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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

INSIDE: Continuing Education Examination

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Prepared by
Devery Howerton, PhD, Nancy Anderson, MMSc, Diane Bosse, MS, Sharon Granade, Glennis Westbrook
Division of Public Health Partnerships, National Center for Health Marketing, Coordinating Center for Health Information and Service

Summary

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), simple, low-risk tests can be waived and performed with no routine regulatory oversight in physicians' offices and various other locations. Since CLIA was implemented, waived testing has steadily increased in the United States. Surveys conducted during 1999–2004 by the Centers for Medicare & Medicaid Services and studies funded by CDC during 1999–2003 evaluated testing practices in sites holding a CLIA Certificate of Waiver (CW). Although study findings indicate CW sites generally take measures to perform testing correctly, they raise quality concerns about practices that could lead to errors in testing and poor patient outcomes. These issues are probably caused, in part, by high personnel turnover rates, lack of understanding about good laboratory practices, and inadequate training. This report summarizes study findings and provides recommendations developed by the Clinical Laboratory Improvement Advisory Committee for conducting quality waived testing. These recommendations include considerations before introducing waived testing, such as management responsibility for testing, regulatory requirements, safety, physical and environmental requirements, benefits and costs, staffing, and documentation. They also cover good laboratory practices for the three phases of testing: 1) before testing (test ordering and specimen collection), 2) during testing (control testing, test performance, and result interpretation and recording), and 3) after testing (result reporting, documentation, confirmatory testing, and biohazard waste disposal). They are intended to be used by those who would benefit from improving their knowledge of good laboratory practices. Continued monitoring of waived testing, with a focus on personnel education and training, is needed to improve practices and enhance patient safety as waived testing continues to increase.

Introduction

Laboratory testing plays a critical role in health assessment, health care, and ultimately, the public's health. Test results contribute to diagnosis and prognosis of disease, monitoring of treatment and health status, and population screening for disease. Laboratory testing affects persons in every life stage, and almost everyone will experience having one or more laboratory tests conducted during their lifetime. An estimated 7–10 billion laboratory tests are performed each year in the United States (*1,2*), and laboratory test results influence approximately 70% of medical decisions (*2–4*). Increasingly, these decisions are based on simple tests performed at the point-of-care using devices that are waived from most federal oversight requirements (and are thus designated as waived tests), including requirements for personnel qualifications and training, quality control (QC) (unless specified as required in the test system instructions), proficiency testing (PT), and routine quality assessment.

Advances in technology have made tests simpler, contributing to this shift in testing. In the past, tests such as prothrombin time, cholesterol, and glucose either used complex manual methodologies or were performed using sizable instrumentation suitable for use by highly trained personnel in traditional clinical laboratory settings. Many tests can now be performed using compact or hand held devices by personnel with limited experience and training. These advances have enabled more testing to be performed in emergency departments, hospital rooms, and physicians' offices and in nontraditional testing sites such as community counseling centers, pharmacies, nursing homes, ambulances, and health fairs. Since the 1992 inception of the program implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the numbers of waived tests and the sites that perform them have

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Corresponding author: Devery Howerton, PhD, National Center for Health Marketing, Coordinating Center for Health Information and Service; 4770 Buford Hwy NE, MS G-23, Atlanta, GA, 30341. Telephone: 770-488-8126; Fax: 770-488-8275; Email: dhowerton@cdc.gov.

increased dramatically. This trend is expected to continue as laboratory testing technology continues to evolve.

The purpose of this report is to highlight quality issues identified in waived testing sites on the basis of surveys conducted on-site by the Centers for Medicare & Medicaid Services (CMS) during 1999–2004 and studies of waived testing practices funded through CDC during 1999–2003. In addition, this report presents recommendations developed by the Clinical Laboratory Improvement Advisory Committee (CLIAC) for improving the quality of waived testing. By following these recommendations, errors that could potentially lead to patient harm and the associated morbidity and mortality can be prevented.

Background

CLIA Requirements for Waived Testing

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under CLIA (*5*). The CLIA program is administered by CMS and is implemented through three federal agencies—CDC, CMS, and the Food and Drug Administration (FDA). When CLIA was implemented in 1992, CLIAC was chartered to provide scientific and technical advice and guidance to the U.S. Department of Health and Human Services (HHS) about laboratory standards and their impact on medical and laboratory practice. The committee consists of 20 members selected by the HHS secretary from authorities knowledgeable in the fields of laboratory medicine, pathology, public health, and clinical practice and includes consumer representatives and an industry liaison. CLIAC also includes three ex officio members from CDC, CMS, and FDA.

By law, CLIA regulations are based on a complexity model, with more complicated testing subject to more stringent requirements (*6*). The three categories of testing for CLIA purposes are waived, moderate complexity (including the provider-performed microscopy procedures [PPMP] subcategory), and high complexity. Facilities performing only waived tests have no routine oversight and no personnel requirements and are only required to obtain a Certificate of Waiver (CW), pay biennial certificate fees, and follow manufacturers' test instructions.

Tests can be waived under CLIA if they are determined to be "simple tests with an insignificant risk of an erroneous result" (*5*). Eight tests were included in the 1992 CLIA regulations (a ninth test was subsequently added) as meeting these criteria and later, the FDA Modernization Act of 1997 clarified that tests cleared by FDA for home use are automatically waived. An additional route to waiver exists through a process in which FDA evaluates studies and other information submitted by manufacturers to demonstrate that a test meets the waiver criteria of being simple and having a low risk for error. Approximately 1,600 test systems representing at least 76 analytes are waived under CLIA (Table 1).

Scope of Waived Testing

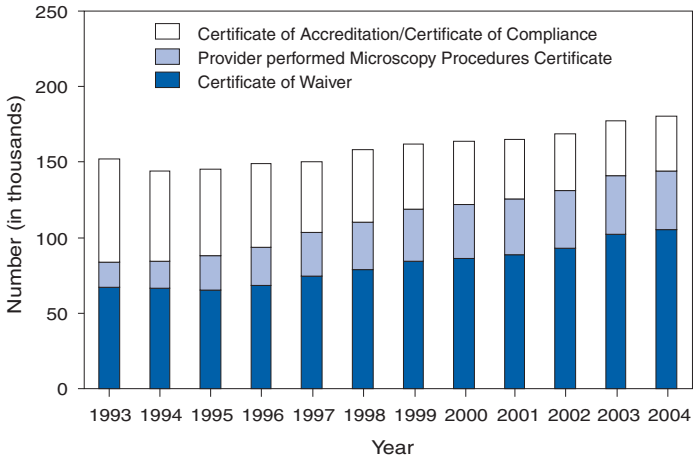
Sites performing only waived tests comprise 58% (105,138) of the approximately 180,000 laboratory testing sites in the United States (Table 1, Figure 1). Waived testing performed in these sites is often wellness testing, screening tests, or other critical testing that introduces a large population of persons into the health-care setting. Although the testing performed in CW sites accounts for <10% of the total U.S. testing volume, this percentage has been increasing each year since the CLIA program began (Table 1). Most testing is not waived and is typically performed in hospital or reference laboratories (Certificate of Compliance and Certificate of Accreditation), which comprise 20% of the total number of testing sites (Figure 1). The remaining testing sites (22%) have PPMP certificates, meaning that in addition to waived tests, direct microscopic examinations of certain specimens can be performed as part of the patient's examination by that patient's

TABLE 1. Increases in waived analytes and test systems, Certificate of Waiver laboratories, and Medicare Part B reimbursed waived testing, 1993–2004

Waived testing measurement parameter	1993	1998	2000	2003	2004
No. of analytes for which waived test systems are available	9	40	53	74	76
No. of waived test systems*	203	608	832	1,495	1,638
No. of laboratories with a Certificate of Waiver†	67,294	78,825	85,944	102,123	105,138
Percentage of laboratories with a Certificate of Waiver†	44%	50%	52%	57%	58%
No. of Medicare Part B reimbursed waived tests	NA§	NA	14,663,751	20,781,297	23,041,693
Percentage of Medicare Part B reimbursed laboratory testing that is waived	NA	NA	6.5%	7.8%	8.1%
Medicare Part B payment amount for waived tests	NA	NA	$69,765,453	$112,247,706	$128,169,398

* Numbers reflect multiple names under which individual tests are marketed and might include waived tests no longer sold.
† Does not include Clinical Laboratory Improvement Amendments (CLIA) exempt laboratories in New York and Washington.
§ Not available.
Source: CDC and Food and Drug Administration CLIA Test categorization databases; Centers for Medicare & Medicaid Services (CMS) Medicare Part B Utilization for CLIA-covered Laboratory Services; and CMS On-line Survey, Certification, and Reporting database.

FIGURE 1. Number of Clinical Laboratory Improvement Amendments of 1988 (CLIA) certified laboratories, by certificate type and year, 1993–2004



Source: Centers for Medicare & Medicaid Services On-line Survey, Certification, and Reporting database.

physician or midlevel health-care practitioner. An increasing shift toward waived testing has resulted in a corresponding increase in health-care expenditures for this testing. Medicare Part B, the federal medical insurance program for persons aged ≥65 years and certain disabled persons, covers diagnostic laboratory testing. Payment data for 2004, provided by CMS, indicated that of the $3,494,840,086 spent on reimbursed laboratory testing for that year, $128,169,398 (3.7%) was for waived tests. The volume of Medicare Part B reimbursed waived laboratory testing in 2004 represented 8% of the total reimbursed testing volume for that year, a 57% increase over the volume in 2000 (Table 1).

Patient Safety Concerns Related to Waived Testing

Efforts to reduce medical errors, improve health-care quality, and increase patient safety have been gaining national attention. A report issued in 1999 by the Institute of Medicine (IOM) presented a national agenda to address these issues and recommended strategies for change that included the implementation of safe practices at the health-care delivery level (*7*). As described in the IOM report, errors most often occur when multiple contributing factors converge, and preventing errors and improving patient safety require a systems approach. Five years after this seminal report, small but consequential changes have occurred that have shifted the focus to improving systems, engaging stakeholders, and motivating health-care providers to adopt new safe practices (*8*).

