

Considerations for Waived Testing

<http://www.cdc.gov/clia/Resources/WaivedTests/>

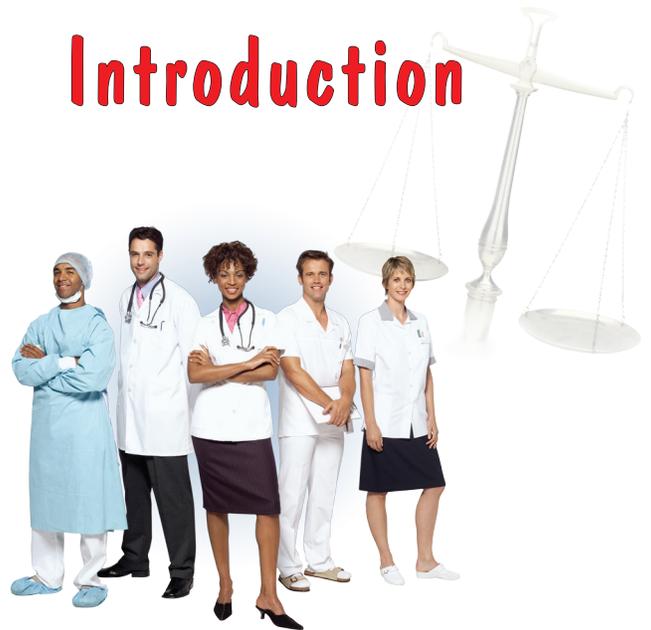
Center for Surveillance, Epidemiology, and Laboratory Services
Division of Laboratory Systems



Introduction

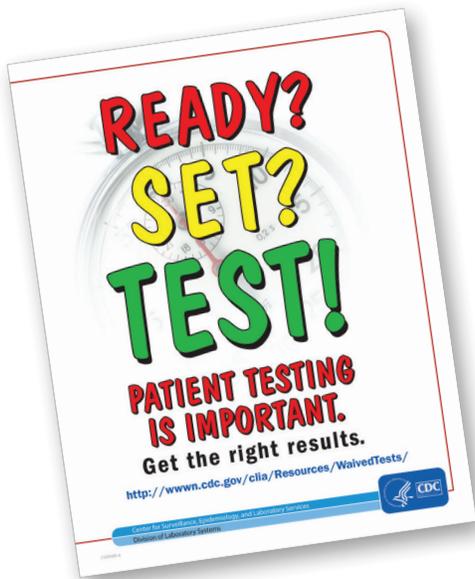
BACKGROUND

Health care providers use laboratory test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. Current practice shows an increased trend for medical decisions based on simple tests performed at the point of care. Many of these test systems are waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).



PURPOSE

This booklet describes considerations and preparations needed prior to performing waived testing and may assist those who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver.



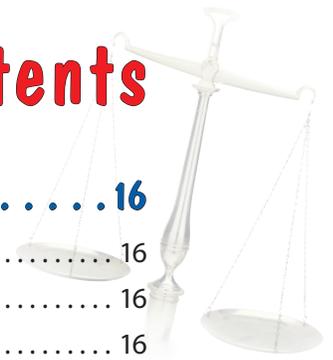
Additional materials that may be useful:

- The **Ready? Set? Test!** booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.
- The **Ready? Set? Test!** poster lists ten good practices for testing.
- The **Ready? Set? Test!** online training provides scenario based training on recommended practices for waived testing and offers continuing education credit.

These materials can be found here: <http://www.cdc.gov/clia/Resources/WaivedTests/>

Although some of the recommendations in this booklet exceed CLIA requirements for waived testing, following these good testing practices will likely lead to reliable, high quality test results and will enhance patient safety.

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Overall considerations



OVERVIEW

Before deciding to begin testing at your facility or adding a new test to your test menu, it is important to carefully weigh the potential benefits in light of the various issues to be considered.

BENEFITS

Some of the benefits of performing waived testing include:

- rapid availability of results while the patient is available for immediate follow-up,
- simple tests have minimal need for training, and
- portability of many waived tests allows for easier testing in nontraditional settings.

ISSUES TO CONSIDER

Although waived testing can be beneficial, infrequent testing may result in concerns about the ability of the testing personnel to perform the test correctly. Infrequent testing may also result in increased cost due to reagents and controls becoming outdated before being used. Consider the following when deciding when to perform testing versus sending samples to a reference laboratory for testing.

- **Oversight of testing**— Someone will need to be responsible for managing testing and making decisions to assure quality testing.
- **Regulatory requirements**— Every site will need to follow applicable federal, state, and/or local requirements for testing, safety, confidentiality, and privacy.
- **Location for testing**— Testing will need to be performed in a location with adequate space, an appropriate physical environment, and accommodations for proper disposal of biohazardous waste.
- **Selecting tests**— Consider the test characteristics, sample requirements, and costs when choosing a test.
- **Testing personnel**— Personnel who perform testing will need to be trained and periodically assessed on their ability to perform quality testing.
- **Starting to test**— Make sure that you have, understand, and follow the current manufacturer's instructions.
- **Quality assessment**— Continually monitor, evaluate, and look for ways to improve the quality of testing.



Oversight of testing

OVERVIEW

Maintaining a consistent high level of quality and service should be part of the daily routine for each employee involved in patient care. Designating someone to oversee testing and provide support to the personnel who perform testing will help your testing site(s) achieve the goal of quality patient testing.

RESPONSIBILITY FOR MANAGEMENT

Each testing site should identify at least one person responsible for overseeing testing and decision-making. The person overseeing testing might be a physician or someone in a senior management position who has the appropriate background and knowledge to make decisions about laboratory testing. The person overseeing testing should:

- ✓ have appropriate background and knowledge for making decisions and solving problems with testing,
- ✓ demonstrate a commitment to the quality of testing,
- ✓ understand how to comply with applicable regulatory requirements, and
- ✓ promote good laboratory practices.

