

- 32% failed to have current manufacturers' instructions
- 32% did not perform quality control as required by manufacturer or Centers for Disease Control and Prevention (CDC)
- 16% failed to follow current manufacturers' instructions
- 7% did not perform calibration as required by manufacturer



Federal (CMS) Project Findings: 2000-2001 (cont'd)

- 23% does not follow manufacturers' storage or handling instructions
- 15% uses reagents past expiration date
- 12% no evaluation of staff for accurate and reliable testing
- 30% of personnel have been asked to repeat a waived test



JCAHO Accreditation for Waived Testing

1. Evaluate waived testing during inspection process
2. Test method/performance verification for accuracy/precision/reference range
3. Quality control
4. Specific education requirement for Point of Care Testing (POCT)
5. Personnel training
6. Identify testing and supervisory personnel for POCT
7. Initial and annual competency
8. Performance appraisal process
9. Continuous quality improvement/Total Quality Management (TQM) Program



JCAHO Accreditation for Waived Testing (cont'd)

10. Written standard operation procedure (SOP) for:
 - a. Specimen collection and preservation equipment
 - b. Quality control (QC)
 - c. Performance maintenance instrument calibration
 - d. Problem and remedial action
 - e. Test performance
11. Annual review of SOP by Director and/or Supervisor of Testing and Laboratory
12. Patient test result reporting
13. Audit trail linking test results across to analyst to QC and to instrument problem
14. Correlation of test results across different instruments and different sites (semiannual)
15. Monitor quality and stability of reagents



JCAHO Standard WT.1.30

- Standard
 - Staff receive, specific training and orientation for the tests they perform, and demonstrate satisfactory levels of competence
- Rationale for WT.1.30
 - For waived tests to be performed properly, the staff performing them must be qualified to do so. Staff members who perform waived testing have specific training in each test performed. This training can be acquired through organization or other training programs, such as those provided by another health care organization or manufacturer.



Elements of Performance for WT.1.30

1. Current competence of testing staff is demonstrated
2. Staff members who perform testing have been trained
3. for each test he or she is authorized to perform
4. Staff members who performs testing have been oriented according to organization's specific services
5. Staff members who perform testing that requires the use of an instrument have been trained on the use and maintenance of that instrument



Elements of Performance for WT.1.30 (cont'd)

6. Competence is assessed according to organizational policy at defined intervals, but at least at the time of orientation
7. Current competency is assessed using at least two of the following methods per person per test:
 - a. Performing a test on a blind specimen.
 - b. Having the supervisor or qualified delegate periodically observe routine work.
 - c. Monitoring each user's quality control performance.
 - d. Written testing specific to the method assessed.
8. The director named on the CLIA Certificate of Waiver or qualified designee evaluates and documents evidence of orientation, training, and competency above



References

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