INSTRUCTIONS FOR PERSONALIZING A NEW LABORATORY WAIVED/PPM MANUAL

Thank you for purchasing the *POC Laboratory Manual.* The following are pages that need to be filled out by the office lab. The manual MUST be personalized to be in compliance. No two labs are the same. If you have questions - call our office for assistance. Keep this list as a guide. If the procedures change after the manual was purchased - the new procedures must be added and the old dated when discontinued (not discarded). Remember to copy blue pages - they are masters. Everything you need to pass an inspection is here!

Section 1 **Review - it contains many of the CLIA regulations**

Section 2 **Quality Assessment**

This is your laboratory plan from the time a test is ordered till it is acted upon. It is important that you personalize this chapter to reflect how you operate your lab. POC can perform an annual quality assessment check if we come in annually. There is a self check you can use after pg 2-35 if you want to do your own check.

Section 3 **Specimen Collection**

pg 3-2 If you do not have a running record of tests performed - copy and use this log.

pg 3-3 If you have tests that are automatically done - fill this in.

pg 3-5 Most offices use a super bill or computer for test request - use this if you only went by verbal orders.

pg 3-18 If you have tests that can not be performed due to a problem - list it here.

Section 4 **Quality Control**

Every test - even waived tests require quality control studies. This chapter gives you logs you can pick and choose from to help document the type of test controls you are running.

If you are in proficiency testing we recommend you copy pgs. 4-12 to 4-14 and keep it with your proficiency testing records.

Section 5 **Maintenance**

This chapter has instrument problem logs, temperature logs, microscope maintenance, timer and centrifuge maintenance. Copy ones you need and keep good documentation.

!!! IMPORTANT !!!!

THANK YOU FOR ORDERING THE P.O.L. WAIVED/PPM LABORATORY MANUAL.

YOUR OFFICE MUST ADD THE PACKAGE INSERT THAT COMES WITH ALL WAIVER PRODUCTS TO THE SECTION TITLED "TEST PROCEDURES". A SHEET PROTECTOR IS PROVIDED FOR EACH PROCEDURE. THE PACKAGE INSERT OR CONTROL INFORMATION SHEET MUST BE ADDED TO THE WRITTEN PROCEDURE. IF THE TEST YOU PERFORM DOES NOT HAVE A PACKAGE INSERT - NOTHING MUST BE ADDED.

Quality concerns uncovered at laboratories doing waived tests

A national survey has found that serious problems exist in the quality of work performed by laboratories doing certificate of waiver tests and provider-performed microscopy procedures.

By Joan Szabo

Serious problems exist in the quality of work performed by laboratories doing certificate of waiver tests (COW) and provider-performed microscopy procedures (PPMP), according to results from a recent national survey by the Centers for Medicare Services (CMS), formerly known as the Health Care Financing Administration (HCFA).

Laboratory tests that receive a waiver from CLIA (Clinical Laboratory Improvement Amendments of 1988) are the least regulated tests, with no routine oversight under that federal law.

CLIA regulations define waived tests as simple laboratory examinations and procedures that are cleared by the federal government for home use; that employ methodologies that are so simple and accurate that erroneous results would be negligible; or that pose no reasonable risk of harm to the patient if the test is performed incorrectly.

CLIA lists a number of lab tests that receive waivers, including fecal occult blood tests, ovulation tests, urine pregnancy tests, and dipstick or tablet reagent urinalysis for bilirubin, glucose, hemoglobin, protein, and nitrite.

Approximately 52 percent of the nation's laboratories perform only waived tests, and 22 percent are limited to performing waived and/or microscopy tests. As a result, more than 74 percent of the nation's laboratories fall outside the purview of routine government oversight, according to CMS. The remaining laboratories, which perform moderate and/or high complexity laboratories tests, must follow specific requirements for quality control and assurance, personnel qualifications, proficiency testing, and routine biennial inspections.