PERSONNEL SUPPORT

Personnel who perform testing should be encouraged to use quality practices, ask questions and seek help when they have concerns. Some recommendations are to:

- Post or have telephone numbers for emergency situations readily available.
- Identify a resource person or expert (for example, a consultant and/or test manufacturer's technical representative), who is available either off-site or on-site, to answer questions and be of assistance.
- Post telephone numbers for manufacturer's technical assistance.
- Make sure all equipment is maintained and service contracts purchased for equipment that require additional maintenance beyond the abilities of the staff.
- Designate one person to discuss new tests and other testing materials with sales representatives or test distributors. This person should understand the responsibilities and impact of changing from one test system to another and introducing a new test.
- Provide employees a way to voice their concerns regarding the quality of patient testing without fear of disciplinary action or other adverse consequences.
- Promote and offer opportunities for employee training and continuing education.



Regulatory requirements



OVERVIEW

Every site that performs laboratory testing must follow applicable regulatory requirements. These include federal, state and local requirements for testing as well as requirements for safety and confidentiality of personal information.

WAIVED TESTS

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those tests approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) criteria. The FDA list of waived tests is continuously being updated. The most current information on FDA-cleared waived tests for verification that the test(s) performed by your laboratory is categorized as waived can be found at the following website: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm>

CLIA CERTIFICATE OF WAIVER

Before testing patient samples, federal regulations require testing sites to have a CLIA certificate issued by CMS. Sites performing only one or more waived tests must file a Certificate of Waiver application and obtain a separate certificate for each location.

To obtain a CLIA Certificate of Waiver, complete CMS form 116 found at: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>

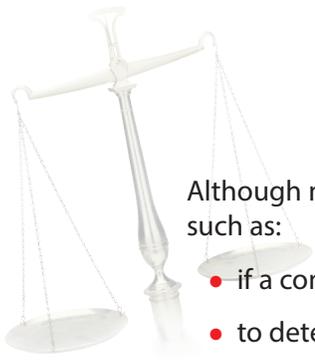
Your completed CMS form 116 should be sent to the address of the local State Agency for the state in which your laboratory resides. You should contact this State Agency for additional forms that may be necessary to complete the registration process. Additionally, the CLIA contact in the Regional Office may provide assistance. The list of CMS State Agency & Regional Office CLIA Contacts can be found at: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html

If you do not have online access and do not have information about your State Agency, you may contact the CLIA program at 410-786-3531 for the address and phone number of your State Agency.

For additional information on how to obtain a Certificate of Waiver, refer to the CMS brochure located online at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/HowObtainCertificateofWaiver.pdf>

Once your site has obtained a CLIA Certificate of Waiver, requirements for testing include:

- ✓ Perform only waived tests.
- ✓ Follow the current manufacturer's instructions for the waived tests you perform, without any changes.
- ✓ Pay the certificate renewal fee every two years.
- ✓ Notify your State Agency of any changes in ownership, name, address, or director within 30 days, or if you wish to add tests that are not waived.
- ✓ Allow announced or unannounced on-site inspections by a CMS representative.



Although not routinely done, CMS will inspect waived testing sites under certain circumstances such as:

- if a complaint has been filed,
- to determine if the testing site is only performing waived tests,
- if there is a risk of harm to a patient due to inaccurate testing, and
- to collect information about practices being used at waived testing sites.

“OFF-LABEL USE” OF WAIVED TESTS

Based on the testing site’s need and the unique population it serves, there may be instances when the site chooses to modify an FDA-cleared or approved test system. Modification means using a test system in a way other than that described in the intended use, precautions, limitations, or other sections of the manufacturer’s instructions. The modified use of a test system is considered “off-label use” because it is not supported by the manufacturer’s clinical data and it is not part of the FDA-cleared or approved instructions. “Off-label use”, or modified use of a test system, defaults the test to the high-complexity testing category under CLIA regulations, and will require sites using the modified test system to meet all applicable CLIA requirements for high-complexity testing. These include requirements for proficiency testing (PT), establishing performance characteristics, quality control (QC), quality assessment, and adherence to personnel qualifications. Laboratories with a CLIA Certificate of Waiver that are using modified test systems will need to upgrade to a CLIA Certificate of Compliance or a CLIA Certificate of Accreditation if they continue to use modified test systems.

Example of “Off-Label Use” of Waived Tests

Using a waived blood glucose monitoring system to test a patient whose hematocrit or oxygenation level is above or below the range indicated in the manufacturer’s instructions would be an “off-label use” of this system. Results of blood glucose testing in this situation may lead to clinical interventions that could cause patient harm. If the patient’s hematocrit and oxygenation level are within the manufacturer’s stated limits, then performing a glucose test using the waived glucose monitoring system would not be considered off-label testing and the test system would still be considered waived.

STATE AND LOCAL REQUIREMENTS

State and local jurisdictions vary in how they regulate laboratory testing. Some have requirements governing testing, personnel licensure or phlebotomy. Often there are specific regulations for biohazard safety or the handling and disposal of medical waste. The person overseeing testing should ensure that all state and local requirements are met. When state, local, and federal requirements are not the same, follow the strictest requirement that applies to your site.

