Waived Testing—Doing it Right

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Recommendations for promoting quality and enhancing patient safety

Overview of Waived Testing

The Food and Drug Administration (FDA) categorizes all new test procedures. The "waived" category includes tests which are simple to use and have a low risk for error. Listings of waived analytes and tests can be found at http://www.fda.gov/cdrh/clia/cliawaived.html. The Current Procedural Terminology (CPT) code must have the modifier QW attached when billing for a waived test. The three most commonly performed waived tests are glucose, dipstick urinalysis and fecal occult blood. Waived laboratories ("CW sites") only perform waived tests and are not subject to regular inspections, personnel requirements, or proficiency testing (PT). They are only required to obtain a CLIA Certificate of Waiver (CW), pay certificate fees, and follow manufacturers' test instructions. Awareness of good laboratory practices and a focus on personnel training and education can improve the quality of health care delivered by the CW site.

For more information regarding the waived testing category, contact ACP's CLIA Specialist, at (800) 338-2746.

Things to Consider Before Introducing Waived Testing or Offering a New Waived Test

Management responsibility for testing. *Who will be responsible and accountable for testing oversight at the CW site, and does this person have the appropriate training for making decisions on testing?*

Each site should identify at least one person responsible for testing operations, later referred to as the CW director. In a physician's office lab (POL), this might be a physician or someone in a senior management position who has the appropriate background and knowledge to make decisions about laboratory testing. Ideally, this would be the person signing the Certificate of Waiver application. The management staff should demonstrate a commitment to the quality of testing service by complying with regulatory requirements and promoting good laboratory practices.

Regulatory requirements. *What federal, state and local regulations apply to testing, and is the site adequately prepared to comply with all regulations?*

- *CLIA certification*: A valid CLIA certificate is required for Medicare reimbursement. Further, it is not legal to perform any laboratory test without a CLIA certificate of some level, regardless of payment method. Each site offering only

waived testing that is not included under any other type of CLIA certificate must obtain a CW before testing patient specimens.

- *State and local regulations*: Some states and localities have specific regulations for testing, some require licensure of personnel who perform testing, and some have phlebotomy requirements. Whenever state or local regulations are more stringent, they supersede the federal CLIA requirements.

Safety. *What are the safety considerations for persons conducting testing and those being tested?*

Each CW site must comply with Occupational Safety and Health Administration (OSHA) standards, including the Bloodborne Pathogens Standard. The requirements of this standard include, but are not limited to:

- A written plan for exposure control, including post-exposure evaluation and follow-up for the employee in the event of an "exposure incident" (e.g. needle stick)

- Use of Universal Precautions, an approach to infection control in which all human blood and body fluids are treated as if known to be infectious.

- Use of safer, engineered needles and sharps which have safety features built in to the design of the device (e.g. retractable needles).

- Use of personal protective equipment (PPE) such as gloves and protective eyewear.

- Provision of hepatitis B vaccination at no cost for those with possible occupational exposure who want to be vaccinated.

- Safety training for handling blood, exposure to bloodborne pathogens and other infectious materials.

- Equipment for the safe handling and disposal of biohazardous waste (e.g. properly labeled or color-coded sharps containers and biohazard trash bags).

Additional safety practices for performing testing are:

- Prohibit eating, drinking and applying makeup in areas where specimens are collected or tested, to prevent hand-to-mouth transmission of pathogens.

- Prohibit storage of food in refrigerators where specimens or testing supplies are stored.

- Provide hand-washing facilities or antiseptic hand-washing solutions.

- Post safety information for employees and patients to read.

Privacy and confidentiality:

Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), CW sites are required to establish policies and procedures to protect the confidentiality of their patients' health information. This information includes patient identification, test results and all records of testing. It must be protected whether on paper, in computers, or communicated orally.

Most physician offices are already required to comply with these standards, so they should not be a barrier to testing.