As more tests are classified as waived, some in the laboratory industry say the definition of waived tests may require review. "When waived testing was established, it was designed for procedures that were simple to perform and didn't have any mechanical element. Now what we have in many of these (waived) applications is a kit or box that is simple to operate, but is complicated internally and accomplishes very sophisticated testing," says Mark Birenbaum, PhD, administrator for the American Association of Bioanalysts (AAB), a national professional association whose members are directors, owners, managers, and supervisors of community clinical laboratories.

To perform waived tests, laboratories must enroll in the CLIA program, become certified, pay a certificate fee, and follow the manufacturer's instructions for each waived test. Many of the laboratories performing waived tests are located in physicians' offices.

Because of the quality problems recently documented by the CMS

What the CMS survey found

In its national survey, the Centers for Medicare and Medicaid Services (CMS) found the following types of quality problems existed in labs performing certificate of waiver tests:

- 32 percent failed to include current manufacturer's instructions
- 32 percent didn't perform quality control as required by the manufacturer or CDC
- 20 percent cut occult blood cards and urine dipsticks
- 19 percent of the labs personnel were neither trained nor evaluated
- 16 percent failed to follow current manufacturer's instructions
- 9 percent were not following manufacturer's storage and handling instructions
- 7 percent didn't perform calibration as required by manufacturer

Source: Center for Medicare and Medicaid Services

Recent waived tests

Following is a list of some of the tests that have recently received a CLIA waiver from the Food and Drug Administration:

Test System Name	Decision Date
Orasure Technologies QED Saliva Alcohol Test	January 22, 2001
Home Diagnostic Genicare Blood Glucose System	February 26, 2001
Home Diagnostics Prestige IQ Blood Glucose System	March 26, 2001
Cholestech LDX	April 13, 2001
Bayer Multistix Pro 11 Reagent Strips	May 1, 2001
Beckman Coulter Icon DS HCG Test Strip (Urine)	April 23, 2001
Genzyme Signify HCG Urine Serum Test	May 2, 2001

Source: U.S. Food and Drug Administration

survey, such as waived labs not performing quality control as required by the manufacturer, industry leaders worry that inaccurate testing will proliferate, causing harm to patients. The survey did not have outcome data to show adverse effects on patient care.

Carolyn Jones, vice present for technology and regulatory affairs for the Advanced Medical Technology Association (AdvaMed) says these concerns are "inappropriate." AdvaMed represents more than 1,000 manufacturers of medical devices, diagnostic products and medical information systems. Further, she says, "a product that is waived has gone through an approval process. The waiver is an additional review to look at the simplicity of the instructions to determine if an untrained user can obtain the same results as a trained user."

Waived tests also have an impact on the laboratories that must comply with CLIA regulations. "Waived laboratories don't have to hire trained personnel, do proficiency testing, or comply with CLIA recordkeeping and quality control requirements, which gives them an economic advantage over a regulated lab," Birenbaum says.

To address the quality problems uncovered in waived laboratories, CMS is taking steps to assure that improvements are made.

CMS survey uncovers quality problems

When CMS surveyed 270 COW laboratories and 190 PPMP laboratories between October 2000 and January of this year, it found 48 percent of waived and 38 percent of PPMP labs were experiencing quality testing problems.

In the COW labs, CMS found a number of problems, including practices such as failing to follow manufacturer's instructions, using expired reagents, and testing beyond the scope of the complexity level for which the lab was certified. With PPMP labs, the deficiencies ranged from not evaluating test accuracy to problems with microscope/centrifuge maintenance.

CMS is not alone in its findings. The Department of Health and Human Services Office of Inspector General (OIG) completed a similar survey of waived laboratories and uncovered deficiencies in both types of labs. Some of the problems the OIG found included misunderstanding of CLIA requirements, untrained staff, and failure to identify incorrect results.

When asked about the results of the survey, Paul Fischer, MD, a primary care physician in Augusta, GA, says that "most of what has been approved for waived testing is perfectly appropriate, and the problems the survey found were not things that are likely to lead to patient care problems." Fischer is a consultant for the American Academy of Family Physicians on laboratory issues and proficiency testing.