SAFETY

Federal Regulations for Safety

The Occupational Safety and Health Administration (OSHA) requires employers to provide a safe and healthy workplace for employees. Each site must comply with OSHA standards including:

- ✓ Comply with OSHA standards to assure the safety and health of employees. OSHA provides a list of regulations that normally apply to medical and dental offices in a brochure, *Medical & Dental Offices— A Guide to Compliance with OSHA Standards*: <http://www.osha.gov/Publications/osha3187.pdf>
- ✓ Treat all human blood and certain human body fluids as if they are infectious. Strictly enforce the use of universal precautions and compliance with the bloodborne pathogens standard: <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>
- ✓ Ensure use of safer, engineered needles, sharps containers and personal protective equipment (PPE) such as gloves and protective eyewear. See OSHA's PPE Fact Sheet: http://www.osha.gov/OshDoc/data_General_Facts/ppe-factsheet.pdf
- ✓ Implement a sharps injury prevention program. CDC provides a *Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program*: http://www.cdc.gov/sharpsafety/pdf/sharpsworkbook_2008.pdf
- ✓ Offer hepatitis B vaccination at no cost for employees with possible occupational exposure.
- ✓ Provide safety training to employees on handling blood and other infectious materials.
- ✓ Provide equipment for safely handling and disposing of biohazardous waste.
- ✓ Have a written plan for exposure control. See an example: <http://www.osha.gov/SLTC/etools/hospital/hazards/tb/sampleexposurecontrolplan.html>
- ✓ Maintain records of occupational injuries and illnesses. OSHA provides a record keeping handbook: https://www.osha.gov/Publications/recordkeeping/OSHA_3245_REVISED.pdf

Additional safety practices when performing testing are:

- ✓ No eating, drinking, or applying makeup in areas where samples are collected and where testing is performed.
- ✓ Do not store food in refrigerators where testing supplies or samples are stored.
- ✓ Have sinks for hand-washing or antiseptic hand washing solutions available.
- ✓ Post safety information for employees and patients.

Development of a site-specific safety plan that describes policies, procedures, and work practices for employee safety provide testing personnel and staff protection from the health hazards that may be involved in testing.

See Appendix A for an example [Safety Plan](#) including an example [Safety Training Checklist](#) and [Incident Report](#).

State Regulations for Safety

Many states have Occupational Safety and Health (OSH) Plans that are monitored by OSHA. If you live in a state that provides a State Plan, you must comply with the State OSH standards. OSHA provides information on State OSH programs: <http://www.osha.gov/dcsp/osp/index.html>





REQUIREMENTS FOR CONFIDENTIALITY AND PATIENT PRIVACY

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) addresses the protection and privacy of personal health information. Testing sites are required to establish policies and procedures to protect the confidentiality of health and personal information about their patients, including patient identification, test results, and all records of testing. All personnel should receive training on maintaining the confidentiality of patient information. Several states have medical privacy laws that apply to testing sites. Refer to the following link for more information on HIPAA: <http://www.hhs.gov/ocr/privacy/>

See Appendix B for an example [Security and Confidentiality Agreement](#) form.

Location for testing



OVERVIEW

Assuring the appropriate physical environment for performing testing is important for achieving reliable test results. In general, testing should be performed in a clean work area with space for patient privacy while safely collecting samples and performing testing. Each testing site should arrange for proper disposal of hazardous waste.

ENVIRONMENT

Assuring the appropriate physical environment for performing testing is important for achieving reliable test results. In general, testing should be performed in a clean work area with space for patient privacy while safely collecting samples and performing testing. Each testing site should arrange for proper disposal of hazardous waste.



- **Workspace**— should be stable, level, and allow patient confidentiality, disinfection, sample collection, proper testing, and storage of supplies and records.
- **Lighting**— sample collection and testing area(s) should be well lit.
- **Ergonomics**— should be considered and evaluated for the tasks employees perform.
- **Safety labels**— equipment and testing areas should be clearly labeled for hazards.
- **Temperature**— can affect reagents and test components, reaction times, the expiration of test kits, and test results. Follow the manufacturer's instructions for storage and testing and avoid temperature extremes.
- **Humidity levels**— can affect reagents and test components, the rate of chemical reactions and sample interaction, and test endpoints.
- **Utilities**— such as electricity and water may be necessary for some testing devices and equipment.
- **Housekeeping**— testing areas should be clean, organized, and free of clutter. If applicable, make sure housekeeping staff are trained on the potential hazards involved in handling biological waste and have proper safety training to work with such material.

WASTE DISPOSAL



Hazardous waste cannot be mixed with regular trash. Use proper biohazard containers to dispose of waste and sharps. Each testing site should have site specific procedures that follow local, state, and federal requirements for safe disposal of biohazardous waste generated from sample collection and testing. Local hospitals and/or clinics may be able to provide information about regulated waste disposal.



Selecting tests

OVERVIEW

Choosing the right test for your site is important for you and your patients. Before deciding to perform waived testing, consider the test characteristics, the types of samples required for testing, and cost.

TEST CHARACTERISTICS

Information on a test can be found in the manufacturer's instructions or by calling the manufacturer's customer service or technical support representative.

When choosing your test, consider:

- **Intended Use**— This describes what is being measured by the test, the type of sample that the test is approved for, and whether the final result is quantitative (number) or qualitative (e.g., positive or negative).
- **Performance characteristics**— Review the data from the manufacturer on the test's accuracy, precision, sensitivity, specificity, and interferences.
- **Patient population**— Some tests may not work on certain age groups such as pediatric patients. In addition, the predictive value of results can vary in different populations.
- **Supplemental testing**— Some tests are used for screening and need follow up testing before a final result can be reported.
- **Patient follow-up**— Some tests, such as HIV tests, may need post-test counseling about the meaning of the test result.
- **The test system**— Consider the simplicity of the test system, length of time to obtain a result, and the level of technical support provided by the manufacturer or distributor. Some tests, such as HIV tests, may require special training, development of a quality assurance program, or provision of information to patients.



TYPES OF SAMPLES

Choosing the right test for you and your patients includes consideration of the following sample characteristics:

- Consider the sample. Remember, only unprocessed samples can be used for waived tests. Tests that use samples that have had any processing such as centrifugation, dilution, or extraction are no longer considered waived tests.
- Check sample collection requirements. Is the sample collection device or kit included in the test kit or sold separately? Caution: Not using the appropriate collection device can result in incorrect test results.
- Consider the length of time samples are stable before testing.
- Consider how you will safely discard samples and other testing material.

COST

Before offering a new test, consider factors that contribute to total cost, such as

- **personnel**— including labor and training,
- **consumables**— including test kits, supplies, reagents, disposables, controls and calibration materials,
- **equipment and related costs**— including repairs or maintenance contracts,
- **safety and biohazard supplies**— including sharps containers and personal protective equipment,
- **cost for record keeping,** and
- **resources needed for additional activities**— including referral testing, licenses and fees.