Testing space and facilities. *What are the physical and environmental requirements for testing?*

Testing should be performed in a separate designated area where enough space is available to safely conduct testing and maintain patient privacy. In addition, some tests have specific environmental requirements described in the manufacturer's product insert that need to be met to ensure reliable test results.

Factors to consider include:

- *Humidity*—Unusually high, low, or extreme fluctuations can cause deterioration of reagents and test components, affect the rate of chemical reactions and specimen interaction, or make test endpoints blurred and difficult to read.

- *Temperature*—Ranges for storage of test components and controls and for the testing area environment are defined by the manufacturer to maintain test integrity. Extreme temperatures can degrade reagents and test components, impact reaction times, cause premature expiration of test kits and affect the test results.

- *Lighting*—Inadequate lighting can negatively affect specimen collection, test performance and interpretation of test results.

- *Work space*—Work surfaces should be stable and level and able to be adequately disinfected. Work space should be adequate in size for patient confidentiality, ease of specimen collection, test performance, and storage of supplies and records.

Benefits and costs. *How will the patient care provided in the CW site benefit by introduction of the new test and what will it cost?*

Evaluate the test system using information from the manufacturer's product insert or by speaking with the manufacturer's technical representatives.

Specific considerations in assessing the potential benefits include:

- *Intended use*—This section of the product insert describes the purpose of the test, what is being measured by the test, the type of specimen for which it is approved, and whether it is a quantitative or qualitative measurement.

- *Performance characteristics*—Review information provided by the test manufacturer or published data including the test's *accuracy* (closeness of the result obtained to the actual value), *precision* (ability to get the same results in repeated tests on the same sample), *sensitivity* (percentage of individuals with a specific condition who yield a positive test result), and *specificity* (how well a negative test result correctly predicts absence of the condition) and *interferences* (medical conditions, drugs or other substances that might influence test results).

- *Patient population*—Some tests have not been evaluated for use in specific age groups (e.g. pediatric patients). Consider the population that will be tested and refer to the product insert for limitations for use in particular patient populations.

- *Test system*—Consider the simplicity of operating the test, length of time to obtain a result (turn around time) and the level of technical support provided by the manufacturer or distributor. Sales restrictions, such as special training requirements, development of a quality assurance program, or provision of information to patients, might apply to some waived tests.

Consider the level of reimbursement and the following factors that will contribute to the total cost:

- Test kits or instruments, supplies required but not provided with the test, control and calibration materials, inventory requirements for anticipated test volume (including seasonal testing), and the shelf life of test components and supplies.

- Equipment maintenance, such as repairs or preventive maintenance contracts.

- Additional safety and biohazard equipment such as PPE, and waste disposal.

- Personnel training, competency assessment, and the potential need for additional personnel.

- Recordkeeping and information systems.

- Required supplemental testing or patient follow up—Some waived tests provide preliminary results (e.g. rapid HIV testing) or results that must be considered in conjunction with other medical information. These may require additional or confirmation testing, or the patient may need post-test counseling about the meaning of the test result. Assess the potential need for additional time, documentation, staffing and a mechanism to refer additional testing to another laboratory.

- Regulatory compliance (e.g. CW renewal fee of $150 every two years).

- Resources needed to manage public health reporting, if required nationally or by the state.

ACP offers to members, free of charge, Office Laboratory Check-Up which can assist in assessing these factors. This can be found at www.acponline.org/pmc/lab.htm.

Staffing. *How will introduction of testing affect the current work flow, are there sufficient personnel to conduct testing, and how will they be trained and maintain testing competency?*

- Determine whether employees have sufficient time and skills to reliably perform all activities needed for testing in addition to their other duties.

- Waived testing sites are subject to high rates of personnel turnover. Consider the staff turnover rate and the ongoing need to provide training for new personnel.

- Factor in the time and resources needed for adequate training and competency evaluation of staff before they can perform testing.

- Be aware that temporary or part-time personnel might be less proficient in performing testing.

- Consider how testing personnel will maintain competency, especially when test volume is low.

- Evaluate staff for color-blindness because this can limit their ability to interpret test results based on color endpoints.

