

You'll make better medical decisions if you make sure you're getting reliable results from your in-office lab.

How to Improve the Quality of Waived Tests

Barbara Mitchell, MS, MT(ASCP), and Cheryl Murray, MPA, MT(ASCP)SM

Every physician would like to believe that his or her in-office lab executes tests properly and delivers results reliably. Unfortunately, a recent multi-year study identified a number of consistent errors in lab tests waived by the Clinical Laboratory Improvement Amendments (CLIA) program. The study, done by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC), identified problems with failure to maintain

and follow manufacturers' instructions, lack of quality control, and lack of documentation and recordkeeping that were outlined in a subsequent CDC report.¹ This article offers suggestions based on the report to help your in-office lab improve quality, reduce testing errors and enhance patient health.

What are waived tests?

By law, lab tests can be classified as "waived" if they are simple tests with an insignificant risk of erroneous results.² The list of waived tests, which originally consisted of eight tests, has grown to more than 1,800 test systems and at least 90 analytes, which are the substances or constituents that the test analyzes.

This proliferation of tests has made it more challenging to operate a waived lab, as each test has a specific set of instructions that must be followed precisely. In 2004, 58 percent of U.S. laboratories held certificates of waiver, which are issued by CMS to labs that only perform waived tests. The majority of these labs are in physician offices where they have no routine oversight or personnel requirements. They are only required to register, pay a biennial fee and follow manufacturers' instructions when testing. As a result, most of the lab personnel do not have formal lab training or testing experience. This lack of exposure to good lab practices, coupled with a high turnover rate among testing personnel, is the source of many of the quality issues identified in the report.

The CDC recommendations are designed to promote the use of good lab practices by physicians, nurses and other providers of waived testing. They are presented here in the order of the testing process. ➤



Follow test directions exactly as stated in the package insert or procedure manual.

The test decision

The CDC suggestions begin with questions you should ask yourself before you decide whether to perform waived testing or to introduce a new waived test. Here are the questions you should consider:

Who will be responsible for testing oversight, and are they properly trained? One staff member should be designated as the site director and held responsible for management of the testing operation. This person should have the appropriate background and training to make decisions about lab testing.

Is the lab prepared to meet all federal, state and local regulations? In addition to the federal requirements under CLIA, many state jurisdictions have regulations concerning personnel licensure, phlebotomy requirements and biohazard safety. If state regulations are more stringent than those specified by CLIA, then they supersede the federal requirements. Your lab can contact your state's department of health to find out if any special rules apply.

What are the safety issues for both patients and testing personnel? Labs that hold certificates of waiver must comply with Occupational Safety and Health Administration (OSHA) worker-safety standards. The OSHA Bloodborne Pathogen Standard, which specifies that all test samples must be handled with universal precautions, also applies to lab workers. You can learn more about this regulation online at http://www.osha.gov/OshDoc/data_BloodborneFacts/. In addition, Health Insurance Portability and Accountability Act (HIPAA) regulations require that patients be protected from privacy violations, including any that might occur in the patient identification, test result reporting and recordkeeping processes. More information on HIPAA regulations is available online at <http://www.hhs.gov/oct/hipaa/>.

About the Authors

Barbara Mitchell is the AAFP's proficiency testing manager. Cheryl Murray is the AAFP's proficiency testing education and technical assistance manager. Author disclosure: nothing to disclose.

Is the physical space adequate? Testing should be performed in a separate, designated area that is large enough to ensure safe testing and patient privacy. To ensure reliable results, environmental factors such as temperature, humidity and lighting must be considered.

What is the cost of offering the test in relation to the benefit in patient care?

Consider the intended use of the test, the performance characteristics and your patient population before deciding to offer a new test. Also factor in costs beyond the actual test system. These could include supplies, reagents or controls that are not included with the test kit; equipment maintenance; the potential need for additional personnel; required confirmatory testing; and regulatory compliance.

