

Recommended Good Laboratory Practices – Waived Testing Sites

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 Certificate of Waiver (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 (refer to Table 6).

Table 6

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
Specimen collection, handling	Results interpretation	Confirmatory testing
Preparing materials, equipment, and testing area	Recording results	Patient follow-up
		Disease reporting
		Biohazard waste disposal

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?
- 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 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 –refer to following 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.

Table 7

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: <ul style="list-style-type: none"> • 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.

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 (see Table 7 on previous page). 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 performed. 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 (37). 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- Refer to Table 8 that follows. 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.

Table 8

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	<i>H. pylori</i>

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 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 A₁C, 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 – Refer to Table 9 that follows. 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 – Refer to Table 10 that follows.

Table 10

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
Telephone number	Birth date, sex, and age	Units of measure
Facility director		Interpretation
		Reference intervals
		Comments or qualifying statement
		Date completed and/ or reported
		Person reporting

Critical Values. 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 – Refer to Table 11 below. 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.

Table 11

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 <i>Borrelia burgdorferi</i> (Lyme disease) antibodies	Western blot
Negative for group A streptococcal antigen (screen from children and adolescents)	Throat culture

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 requirements 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.

Report 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.

Note: For complete references and report information visit CDC website address listed in the header of this document.