Documents and records. *What written documentation will be needed and how will test records be maintained?*

Logbooks or electronic systems can be used for maintaining and tracking information. Proper documentation, kept in chronological order, will be helpful in monitoring test performance, identifying and resolving problems, and retrieving and verifying information. State regulations or other governmental agencies might require CW sites to retain documents and records for a specific length of time.

Records should be kept for the following aspects of testing:

- Test orders.

- Written test procedures or work instructions, and current product inserts.

- Daily records of temperatures for refrigerators, freezers and the testing area.

- Lot numbers, dates used and expiration dates of test systems and reagents.
- Equipment function checks and any maintenance performed.
- Notifications from manufacturers about product recalls or other problems.
- Patient test results, including any confirmatory or supplemental testing.
- Quality Control (QC) testing and corrective action taken if control results are unacceptable.
- Any test system failures, troubleshooting and corrective action taken when problems are identified, including related communication.
- Personnel training and competency assessment.
- PT or other external or internal quality assessment.
- Periodic review of records by the CW site director.

The extensiveness of the documentation needed to assure quality will vary based upon the number and types of tests performed. The most important point is to keep documentation *simple and easy to use*.

Developing Written Test Procedures

A comprehensive procedure manual is a valuable resource for testing personnel. Although the manufacturer's testing instructions, outlined in the product insert, can be used as a test procedure, these instructions will typically need to be supplemented with information that is unique to the CW site's operations and workflow. The procedure manual should be updated as tests or other aspects of testing change, and should be reviewed by the CW site director whenever changes are made. New procedures should be reviewed by the director before incorporating them into the procedure manual. When procedures are discontinued, they should be removed from the manual and retained with a notation of the dates during which they were in service.

When writing procedures it might be helpful to:

- Use a template with standard component headings for a standardized format.
- List all materials needed and how to prepare them before testing.
- Include instructions for patient preparation and specimen collection.

- Highlight key steps in the procedure (e.g. incubation times).

- List test limitations.

- Describe actions to take when the test does not perform as expected.

- Integrate control procedures with the steps for performing patient testing to assure that control testing is performed.

- Include established reference intervals or ranges.

- Define critical values for the test.

- Describe how to record and report results.

- Explain how to handle critical values and supplemental or confirmatory testing.

The most important aspect, though, is to make sure that the current manufacturer's package insert is available and that the instructions are followed, as this is the sole requirement for waived labs under CLIA.

Personnel Training

Trained and competent personnel are essential to good quality testing and patient care. Testing personnel should be fully trained and proven competent in each test they will perform before reporting patient results. Training should also include aspects of safety (e.g. Universal Precautions), QC and critical values. Training checklists are helpful to ensure the training process is comprehensive and documented.

The training process. Training should be provided by a qualified person (e.g. outside consultant or experienced co-worker) with knowledge of the test performance, good laboratory practices and the ability to evaluate the effectiveness of the training.

On-the-job training should include the following steps:

1. The trainee reads the testing instructions.

2. The trainer demonstrates the steps for performing the test.

3. The trainee performs the test while the trainer observes.

4. The trainer evaluates test performance, provides feedback and additional instruction and follow-up evaluations to ensure effective training.

5. Both trainer and trainee document completion of training.

Training resources. The manufacturer's test system instructions and instrument operating manuals should be the primary resource for information and training. Manufacturers and distributors often provide technical assistance, product updates and limited training.

Other sources for training include:

- Instructional videos and computer-based programs.

- Professional organizations that can provide workshops or other training tools (e.g. American Society for Clinical Laboratory Science or American Medical Technologists)

- State health departments or other government agencies that can provide limited training.

Competency assessment. To ensure that testing procedures are performed consistently and accurately, periodic evaluation of testing personnel's competency is recommended, with retraining as needed based on results of the evaluation. Assessment activities should be carried out in a positive manner with an emphasis on education and promoting good testing practices.

Competency can be evaluated by these methods:

- Observation.

