



COMMITTEE DISCUSSION

Good Laboratory Practices for Waived Testing

February 16, 2005



Workgroup Considerations

- ❖ **Considerations before testing**
- ❖ **Test performance**
- ❖ **Personnel training/Continuing education**
- ❖ **Mechanisms for disseminating the guidelines**



Considerations Before Testing



- ❖ **What needs to be considered by management or the laboratory director when deciding whether to perform waived testing or when considering the addition of a specific waived test to the testing menu?**
 - Considerations before testing are the most critical issues, and persons providing/using the test will benefit from considering all these issues
 - Careful consideration and evaluation of a test prior to use is an essential issue and is part of assuring patient safety



Considerations Before Testing (cont.)

- Each test should be evaluated for use in the individual practice or test site
- The person assessing the test should have appropriate background/training
- The guidelines should specify the laboratory director as accountable for the laboratory results; the director/physician should approve/sign-off on all new tests
- Determine how to maintain records of results, where results are stored and who has access to records



Determine Whether State Regulations Apply

- ❖ **State and local requirements may be more stringent than CLIA requirements for performing laboratory tests**
 - The guidelines should include information on where to find state laws/regulations



CLIA Certificate of Waiver (COW)

- ❖ **A CLIA Certificate of Waiver (COW) or other CLIA certificate must be obtained prior to performing any laboratory testing**
- ❖ **To obtain the COW**
 - Complete CMS Form 116
 - Submit the fee
- ❖ **The COW must be renewed every two years**



CLIA Certificate of Waiver (COW) (cont.)

❖ COW laboratory requirements

- Testing is limited to tests/test systems categorized as waived
- Follow manufacturer's instructions for testing
 - Any modification of the test procedure or use of the test changes its complexity to uncategorized and it cannot be used by a facility with a COW
- COW facilities are exempt from CLIA standards
 - No routine oversight/inspections by CMS
 - CLIA personnel standards do not apply



CLIA Certificate of Waiver (COW) (cont.)

Additional Comments

- ❖ **Identify a person responsible for oversight and document the delegation**
- ❖ **The “point person” or person who is accountable should sign the COW application**
- ❖ **FDA should require manufacturers to include in test system information, instructions for obtaining a Certificate of Waiver**



Management Responsibility for Safety

- ❖ **Provide safe environment for personnel and patients**
 - Distinguish between CLIA and OSHA requirements
 - Regardless of the type of CLIA certificate, a facility must comply with OSHA requirements, which are independent of CLIA
 - Staff handling human specimens should have information on bloodborne pathogens and contamination
 - Explain adequate space, using examples



Management Responsibility for Safety (cont.)

- ❖ **Comply with OSHA, state, local requirements for handling and transport of human specimens, disposal of biohazard waste, availability of hepatitis B vaccine**
 - Provide state websites to access information, or a state contact. State Survey Agency contact information can be found on CMS website
<http://www.cms.hhs.gov/clia/ssa-map.asp>
 - Provide resources for additional information



Management Responsibility for Safety (cont.)

- ❖ **Have a separate specimen collection area**
 - Eating and drinking are not permitted where specimens are collected or testing is performed
 - Post good laboratory practice information for patients



Diagnostic and Patient Benefits

- ❖ **Will the diagnostic and patient benefits be met by the test?**
 - The decision-maker needs to understand the intended use as described in the product insert
 - Product information should indicate if the test is a screening or diagnostic test
 - Medical indications/limitations affecting the test
 - Limitations of the test must be understood
 - Appropriate patient population for test performance
 - Test performance (accuracy) in varying prevalence populations



Diagnostic and Patient Benefits (cont.)

- Review accuracy and precision information provided in the product insert
- Patient follow-up, counseling, confirmatory testing needed
 - Limitations of the test should be clarified and communicated to the patient



Physical Requirements for Testing

- ❖ **What are the physical requirements for conducting testing?**
 - Laboratory environment – temperature, humidity, adequate lighting, electrical requirements
 - Workflow, space required for testing, equipment, storage of tests/reagents/supplies
 - Additional equipment and disposal needs



Total Cost Considerations

- ❖ **Which factors need to be considered in assessing the total cost of testing?**
 - Reimbursement
 - Inventory control
 - Shelf life (expiration dates) of test components and supplies
 - Items not supplied with test
 - Cost of performing control procedures/maintaining equipment
 - Total volume of testing/seasonal testing
 - Personnel costs, e.g. time for testing and training associated with testing
 - Cost of connecting data to information system(s)



Test System Considerations

- ❖ **Are there considerations specific to a particular test system?**
 - Accuracy and precision published in product insert
 - Simplicity of test system/instrument operation, maintenance, and reliability
 - Determine the level of technical support provided by the manufacturer



Test System Considerations (cont.)