Testing personnel

OVERVIEW

Choosing the right employees to perform testing is only the first step. Employees will need to be trained on the test before they perform patient testing. After training, employees will need to be periodically assessed on their ability to perform quality testing.

CHOOSE THE RIGHT EMPLOYEE

Employee performance and turnover affect the quality and reliability of waived test results. There are no federal requirements (CLIA) for qualifications of personnel who perform waived testing; however, applicable state or local personnel regulations must be met. Additionally:

- ✓ Consider the time and skills needed to perform testing, especially if personnel have additional duties or responsibilities.
- ✓ Consider evaluating the staff for color-blindness because this can limit their ability to interpret test results that are determined based on color.
- ✓ Be aware that temporary or part-time staff may not perform testing often enough to maintain the ability to perform the test correctly.
- ✓ Consider the turnover rate of staff and training needed for new employees.

EMPLOYEE TRAINING

Well-trained, skilled personnel are essential for quality testing and patient care. The person overseeing testing should make sure personnel receive adequate training before they perform testing and report patient results.

A qualified person should provide training based on the test procedure (for example, an experienced co-worker or an outside consultant) and have knowledge of:

- ✓ how to accurately demonstrate the performance of the test(s),
- ✓ good laboratory practices, and
- ✓ safety practices, such as:
 - universal precautions,
 - handling hazardous waste, and
 - appropriate use of PPE.

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

1. The trainee reads the test instructions.
2. The trainer demonstrates how to do the test.
3. The trainee performs the test.
4. The trainer evaluates test performance by the trainee, provides feedback, and follows-up with additional instruction if needed.
5. Both trainer and trainee document the training.

See Appendix C for an example [Training Checklist](#) and Appendix D for an example [Training Evaluation form](#).



Additional resources for employee training are:

- manufacturers and distributors,
- professional organizations, and
- state health departments or other government agencies.



EMPLOYEE PERFORMANCE

To make sure testing is consistent and accurate, the person overseeing testing should periodically check the performance of testing personnel and provide additional training when needed. Personnel assessments should be done in a positive manner that emphasizes education and promotes good testing practices. See Appendix E for an example [Competency and Performance Assessment form](#). Performance can be evaluated by:

- watching the person do the test,
- giving the person mock samples for testing (these can be control samples or previously tested patient samples),
- checking documents for accuracy and completeness, and
- participating in external assessment activities (proficiency testing programs).



Starting to test

OVERVIEW

Before performing patient testing, it is important to have the current manufacturer's instructions for the test system you are using and make sure that all testing personnel understand and follow these instructions.

MANUFACTURER'S INSTRUCTIONS



For each test offered, the current manufacturer's instructions or a written procedure containing information from the current manufacturer's instructions should be available in the testing area. These instructions are found in a product insert or testing manual. Check the revision date on each lot of testing kits and/or supplies to make sure that the current version of the manufacturer's instructions is being used. If changes have been made to the manufacturer's instructions, make sure all testing personnel are following the updated instructions.

Quick Reference Instructions

Some manufacturers provide quick reference instructions with the essential steps for the test listed on a card or small sign containing diagrams or flow charts. These instructions are not a substitute for a complete written test procedure. If used, they should be clearly posted where testing is performed. **Caution: when using quick reference instructions, use the current version and make sure they are for the manufacturer and test you are performing. The specific test system name should be on these instructions to avoid confusion.**

PROCEDURES

Written procedures can be developed from the manufacturer's instructions to include specific instructions for your testing site. When writing procedures, it is helpful to use a general template with standard headings. See Appendix F for [Procedure Contents and Tips](#).

Procedure Manual

Procedure manuals may be created by a testing site in order to provide a single location for all documents, forms, and instructions used by the testing site. The individual overseeing testing should review and sign the procedure manual once a year and whenever changes are made. Copies of old versions of procedures should be removed from the active manual, clearly labeled as inactive, and filed.

Procedure manuals should have instructions and forms for:

- ✓ preparing the test and reagents,
- ✓ performing the test(s),
- ✓ performing quality control (QC) procedures,
- ✓ interpreting and reporting the test result(s),
- ✓ troubleshooting testing problems,
- ✓ training new personnel,
- ✓ recording temperatures of refrigerators and storage, areas,
- ✓ keeping inventories and lot numbers of kits and reagents,
- ✓ maintaining equipment,
- ✓ handling hazardous waste,
- ✓ cleaning and disinfecting work areas and equipment,
- ✓ selecting and using personal protective equipment,
- ✓ performing work area environmental and ergonomic assessments,
- ✓ reporting infectious disease test results to public health agencies, and
- ✓ referring testing to outside laboratories.





Quality assessment

OVERVIEW

Assessing testing quality requires planned and systematic monitoring and evaluation of the testing process. Conducting these activities can lead to reduced errors, improved patient outcomes, improved patient and employee safety, and reduced costs.

ASSESSMENTS

Both internal and/or external mechanisms for quality assessment may be used depending on the needs, resources, and practices of the testing site. Examples are listed below.

Internal assessments are processes for staff performing and overseeing testing to evaluate their current practices, including:

- performing and documenting quality control (QC) procedures and results,
- reviewing QC records and test results,
- reviewing room and refrigerator temperature log sheets for complete documentation,
- documenting and reviewing problems and establishing a plan to improve processes, and
- documenting and reviewing injury/incident reports.

External assessments are typically performed by an outside party to evaluate current practices and offer opportunities for education. Possible options for external review include:

- undergoing voluntary inspections by peers or consultants who would evaluate testing practices and documentation systems, and offer suggestions for improvement.
- subscribing voluntarily to PT programs. PT programs periodically send challenge samples to test like patient specimens; the program then compares the results with an assigned value, and reports the results back to the participating laboratory or testing site. Many PT programs offer modules for waived tests. Although use of a CLIA-approved PT program is not a CLIA requirement, a list of these can be found at: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ptlist.pdf>
- exchanging samples with other testing sites using the same test method(s) to compare results.