Although by law waived tests should have insignificant risk for erroneous results, these tests are not completely error-proof and are not always used in settings that employ a systems approach to quality and patient safety. Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system and how testing is integrated into the facility's workflow. Although data have not been systematically collected on patient outcomes with waived testing, adverse events can occur (*9*). Some waived tests have potential for serious health impacts if performed incorrectly. For example, results from waived tests can be used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy and glucose monitoring in diabetics. In addition, erroneous results from diagnostic tests, such as those for human immunodeficiency virus (HIV) antibody, can have unintended consequences.

The lack of oversight and requirements for personnel qualifications and training for an increasingly large number of CW sites is a concern and could contribute to errors and patient harm. During 1999–2001, CMS conducted on-site surveys of a representative sample of CW sites in 10 states to assess the quality of testing in these sites. These pilot surveys identified quality issues that could result in medical errors (*10*). Contributing factors included inadequate training in good laboratory practices and high turnover rates of testing personnel. As a result, during 2002–2004, CMS conducted nationwide on-site surveys of CW facilities to collect additional data that would provide an assessment of testing, promote good laboratory practices and encourage improvement through educational outreach, and make recommendations on the basis of cumulative survey findings. The data collected from these surveys, along with data on waived testing practices gathered through CDC-funded studies conducted during 1999–2003 by the state health departments of Arkansas, New York, and Washington (collectively referred to as the Laboratory Medicine Sentinel Monitoring Network [LMSMN]), support the initial CMS findings of gaps in good laboratory practices in these sites (*11–16*). In addition, a 2001 report issued by the HHS Office of Inspector General (OIG), following their investigation of CLIA certification and enrollment processes, identified the lack of routine on-site visits to CW sites by surveyors representing state agencies and private sector accreditation organizations as presenting vulnerabilities in these sites. The OIG report indicated that approximately half of the state respondents reported problems related to quality issues with the waived laboratories in their states (e.g., failure to follow manufacturers' instructions or failure to identify incorrect results and performing unauthorized testing) (*17*). The concerns noted by states were similar to those identified in the CMS pilot studies.

CLIAC Response

An initial CMS report of its 2002–2003 survey findings, presented to CLIAC in 2004, supported earlier concerns about the quality of testing practices and the need for education and training of testing personnel in CW sites. In response, the committee recommended publication of the 2002–2004 CMS data in conjunction with other data pertinent to waived testing performance along with recommendations for good laboratory practices for waived testing sites. This information would then be available to provide guidance to physicians, nurses, and other health-care providers in CW facilities. As a result, a workgroup was appointed to consider practices associated with the waived testing process and their impact on the quality of waived testing. This workgroup was comprised of key stakeholders in waived testing (i.e., CLIAC members; physicians; nurses; laboratorians; manufacturers; distributors; and representatives from CDC, CMS, and FDA). In its evaluations, the workgroup considered existing practice guidelines from professional organizations, waived testing recommendations from CMS, personal and professional experience, and publications related to waived testing. The workgroup's findings were presented to CLIAC for its deliberations at the February 2005 meeting, at which time CLIAC provided recommendations to HHS concerning good laboratory practices for waived testing sites. CLIAC supported publication of the recommendations, along with the data from the studies of CW sites, and suggested the publication could serve as a comprehensive source document that could be used to develop additional educational tools appropriate for specific target audiences.

Surveys of Waived Testing Sites

Methods

During 2002–2004, approximately 150 CMS and state agency surveyors conducted on-site surveys nationwide using a questionnaire at 4,214 sites performing testing under a CLIA CW. Surveyors self-selected CW sites on the basis of test volume, location, and facility types. Different facilities were surveyed each year so that no repetition exists among CW sites represented in the CMS data in this report. LMSMN obtained additional waived testing data from 1999–2003. Within LMSMN, the Washington State Department of Health established the Pacific Northwest Sentinel Network (PNWSN), which included approximately 650 waived and nonwaived laboratories in Alaska, Idaho, Oregon, and Washington. The Arkansas Sentinel Network (ASN) consisted of 94 local health units integrated into the state health agency (mostly waived testing sites) and approximately 600 waived and nonwaived laboratories in Arkansas and surrounding states. PNWSN and ASN gathered data about waived testing practices through questionnaires mailed to network members (*11*). The New York Sentinel Network (NYSN) consisted of approximately 600 limited service laboratories (facilities other than physician office laboratories [POLs] that perform only waived tests and PPMP). NYSN collected its data through on-site surveys during which waived testing practices were assessed by surveyor observation and record reviews (*11*).

Survey Findings

Demographics

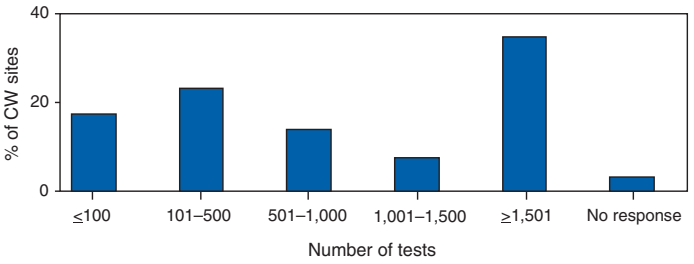
CMS surveyed 4,214 CW sites during April 15, 2002–November 12, 2004. This included 897 sites in 2002, 1,575 sites in 2003, and 1,742 sites in 2004. Of the CW facility types surveyed, POLs compose the largest percentage (47%), followed by skilled nursing facilities (14%) (Table 2). The CW sites surveyed estimated performing a broad range of annual test volumes (Figure 2). Of the facilities surveyed by

TABLE 2. Percentage of facilities with a Certificate of Waiver (CW), by type of facility, from the Centers for Medicare & Medicaid Services (CMS) surveyed sites, 2002–2004, and all CW sites, February 25, 2004

Facility type	CMS surveyed sites %* (n = 4,214)	All CW sites† %* (n = 109,820)
Physician office	47	46
Nursing facility	14	13
Ambulatory surgery center	4	3
End-stage renal disease dialysis center	4	3
Home health agency	3	8
Community clinic	3	2
Pharmacy	2	3
School (student health)	2	1
Industrial	2	1
Hospital	1	1
Other practitioner	1	1
Ancillary test site	1	1
Ambulance	1	2
Independent	1	1
Mobile unit	1	1
Intermediate care (mentally retarded)	1	1
Rural health clinic/Federally qualified health center	1	1
Hospice	<1	1
Health fair	<1	<1
Blood bank	<1	<1
Health maintenance organization	<1	<1
Comprehensive outpatient rehabilitation	<1	<1
Public health laboratory	<1	<1
Insurance	<1	<1
Other	9	9
Invalid/Missing data	2	0

* Totals might not equal 100% because of rounding.
† Data from CMS On-line Survey, Certification, and Reporting database.

FIGURE 2. Estimated annual number of tests for Certificate of Waiver (CW) sites, from the Centers for Medicare & Medicaid Services surveyed sites, 2002–2004*



* N = 4,214.

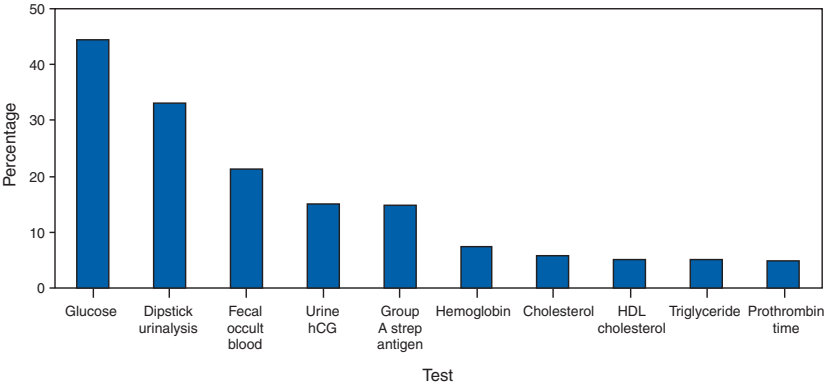
CMS during 2003–2004 (2002 data not available), 90% reported that they performed no more than five different waived tests, and 99% performed no more than 10 different waived tests. Although the exact volume of each test performed per site is not known, on the basis of the number of sites testing for each analyte, the five most commonly performed waived tests were identified as glucose, dipstick urinalysis, fecal occult blood, urine human chorionic gonadotropin (hCG) (visual color comparison), and group A streptococcal antigen (direct test from throat swabs) (Figure 3). This correlates with data for the top five waived tests identified through the LMSMN, especially for POLs (*11*). Although not among the most commonly performed, waived tests are available for certain infectious diseases of public health significance and were reportedly performed by CW sites in the CMS surveys (influenza, 46 sites; HIV, four; and Lyme disease, one).

Personnel and Training

Under CLIA, no education or training is required for the director or testing personnel in CW sites. The educational background and qualifications for directors and testing personnel at CW sites were collected as part of the CMS surveys and by LMSMN (PNWSN and NYSN). The CMS surveys indicated that in 69% of CW sites, physicians served as directors, followed by nurses (17%) (Table 3). Similarly, 59% of the PNWSN CW site directors were physicians, with the remaining 41% having other backgrounds or degrees (*12*). For CW testing personnel, according to the CMS data, the top four categories were nurses (46%), medical assistants (25%), physicians (9%), and high school graduates (7%) (Table 3). NYSN reported that registered nurses (RNs) and licensed practical nurses (LPNs) served as testing personnel in 84% of the limited service laboratories they surveyed (*13*). Trained laboratorians (i.e., medical technologists and medical laboratory technicians) accounted for 2% of laboratory directors and testing personnel in the CW sites surveyed by CMS and a smaller percentage in the limited service laboratories surveyed by the NYSN (*13*).

CMS surveys indicated that 43% of CW sites experienced a change in testing personnel during the preceding 12 months. Among the top categories of testing personnel in the PNWSN, turnover rates were highest for medical assistants (17%), followed by LPNs (13%), RNs (9%), and physicians (2%) (*14*). Although the majority of CW sites in the CMS surveys (90%) reported that new personnel were trained, fewer sites (85%) evaluated staff to ensure competency. Data identifying who provided training were not submitted for all sites in the surveys. However, according to the CW sites that provided this information for 2003–2004 (Table 4), nurses most frequently provided waived test training (33%), followed by the manufacturer or sales representatives (15%). Findings from a PNWSN study indicated that the highest percentage of personnel were initially trained by another employee (25%) or trained themselves by using instructions provided with the waived test system (17%) (*15*). Another PNWSN study indicated that most training (77%) took place in a day or less (*14*). Comments from this study reflected the thinking that training is not always necessary or that minimal time should be spent on training because persons have been trained in school or on other jobs. The time spent on training was not captured as part of the CMS surveys.