- Sales restrictions such as
 - Training requirements for testing personnel
 - Quality assurance program
 - Provision of test information to patients
- Include customer letter in every kit stating the responsibility for each testing site to obtain a CLIA certificate and use the test properly



Test System Considerations (cont.)

- Test interpretation and reporting
 - Test performance limitations
 - Precautions for color-blindness
 - Confirmatory or referral testing
 - Status of the disease process can affect test results
- Public health disease reporting requirements
 - Provide examples of reportable diseases



Appropriate Personnel

- ❖ **Does the laboratory/facility have appropriate personnel for testing?**
 - Sufficient staffing in place, effect of turnover
 - Temporary or part-time personnel may be less proficient in performing the test appropriately
 - Determine whether current staff have adequate time to perform testing



Appropriate Personnel (cont.)

- Overall staff competency, training required
 - Need to ensure the test can be performed consistently and the correct result obtained
 - Staff should have periodic retraining/reminders to maintain good testing procedures



Appropriate Personnel (cont.)

- Identify a resource person or expert to answer questions
 - May be in the office or available by phone/hotline
 - May be from the reference laboratory, state health department, manufacturer's technical assistance
- Post telephone numbers for health departments
- Post 800 telephone numbers for the manufacturer/distributor of each test system



Appropriate Personnel (cont.)

- Encourage staff to ask/call for help
- There should be a “contact person” for questions or to discuss new test systems/kits with sales representatives. This person needs the appropriate information or training to know what to ask sales representatives or distributors.



COMMITTEE DISCUSSION



Test Performance Overview

- ❖ **Pre-testing Phase - test ordering and specimen collection**
- ❖ **Testing Phase - performing the test and interpreting results**
- ❖ **Post-testing Phase - reporting results and maintaining records**



Pre-testing Phase

- ❖ **Activities or practices to promote quality in the pre-testing phase**
 - Test requisitions/orders
 - Confirm patient identification, test ordered
 - Provide patient instructions, patient information as necessary
 - Give examples, e.g. fasting for glucose testing
 - Ask patients if they were given instructions, did they understand them, and can they explain them
 - Discuss with patients factors that can affect test results, including limitations



Pre-testing Phase (cont.)

- Specimen collection and handling
 - Use only direct unprocessed specimen(s) approved for the test – give examples
 - Follow the specimen collection procedure specified in the product instructions
 - Serum and plasma are not appropriate for waived testing
 - Use container/collection device provided with the test
 - Label the specimen (patient identifier; date; person collecting; time, if required)
 - Follow manufacturer's instructions for handling, storage and disposal



Pre-testing Phase (cont.)

- ❖ **Before testing, prepare testing materials (kit, reagents, controls, etc.)**
 - Check product inserts for changes in instructions
 - Check expiration dates
 - Write date opened and expiration in marker on the outside container of kit, vial, etc.
 - Explain that expiration dates may change due to other factors (e.g., based on storage, temperature, once opened)
 - Explain the importance of adhering to manufacturers' expiration dates (give examples)



Pre-testing Phase (cont.)

- Control ranges may change with lot numbers – refer to current lot number information
- Do not mix components of different kits, lots or tests



Testing Phase

- ❖ **Activities or practices to promote quality in the testing phase**
 - Written test procedures
 - Have a current procedure manual
 - May include manufacturer's product inserts and various forms, such as forms for reporting diseases to public health departments
 - Each testing procedure should be written with instructions that include all steps for your facility
 - Use a format or template to write new procedures
 - Written procedures should integrate procedural steps and control testing instructions



Testing Phase (cont.)

- Follow current manufacturer's instructions for test system in use
 - Check product inserts for any changes in instructions
 - It may be useful to highlight the most important parts of procedures
- Read, understand instructions prior to testing
- Separate retired procedures, retain and document inclusive dates of service
- Laboratory director should review periodically
- At workstation use Quick Reference Instructions that include the specific test name at workstation



Testing Phase (cont.)

❖ Procedural steps

- Set up testing materials, instrument, workstation
 - Electronic equipment
 - Include a warning that if “portable” equipment is moved, it may be subject to inaccurate results and may require additional quality assurance to verify it is fully functional and operating properly
- Follow the steps in the order described, including control procedures and control testing



Testing Phase (cont.)