- Evaluating adequacy of documentation.

- Introduction of mock specimens for testing, using control materials or previously tested patient samples.

- Voluntary PT programs (e.g. ACP's Medical Laboratory Evaluation program).

Additional measures to help staff ensure reliable results:
The CW director or person overseeing testing should promote quality testing and encourage staff to ask questions and seek help when they have concerns.

- Certain manufacturers provide quick reference instructions formatted as cards or small signs. Post these where testing is performed, along with telephone numbers for manufacturers' technical assistance representatives.

- Identify a resource person or expert available either off-site or on-site (e.g. a consultant or technical service representative) to answer questions and be of assistance.

- Designate an appropriately trained person to discuss new products with sales representatives. Uninformed personnel might mistakenly use a promotional test kit for patient testing without realizing the consequences of substituting one test system for another.

Recommended Practices Before Testing

Test orders. Confirm that the written test order is correct. If there is a question, check with the ordering clinician before proceeding.

Patient identification. Identify the patient before collecting the specimen. Because names can be similar and lead to confusion, use birth dates, middle initials, identification numbers or other means to ensure the specimen is collected from the correct patient.

Pretest instructions and information. Some tests require special preparation on the patient's part (e.g. fasting), or that the patient collect the specimen (e.g. urine or stool). Provide the patient with pretest instructions when appropriate, and verify that patients have received instructions before collecting or accepting the specimen. Ask them to explain how they prepared for the test to determine if they have followed the instructions properly.

About waived test specimens: *Waived tests are approved for use only with direct, unprocessed specimens that do not require operator manipulation*. Some test systems can use both processed and unprocessed specimen types, but are categorized as waived only for the unprocessed specimens. Specimens, such as serum or plasma, that are manipulated by centrifugation, dilution, extraction or other preparation steps that require special training or instrumentation are not appropriate for waived tests and should not be tested by CW sites. For example, a single product insert might include instructions for performing a waived test using unprocessed whole blood and for performing the same test using plasma, which would not be waived.

Specimen collection and handling. The product insert provides details on proper collection, handling and storage of patient specimens. The person collecting the patient specimen or giving the collection instructions should have a thorough understanding of the specimen type, proper collection method, and handling necessary to assure a quality specimen for testing.

- *Collect waived test specimens exactly as described in the instructions to obtain a quality specimen.* Improperly collected, stored, or compromised specimens should not be tested. Hand hygiene should be performed between patients. When gloves are worn during specimen collection, they should be removed and discarded, and hands should be washed or sanitized before contact with another patient.

- *Use the appropriate specimen collection device or container*. These devices are integral to the test system and should be used to ensure the correct specimen type and

volume to provide reliable results. They might be provided by the manufacturer or specified in the product insert and purchased separately. Containers and collection devices can contain materials that affect the specimen or are part of the test, and should not be substituted or altered. For example, whole blood capillary tubes (e.g. used for cholesterol or hemoglobin A1C) may look alike, but they can hold different volumes or contain additives which affect test reactions and results

- *Fingerstick and venipuncture collection devices are for one-time use only*. Never reuse needles, syringes or lancets. To avoid transmission of bloodborne pathogens, appropriately discard sharps, lancets and platforms for spring-loaded lancets, and disinfect instruments and surfaces contaminated by blood or body fluids.

- *Specimens need to be adequately labeled to prevent mix-up*. To prevent errors, always label specimens as soon as they are collected with pertinent patient information (e.g. full name and/or unique identifying number). Labeling might also include the date and time of collection and identification of the collector.

Preparing the testing area, materials and equipment.

- Clear work surface and remove clutter.

- Before beginning, read and understand the test instructions specified in the product insert and included in the CW site's procedures.

- Verify that the instructions are current for the test in use and that no changes have been made.

- Allow time for any refrigerated items, including reagents or patient specimens, to reach room temperature before testing, if specified in the product insert.