FIGURE 3. Percentage of Certificate of Waiver sites that perform specific waived tests, by selected test, from the Centers for Medicare & Medicaid Services surveyed sites, 2003–2004*



* N = 3,317. 2002 data not available.

Testing Practices

The CMS surveys indicated that the majority of the CW sites were aware of and followed some practices for ensuring the accuracy and reliability of their testing. However, lapses in quality were identified at certain sites, some of which could result in patient harm. In some instances, CW sites were determined to be performing testing

TABLE 3. Percentage of Certificate of Waiver site directors and testing personnel, from the Centers for Medicare & Medicaid Services surveyed sites, 2002–2004

Personnel category	%
Site directors (n = 3,788 responses*)	
Physician (MD, DO, DPM, DDS)†	69
Nurse (LPN, RN, NP, midwife)	17
Administrator/Nursing home administrator	3
Medical technologist/Medical laboratory technician	2
Pharmacist	2
High school, GED	1
Emergency medical technician/Paramedic	1
PhD, MS, BS degree (diverse majors)	<1
Medical assistant	<1
Other§	4
Testing personnel (n = 5,511 responses*)	
Nurse (LPN, RN, NP, Midwife)	46
Medical assistant	25
Physician (MD, DO, DPM, DDS)	9
High school, GED	7
Medical technologist/Medical laboratory technician	2
Emergency medical technician/Paramedic	2
Nursing assistant	1
Pharmacist	1
Physician assistant	1
Other¶	6

* All sites did not provide this information, and some sites responded with multiple answers for each category. For example, for the site director, a site could have responded with Medical Technologist and Bachelor of Science degree for the same person. For testing personnel, some sites indicated multiple personnel types. All responses were included in the data.

† MD=Doctor of Medicine; DO=Doctor of Osteopathy; DPM=Doctor of Podiatric Medicine; DDS=Doctor of Dental Surgery; LPN=licensed practical nurse; RN=registered nurse; NP=nurse practitioner; GED=general equivalency diploma; PhD=Doctor of Philosophy; MS=Master of Science; and BS=Bachelor of Science.

§ Others identified as site directors were chiropractors, social workers/counselors, physician assistants, fire chiefs, military trained personnel, naturopaths, optometrists, physical therapists, and nutritionists.

¶ Other testing personnel were radiology technicians, patient-care technicians, phlebotomists, hemodialysis technicians, chiropractors, nutritionists, surgical technicians, office managers, patients/clients (self-testing), nuclear medical technicians, social workers/counselors, medical/nursing/pharmacy students, respiratory therapists, community-health representatives, naturopaths, clerical staff, cardiac technicians, home health assistants, and certified rehabilitation technicians.

TABLE 4. Number and percentage of training providers for Certificate of Waiver testing personnel, by type of training provider, from the Centers for Medicare & Medicaid Services surveyed sites,* 2003–2004

Training provider	No.	(%)
Nurse	699	(33)
Manufacturer/Sales representative	329	(15)
Physician	220	(10)
In-service/Training coordinator	152	(7)
Other employees	144	(7)
Self-trained/Video	98	(5)
Director/Medical director	97	(5)
Medical assistant	92	(4)
Supervisor/Manager	42	(2)
Office manager	52	(2)
Laboratory director	49	(2)
Laboratory personnel	39	(2)
Hospital laboratory staff	37	(2)
Medical technologist/Medical laboratory technician	37	(2)
Laboratory consultant	19	(1)
Emergency medical technician/Paramedic	24	(1)
Pharmacist	23	(1)
Physician assistant	6	(<1)
Other	93	(4)
Physician testing only†	54	(2)
Training not documented	51	(2)

* N = 2,139 sites. A total of 3,317 sites were surveyed. However, all sites did not provide information on training sources, and some sites identified more than one training provider. All responses were included in the data.

† Sites did not specify who provided training to these physicians.

that was an imminent and serious threat to the public's health because they were performing nonwaived testing in the absence of CLIA-required quality measures. The CMS surveys indicated that 5% of CW sites were conducting tests that were not waived, the most frequently performed nonwaived procedures (72%) being direct microscopic examinations (e.g., potassium hydroxide preparations, wet mounts, or urine sediment examinations). Surveyed CW testing sites also reported performing various other nonwaived tests (e.g., urine and throat cultures, Rh antigen testing, and the use of glucometers to perform diagnostic glucose tolerance testing [an intended use not specified in manufacturers' instructions]). When performing nonwaived tests, surveyors noted that, in some instances, the sites were not meeting CLIA requirements for qualified personnel, QC, PT, or test system maintenance. In addition, these sites did not have adequate records of their testing activities, including test system procedures, training records, or other documentation.

Of the CW facilities CMS surveyed, 12% did not have the most recent instructions for the waived test systems they were using, and 21% of the sites reported they did not routinely check the product insert or instructions for changes to the information (Table 5). On the basis of manufacturer's instructions, 21% of the CW sites did not perform QC testing as specified, and 18% of the sites did not use correct terminology or units of measure when reporting results. Among other quality deficiencies identified were failure to adhere to proper expiration dates for the test system, reagents, or control materials (6%) and failure to adhere to the storage conditions as described in the product insert (3%). Six percent of CW sites did not perform follow-up confirmatory tests as specified in the instructions for certain waived tests (e.g., group A streptococcal antigen), and 5% did not perform function checks or calibration checks to ensure the test system was operating correctly. Findings from the LMSMN studies were similar to the CMS findings for these quality deficiencies (*11*).

Although not usually specified in the product insert (and therefore not a CLIA requirement), proper documentation and recordkeeping of patient and testing information are also important elements of good laboratory practices. CMS surveys indicated that 45% of CW sites did not document the name, lot number, and expiration dates for tests performed;

TABLE 5. Number and percentage of quality deficiencies related to following manufacturer's instructions and documentation in Certificate of Waiver sites, from the Centers for Medicare & Medicaid Services surveyed sites,* 2002–2004

Quality deficiencies	No. of sites	(% of sites)
Following manufacturer's instructions†		
The site did not		
Have current manufacturer's instructions	485	(12)
Routinely check new product inserts for changes§	701	(21)
Based on manufacturer's instructions, the site did not		
Perform quality control testing	866	(21)
Report test results with terminology or units described in package insert	744	(18)
Adhere to proper expiration dates	267	(6)
Perform required confirmatory tests	265	(6)
Perform function checks or calibration	195	(5)
Adhere to storage and handling instructions	135	(3)
Perform instrument maintenance	125	(3)
Use appropriate specimen for each test	81	(2)
Add required reagents in the prescribed order	24	(1)
Documentation¶		
The site did not		
Document the name, lot number, and expiration date for all tests performed§	1,493	(45)
Maintain a quality-control log§	1,151	(35)
Maintain a log of tests performed	1,318	(31)
Require test requisition (or patient chart) before performing a test§	304	(9)
Keep the test report in the patient's chart§	56	(2)
Check patient identification§	31	(1)

* N = 4,214 sites.
† Required for waived testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
§ 2003–2004 data only (n = 3,317).
¶ Not required for waived testing under CLIA.

35% did not maintain logs with records of their QC testing; 31% did not maintain a log or record of tests performed; and 9% did not require a requisition or test orders documented in a patient chart before performing a test (Table 5). NYSN observed similar findings but noted increased compliance with state requirements for documentation/recordkeeping when laboratories had formal affiliations with New York State-licensed laboratories (*11*).

Discussion

The findings from the CMS surveys and LMSMN studies indicated that the majority of CW testing sites performed testing correctly and provided reliable service. However, in CW sites, most directors and testing personnel did not have formal laboratory training or testing experience, there was a high turnover of personnel, and lapses in following manufacturers' instructions and instituting practices to ensure the quality of the testing were noted. The survey findings indicated that 485 (12%) of the 4,214 CW sites surveyed did not have the current manufacturers' instructions available, and 701 (21%) of the 3,317 sites surveyed during 2003–2004 did not check to be sure there had been no changes to the instructions. Test system instructions can change over time and CW sites sometimes switch test systems that could have different instructions. CMS survey results also indicated that, in varying proportions, when CW sites had the current instructions, they did not follow critical steps in the testing process (e.g., performing QC testing, reporting results correctly, adhering to expiration dates and appropriate storage requirements, and performing test system function checks or calibration checks). This is a concern because the only CLIA requirement for performing waived testing is to follow the manufacturer's instructions. Neglecting to follow instructions could cause inaccurate test results that could lead to incorrect diagnoses, inappropriate or unnecessary medical treatment, and poor patient outcomes.

CMS surveys indicated that certain CW sites (5%) were performing testing more complex than waived testing without taking required measures to ensure quality. In certain CW sites, nonwaived microscopic examinations were being performed by personnel who lacked the education and training needed to develop the interpretive and judgment skills necessary to accurately perform these procedures. In addition, measures such as QC, PT, adequate documentation, and monitoring are required to ensure the accuracy and reliability of nonwaived test results. Although direct microscopic examinations can be conducted by a physician or midlevel health-care practitioner as part of a patient examination, testing must be conducted under a CLIA PPMP certificate.

The quality issues identified through these surveys might have been caused, in part, by high turnover rates of testing personnel in CW sites, inadequate training with respect to waived testing, and lack of understanding of good laboratory practices, including the importance of following all aspects of the manufacturers' instructions. Although the study results indicated that most testing personnel were trained, they were often trained for minimum periods by persons who did not have formal education or training in clinical laboratory testing and who might not have understood the importance of measures to ensure quality testing. Certain testing personnel also were self-trained. In addition, when testing personnel were not evaluated to determine their competency level following training or on an ongoing basis, no assessment was conducted to determine whether the training was effective. The data demonstrate a need for educational information among CW site directors and testing personnel about the importance of following manufacturers' instructions, adhering to expiration dates, performing QC testing, and proper documentation and recordkeeping. One of the recommendations in the 2001 OIG

report was that CMS should provide educational outreach to directors of waived and PPMP laboratories about the CLIA requirements (*17*).