The following checklist summarizes the steps that should be taken when implementing and overseeing waived testing or offering a new test under a CLIA Certificate of Waiver.

OVERSIGHT OF TESTING

- Designate someone to oversee testing.
- Provide support to personnel who perform the testing to encourage the use of quality practices, ask questions, and seek help when they have concerns.

REGULATORY REQUIREMENTS

- Obtain a CLIA Certificate of Waiver (CW) before offering testing.
- Renew the CW every 2 years.
- Perform only waived tests.
- Follow test instructions, without modification, according to the manufacturer's most current product insert.
- Notify your State Agency of any changes in ownership, name, address, or director within 30 days, or if you wish to add tests that are not waived.
- Allow announced or unannounced on-site inspections by CMS representatives.
- Follow all applicable state and local requirements.
- Follow regulations for safety and confidentiality.

LOCATION FOR TESTING

- Perform testing in a stable and level area with adequate space for patient privacy while safely collecting samples and performing testing.
- Consider environmental issues, such as temperature and humidity, especially in nontraditional test settings.
- Have clean work surfaces and good lighting for sample collection and testing.
- Dispose of waste safely.

SELECTING TESTS

- Check the manufacturer's instructions for limitations, conditions, or restrictions that may apply to the use of the test.
- Consider sample requirements and restrictions.

TESTING PERSONNEL

- Choose skilled employees to perform patient testing.
- Make sure that all testing personnel understand and can perform the test correctly before they report patient results.
- Periodically assess the performance of testing personnel.

STARTING TO TEST

- Understand and follow the current manufacturer's instructions for each test you perform.
- Consider writing procedures developed from the manufacturer's instructions that include specific instructions for your testing site.

QUALITY ASSESSMENT

- Monitor, evaluate, and improve your current practices.



Resources

- Appendix G: [Terms and Abbreviations](#)
- “Good Laboratory Practices for Waived Testing Sites” Morbidity and Mortality Weekly Report (MMWR), Recommendations and Reports; November 11, 2005, vol 54(RR13);1-25. <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm>
- “Quality Assurance Guidelines for Testing Using Rapid HIV Antibody Tests Waived Under the Clinical Laboratory Improvement Amendments of 1988.” http://www.cdc.gov/hiv/pdf/testing_qa_guidlines.pdf
- CMS CLIA overview: <http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/>
- CLIA regulations: <http://wwwn.cdc.gov/clia/Regulatory/default.aspx>
- CLIA CW Application: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms116.pdf>
- CLIA State Agency Contacts: http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html
- FDA’s CLIA Waived Test List: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm>
- HIPAA regulations: <http://www.hhs.gov/ocr/privacy/>
- State Reportable Conditions Website: <http://www.cste2.org/izenda/entrypage.aspx>
- For additional information <http://wwwn.cdc.gov/clia/Resources/WaivedTests/>

Safety Links

- The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) Biosafety link: <http://www.cdc.gov/biosafety/>
- List of OSHA publications and links: <http://www.osha.gov/pls/publications/publication.html>
- State occupational safety and health programs: <http://www.osha.gov/dcsp/osp/index.html>
- Medical & Dental Offices – A Guide to Compliance with OSHA Standards at: <https://www.osha.gov/Publications/osh3187.pdf>
- Bloodborne Pathogens Standard <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>
- OSHA’s PPE Fact Sheet http://www.osha.gov/OshDoc/data_General_Facts/ppe-factsheet.pdf
- CDC Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program http://www.cdc.gov/sharpsafety/pdf/sharpsworkbook_2008.pdf
- WHO patient safety website: <http://www.who.int/patientsafety/en/>
- “Transporting Infectious Substances Safely.” PHMSA/DOT, October, 2006. http://www.hercenter.org/regsandstandards/Transporting_Infectious_Substances_Safely.pdf
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration link: <http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html>
- Frequently Asked Questions (FAQs) Regarding Assisted Blood Glucose Monitoring and Insulin Administration link: http://www.cdc.gov/injectionsafety/providers/blood-glucose-monitoring_faqs.html



EXAMPLE

SAFETY PLAN

I. INTRODUCTION

The safety plan describes policies and procedures to ensure the safety of the personnel who perform testing. Participation and cooperation in following safety precautions may also prevent endangerment of the health and safety of fellow workers and the surrounding community.

II. PLAN AVAILABILITY

The plan that includes policies and procedures to assure safety needs to be available to all employees for review. All employees are expected to familiarize themselves with these safety responsibilities. A site-specific copy of the safety plan needs to be located in each testing area. Some useful safety documents can be found here:

<http://www.cdc.gov/biosafety/>

III. RESPONSIBILITIES

Implementation of the safety plan is a shared responsibility. The individual overseeing testing and personnel who perform the testing all have roles to play. These roles are outlined below.

A. Individual Overseeing Testing

1. Establish a plan that includes policies and procedures for employee safety.
2. Designate an area in each testing area for storage and easy access of the site-specific safety plan.
3. Make sure testing personnel and other staff follow the guidelines in the safety plan.
4. Provide site-specific safety training to all new employees BEFORE they perform testing.
5. Document completion of safety training for all employees, including housekeeping staff, and maintain training records.
6. Provide appropriate personal protective equipment (PPE) and engineering controls needed to work safely. Make sure that such equipment is used correctly and is in working order.
7. Identify and offer to employees appropriate immunizations for the testing being performed.
8. Correct all unsafe practices immediately.
9. Review and update policies and procedures for employee safety annually.

B. Testing Personnel

1. Review the site-specific safety plan.
2. Attend laboratory safety training.
3. Make sure training is properly documented.
4. Complete the Appendix A1. Safety Training Checklist.
5. Follow all safety policies and procedures.



6. Use appropriate engineering controls and PPE.
7. Report all incidents, accidents, and potential exposures to the individual overseeing testing.

