

CLIA and the CDC Aim to Improve Laboratory Practices and Patient Safety at Waived Testing Sites.



TIPS FOR QUALITY TESTING AT WAIVED SITES:

CDC Releases Recommendations on Good Laboratory Practices

The use of simple, low-risk testing waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) is on the rise among healthcare providers. The tips in this document are adapted from recommendations by the Clinical Laboratory Improvement Advisory Committee (CLIAAC) and published by the Centers for Disease Control and Prevention (CDC).

NEW RECOMMENDATIONS

Certificate of Waiver (CW) sites are not subject to regulatory oversight or personnel requirements. In an effort to identify quality issues and to educate personnel at CW sites, the Centers for Medicare & Medicaid Services (CMS) recently conducted multi-year, on-site surveys of a representative sample of these sites. Following this, CLIAAC provided and the CDC published recommendations in 2005 to improve laboratory practices and enhance patient safety.

CONSIDERATIONS BEFORE INTRODUCING WAIVED TESTING

1. Identify a knowledgeable person to be responsible for testing oversight.
2. Be familiar with applicable federal, state, and local regulatory requirements—including those for workplace safety.
3. Determine if testing space and facility environmental conditions are adequate.
4. Evaluate waived testing benefits and costs.
5. Assess staffing and training needs, and the impact on workflow.
6. Determine what documents/records will need to be developed and maintained.

PRE-TESTING RECOMMENDATIONS

Preparations that include proper patient identification, specimen collection, and attention to the tests ordered contribute to quality test results. The checklist below provides additional tips.

- Confirm the written test order(s)** are correct; consult the ordering physician with any questions. Document standing test orders.
- Identify the patient** before collecting a specimen.
- Note pre-test directions** that may require special patient preparations, e.g. fasting. Inform patients of any requirements in advance; have them explain the preparations to ensure their understanding.
- Provide patients with pertinent information**, such as medical indications or test limitations that could affect results. Provide pamphlets from the test manufacturer when specified in product inserts.
- Read all product insert information** on specimen collection and handling. Ensure the waived test is being used only for direct, unprocessed specimens that do not need operator manipulation.
- Thoroughly understand proper specimen collection**, including proper specimen types, proper collection methods (e.g., the first drop of fingerstick blood vs. the second), specimen handling, and hygiene rules.
- Use the manufacturer-supplied or manufacturer-specified collection devices**, e.g. containers, to ensure correct specimen type, volume, etc.
- Establish labeling procedures** to prevent specimen mix-ups. Note pertinent patient information, collection dates, and times.
- Prepare testing areas, materials, and equipment in advance** to maintain efficient workflow and test quality. Make sure insert information is current and abide by test expiration dates. Allow refrigerated reagents/patient specimens to reach room temperature if specified by product insert.

RECOMMENDATIONS DURING TESTING

This phase of waived testing includes quality control (QC) testing, patient test performance, and result interpretation and recording. See the checklist below to identify key steps and provide assurances that the test is working properly and to detect potential problems due to operator error, test kit deterioration, malfunctions, or improper environmental conditions.

- Determine an appropriate QC testing frequency** for your CW lab. Waived tests may have internal controls that are built-in and designed to verify the test is working properly and/or external controls that mimic patient specimens in order to monitor the entire testing process.
- Take corrective action if QC testing fails.** Stop testing and do not report results until resolved.
- Have manufacturer contact information readily available** to address product problems.
- Document and monitor QC test results.** Review these periodically to detect shifts over time.
- When performing the test:** Follow the test procedure steps in the exact order specified in the product insert, perform QC tests with appropriate frequency, pay attention to timing as some results must be read at certain intervals. Use timers as needed.
- Interpret results** using product instructions. For quantitative tests, numerical results are displayed that indicate the concentration of a substance in a specimen. For qualitative tests, positive or negative results indicate the presence or absence of a substance. Invalid results identify a problem with the test or specimen.
- Record test results** via patient charts, log books, or on a separate form. Record quantitative results using the test system's unit of measure. Record qualitative results using interpretive words and abbreviations instead of + or – symbols to avoid clerical errors.

POST-TESTING RECOMMENDATIONS

Tasks to be done after waived testing is completed include: test reporting, supplemental or confirmatory testing, public health disease reporting, documentation, and cleanup. This checklist notes recommended actions during this phase of waived testing.

- Create standardized, legible, and timely on-site reports** that are easily distinguishable from referral lab reports. Define critical values at your test site that are needed for immediate patient follow-up.
- Supplemental or confirmatory testing** may be needed with some waived tests, e.g. HIV tests. These tests may be performed at referral labs. Document when additional testing is needed with instructions for test ordering, specimen collection, labeling, and safe specimen transport. Keep good test records to help track and retrieve results/reports.
- Comply with government reporting regulations** for certain infectious diseases if required.
- Dispose of any bio-hazardous waste** in the appropriate manner.
- Maintain testing records and QC records** in chronological order for easy comparison. Review periodically and note that some agencies may require they be kept for a certain length of time.
- Recommended testing documentation** includes records of: 1. Test orders, procedures, and instructions. 2. Test materials used, function checks, and maintenance, e.g., refrigerator temperatures, lot numbers, dates used, and expiration dates. 3. QC test results and corrective action. 4. Personnel training/competency assessment. 5. Proficiency testing or external quality assessment, if conducted.
- Evaluate and improve waived testing** with flexible, low cost internal assessments such as self-conducted inspections and a supervisory review of processes, problems, and performance. Or utilize external assessment methods, such as voluntary inspections by peers or consultants.

Your Distributor Can Help You!

- Product training and demonstrations
- Information for product evaluation
- Product samples
- Education about compliance requirements

Additional Resources:

The Center for Disease Control and Prevention's 2006 report on Good Laboratory Practices at <http://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf>

**Sources:*

Recommendations were adapted from the Nov. 11, 2005 (Vol. 54, No. RR-13) issue of the CDC's Morbidity and Mortality Weekly Report (MMWR) on "Good Laboratory Practices for Waived Testing Sites."

For reprints visit www.HIDA.org or call (703) 549-4432.

Copyright ©2006: Health Industry Distributors Association. All rights reserved. The contents of this tool may not be reproduced by any means, in whole or in part, without prior written consent from HIDA.