The findings in the 2002–2004 CMS surveys are subject to at least three limitations, and caution should be used in extrapolating the survey data to make generalizations about waived testing. First, the CMS surveys were not intended to be a scientific study of a random sample of CW sites. Waived testing data were collected by CMS to provide an assessment of testing practices, promote good laboratory practices, and encourage improvement through educational outreach. Although surveyors attempted to include a wide variety of CW sites in the sample, the sites were self-selected by surveyors and selection was based, to some degree, on convenience to the surveyors and willingness of the sites to participate in the voluntary surveys. However, few sites refused to participate in the surveys. Overall, the sites represent a nationwide sample and the distribution of CW facility types is similar to the distribution of CW facility types in the United States (Table 2). In addition, the 2002–2004 CMS survey findings resulted in the same general conclusions as the earlier CMS pilot studies, which were conducted on a random sample of laboratories (*10*). Second, the CMS data were collected and entered into the database by a large number of persons, introducing variability. Although training was provided before the surveys were conducted, the intent of the survey questions was subject to individual interpretation. Because the phrasing of some questions differed slightly from 2002 to 2003–2004, in certain cases, the meanings of the questions also changed. Finally, the CMS surveys did not assess the frequency of erroneous test results in CW sites or whether lapses in following manufacturers' instructions directly affected test results or patient outcomes. Similar limitations to these were identified in the LMSMN studies (*11*).

The findings of the CMS and LMSMN studies are strikingly similar. Even though the majority of CW sites meet the CLIA requirement to follow manufacturers' instructions for test performance, and many sites follow additional good laboratory practices, over the years these studies have demonstrated that a persistent percentage of CW sites do not meet minimal requirements and are not aware of recommended practices to help ensure quality testing. Because surveying all CW sites is not feasible, the proposed actions to improve and promote quality testing in CW sites emphasize the importance of education and training for CW site directors and testing personnel. To provide a guide that can be adapted for use, either in part or as a whole, by persons or facilities considering the initiation of waived testing and personnel performing waived testing, CLIAC provided recommendations for good laboratory practices. By implementing these recommendations, CW sites could improve quality, reduce testing errors, and enhance patient safety.

Recommended Good Laboratory Practices

Overview

These recommendations are intended to promote the use of good laboratory practices by physicians, nurses, and other providers of waived testing in a variety of CW sites. They were developed on the basis of recommendations and other resources that provided additional information for promoting patient safety and the quality of CLIAC waived testing in laboratories or nontraditional testing sites (*18–22*). These recommendations address decisions that need to be made and steps to be taken as a facility begins offering waived testing or adds a new waived test. They also address developing procedures and training CW personnel and describe recommended practices for each phase of the total testing process, or path of workflow, including the important steps or activities before, during, and after testing. The activities that occur in each of these phases are critical to providing quality testing (Table 6).

Considerations Before Introducing Waived Testing or Offering a New Waived Test

Forethought, planning, and preparation are critical to initiating high-quality waived testing in any type of setting. This section describes factors to consider before opening a waived testing site or offering an additional waived test. Questions to address include the following:

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

TABLE 6. Activities within each phase of the total testing process

Before testing	During testing	After testing
Test ordering	Control testing/checks	Reporting results
Patient identification, preparation	Test performance	Documenting
	Results interpretation	Confirmatory testing
Specimen collection, handling	Recording results	Patient follow-up
		Disease reporting
Preparing materials, equipment, and testing area		Biohazard waste disposal

- Safety. What are the safety considerations for persons conducting testing and those being tested?
- Testing space and facilities. What are the physical and environmental requirements for testing?
- Benefits and costs. How will the care offered in the site benefit by introduction of testing or the addition of a new test, and what will it cost?
- 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?
- Documents and records. What written documentation will be needed, and how will test records be maintained?

Management Responsibility

Each testing site should identify at least one person responsible for testing oversight and decision-making, later referred to as the CW site director. In POLs, 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, the person signing the CW application (CMS Form 116) is responsible for management of the testing operations. The management staff should demonstrate a commitment to the quality of testing service by complying with applicable regulatory requirements and promoting good laboratory practices.

Regulatory Requirements

CLIA certification. Each site offering only waived testing that is not included under any other type of CLIA certificate must obtain a CLIA CW before testing patient specimens. Certain sites offering waived testing can be certified as part of a larger health-care organization that holds a CLIA Certificate of Compliance or Certificate of Accreditation. In addition, certain public health testing sites offering only waived testing can be included under a limited public health or mobile testing exception. A valid CLIA certificate is required for Medicare reimbursement.

To apply for a CLIA certificate, CMS Form 116 (http://www.cms.hhs.gov/clia/cliaapp.asp) must be completed and sent to the state agency for the state in which the testing site is located. This form asks for specific information, including the type of testing site (laboratory type), hours of operation, estimated total annual volume of waived testing, and the total number of persons involved in performing waived testing. The form must be signed by the facility owner or the facility director. Specific state agencies and contacts are available at http://www.cms.hhs.gov/clia/ssa-map.asp. The state agency will process the application and send an invoice for the registration fee. If additional assistance is required, contact the appropriate CMS regional office (http://www.cms.hhs.gov/clia/ro-map.asp).

CLIA requirements that apply to testing sites operating under a CW include the following:

- Renew the CW every 2 years.
- Perform only waived tests. Waived tests include test systems cleared by FDA for home use, and simple, low-risk tests categorized as waived under CLIA. Sometimes a test that can be performed using different specimens or procedures might be waived only for certain specimen types or procedures. Because the list of waived tests is constantly being revised as new test systems are added, the most current information about waived tests and appropriate specimens is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm.
- Follow the instructions in the most current manufacturer's product insert, without modification, when performing the test. Changes to the timing of the test or physical alteration of the test components (e.g., cutting test cards or strips to increase the number of specimens tested per kit) are examples of modifications. If modified, tests are no longer waived tests and become subject to the more stringent CLIA requirements for nonwaived testing.
- Permit announced or unannounced on-site inspections by CMS representatives.

State and local regulations. States and local jurisdictions vary as to the extent to which they regulate laboratory testing. Some states and localities have specific regulations for testing, some require licensure of personnel who perform testing, and some have phlebotomy requirements. State and local jurisdictions often regulate biohazard safety, including handling and disposal of medical waste. The person responsible for testing oversight should ensure that all state and local requirements are met. These requirements might be more or less stringent than federal requirements. When state or local regulations governing laboratory testing are more stringent than the federal CLIA requirements, they supersede what is required under CLIA.

Safety requirements. The Occupational Safety and Health Administration (OSHA) and individual state standards require employers to provide a safe and healthy work environment for employees. Each CW site must comply with OSHA standards pertinent to workplace hazards (*23*). Regulatory requirements for all OSHA standards, including specific information for medical and dental offices (*24*), are available at http://www.osha.gov and by telephone, 800-321-6742.

The OSHA Bloodborne Pathogens Standard applies to sites where workers have potential occupational exposure to blood and infectious materials (*25*). The requirements for compliance with this standard include, but are not limited to:

- A written plan for exposure control, including postexposure evaluation and follow-up for the employee in the event of an "exposure incident;"
- Use of Universal Precautions, an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B virus, hepatitis C virus, and other bloodborne pathogens. Universal Precautions is one component of Standard Precautions, a broader approach designed to reduce the risk for transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals;
- Use of safer, engineered needles and sharps;
- 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; and
- Equipment for the safe handling and disposal of biohazardous waste (e.g., properly labeled or color-coded sharps containers and biohazard trash bags and bins).

Additional safety practices for performing testing are:

- Prohibit eating, drinking, or applying makeup in areas where specimens are collected and where testing is being performed (i.e., where hand-to-mouth transmission of pathogens can occur);
- Prohibit storage of food in refrigerators where testing supplies or specimens are stored;
- Provide hand-washing facilities or antiseptic hand-washing solutions; and
- Post safety information for employees and patients.

Specific information on the Bloodborne Pathogens Standard and needlestick prevention is available at http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

CDC and the Clinical and Laboratory Standards Institute (CLSI) (formerly NCCLS) have also published information about biosafety and precautions for preventing transmission of bloodborne pathogens in the workplace (*26*–*30*).

Privacy and confidentiality requirements. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established federal privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals, and other health-care providers. Under HIPAA, CW sites are required to establish policies and procedures to protect the confidentiality of health information about their patients, including patient identification, test results, and all records of testing. These medical records and other individually identifiable health information must be protected, whether on paper, in computers, or communicated orally. In addition, CW sites should be aware that applicable state laws that provide more stringent privacy protections for patients supersede HIPAA. Additional information on HIPAA is available at http://www.hhs.gov/ocr/hipaa.

Physical Requirements for Testing

Testing should be performed in a separate designated area where adequate space to safely conduct testing and maintain patient privacy is available. 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. Meeting these environmental conditions can be challenging in nontraditional settings (e.g., health fairs) or community outreach venues (e.g., shopping malls, meeting rooms, parks, parking lots, mobile vans, and buses). Factors to consider include:

- Humidity — Unusually high, low, or extreme fluctuations in humidity 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 — Temperature ranges for storage of test components and controls and for test performance 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 be 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.

Benefit and Cost Considerations

Evaluating the benefits of a particular test. Evaluate the test system, its intended use, performance characteristics, and the population to be tested when assessing whether to introduce waived testing or a new waived test. Information for this evaluation can be obtained from the test manufacturer's product insert (Table 7) or by speaking with the manufacturer's technical representatives. Specific considerations include:

- Intended use – Be aware of the intended medical use for which FDA approved the test system as explained in the product insert. This section describes 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 — Assess the information on performance provided by the test manufacturer or published data. Review data that includes the test's accuracy, precision, sensitivity, specificity, and interferences.
- Patient population — Consider the population that will be tested before offering a test. Some tests have not been evaluated for use in specific age groups (e.g., pediatric populations). The predictive value for certain types of test results in a specific patient population depends on the test's sensitivity, specificity, and the prevalence of the condition in the population. For example, when testing for a certain condition or disease in a low-prevalence population, the predictive value of a positive result will be low compared with the predictive value of a negative result. Refer to the product insert for limitations for use in particular patient populations.
- Need for supplemental testing or patient follow up — Some waived tests provide preliminary results as part of a multitest series (e.g., rapid HIV testing) or results that must be considered in conjunction with other medical information. These test results might require additional testing before a definitive test result is obtained, and patients might need posttest counseling about the meaning of the test result. Assess the potential need for additional time, documentation, and staffing and a mechanism to refer additional testing to another laboratory when offering such tests.
- Test system considerations — Consider the simplicity of operating the test system, length of time to obtain a result, 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 and require additional planning and resources.