- Check expiration dates and discard expired reagents and test kits as soon as the expiration date elapses. **Do not use expired kits or reagents.**

- When opening a new kit, check for notifications in the external labeling or special notices that might be included with product inserts or packaging. Write the date opened on the outside of the vial or test kit.

- Visually inspect reagents or vials for damage, discoloration or contamination.

Recommended Practices During Testing

Quality Control testing. Performing QC provides assurance that the test system performs as expected and alerts the user when problems occur which may affect patient results. QC testing is designed to detect problems that might arise because of operator error, reagent or test kit deterioration, instrument malfunction or improper environmental

conditions. The test procedure should describe the type of controls to be used, how to perform QC testing, frequency, and actions to be taken when QC results are unacceptable. For certain test systems, the product insert describes the minimum recommended frequencies for testing internal and/or external controls (e.g. with each test run, daily, or weekly). *These controls are required to be performed if specified in the product insert, even in waived laboratories.*

- *Internal, procedural or built-in controls* are designed to verify that certain aspects of the test are working properly, that sufficient specimen was added and, for unitized test devices, whether it migrated through the test strip properly. Certain systems might have electronic internal controls to monitor electronic functions.

- *External controls* mimic patient specimens and monitor the testing process from specimen application to result interpretation. They might be provided as liquid or other materials similar to patient specimens and might be included with the test system or purchased separately. *At a minimum, external controls should be tested with each new shipment of test devices, when testing with a new lot number, and by each new operator before conducting patient testing.* Controls should be tested either before or concurrent with patient specimens by the same personnel who routinely perform patient testing.

If control testing fails to perform as expected, patient testing should not be performed or results should not be reported until the problem is identified and corrected. The product insert should provide information for handling unexpected control results, identifying sources of error including interfering substances, and contact information for technical assistance.

Documenting and monitoring control testing results provides an indication that the test was properly performed by the operator and the test system performed as expected. Records of control results should be periodically reviewed by the person responsible for testing oversight to detect shifts or changes in performance over time which may affect patient results.

Performing the test.

- Follow the steps in the test procedure in the exact order described in the manufacturer's product insert.

- Test controls at the frequency determined by the CW site.

- Pay attention to timing, particularly with unitized test devices that must be read during specific time intervals. Time intervals shorter or longer than those specified can result in false positive, false negative or invalid results. Suggestions for helping to ensure correct timing of tests include: using timers that beep until turned off, using timers that can easily be worn or attached to clothing, using multiple timers when

performing more than one test at a time, and having extra timers and batteries available.

Test results interpretation. When the test is complete, interpret the results according to instructions in the product insert (including the quick reference guide).

- *Quantitative tests* provide numerical results generated by the test device or instrument. Numerical values correspond to the concentration of the substance being measured and include specific measurement units (e.g. a glucose result of 100 mg/dL). No interpretation is necessary to read the result.

- *Qualitative tests* detect whether a particular substance is present or absent. Results are generally interpreted as positive, negative or invalid. Invalid results indicate a problem with the specimen, test system or user technique. Guides for interpretation such as diagrams, color photographs and color-comparison charts are often part of the product insert and quick reference guide.

Resolving problems. If the results are invalid, or a discrepancy is found between the patient's test results and the clinical information, testing should be repeated. *Results should not be reported until the problem is resolved*. Consult the product insert for steps to resolve problems with test results. If repeat testing does not resolve the problem, contact the manufacturer or technical representative. Quantitative results can be beyond the measuring range of the instrument or test device, either high or low. Each site should have documentation of test measuring ranges and a procedure for handling test results that are above or below the reportable range.

Recording results. Results can be recorded directly in a patient's chart, in log books or on a separate report form. Records of test results should have enough detail so the test site can retrieve information.

- Quantitative test results should be recorded using the units of measurement of the test system.

- Qualitative test results should be recorded using interpretive words or abbreviations instead of symbols to help avoid clerical errors (e.g. "negative" or "neg" instead of a minus sign " - ").