Do you have sufficient personnel with adequate training to perform the test? Is your current staffing adequate? What will the impact be on workflow? How will you train new employees and maintain competency? You might want to assess your staff for color blindness, which can affect their ability to interpret test results based on color changes.

How will records and documentation be recorded and maintained? Documentation should include written test procedures that are easily accessible to testing personnel. (See "Key components of a waived test procedure manual" on page 51.) A comprehensive procedure manual might incorporate manufacturer package inserts. However, you should regularly review any package inserts included in your manual to see if they've been revised by the manufacturer. In the CMS/CDC study, 21 percent of waived labs reported that they did not routinely check the product insert for changes to the procedure, and 12 percent lacked the most recent instructions for the waived tests they were performing.

In addition, inserts should be supplemented with testing information unique to your office. Personnel training and periodic competency assessment must also be documented. Competency can be evaluated through observation, split sample testing or external proficiency testing programs.

■ Simple lab tests with an insignificant risk of erroneous results can be classified as "waived."

■ A recent study found that in-office labs were consistently making a number of errors in waived tests.

■ The study's results prompted the CDC to develop the recommendations for good lab practices that are outlined in this article.

The pre-analytical phase

The next stage of lab practice, referred to as the pre-analytical phase, occurs before testing begins. These good lab practices should be followed:

Confirmation of test orders. Confirm written orders by comparing them with chart notes or the presumptive diagnosis. Verbal orders for tests are acceptable if a system is in place to follow up with written confirmation.

Patient identification. Use middle initials, birth dates or identification numbers to avoid confusing patients who have similar names.

Patient preparation and pretest information. Provide patients with appropriate instructions if tests have special preparation (e.g., fasting before glucose testing). Advise patients about test limitations and the ways in which medications or medical conditions such as pregnancy might affect the test results.

Procedures for specimen collection and handling, including labeling. Directions for specimen collection from the package insert must be followed explicitly, including using appropriate collection devices. Substituting or altering collection devices can invalidate test results. Label samples immediately upon collection. If a sample is applied directly to the test device, then label the test strip/cassette before sample collection.

Preparation of test area and materials. Perform and record temperature checks and instrument calibration. Check and record expiration dates, discarding any outdated kits or reagents. Verify that instructions are current and unchanged for the test in use. Visually examine reagents or test kits for signs of deterioration. When you open a kit or prepare fresh reagents, record the lot numbers, expiration date and preparation date. Do not mix or combine reagents between lot numbers.

The analytical phase

The report contains the follow recommendations for the testing, or analytical, phase:

Quality control. Quality control includes both internal controls (e.g., built-in or electronic monitors) and external controls (e.g., liquid). Although the frequency of quality control testing needs to be established by the individual lab, it should never be done less frequently than specified by the manufacturer. If controls fail, then patient results must not

be reported until the discrepancy is resolved. Quality control results should be recorded each time they are performed, and the results should be periodically monitored to detect shifts or trends. Keep phone numbers for manufacturers' technical support service, the lab director, consultants and public health labs handy for assistance in solving quality control problems.

Test performance. Follow test directions exactly as stated in the package insert or procedure manual, paying particular attention to timing. Failure to add reagents or read results within the specified time limits can produce invalid results. Consider using timers that can be attached to clothing, and keep extra timer batteries on hand.

Interpretation. Quantitative results are numerical values and do not require interpretation to report. Report the actual value, including units of measure. Qualitative results are reported as positive/negative, reactive/nonreactive, etc. Results may be compared to color charts, photographs or diagrams for interpretation.

Problem resolution. If testing produces results that are invalid, outside the measuring range of the instrument or incompatible with the patient's clinical picture, the results should not be reported until the discrepancy is resolved. Resolution may involve repeating the test using a fresh device, referring to quality-control results or consulting with manufacturers' technical support service.

Recording results. Results may be recorded directly in the patient chart, or in a paper or electronic logbook. Quantitative results must include the units of measure, and qualitative results should be recorded using interpretative words rather than symbols

Before offering waived tests, consider who will be responsible for oversight, whether your lab meets regulations and what the safety issues are.