Cost considerations. A fiscal assessment of testing is part of a good management program. Before offering a new test, consider the level of reimbursement and factors that contribute to total test cost. These factors include:

- Test kits or instruments, supplies 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.
- Personnel training, competency assessment, and the potential need for additional personnel.
- Recordkeeping and information systems.
- Required supplemental/confirmatory testing.
- Regulatory compliance.
- Resource needs to manage public health reporting, if required nationally or by the state.

Personnel Considerations

Personnel competency and turnover are important factors affecting the quality and reliability of waived testing results. No CLIA requirements exist for waived testing personnel qualifications; however, applicable state or local personnel regulations must be met. Personnel issues to consider include:

- Is staffing adequate?
  - — Determine whether employees have sufficient time and skills to reliably perform all activities needed for testing in addition to their other duties.
  - — Be aware that temporary or parttime personnel might be less proficient in performing testing.
  - — Evaluate staff for color-blindness because this can limit their ability to interpret test results based on color endpoints.
- How much training will be needed?
  - — Take into account the staff turnover rate and the ongoing need to provide training for new personnel.
  - — Factor in the time and resources for adequate training and competency evaluation of staff before they perform testing.
  - — Consider how testing personnel will maintain competency, especially when testing volume is low.

Developing Procedures and Training Personnel

After the decision is made to offer waived testing, it is good practice to develop written policies and procedures so that responsibilities and testing instructions are clearly described for the testing personnel and facility director. The testing procedures form the basis of training for testing personnel. These procedures should be derived from the manufacturer's instructions and should be in a language understandable to testing personnel.

Written Test Procedures

To comply with CLIA requirements and provide accurate testing, CW sites must adhere to the manufacturer's current testing instructions. These instructions, as outlined in the product insert, include directions for specimen collection and handling, control procedures, test and reagent preparation, and instructions for test performance, interpretation, and reporting (Table 7). In addition, certain manufacturers provide quick reference instructions formatted as cards or small signs containing essential steps in conducting a test. Quick reference instructions should be clearly posted where testing is per-

TABLE 7. Components of the manufacturer's product insert*

Component	Information provided
Intended use	Describes the test purpose, the substance being detected or measured, test methodology, appropriate specimen type and the Food and Drug Administration-cleared conditions for use. Might address whether the test is to be used for diagnosis or screening the target population and whether it is for professional use or self-testing.
Summary	Explains what the test detects and a short history of the methodology, including the disease process or health condition being detected or monitored. Might include the response to disease (e.g., development of IgM antibodies), the symptoms and their severity, and the disease prevalence. Includes literature citations as applicable.
Test principle	States the methodology used in the test. Details the technical aspects (chemical, physical, physiologic, or biologic reactions) of the test, and explains how the components of the test system interact with the patient specimen to detect or measure a specific substance.
Precautions	Alerts the user of practices or conditions that might affect the test and warns of potential hazards (e.g., handling infectious specimens or toxic reagents). Frequent precautions include directions to not mix components from different lot numbers, to not use products past expiration dates, and the need for safe disposal of biohazardous waste. Might address conditions for specimen acceptability.
Storage/Stability	Specifies conditions for storing reagents and test systems to protect their stability. Includes recommended temperature ranges and, as applicable, physical requirements (e.g., protection from humidity and light). Also addresses the stability of reagents and test systems when opened or after reconstitution and/or mixing. Describes indicators of reagent deterioration.
Reagents and materials supplied	Lists the reagents and materials supplied in the test system kit and the concentration and major ingredients used to make the reagents.
Materials required but not provided	Lists materials needed to perform the test but not provided in the test system kit.
Specimen collection and preparation	Details the procedures for specimen collection, handling, storage, and stability, including, as applicable, instructions for performing a fingerstick, appropriate anticoagulant or swab type, and directions for specimen preparation. Might address conditions for specimen acceptability.
Test procedure	Provides step-by-step instructions for performing the test and frequently includes visual aids (e.g., pictures or graphs). Critical information (e.g., the order of reagent addition, timing of test steps, mixing and temperature requirements, and reading of the test results) is included.
Interpretation of results	Describes how to read and interpret the test results and often includes visual aids. Alerts the user when the results are invalid and gives instructions on what to do when the results cannot be interpreted. Might include precautions against reporting results unless supplementary/confirmatory testing is performed.
Quality control (QC)	Explains what aspects of the test system are monitored by QC procedures and provides instructions on how to perform QC. Includes recommendations on how frequently QC should be performed, acceptable QC results, and what to do when QC values are not acceptable. Might include specific information about external QC and, as applicable, internal procedural QC.
Limitations	Describes conditions that might influence the test results or for which the test is not designed. Limitations could include: • possible interferences from medical conditions, drugs, or other substances. • warning that the test is not approved for use with alternate specimen types or in alternate populations (e.g., pediatric). • indications of the need for additional testing that might be more specific or more sensitive. • warning that the test does not differentiate between active infection and carrier states. • statement that the test result should be considered in the context of clinical signs and symptoms, patient history, and other test results.
Expected values	Describes the test result the user should expect (positive/negative or within/outside of a reference interval). Explains, as applicable, how results can vary depending on disease prevalence and the season of the year. Might include a brief description of studies conducted to derive this information.
Performance characteristics	Details the results of studies conducted to evaluate test performance. Included are data used to determine accuracy, precision, sensitivity, specificity, and reproducibility of the test and results of cross-reactivity studies with interfering substances.

* Product inserts vary in format, but the majority contain the information described above. Some information might appear in different sections than listed above because of format variations between manufacturers. Certificate of Waiver site directors and testing personnel should read this information for a complete understanding of each test.

formed. The specific test system name should be on the quick reference instructions to avoid confusion.

A comprehensive procedure manual is a valuable resource for CW sites. Although product inserts can be used as test procedures, these instructions will typically need to be supplemented with testing information that is unique to the CW site's operations and workflow (*31*). A procedure manual can also include examples of forms used (e.g., charts to record daily test kit storage temperatures, infectious disease reporting forms, or logs for recording control testing and test results) and check lists for personnel training. New testing procedures should be reviewed and signed by the CW site director before incorporating them into the procedure manual. The manual should be updated as tests or other aspects of the testing service change and should be reviewed by the director whenever changes are made. When procedures are no longer used, they should be removed from the manual and retained with a notation of the dates during which they were in service.

When writing procedures for each CW site, it might be helpful to:

- Use a template with standard component headings to facilitate writing a new procedure and promote ease of use when performing testing;
- 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., test incubation time);
- 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 control testing is performed;
- Include established reference intervals and critical values for the test; and
- Describe how to record and report results and how to handle critical values.

Personnel Training

Trained and competent testing personnel are essential to good quality testing and patient care. Data from CDC and CMS surveys demonstrate that waived testing sites are subject to a high rate of personnel turnover. Personnel should be trained and competent in each test they will perform before reporting patient results (*32,33*). In addition, training should include aspects of safety (including Universal Precautions) and QC. The CW site director or other person responsible for overseeing testing should ensure that testing personnel receive adequate training and are competent to perform the procedures for which they are responsible. 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., experienced co-worker, facility expert, or outside consultant) with knowledge of the test performance, good laboratory practices, and the ability to evaluate the efficacy 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. Resources for training are available from various sources. Tools for training continue to evolve and are not limited to traditional methods. Instructional videos, workshops, computer-based programs, and other methods can be used. The manufacturer's test system instructions and instrument operating manuals should be the primary resource for information and training in CW sites. Other sources for training on waived testing or specific tests include:

- Manufacturers and distributors who often provide technical assistance, product updates or notifications, and limited training.
- Professional organizations that can provide workshops or other training tools.
- State health departments or other government agencies that can provide limited training.

Competency Assessment

To ensure testing procedures are performed consistently and accurately, periodic evaluation of competency is recommended, with retraining, as needed, on the basis of results of the competency assessment (*32*). Assessment activities should be conducted in a positive manner with an emphasis on education and promoting good testing practices. Competency can be evaluated by methods such as observation, evaluating adequacy of documentation, or the introduction of mock specimens by testing control materials or previously tested patient specimens. External quality assessment or evaluation programs, such as voluntary PT programs, are another resource for assessment.

Additional Measures to Help Testing Staff Ensure Reliable Results

The CW site director or person overseeing testing should promote quality testing and encourage staff to ask questions and seek help when they have concerns. Recommendations include:

- Identifying a resource person or expert (e.g., a consultant or manufacturer's technical representative), available either off-site or on-site, to answer questions and be of assistance.
- Posting telephone numbers for manufacturers' technical assistance representatives.
- Designating an appropriately trained person, who understands the responsibilities and impact of changing from one test system to another, to discuss new products with sales representatives. Uninformed personnel might mistakenly use a promotional test kit, provided by a distributor or manufacturer's representative, for patient testing without realizing the consequences of test substitution.

Recommended Practices Before Testing

Preparations before performing patient testing are a critical element in producing quality results. Paying attention to test orders, properly identifying and preparing the patient, collecting a good quality specimen, and setting up the test system and testing area all contribute to reliable test results.

Test Orders, Patient Identification, and Preparation

Before collecting the specimen, confirm the test(s) ordered and the patient's identification and verify that pretest instructions or information, as applicable, have been provided. This includes:

- Test orders — CW sites performing various waived tests should routinely confirm that the written test order is correct. If there is a question, check with the ordering clinician. Standing orders for certain tests might apply, but they should be documented.
- 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 — Some tests require special preparation on the patient's part (e.g., a fasting state for glucose testing). Provide the patient with pretest instructions, when appropriate, and when special preparation is needed, verify that patients received instructions before testing. To determine if patients followed the instructions, ask them to explain how they prepared for the test.
- Pretest information — Discuss factors, test limitations, or medical indications that can affect test results with the patient, as appropriate, and provide pertinent information such as pamphlets supplied by the test manufacturer, when specified in the product insert.

Specimen Collection and Handling

The product insert provides details on proper collection, handling, and storage of patient specimens. Collect waived test specimens exactly as described in the test system instructions, using the appropriate collection device and method to obtain a quality specimen (*33–36*). Improperly collected, stored, or compromised specimens should not be tested. Specimens and, in some cases, test devices need to be appropriately labeled to prevent mix-up.