IV. GENERAL SAFETY GUIDELINES

To ensure a safe work environment, follow the guidelines below.

A. Conduct

1. Maintain professionalism at all times.
2. Avoid working alone, if possible.
3. No horseplay in the workplace.
4. Learn the proper location, operation, and maintenance of safety equipment (i.e. fire alarms, fire extinguishers, eye wash stations, and safety showers).

B. Avoidance of Routine Exposures

1. Make certain that you are familiar with emergency and evacuation procedures.
2. Read all warning labels and manufacturer instructions prior to operating ANY equipment. *Do not use damaged equipment.
3. Be aware of potential hazards in the testing area.
4. Wear appropriate PPE.
5. Report ALL exposures immediately to the individual overseeing testing.

C. Personal Hygiene

1. Smoking, drinking, eating, gum chewing, applying or removing contact lenses and the application of cosmetics are forbidden in the testing area.
2. Do not store food in freezers or refrigerators designated for testing.
3. Wash hands frequently and thoroughly. At a minimum, before and after each patient.
4. Wear footwear that completely covers the feet.
5. Tie or pin-up long hair while performing the testing procedures.
6. Be cautious of any unsafe laboratory conditions. Notify the individual overseeing testing of any hazards.

D. Housekeeping Practices

1. Keep testing areas clean, organized, and free of clutter.
2. Clean spills efficiently and properly from work area and floors. Notify the individual overseeing testing.
3. Do not impede or use doorways and walkways for storage.
4. Keep all exits, emergency equipment and controls accessible.
5. Flush eyewash stations, if available, weekly and emergency showers every six months. Keep records for documentation.



E. Ergonomics

1. Perform an ergonomic assessment of work area, including chair, workstation, desk, and computer.
2. Provide an environment that limits ergonomic stress.

V. SAFETY SIGNAGE AND LABELING

The individual overseeing testing is responsible for posting safety and hazard warning signs, as necessary, for use by all employees. The following information should be posted in and next to testing areas:

- A. Phone numbers of emergency personnel/facilities, and the individual overseeing testing.
- B. Identity labels, showing contents of containers and associated hazards.
- C. Location signs for safety showers, eyewash stations, other safety and first aid equipment and exits.
- D. Warnings at areas or equipment where special or unusual hazards exist.

VI. SHARPS REDUCTION POLICY PRACTICES

The Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard requires laboratories to institute practices that reduce injuries from needles and other sharp objects used in the testing site. The following practices need to be used by all personnel who collect samples and perform testing:

- A. Needleless systems should be used whenever possible. Sharp objects such as needles, glass pipettes, etc. should be used only when there is no alternative available.
- B. Needles (do not resheath, recapping of needles is prohibited), syringes, slides, pipettes, capillary tubes, scalpels, broken glass must be placed in a rigid puncture-resistant disposable container with a lid.
- C. Do not touch broken glass; it should be removed mechanically using forceps, brush and dust pan, etc. Deposit in sharps container.

VII. CONTAMINATION PROCEDURES

The procedures listed below are intended as a resource for preparing and responding to spills and testing personnel exposure.

A. Spill Kit

1. Testing sites should keep a spill kit handy if working with a hazardous or infectious substance.
2. Biohazard Spill Kit Contents:
 - a) Disinfecting solution
 - b) Forceps or tongs, disposable broom and dustpan or other device for handling sharps
 - c) Paper towels
 - d) Biohazard bags
 - e) Waterproof utility gloves and examination gloves



- f) Face protection (face shield, splash goggles, disposable face mask)
- g) Disposable scrubs
- h) Spill sign to post on door to room

B. Biohazard Spill Procedure

1. Avoid inhaling airborne material while quickly leaving the room.
2. Notify others to leave. Close door and post with a warning sign.
3. Remove contaminated clothing, turn exposed area inward and place in a biohazard bag. Launder contaminated clothing/lab coats in hot water with bleach.
4. Wash exposed skin with antiseptic soap and water.
5. Wear appropriate PPE: gloves, lab coat, and splash goggles.
6. Cover spill with paper towels and carefully pour a 10% sodium hypochlorite (bleach) solution or other appropriate disinfectant on the towels and around the spill allowing it to mix with the material. If using a disinfectant product, follow the manufacturer's instructions for proper use, concentration, and contact time. When using bleach for this initial decontamination step, allow it to soak for at least 20 minutes.
7. Using forceps or tongs pick up any pieces of broken glass and place them in a sharps container.
8. Carefully pick up the absorbent toweling and the bulk of the spill material and discard these into a biohazard bag. Use fresh toweling to wipe up any residual material and discard along with the other disposable materials.
9. Clean the surface with an EPA-registered detergent/disinfectant and allow to air dry. Alternatively, clean the surface with detergent and water, followed with an application of bleach solution. Allow to air dry.
10. Remove disposable gloves and discard as biohazardous waste. Discard any disposable protective clothing used during spill clean-up. Clean and disinfect utility gloves, face shield, goggles, and any other reusable item used during spill clean-up.
11. Wash hands with antiseptic soap and water.
12. Dispose of biohazardous waste following applicable regulations.
13. Notify individual overseeing testing and document the incident accordingly.
14. Replenish or replace any items used in the spill kit.

C. Exposed Personnel Procedures

1. Splashes to face (eyes, nose and mouth)
 - a) Use the eyewash to flush exposed area.
 - b) Report to the individual overseeing testing immediately for prophylaxis, if necessary.



2. Hands or other exposed skin
 - a) Wash with antiseptic or soap.
 - b) Report to the individual overseeing testing immediately for prophylaxis, if necessary.
3. Needlesticks and Puncture Wounds
 - a) Squeeze around the injury to encourage the flow of blood out of the wound.
 - b) Report to the individual overseeing testing immediately for prophylaxis, if necessary.