- Follow manufacturer's timing for test performance and interpretation
 - Include hints for timing tests
 - Explain the importance of correct timing for tests and how inaccurate timing can affect results- provide examples
- Do not mix components of different kits, lots or tests
- Check and document test system lot number and expiration date
 - Explain the importance of documentation (e.g., tracking or traceability of product recalls)



Testing Phase (cont.)

❖ Control testing

- Explain what quality control is, why it is important, how to perform and interpret results
- Perform at intervals stated by manufacturer
- Understand types of test system controls - define in a glossary
 - Built-in
 - Procedural
 - Electronic
 - External control materials



Testing Phase (cont.)

- Manufacturer should either supply external control materials with test kits, when possible, and include instructions for use, or provide information for user to purchase appropriate control materials
- Document results of internal and external control testing and actions taken if out-of-range
- For external controls, document lot numbers and expiration dates
- Use the correct reference ranges



Testing Phase (cont.)

❖ Test Results-Interpretation and Reporting

- Follow manufacturer's instructions for result interpretation and recording
- Evaluate the results to determine whether the test result is reasonable for the patient - include examples
- Records of patient test results may include
 - Test name, lot number, expiration date
 - Patient or specimen identifier
 - Test results, date performed, initials of person performing
 - Control test results may be recorded with patient test results



Testing Phase (cont.)

- Test system problems/failures
 - Refer to manufacturer's instructions for
 - Identifying sources of error, interferences-
drugs, nutritional additives that can affect a test
 - Steps to resolve problems
 - Problems with control testing
 - Manufacturer contact information for assistance
 - FDA MedWatch medical products reporting
program and contact information (Note: this is
not in current product instructions)



Testing Phase (cont.)

- Resolve problems before reporting patient results
- Record actions taken to resolve problems including actions taken when control results are unacceptable
- Maintain records for the minimum timeframe required by state regulations, if applicable
- Provide staff with contact information for “Go To” person such as a consultant/resource person



Testing Phase (cont.)

- Encourage staff to request help with problems
 - Results should not be reported if there is a question about the procedure or how the test was performed
 - Test results should not be released until problems are resolved



Post-testing Phase

- ❖ **Activities or practices to promote quality in the post-testing phase**
 - Test results should be easily retrievable
 - Reporting results
 - Assure written reports are legible, reported in a timely manner to the appropriate person
 - Point-of-care/office testing results may be accurately and legibly recorded directly in patient's medical record (for practices with multiple locations, note the office where testing was performed)



Post-testing Phase (cont.)

- Reporting results (cont.)
 - Have a process for reporting critical/action values
 - Issue verbal reports and critical values according to testing site policies; follow with a written report
- Reports may include information appropriate to the facility but are not be limited to
 - Testing facility information
 - Name, address/site/clinic number, phone number (suitable to the type of facility)
 - Director/physician responsible for the facility



Post-testing Phase (cont.)

- Patient information/identifier
- Date report is issued, person issuing report when appropriate
- Relevant test information
 - Results with appropriate units, interpretation, reference ranges (normal values)
 - Date performed
 - Comments, if appropriate



Post-testing Phase (cont.)

- Standardized report format should be appropriate for the testing site so reports generated onsite are easily distinguishable from reference laboratory reports
Example: A notation in the policy or procedure manual could indicate “Unless otherwise specified, all testing is performed in this facility.”
- Comply with local, state disease reporting requirements
 - Provide contact information



Post-testing Phase (cont.)

- Confirmatory/supplemental testing
 - Give examples
 - Follow testing protocol required by your facility or manufacturer's instructions
 - Consult the ordering physician
 - Collect a new specimen if necessary
 - Follow safe specimen transport procedures
 - Specific instructions may be provided by the reference laboratory receiving the patient sample
 - Have contact information readily available
 - Post instructions for easy reference



Post-testing Phase (cont.)

- Use only CLIA-certified laboratories for referral
- Record information for tracking
 - Patient test results may be provided from a variety of sources, which should be identified
 - Link referred specimen to patient identifier
 - Test request, date referred, reference laboratory
 - Referred test results, date received and date reported



Post-testing Phase (cont.)

- Maintain copies of reference test reports
- Issue and maintain reports of supplemental testing
- Retain patient test results
- Retain records of controls, calibration records, instrument maintenance, repairs and replacements



COMMITTEE DISCUSSION



Personnel Training & Continuing Education

- ❖ **Mechanisms for providing training and continuing education to waived testing personnel**
 - Personnel training – personnel turn-over is a major challenge and adequate staff and proper training of personnel are essential for quality testing
 - Personnel must be trained/oriented to each test procedure before testing patient samples
 - Ensure competency before patient testing
 - Include training in specimen collection
 - Include training in bloodborne pathogens



Personnel Training & Continuing Education (cont.)