Waived test specimens. Waived tests are approved for use only with direct, unprocessed specimens that do not require operator manipulation (Table 8). Specimens that are processed or manipulated by the user (e.g., serum or plasma) require centrifugation, dilution, extraction, or other preparation steps that require special training or instrumentation and are not appropriate for waived tests. Sometimes, tests can be performed using both processed and unprocessed specimen types, but are waived only for the unprocessed specimens, in which case the product insert should identify the appropriate specimen for the waived test. 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. Other examples include group A streptococcal antigen testing, which is waived only when performed on a throat swab and not when performed on a microbiology culture, and visual color comparison tests for hCG (pregnancy tests) using urine that are waived, whereas serum or plasma hCG tests are not waived.

Specimen collection. The person collecting the patient specimen or giving the collection instructions should have a thorough understanding of the specimen type, proper collection method (including the need to wear gloves or other PPE as appropriate), and handling to assure a quality specimen (*33–36*). Directions for specimen collection, handling, and storage are included in the product insert and must be followed explicitly. For example, instructions might specify one

TABLE 8. Types of direct, unprocessed specimens suitable for waived testing

Specimen type	Examples of waived tests
Whole blood (fingerstick or anticoagulated blood collected by venipuncture)	Glucose, cholesterol, prothrombin time, infectious mononucleosis, and HIV antibody
Urine	Dipstick urinalysis and pregnancy test (hCG)
Throat swab	Group A streptococcal antigen
Nasopharyngeal swab, nasal wash, or aspiration	Influenza
Stool	Occult blood
Saliva	Alcohol
Oral fluid	HIV antibody
Gastric biopsy	*H. pylori*

drop of capillary blood or include precautions to use the second drop of blood from a fingerstick rather than the first. When gloves are worn during specimen collection, they should be removed and discarded in an appropriate waste receptacle before contact with another patient. Hand hygiene should be performed between patients.

Collection devices. Manufacturers might provide or specify specimen collection devices. These devices, whether supplied with the test system or specified in the product insert, are integral to the test system and should be used to ensure the correct specimen type and volume to provide reliable results. Containers and collection devices might have additives that affect the specimen or are part of the test and should not be substituted or altered. For example, throat swab collection kits used with group A streptococcal antigen tests might look the same; however, they might be made from a variety of fibers or contain different materials that could interfere with the test or affect organism viability. Whole blood capillary tubes (e.g., used for cholesterol, hemoglobin A_1C, or *Helicobacter pylori* testing) can have additives or hold different specimen volumes 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 hepatitis B virus, hepatitis C virus, HIV, and other bloodborne pathogens, appropriately discard sharps, lancets, and platforms for spring-loaded lancets and disinfect instruments contaminated by blood (*9, 28*).

Specimen labeling. Labeling procedures should meet the needs of the testing site and should be adequate to prevent specimen mix-up. To prevent errors, always label specimens with pertinent information (e.g., unique patient name or other unique identifier). Depending on workflow, specimen labeling also might include the date and time of collection and identification of the collector. For waived tests in which the specimen is applied directly to the test device (e.g., throat swabs for group A streptococcal antigen), the test strip, cassette, or other device should be labeled with the patient identification before collecting the specimen, especially if more than one test is being performed at the same time.

Preparing the Testing Area, Test Materials, and Equipment

Preparing the testing area and materials (e.g., kits, reagents, control materials, and equipment) before testing patient specimens is essential to maintaining efficient workflow and good quality testing (Table 9). Before beginning the test, 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. Do not use product inserts that are out of date for the test system currently in use. When opening a new kit, check for notifications in the external labeling or special notices that might be included with product inserts or packaging.

TABLE 9. Pretesting task checklist for waived tests

Testing area
Clean work surfaces and remove clutter or trash
Ensure adequate lighting
Check and record temperatures (e.g., testing environment and refrigerators)
Replenish supplies (e.g., specimen collection, biohazard waste containers, and forms)
Test system and reagents
Check the product insert and exterior labeling on kits and reagents for changes
Check and record expiration dates (Do not use expired reagents or kits)
Check and record lot numbers for test kits, test devices and controls (Do not mix reagents from different products or lot numbers. If new lot, set up quality control as needed and refer to product insert for any changes in control ranges)
Visually inspect reagents or vials for damage, discoloration, or contamination
Prepare reagents according to instructions (If opening new reagents, write the date opened on the outside of the vial or test kit)
Inspect equipment and electrical connections for integrity
If the test system incorporates internal calibration steps that need to be checked before testing, conduct the calibration check or set the test system as specified by the manufacturer*

* Portable equipment, if moved, might be subject to inaccurate results. To verify proper test system functioning, perform control testing or calibration check procedures even if not specified by the manufacturer after moving the equipment.

Additional considerations for good testing practices are:

- Abide by expiration dates and discard expired reagents and test kits as soon as the expiration date elapses.
- When preparing to perform testing, allow time for any refrigerated items, including reagents or patient specimens, to reach room temperature before testing, if specified in the product insert.

Recommended Practices During Testing

When the testing area is prepared and the specimen has been collected, the process continues to the testing phase. Important activities during this phase include QC testing, test performance, result interpretation and recording.

Quality Control Testing

Performing QC testing procedures provides assurance that the test performs as expected and alerts the user when problems occur. 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. Test procedures should describe the type of

controls to be used, how to perform QC testing (including QC testing frequency), and actions to be taken when QC results are unacceptable.

Types of controls. Two types of controls typically found in waived tests are:

- Internal, procedural, or built-in controls — evaluate whether certain aspects of the test system are working properly. They are designed to verify that the test system is working as expected, that sufficient specimen was added and, for unitized test devices, whether it migrated through the test strip properly. Certain test 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, to assure proper test performance. They might be provided as liquid or other materials similar to patient specimens and might be included with the test system or purchased separately.

Frequency of control testing. For certain test systems, the product insert describes the minimum conditions or recommended frequencies for testing internal and/or external controls. Each site should determine the appropriate control testing frequency for each test system and the frequency should not be less than specified in the product insert. When determining the frequency for running external controls, consider the robustness of the test, stability of the environment, and skills and knowledge of the testing personnel. At a minimum, external controls should be tested with each new shipment of utilized test devices, when testing a new lot number, and by each new operator before conducting testing. Controls should be tested either before or concurrent with patient specimens by the same personnel who routinely perform patient testing.

Corrective action when control testing fails. If controls do not perform as expected, patient testing should not be performed or results reported until the problem is identified and corrected. The product insert should provide information on procedures for handling unexpected control results, identifying sources of error (including interfering substances), and manufacturer contact information for technical assistance. This information might be incorporated into the facility's procedures or posted for quick reference. The test site should have telephone numbers or other contact information readily available (e.g., numbers for manufacturers' technical assistance, the facility's director, consultant, or public health departments).

Documentation. Documenting and monitoring control testing results provides an indication that the test was properly performed by the operator and the test system (reagents, instruments, or any components) performed as expected. Records of control results should be periodically reviewed to detect shifts or changes in performance over time.

Performing the Test

The following points are important to remember when performing the test:

- Follow the steps in the test procedure in the exact order described in the product insert.
- Test controls at the frequency determined by the CW site.
- Pay attention to timing for waived tests, particularly unitized test devices that must be read during specific time intervals. Incorrect timing of these types of tests can give erroneous test results. Insufficient timing can result in false negative or invalid results because the specimen might not react completely with test system reagents. Time intervals longer than those specified in the product insert can result in false positive, false negative, or invalid results because of exaggerated color development, fading of reaction products, or migration beyond a visible range. Therefore, it is important to have a system established to read results during the correct timeframe, especially if conducting more than one test at a time. 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 maintaining extra timers and batteries.

Test Results Interpretation

When the test is complete, interpret the results according to instructions in the product insert (including the quick reference guide). Test results are of the following two types:

- Quantitative — Tests that provide numerical results generated by the test device or instrument. Numerical results are values corresponding to the concentration of the specific substance being measured. The value includes specific measurement units (e.g., such as a glucose result of 100 mg/dL). No interpretation is necessary to read the result.
- Qualitative — Tests that detect whether a particular substance, condition, or microbiological organism is present or absent. Results are interpreted as positive/reactive, negative/nonreactive, or invalid. Invalid results might indicate a problem with the specimen or the test system. Diagrams, color photographs, and color-comparison charts are often part of the product insert and quick references and serve as guides for interpretation.

Resolving Problems

If a discrepancy is identified between the patient's test results and the clinical information or if the results are invalid

or otherwise compromised, testing should be repeated. Results should not be reported until the problem is resolved. Follow the steps in the product insert to resolve problems with test results. Unitized test system instructions usually suggest repeating the test with a new device and referring to QC or trouble-shooting procedures. If repeat testing does not resolve the problem, contact the manufacturer or product technical representative. Quantitative results can be obtained that are beyond the measuring range of the instrument or test device. Each site should have documentation of quantitative test measuring ranges and a procedure for handling test results that are beyond the reportable ranges, either low or high.

Recording Results

Record test results according to the site's policy. Results can be recorded directly in a patient's chart, in log books, or on a separate report form. Records or logs of test results should have enough detail so the test site can retrieve information. Quantitative results should be recorded using the units of measurement of the test system. Qualitative test results should be recorded using interpretive words or abbreviations such as positive, negative, reactive or R, or nonreactive or NR instead of symbols like plus and minus (+, -) to help avoid clerical errors because a negative (-) sign can easily be changed to a positive (+) sign. If a test result is not acceptable or requires repeat testing (e.g., out of range or invalid), record the initial result, noting 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

After-testing activities include issuing test reports, supplemental or confirmatory testing, public health disease reporting (if required), testing area cleanup, biohazard waste disposal, and documentation of testing activities.

Test Reports

After the completion of the test, results are documented and reported. 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. Waived testing sites, such as point-of-care sites or physicians' offices, might accurately and legibly record results directly in the patient's record as a matter of practice. If results are not recorded directly in a patient's chart, they should be recorded in a written report format that includes all information needed to correctly identify and interpret the results as determined by the testing site (Table 10).