D. Documentation Procedures

1. All spills and/or exposures should be documented.
2. The incidents should be reviewed by the individual overseeing testing and work practices put in place to prevent reoccurrence, if necessary. [Appendix A2: Example Incident Report](#).
3. Comply with OSHA injury and illness reporting.

VIII. APPENDICES

A1. Safety Training Checklist

A2. Incident Report



Appendix A1

SAFETY TRAINING CHECKLIST INSTRUCTIONS

Purpose:

Workers in many different occupations are at risk of exposure to bloodborne pathogens, including hepatitis B, hepatitis C, and HIV. First aid team members, housekeeping personnel, nurses, and other healthcare providers are examples of workers who may be at risk of exposure.

Contents:

There are many ways to document safety training for new employees. A blank checklist is included for your use, along with an example checklist that demonstrates how to correctly enter site specific information.

1. Example Safety Training Checklist Completed.
2. Blank Safety Training Checklist.

Instructions for Completing the Safety Training Checklist:

1. Train new employees on work practices, procedures, and the importance of safety.
2. Employees should sign the Safety Training Checklist indicating their understanding and willingness to follow established safety practices.
3. File signed form with employee records.

EXAMPLE

Facility: *Dr. Smith's Office*

Location: *123 Main Street
Atlanta, GA 5555*

Safety Training Checklist

Purpose: To ensure new employees have been properly advised and trained regarding safety-related issues. MUST be completed before employee performs testing.				
Objective	Date completed	Employee initials	Trainer initials	Comments
Discussed use of universal precautions when working with human blood or body fluids including Bloodborne Pathogen training.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Received appropriate immunizations as determined by individual overseeing testing.	<i>2/12/2015</i>	<i>CO</i>	<i>SS</i>	
Discussed hazardous chemical inventory and safe use of hazardous chemicals in the laboratory. Reviewed Material Safety Data Sheets (MSDS).	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Shown where First AID Kits and AED's (if available) are located.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Shown where Biosafety and Chemical Spill Kits (if applicable) are located.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Reviewed procedures for obtaining supplies.	<i>2/16/2015</i>	<i>CO</i>	<i>SS</i>	
Discussed required use of personal protective equipment (PPE).	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Provided appropriate PPE.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Shown where fire extinguishers are located.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Discussed ergonomics in the work place.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Reviewed procedure on waste disposal:	<i>2/16/2015</i>	<i>CO</i>	<i>SS</i>	
Infectious	<i>2/16/2015</i>	<i>CO</i>	<i>SS</i>	
Non-infectious	<i>2/16/2015</i>	<i>CO</i>	<i>SS</i>	
Hazardous chemical	<i>2/16/2015</i>	<i>CO</i>	<i>SS</i>	
Sharps	<i>2/16/2015</i>	<i>CO</i>	<i>SS</i>	
Reviewed emergency response procedures:	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Infectious material spill or release	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Hazardous chemical spill or release	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Fire or explosion	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Medical emergency	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Bomb threat	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Shelter In Place	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	
Provided instructions on Incident Reporting.	<i>2/15/2015</i>	<i>CO</i>	<i>SS</i>	

Comments: *Colleen has worked in a CLIA certified laboratory previously and is familiar with the appropriate safety requirements. We reviewed everything and I feel confident that she understands and will comply with our safety rules.*

Trainer Signature: *Sara Smith* Date: *02/16/2015*
 Employee Signature: *Colleen Olson* Date: *02/16/2015*
 Supervisor Review: *Joe Smith, MD* Date: *02/16/2015*

Facility:

Location:

Safety Training Checklist

Purpose: To ensure new employees have been properly advised and trained regarding safety-related issues. MUST be completed before employee performs testing.				
Objective	Date completed	Employee initials	Trainer initials	Comments
Discussed use of universal precautions when working with human blood or body fluids including Bloodborne Pathogen training.				
Received appropriate immunizations as determined by individual overseeing testing.				
Discussed hazardous chemical inventory and safe use of hazardous chemicals in the laboratory. Reviewed Material Safety Data Sheets (MSDS).				
Shown where First AID Kits and AED's (if available) are located.				
Shown where Biosafety and Chemical Spill Kits (if applicable) are located.				
Reviewed procedures for obtaining supplies.				
Discussed required use of personal protective equipment (PPE).				
Provided appropriate PPE.				
Shown where fire extinguishers are located.				
Discussed ergonomics in the work place.				
Reviewed procedure on waste disposal:				
Infectious				
Non-infectious				
Hazardous chemical				
Sharps				
Reviewed emergency response procedures:				
Infectious material spill or release				
Hazardous chemical spill or release				
Fire or explosion				
Medical emergency				
Bomb threat				
Shelter In Place				
Provided instructions on Incident Reporting.				

Comments: _____

Trainer Signature: _____ Date: _____

Employee Signature: _____ Date: _____

Supervisor Review: _____ Date: _____



INCIDENT REPORT INSTRUCTIONS

Purpose:

Some injuries, exposures, or other incidents require immediate first aid and post-exposure intervention to limit risks to life and health. Workers should be familiar with all aspects of the work being done in their work areas and the appropriate steps to take if a workplace safety or medical incident occurs.

Patient testing has the potential to expose individuals to a large variety of biological and chemical agents while performing job duties. Extreme care should be taken to limit this risk. If such an event should occur, follow the site-specific guidelines in your work area for immediate intervention. Be familiar with the recommendations for immediate response if an exposure occurs. Ask the individual overseeing testing for site-specific information regarding your own work area.

All work-related injuries, illnesses, and incidents (chemical spill, minor fire, injury, etc.) should be evaluated from a standpoint of future prevention. Occupationally-related injuries and illnesses may offer opportunities for work practice or safety improvements in the workplace.

Contents:

There are many ways to document incidents. A blank report is included for your use, along with an example report that demonstrates how to correctly enter site specific information.