Good lab practices in the pre-analytical phase include confirming test orders, giving patients proper instructions and prepping the test area.

If a test result is incompatible with the patient's clinical picture, it should not be reported until the discrepancy is resolved.

KEY COMPONENTS OF A WAIVED TEST PROCEDURE MANUAL

- Intended use
- Summary
- Test principles
- Precautions
- Storage/stability
- Reagents and materials supplied
- Materials required but not provided
- Specimen collection & preparation
- Test procedure
- Interpretation of results
- Quality control
- Limitations
- Expected values
- Performance characteristics

(e.g., positive/negative vs. +/-) to avoid clerical errors. Unacceptable results or repeat testing should also be recorded.

The post-analytic phase

Good lab practices do not end when the test is complete. There are a number of important aspects to the post-analytic phase:

Reporting test results. Reports should be timely, legible and standardized. Verbal reports should be documented and followed by written reports. Panic values should be established for each practice, and procedures should be in place to ensure prompt communication of critical results. Labs should have a system for notifying federal and state public health agencies when a reportable disease is confirmed.

Confirmatory testing. The package insert will explain when supplemental or confirmatory testing is needed. Your lab should have procedures in place to ensure that this follow-up testing is performed. The procedure should include directions for specimen collection and handling, instructions for specimen packaging and transport if being sent to a reference lab, and a mechanism for tracking results.

Record keeping. Documentation is essential to assure quality waived testing. Documents should be easily retrievable and maintained in chronological order. Records should be maintained for the time specified by state or other regulatory agencies. You should consider keeping documentation for each item listed below in “Records to maintain.” To meet CLIA requirements, most lab records should be maintained for a minimum of two years.

Quality assessment. You have two options – internal or external quality assessment. Internal assessment is a low-cost, flexible option for evaluating quality. It may be accomplished by self-inspection, review of procedures and quality control documentation. It can also be done by exchanging specimens with another lab using the same methodology and comparing results. External assessment offers extra opportunities for training and education. Arranging for inspections by peers or consultants will help you evaluate performance and quality.

Proficiency testing programs (see list below) offer an objective measure of lab performance. While voluntary for waived labs, they are strongly recommended by many state and other accreditation agencies. Proficiency testing allows you to assess your lab’s individual performance and to see how your lab is performing compared with peer groups using the same test methodologies.

Better practices and health

Although the CDC recommendations lack the force of law, the power of improved quality, reduced errors and better patient health – not to mention the avoidance of possible regulatory action – should be enough to steer your in-office lab toward improvement. **FPM**

Send comments to fpmedit@aafp.org.

- Centers for Disease Control and Prevention. Good laboratory practices for waived testing sites. *Morb Mortal Wkly Rep*. 2005;54(13):1-25.
- Centers for Disease Control and Prevention. Current CLIA Regulations. Available at: <http://www.phppo.cdc.gov/clia/regs/toc.aspx>. Accessed Sept. 13, 2006.

Your lab’s records should be chronologically ordered and easily retrievable.

Following the CDC recommendations should lead to fewer lab errors and better patient health.

RECORDS TO MAINTAIN

Test orders

Written procedures

Records of testing materials; test system and equipment checks; maintenance logs:

- Daily temperature checks
- Lot numbers, dates used and expiration dates of test kits and reagents
- Date of equipment function checks

Product recall notifications

Test results, including confirmatory or supplemental results

Quality control test results and corrective action

Records of test-system failures, troubleshooting and corrective action

Records of personnel training and competency assessment

Results of proficiency testing or other external control

PROFICIENCY TESTING PROGRAMS

AAFP	Leewood, Kan.	800-274-7911
American Association of Bioanalysts	Brownsville, Texas	800-234-5315
College of American Pathologists (EXCEL)	Northfield, Ill.	800-323-4040
American College of Physicians (MLE)	Washington, D.C.	800-338-2746
Wisconsin State Laboratory of Hygiene	Madison, Wis.	800-462-5261