Critical values are test results necessary for patient evaluation or treatment that require immediate notification to the clinician. Each site should define the critical values, if appropriate, for the tests in use and ensure that testing personnel are aware of these values and the procedure for alerting the clinician. Procedures should be 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 supplemental testing is needed to confirm a waived test result or when the test is to be used as part of a multitest algorithm. A confirmatory test could be a different waived test (performed at the testing site or another CW site) or a nonwaived test performed by a CLIA-certified referral laboratory (*37*) (Table 11). When nonwaived confirmatory testing is needed, the patient can be sent to another facility for specimen collection and testing, or the specimen can be collected at the CW site and sent to a referral laboratory.

The CW site should have written policies to ensure confirmatory and supplemental testing is performed when needed. For each waived test that requires additional testing, the CW site should document the processes and procedures necessary to manage referral or confirmatory testing. When a CW site collects specimens for referral, procedures should include the following:

- Instructions for ordering additional tests, contact information for the referral laboratory used, and examples of completed test request forms.
- Specimen collection and labeling procedures with examples of forms used to track referred specimens.
- Safe specimen transport or shipping information as necessary, including special packaging and shipping require-

TABLE 10. Examples of test report information

Testing facility information	Patient information	Test information
Name	Name, anonymous identifier	Test ordered
Address, site, or clinic number	Record/billing number	Test result Units of measure
Telephone number	Birth date, sex, and age	Interpretation
Facility director		Reference intervals
		Comments or qualifying statement
		Date completed and/ or reported
		Person reporting

TABLE 11. Examples of supplemental/confirmatory testing for waived infectious disease tests

Waived test method result	Supplemental/Confirmatory test
Preliminary positive for HIV-1 antibody	Western blot or immunofluorescence assay
Presumptive negative for influenza A or B	Viral culture
Presumptive positive for *Borrelia burgdorferi* (Lyme disease) antibodies	Western blot
Negative for group A streptococcal antigen (screen from children and adolescents)	Throat culture

ments for confirmatory or supplemental tests for infectious diseases (e.g., HIV).

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, and
- The date the final report is issued.

Public Health Reporting

Federal and state public health agencies require testing facilities to report confirmed positive results for certain infectious diseases (e.g., HIV, influenza, and Lyme disease) (*38,39*). Testing facilities should confer with local public health agencies for the most current information on required reporting procedures since diseases identified for reporting can change over time, and state requirements might vary.

Biohazard Waste Disposal

Dispose of the biohazardous waste generated in specimen collection and testing according to site procedures that need to be in compliance with local ordinances, state, and federal OSHA regulations as previously discussed.

Documents and Records

Documentation is essential to assure quality waived testing. Proper documentation is necessary for monitoring and assessing test performance, identifying and resolving problems that could affect patient testing, retrieving and verifying information, and maintaining adequate patient and personnel records. Log books or electronic systems can be used for maintaining and tracking information. In some cases, records might be part of the patient's medical chart. Testing records should be maintained in chronological order to facilitate retrieval of information if needed. In addition, control records should be kept in the order in which they were completed so they can easily be compared with test records if there are questions about testing performed within a specific time period. The person responsible for testing oversight and decision-making should review records periodically. State regulations or other governmental agencies might require CW sites to retain documents and records for a specific length of time.

Aspects of testing for which records or documentation are recommended include:

- Test orders
- Test procedures or work instructions (e.g., written procedures specific to the CW site and current product inserts)
- Records of testing materials used, test system and equipment function checks, and maintenance
  - — Daily records of temperatures for refrigerators, freezers, and the testing area, as needed for the tests performed
  - — Lot numbers, dates used, and expiration dates of test systems and reagents
  - — Date and time (if applicable) of equipment function checks and any maintenance performed
  - — As applicable, notifications from manufacturers about product recalls or other problems, especially if the recalls or warnings refer to specific lot numbers or test systems
- Test results, including any confirmatory or supplemental testing
- QC testing results and corrective action taken if control results are unacceptable
  - — Date and time (if applicable) of control testing
  - — Lot number and expiration date of external controls
- Records of any test system failures, troubleshooting, and corrective action taken when problems are identified, including related communication with testing personnel
- Personnel training and competency assessment
- Records of PT or other external quality assessment

Quality Assessment

Good laboratory practices can be expanded to include assessment activities to evaluate and improve the quality of CW site testing. Assessment activities can be either internal or external, depending on the needs, resources, and practices of the site.

Internal Assessment

Objective internal assessment offers flexible, low-cost options for evaluating quality such as self-conducted inspections, supervisory review of documented problems that occur

in the different phases of the testing process, review of QC documentation, and testing and reporting procedures. Test performance can be assessed, if specimens are suitable, by exchanging specimens with another testing facility using the same test method(s) and comparing the results. Results from these assessment activities should be documented and evaluated, noting any irregularities and the actions taken to resolve problems or improve processes or procedures.

External Assessment

Because CW sites are not routinely inspected by CMS, voluntary inspections by peers or consultants can offer additional educational opportunities and feedback on current practices along with ideas for quality improvement. Voluntary external inspections evaluate the testing site practices and documentation systems, and a more narrowly focused assessment of test performance can be accomplished by participating in performance evaluation programs or subscribing to PT programs. These programs provide challenge samples to test as if they were patient specimens and the results are evaluated with respect to how close they are to the intended target values. Participation in these types of programs can be used to evaluate overall testing performance and as a training or educational tool for testing personnel.

Conclusion

This report summarizes the findings of multiple surveys of sites performing waived testing throughout the United States. Although the surveys were conducted through several mechanisms, the findings lead to similar conclusions about lapses in quality in CW sites, and they highlight the need for additional education and training related to waived testing for CW site directors and testing personnel. The recommendations provided in this report are intended to serve as a guide to improve the quality of testing in CW sites and enhance patient safety. They can be disseminated by a variety of individuals and organizations and adapted for use in different settings where waived testing is conducted. Continued surveillance and monitoring of waived testing performance is needed to determine the effectiveness of these recommendations on protecting and improving the public's health.

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Liaison Representative: Luann Ochs, MS, Roche Diagnostics Corporation, Indianapolis, Indiana.

Terms and Abbreviations Used in this Report

accuracy	true or target value; freedom from error; the accuracy of results can be measured by comparing them to results accepted as correct (e.g., standard methods), or by comparing them with those from another laboratory that uses a comparable method
analyte	a substance or constituent for which a laboratory conducts testing
antibody	a protein formed in the body in response to a foreign substance (e.g., bacteria, viruses or chemical toxins) and that interacts with the foreign substance to weaken or neutralize it
antigen	any substance that, when introduced into the body, causes the development of an immune response, such as antibody production
ASN	Arkansas Sentinel Network
biohazard	a biological agent that has the capacity to produce deleterious effects on humans, such as microorganisms and toxins
biohazardous waste	waste containing pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease
biosafety	the application of combinations of laboratory practice and procedure, laboratory facilities, and safety equipment when working with potentially infectious microorganisms to prevent infection
bloodborne pathogens	microorganisms that, when present in human blood, can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV)
calibration (check)	the process of testing and adjusting an instrument or test system to provide a known relationship between the value of the substance being measured by the test and the test system's measurement response. A calibration check is a mechanism to be sure the test system has remained stable and the results remain accurate
centrifugation	a process of separating blood or other body fluid cells from liquid components using a device (centrifuge) containing compartments that spin rapidly around a central axis
CLIA	Clinical Laboratory Improvement Amendments of 1988
CLIAC	Clinical Laboratory Improvement Advisory Committee
CLSI	Clinical and Laboratory Standards Institute (formerly NCCLS)
CMS	Centers for Medicare & Medicaid Services
competency assessment	evaluation of a person's ability to perform a test and to use a testing device; this includes all aspects of testing, from specimen collection to result reporting

confirmatory test	an additional more specific test performed to rule out or confirm a preliminary test result to provide a final result
control	a device or solution used to monitor a test system to ensure proper test performance and correct results
critical values	test results that require immediate notification to the clinician for patient evaluation or treatment
CW	Certificate of Waiver
CW testing site	the location where waived testing takes place; a facility holding a CW
diagnostic test	a test that identifies a disease or condition
direct microscopic examination	the direct examination of a patient specimen using a microscope
external controls	control materials that mimic patient specimens and monitor the testing process from specimen application to result interpretation
FDA	Food and Drug Administration
FDAMA	FDA Modernization Act
HHS	United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	human immunodeficiency virus
internal controls	procedural or built-in controls; controls that are built into a testing device and designed to verify that the test system is working as expected
kit	a packaged set containing test devices, instructions, reagents, and supplies needed to perform a test and generate results
LMSMN	Laboratory Medicine Sentinel Monitoring Network
nonreactive or NR	a result that indicates the absence of the constituent that the test is designed to detect
nonwaived tests	complex tests that do not meet the CLIA criteria for waiver and require training and specific quality measures to ensure the accuracy and reliability of test results
NYSN	New York Sentinel Network
OIG	Department of Health and Human Services Office of Inspector General
OSHA	Occupational Safety and Health Administration

plasma	the liquid portion of anticoagulated blood that does not contain cells. If a chemical agent or anticoagulant is added to a blood specimen to prevent clotting, the specimen can be separated by centrifugation into cells and plasma
PNWSN	Pacific Northwest Sentinel Network
POL	physician office laboratory
PPE	personal protective equipment; specialized clothing or equipment worn by an employee for protection against a hazard
PPMP	provider-performed microscopy procedures; a subcategory of moderate complexity testing under CLIA
precision	reproducibility; the measure of the closeness of the results obtained when analyzing the same sample more than once; the measure of agreement between replicate measurements of the same material
procedure manual	a handbook that contains test methods and other information needed to perform testing
product insert	written product information usually supplied by the manufacturer with each test kit or test system containing instructions and critical details for performing the test; also referred to as package insert
PT	proficiency testing; an external quality assessment program in which samples are periodically sent to testing sites for analysis
qualitative test	a test that detects whether a particular analyte, constituent, or condition is present or absent
quality assessment	a group of activities to monitor and evaluate the CW site's entire testing process to help ensure that test results are reliable, improve the testing process, and promote good quality testing practices
QC	quality control; the procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time
quantitative test	a test that measures the concentration or amount of an analyte in a specimen, whose results are expressed numerically
quick reference instructions	cards or small signs containing diagrams or flow charts with essential steps for conducting a test that are often included with waived test systems
reactive or R	a result that indicates the presence of the constituent that the test is designed to detect
reagent	a substance that produces a chemical or biological reaction with a patient specimen that allows detection or measurement of the analyte for which the test is designed