- If a test result is not acceptable or requires repeat testing, record the initial result, noting that it was unacceptable, take steps necessary to resolve the problem, then record the correct result. *Good laboratory practices include recording what happens, whether acceptable or not, and what is done to correct problems encountered during testing.*

Recommended Practices After Testing

Testing area cleanup and biohazard waste disposal. Disinfect surfaces and dispose of biohazardous waste generated according to local, state and federal OSHA regulations as previously discussed. Replenish supplies used in specimen collection and testing.

Issuing test reports. Patient reports should be legible and reported in a timely manner to the appropriate person. Reports should meet the needs of the testing site and should be appropriately standardized so reports generated on-site are easily distinguishable from referral laboratory reports. Verbal reports of test results should be documented and followed by a written report.

If reports are not recorded directly in a patient's chart, they should be recorded in a written report format that includes the following information:

- Testing facility name, address and telephone number.
- Patient name or anonymous identifier and record/billing number. Birth date, sex and age are optional.
- Test ordered, test result, units of measure, interpretation, reference intervals (e.g. normal range), comments or qualifying statement, date completed and/or reported and person reporting.

Critical values are abnormal test results that require immediate notification to the clinician. Each site should have procedures in place to ensure documentation of critical values and timely notification of the proper medical personnel.

Supplemental or confirmatory testing. The product insert should explain when additional testing is needed to confirm a waived test result or when the test is to be used as part of a multi-test algorithm (e.g. throat culture needed to confirm a negative result for group A strep antigen). The CW site should have written policies and procedures to ensure that confirmatory and supplemental testing is performed when needed. When the CW site collects specimens for referral to another laboratory, follow the instructions provided by the reference laboratory and use the correct request form for that laboratory.

Maintaining records of referred testing is important for patient care and follow-up. Logs and other records should have sufficient information to track and retrieve the test results and reports, such as:

- Information linking the referred specimen to patient identification.
- The name and contact information for the referral laboratory.
- The test name and date referred.

- Complete test results and the date received.

- The date the final report is issued.

A designated employee should be responsible for ensuring that all tests ordered from a referral laboratory are returned and charted appropriately for review by the ordering clinician.

Public health reporting. Federal and state public health agencies require testing facilities to report confirmed positive results for certain infectious diseases (e.g. HIV or influenza). Testing facilities should confer with local public health departments for the most current information on required reporting procedures since diseases identified for reporting change over time and state requirements might vary.

Quality assessment. Good laboratory practices can be expanded to include activities to evaluate and improve the quality of CW site testing.

- *Internal assessment* offers flexible, low-cost options for evaluating quality such as self-conducted inspections and supervisory review of documentation and procedures. A simple, quick check is to verify that you have been getting both positive and negative patient results on qualitative tests, and ranges of patient results on quantitative tests. Test system performance can be assessed by exchanging specimens with another testing facility that uses the same method and comparing the results.

- *External assessment*, such as voluntary inspections by peers or consultants, can offer feedback on current practices along with ideas for improvement. Participation in performance evaluation programs or PT programs can be used to evaluate overall testing performance and as a training and educational tool for testing personnel.

Results from these assessments activities should be documented and evaluated, noting any irregularities and the actions taken to resolve problems or improve processes or procedures.

Summary

This guide is a comprehensive review of all possible quality assurance procedures for CLIA waived laboratory testing. Physicians, nurses and other health-care providers in CW facilities can help to reduce medical errors, improve health-care quality and increase patient safety by following these recommendations.

Key elements important to remember are:

- Thorough training and regular competency assessment for personnel.

- Employee safety and use of appropriate PPE when handling specimens.

- Keeping manufacturer's instructions current and following them exactly, including the QC requirements.

- Proper storage and handling of reagents and kits, including disposal at expiration.

- Positive patient/specimen identification and accurate reporting of test results.

This process should not be difficult or complicated. A well thought out quality system should take personnel less than 2 minutes per day to maintain and will reap benefits for clinicians and their patients in assurance of accurate testing.

References

CDC. Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing. MMWR 2005;54:1-25.