- Describe on-the-job training
 - The trainer demonstrates the procedure/steps involved
 - The trainee performs the test to demonstrate understanding and ability to perform the test correctly
 - Training should be provided by a qualified person who can train, provide feedback, evaluate staff and conduct follow-up evaluations to ensure training is effective



Personnel Training & Continuing Education (cont.)

- Training modules or activities should be specific for different intended audiences
- Training and competency assessment must be on-going
- Manufacturers and distributors provide technical assistance, product updates, notifications and may provide training



Personnel Training & Continuing Education (cont.)

❖ **Competency assessment**

- Periodically assess testing personnel
- External evaluation programs and control materials can be used for competency assessment
- Participate in voluntary proficiency testing (PT)
 - Explain what PT is and how to obtain it
 - Explain participation in voluntary PT programs provides benchmarking and ensures testing is accurately performed



Personnel Training & Continuing Education (cont.)

- Training/continuing education sources
 - Manufacturers, distributors
 - Professional organizations– ASCLS, CAP, COLA, JCAHO, etc.
 - State laboratories, reference laboratories
 - CDC
 - CMS
 - FDA
 - NLTN



Personnel Training & Continuing Education (cont.)

- Other considerations/sources for training or continuing education
 - Provide on-line internal audits based on checklists for laboratories to assess their performance
(Note: many POLs do not have internet access)
 - Provide consultation to POLs, when requested. This could be a service financed with user fees
 - Provide education to MDs at group meetings, national meetings, COLA, other organizations with free training (Major problem: time constraints)
 - Suggest using a coordinated approach working through public health systems



COMMITTEE DISCUSSION



Additional Workgroup Comments

- ❖ **CDC publication is a powerful tool;**
“Recommendations” can become a standard of care
 - Use a uniform format or consistent language
 - Use different approaches for different user populations
 - Write the guidelines in simple language directed to non-laboratorians – 7th grade reading level
 - Provide information for physicians on the simplest ways to comply with the guidelines
 - Identify which recommendations are the most critical
 - Try to avoid having the guidelines seem confusing or burdensome to physicians and non-laboratorians



Additional Workgroup Comments

- ❖ **Physicians and healthcare professionals want to do their best but do not have adequate training in laboratory testing**
- ❖ **Stress that patient safety is the goal, and not performing some type of quality assurance increases liability**
- ❖ **Distribution of the guidelines to physicians, manufacturers, managed care providers can influence the appropriate use of waived tests because these stakeholders do not want to be at risk for lawsuits**



Additional Workgroup Comments

- ❖ **Variability among product inserts makes it hard to find needed information**
- ❖ **Manufacturers should incorporate quality control performance in the test procedure instructions**
- ❖ **In the guidelines, include a glossary of terms with definitions or provide an explanation in simple terms**
 - **Laboratory – any site where testing is performed**
 - **Use appropriate language to relate to POLs, RNs, MDs, office managers because they do not think of their testing as laboratory testing, nor their facility as a laboratory**



Additional Workgroup Comments

- “Laboratory director/manager” is an unfamiliar term for those who do not see their activities as directing/managing a laboratory; “responsible party” may be a better term
- Test system
- Accuracy
- Precision
- Quality control, including types of controls
- Proficiency testing – present as an educational tool
- Explain the intent of language used in inserts such as “should,” “may,” vs. “must”



COMMITTEE DISCUSSION



Disseminating Good Laboratory Practice Guidelines

- ❖ ***MMWR* may offer CMEs for physicians to receive educational credit related to laboratory testing/use**
- ❖ **Reach risk managers, managed care providers, insurance companies, malpractice carriers, hospital administrators, American College for Physician Executives, professional organizations, etc., and inform them that following good laboratory practice guidelines will lower the legal risk to their organizations**



Disseminating Good Laboratory Practice Guidelines

- ❖ **Design and distribute a Top 10 list of most important good practices for performing waived testing**
 - Suggested Top 10 subjects: specimen, reagents, QC, reports, training/competency, records, procedure, patient ID, expert in office, expert to call
 - To develop the Top 10 for different user groups, use focus groups (the intended audience) for input - especially on mode of dissemination
 - Design and distribute wall posters, laminated handouts featuring the Top 10 list



Disseminating Good Laboratory Practice Guidelines

- ❖ **Manufacturers and distributors could endorse good laboratory practices for waived testing guidelines in product information**
- ❖ **Important part of effort is to reach patients/consumers; determine mechanisms to reach the public**
 - Provide posters with information for patients explaining what they should expect from laboratory testing
- ❖ **Guideline information needs to be provided in languages other than English**



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