reference interval	the range of test values expected for a designated population of persons (e.g., 95% of persons presumed to be healthy [or normal])
referral laboratory	a laboratory that receives specimens from CW sites to perform additional testing, often for follow-up confirmatory testing; the majority of referral laboratories perform nonwaived testing
reportable range	the span of test result values for which the instrument or test device can accurately measure
sensitivity	the lowest concentration of an analyte that can reliably be detected or measured by a test system
serum	the cell-free liquid remaining after whole blood has clotted or coagulated
specificity	the ability of a test to detect a particular substance or constituent without interference or false reactions by other substances
Standard Precautions	an approach used in healt-care settings to reduce the risk for transmission of microorganisms from both recognized and unrecognized sources of infection in a wide variety of human sources. The nature of medical procedures and testing in these settings requires expansion of Universal Precautions to include feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus, even when no visible blood is evident.
state agency	the state health agency or other appropriate state or local agency that has an agreement under Section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections
test system	the instructions and all of the instrumentation, reagents, and supplies needed to perform a test and generate results
total testing process	series of activities or path of workflow for performing testing that can be divided into three major phases; before testing, during testing, and after testing
unitized test device	a self-contained test device to which a specimen is added directly and in which all steps of the testing process occur. A unitized device is used for a single test and must be discarded after testing.
Universal Precautions	an approach to controlling infection. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B virus, hepatitis C virus, and other bloodborne pathogens.
waived test	a test system, assay, or examination that has been cleared by the FDA for home use, or HHS has determined meets the CLIA criteria of being a simple test with an insignificant risk for an erroneous result
whole blood	blood containing all its cellular components that has not undergone centrifugation or had the plasma removed

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By Mail or Fax

1. Read this *MMWR* (Vol. 54, RR-13), which contains the correct answers to the questions beginning on the next page.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Goal and Objectives

This *MMWR* highlights quality issues identified in study findings of testing sites holding a Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certificate of Waiver (CW). The goal of this report is to provide recommendations for good laboratory practices to improve the quality of waived testing and enhance patient care and safety. Upon completion of this educational activity, the reader should be able to describe 1) the quality issues reported in the study findings; 2) the requirements for obtaining a CW; 3) management's considerations before introducing waived testing; 4) the good laboratory practice recommendations for the three phases of testing; and 5) resources for personnel training and quality assessment.

To receive continuing education credit, please answer all of the following questions.

1. According to CLIA regulations, facilities performing only waived tests have…
- A. routine inspections, but no requirements for director or test personnel qualifications.
- B. no routine inspections and no requirements for director or test personnel qualifications.
- C. no routine inspection, but requirements for director qualifications.

2. CLIA regulations require facilities performing only waived tests to…
- A. obtain a Certificate of Waiver.
- B. use Universal Precautions.
- C. follow current manufacturers' test instructions.
- D. A and B.
- E. A and C.

3. Factors contributing to gaps in quality found by CMS in CW sites include…
- A. inadequate training in good laboratory practices.
- B. high turnover rates of testing personnel.
- C. failure to follow current manufacturers' instructions.
- D. all of the above.

4. Which of the following specimen types are NOT acceptable for waived tests?…(*Indicate all that apply.*)
- A. urine.
- B. oral fluid.
- C. whole blood.
- D. plasma.
- E. throat swab.

5. Before performing a waived test, one should…
- A. confirm the test order is correct.
- B. collect test specimens exactly as described in the test system instructions.
- C. prepare the testing area and materials.
- D. confirm patient identity to ensure specimen collection from the correct patient.
- E. B, C and D.
- F. all of the above.

6. With unitized test use devices, external controls should be tested…
- A. with each new shipment of test devices.
- B. by each new operator before conducting the test.
- C. after testing patient specimens.
- D. when testing a new lot number.
- E. A, B, and D.
- F. A, C, and D.

7. Waived test results can be affected by…
- A. timing of the test.
- B. order in which testing steps are performed.
- C. storage temperature of test kits.
- D. A and B.
- E. all of the above.

8. Examples of waived test results that need follow-up/confirmatory testing include…
- A. presumptive positive for Lyme disease antibodies.
- B. presumptive positive for influenza A or B.
- C. negative group A streptococcal antigen from children and adolescents.
- D. presumptive positive for HIV antibodies.
- E. A, B, and C.
- F. A, C, and D.

9. Essential information for which documentation should be maintained includes…(*Indicate all that apply.*)
- A. test kit lot numbers.
- B. test kit/reagent expiration dates.
- C. quality control results.
- D. personnel training.
- E. all of the above.

10. The person responsible for evaluating and implementing waived testing or the CW site director should…
- A. be able to perform the test better than anyone else.
- B. have the appropriate background and training to understand and evaluate a test.
- C. approve written test procedures.
- D. A, B and C.
- E. B and C.

11. Important information contained in the product insert includes... (*Indicate all that apply.*)
- A. steps to perform the test and controls.
- B. an explanation of the principle of the test.
- C. a description of the type of specimen to be used with the test.
- D. instructions for writing the CW site test procedure.

12. Which of the following is NOT true regarding considerations for testing personnel?
- A. Overall staff competency is a key element to accurate, reliable testing.
- B. Personnel should have adequate training before performing patient testing.
- C. Once trained, testing personnel do not need refresher training in good testing practices because they are using waived tests.
- D. Personnel should have resources available for consultation, either on-site or off-site.

13. Which best describes your professional activities:
- A. Physician.
- B. Nurse.
- C. Health educator.
- D. Office staff.
- E. Other.

14. I plan to use these recommendations as the basis for…(*Indicate all that apply.*)
- A. Health education materials.
- B. Insurance reimbursement policies.
- C. Local Practice guidelines.
- D. Public policy.
- E. Other.

15. Overall, the length of the journal article was…
A. Much too long.
B. A little too long.
C. Just right.
D. A little too short.
E. Much too short.

16. After reading this report, I am confident I can describe the quality issues reported in the study findings.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

17. After reading this report, I am confident I can describe the requirements for obtaining a CW.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

18. After reading this report, I am confident I can describe management's considerations before introducing waived testing.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

19. After reading this report, I am confident I can describe the good laboratory practice recommendations for the three phases of testing.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

20. After reading this report, I am confident I can describe the resources for personnel training and quality assessment.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

21. The learning outcomes (objectives) are relevant to the goals of this report.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

22. The instructional strategies used in the report (text, figures, and tables) help me learn the material.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

(Continued on pg CE-4)

Detach or photocopy.

MMWR Response Form for Continuing Education Credit
November 11, 2005/Vol. 54/No. RR-13

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

To receive continuing education credit, you must
1. provide your contact information (**please print or type**);
2. indicate your choice of CME, CME for nonphysicians, CEU, or CNE credit;
3. answer all of the test questions;
4. sign and date this form or a photocopy;
5. submit your answer form by **November 11, 2007**.

Failure to complete these items can result in a delay or rejection of your application for continuing education credit.

Last Name (**print or type**) First Name

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Apartment or Suite

City State ZIP Code

Phone Number Fax Number

E-Mail Address

Check One
☐ CME Credit
☐ CME for nonphysicians Credit
☐ CEU Credit
☐ CNE Credit

Fill in the appropriate blocks to indicate your answers. Remember, you must answer all of the questions to receive continuing education credit!

1. [ ]A [ ]B [ ]C	16. [ ]A [ ]B [ ]C [ ]D [ ]E		
2. [ ]A [ ]B [ ]C [ ]D [ ]E	17. [ ]A [ ]B [ ]C [ ]D [ ]E		
3. [ ]A [ ]B [ ]C [ ]D	18. [ ]A [ ]B [ ]C [ ]D [ ]E		
4. [ ]A [ ]B [ ]C [ ]D [ ]E	19. [ ]A [ ]B [ ]C [ ]D [ ]E		
5. [ ]A [ ]B [ ]C [ ]D [ ]E [ ]F	20. [ ]A [ ]B [ ]C [ ]D [ ]E		
6. [ ]A [ ]B [ ]C [ ]D [ ]E [ ]F	21. [ ]A [ ]B [ ]C [ ]D [ ]E		
7. [ ]A [ ]B [ ]C [ ]D [ ]E	22. [ ]A [ ]B [ ]C [ ]D [ ]E		
8. [ ]A [ ]B [ ]C [ ]D [ ]E [ ]F	23. [ ]A [ ]B [ ]C [ ]D [ ]E		
9. [ ]A [ ]B [ ]C [ ]D [ ]E	24. [ ]A [ ]B [ ]C [ ]D [ ]E		
10. [ ]A [ ]B [ ]C [ ]D [ ]E	25. [ ]A [ ]B [ ]C [ ]D [ ]E		
11. [ ]A [ ]B [ ]C [ ]D	26. [ ]A [ ]B [ ]C [ ]D [ ]E		
12. [ ]A [ ]B [ ]C [ ]D [ ]E	27. [ ]A [ ]B [ ]C [ ]D [ ]E		
13. [ ]A [ ]B [ ]C [ ]D [ ]E	28. [ ]A [ ]B [ ]C [ ]D [ ]E		
14. [ ]A [ ]B [ ]C [ ]D [ ]E	29. [ ]A [ ]B		
15. [ ]A [ ]B [ ]C [ ]D [ ]E	30. [ ]A [ ]B [ ]C [ ]D [ ]E [ ]F		

Signature ***Date I Completed Exam***

23. The content was appropriate given the stated objective of the course.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

24. The content expert(s) demonstrated expertise in the subject matter.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

25. Overall, the quality of the journal article was excellent.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

26. These recommendations will improve the quality of my practice.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

27. The availability of continuing education credit influenced my decision to read this report.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

28. The *MMWR* format was conducive to learning this content.
A. Strongly agree.
B. Agree.
C. Neither agree nor disagree.
D. Disagree.
E. Strongly disagree.

29. Do you feel this course was commercially biased?
A. Yes.
B. No.

30. How did you learn about the continuing education activity?
A. Internet.
B. Advertisement (e.g., fact sheet, *MMWR* cover, newsletter, or journal).
C. Coworker/supervisor.
D. Conference presentation.
E. MMWR subscription.
F. Other.

Correct answers for questions 1–12.
1. B; 2. E; 3. D; 4. D; 5. F; 6. E; 7. E; 8. F; 9. E; 10. E; 11. A, B, C; 12. C.

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