Education is key to improvement

As a result of the deficiencies uncovered, CMS is calling on waived and PPMP laboratories to take a number of corrective steps.

The primary focus of the agency's recommendations is education, says Judith Yost, the CMS official who oversees CLIA for the agency. "Education is the most important and the first thing we will work on," she adds. The aim of such efforts is to help those in the lab to better understand how to perform the tests properly.

Because those performing waived tests often don't understand the labeling instructions, CMS also plans to work with professional associations, such as AdvaMed, to help spearhead education efforts for waived lab personnel. "We need to clarify the language as well as the instructions," Yost says.

Jones says AdvaMed strongly supports better education to improve the quality of work waived labs perform. Manufacturers would

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be "prepared to help with such an effort," she adds.

Jones also points out that the difficulties in dealing with small labs is that they are somewhat disconnected from the rest of the lab community. It would help, she believes, if the rest of the lab community finds some way to make small labs more connected so the same type of information distributed to traditional clinical labs can find their way to waived labs.

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In addition to education, CMS is considering the development of a self-assessment tool for PPMP labs. Yost says the agency may continue to periodically survey both types of labs to make sure the recent problems are being addressed by lab personnel as well as physicians and nurses who are ultimately responsible for the work being performed.

The OIG issued a set of recommendations to address quality problems it found. It suggested that routine inspections of moderate/high complexity labs include a review of any waived/PPMP testing performed.

"Even though all the corrective steps that have been proposed would be beneficial, they are not really addressing the core of the problem," says AAB's Birenbaum. "The major problem centers on the definition of waived tests, which has been expanded beyond what Congress originally intended."

FDA's role

While CMS works on finding a way to educate waived labs on how to improve the quality of the work performed, some in the lab industry are concerned about the expanded role the Food and Drug Administration (FDA) now has with regard to waived testing.

Over the past year, FDA has been granting premarket approval for many new diagnostic kits that are coming to market. In addition, when the FDA approves a test for home and over-the-counter use, that test also wins approval under law for a CLIA waiver.

The FDA has responsibility to categorize lab tests, determining whether they should be considered waived, moderate, or high complexity. This was formerly accomplished by the Centers for Disease Control and Prevention (CDC). In 1999, an interagency agreement transferred the responsibility for this job from CDC to FDA.

In this role, the FDA recently asked for comments on draft guidance it proposed to medical device manufacturers and others on an alternative method to obtain CLIA waived status for products. Critics claim the FDA proposal will result in the agency being less restrictive on granting waivers than was the CDC.

Responding to the FDA request for comments, AAB said it believes "all tests granted CLIA waiver should be held to the same stringent standards for accuracy and precision and meet the same requirements for design, labeling, quality control, and training and monitoring of field users."

AAB's Birenbaum says that once a manufacturer gets a home test kit or product into the waived category, it has a big marketing advantage. He explained that once in the waived category, the test can be sold to physician laboratories.

The Clinical Laboratory Improvement Advisory Committee has expressed its concern over the FDA's decision to automatically waive home-use tests. The panel is concerned that home use approval will become a "back door" method for winning CLIA waiver approval. It pointed out that the criteria used for home-use tests are not equal to other waiver approval criteria.

As manufacturers and physicians push to win approval for more waivers, some in the lab field worry that the industry is headed toward deregulation. "If the government keeps expanding the category of waived testing, soon the federal rules won't apply to anything," Birenbaum says. Organized medicine, he says, has been trying to repeal CLIA for some time. "They were unsuccessful, and they see this (waiver route) as another way to achieve the same objective," he says.

In addition, he points out that manufacturers are following "the route of least resistance. If it is much simpler to get a test approved via the home test kit, then they will take that route."

While AdvaMed understands these concerns, Jones says the lab industry is "going to have to come to grips with the fact that traditional clinical labs may not stand the test of time."

In the meantime, CMS' Yost says the agency will continue to monitor waived labs and pursue efforts to bring about better management of the program. □

Joan Szabo, a Washington-based freelance writer, is the author of "Washington Report," a monthly column in *MLO*.