1. Example Incident Report Completed.
2. Blank Incident Report.

Instructions for Completing the Incident Report:

1. The employee involved in the incident should complete the Incident Report to the best of their abilities.
2. Once completed, the incident should be evaluated for corrective action.
3. Corrective action should be taken and documented on the Incident Report.
4. The individual overseeing testing should review and sign the report.
5. File the report accordingly.
6. If the site has ten or more employees at any time during the last calendar year, you must keep OSHA Injury & Illness Recordkeeping Forms, 300 series available at: <https://www.osha.gov/recordkeeping/RKforms.html>
7. If your company has ten or fewer employees at all times during the last calendar year, you do not need to keep OSHA injury and illness records unless OSHA informs you in writing that you must keep records.
8. Report to OSHA any workplace incident resulting in the death of any employee from a work-related incident or the in-patient hospitalization of three or more employees as a result of a work-related incident. Reporting of the fatality/multiple hospitalization may be done by telephone or in person to the OSHA office nearest to the site of the incident.

EXAMPLE

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 5555

Incident Report

Name of Person Involved in Incident: Sara Smith

Date of Incident: 06/30/2015 Time of Incident: 2:30 PM

Location of Incident: Well patient room 2

Description of Incident: [Type of incident, e.g., illness, accident, injury. Indicate circumstances and who was involved. Indicate any substances (e.g., amount and kind of chemical) or object involved.]

Applied fingerstick device to self instead of patient and triggered the device.

The device was held the wrong way, with the opposite end facing the patient's finger.

When triggered, the device inserted the needle into Ms. Smith's finger instead of the patient

Action Taken:

A. First Aid: Wash, Burn, Band-Aid, Eyewash, or other _____

_____ B. Medical Treatment beyond First Aid: _____

_____ C. Clean-up or Spill _____ D. Fire _____ E. Evacuation

Preventive Measures to Prevent Reoccurrence (if applicable):

Re-trained personnel on proper use and safety of fingerstick devices.

Training performed on 6/12/2008, documented and filed.

To be completed by person involved in incident:

Did your supervisor advise you on the hazards of the workplace as part of training? Y / N

Were you wearing appropriate PPE (gloves, face shield, etc) properly? Y / N

Did you read and sign the Safety Training Checklist before working in the lab? Y / N

What do you believe was the cause of the incident?

Not paying attention and made a mistake

Reviewed by: Colleen Olson Date: 06/30/2015

Facility:

Location:

Incident Report

Name of Person Involved in Incident: _____

Date of Incident: _____ **Time of Incident:** _____

Location of Incident: _____

Description of Incident: [Type of incident, e.g., illness, accident, injury. Indicate circumstances and who was involved. Indicate any substances (e.g., amount and kind of chemical) or object involved.]

Action Taken:

_____ A. First Aid: Wash, Burn, Band-Aid, Eyewash, or other _____

_____ B. Medical Treatment beyond First Aid: _____

_____ C. Clean-up or Spill _____ D. Fire _____ E. Evacuation

Preventive Measures to Prevent Reoccurrence (if applicable):

To be completed by person involved in incident:

Did your supervisor advise you on the hazards of the workplace as part of training? Y / N

Were you wearing appropriate PPE (gloves, face shield, etc) properly? Y / N

Did you read and sign the Safety Training Checklist before working in the lab? Y / N

What do you believe was the cause of the incident?

Reviewed by: _____ Date: _____



SECURITY AND CONFIDENTIALITY AGREEMENT INSTRUCTIONS

Purpose:

The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement the requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule standards address the use and disclosure of individuals' health information— called protected health information (PHI) by organizations subject to the Privacy Rule— called covered entities, as well as standards for individuals' privacy rights to understand and control how their health information is used.

The Privacy Rule protects all PHI held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. PHI is information including demographic data that relates to:

- the individual's past, present or future physical or mental health or condition,
- the provision of health care to the individual, or
- the past, present, or future payment for the provision of health care to the individual, and
- identifies the individual or for which there is a reasonable basis to believe can be used to identify the individual.

PHI includes many common identifiers (e.g., name, address, birth date, Social Security Number).

Good work practices should be in place to prevent the disclosure of PHI. New employees should be trained on these practices. This Security and Confidentiality Agreement form documents the agreement of all employees to abide by HIPAA's Privacy Rule and prevent disclosure of patient PHI.

Contents:

There are many ways to document compliance training with HIPAA. A blank form is included for your use, along with an example form that demonstrates how to correctly enter site specific information.

1. Example Security and Confidentiality Agreement Form Completed.
2. Blank Security and Confidentiality Form.

Instructions for Completing the Security and Confidentiality Agreement Form:

1. Train new employees on the work practices and the importance of HIPAA.
2. Employees should sign the Security and Confidentiality Agreement Form indicating their understanding and willingness to adhere to HIPAA.
3. File signed form with employee records.

EXAMPLE

Facility: *Dr. Smith's Office*

Location: *123 Main Street
Atlanta, GA 5555*

Security and Confidentiality Agreement

1. I understand that the patient and organization information I will be able to access on-line, by voice-transmission, and/or on paper is confidential and may be legally privileged. I have an obligation to protect data from loss, misuse, or unauthorized access or disclosure. The obligation to maintain confidentiality of information extends beyond work time to include personal time as well.
2. I acknowledge that patient information including demographics, patient care and results, are confidential, and are protected by legal and regulatory guidelines. Further, this data should not be shared without appropriate consents, authorizations or considerations. Accordingly, I understand that I am not allowed to share my password/ID access with others and that I have an obligation to close any computer session I open so that my access cannot be used by others.
3. I understand that improper access or disclosure of data may subject me to disciplinary and legal action. Similarly, if I exceed my computer system access authority or engage in conduct outside of the scope of my duties, I may be subject to disciplinary action.
4. I understand and agree to behave in a professional, ethical manner at all times regarding patient and organizational confidentiality.

Colleen Olson

Employee Signature

02/15/2012

Date

Colleen Olson

Printed Name

Facility:

Location:

Security and Confidentiality Agreement

1. I understand that the patient and organization information I will be able to access on-line, by voice-transmission, and/or on paper is confidential and may be legally privileged. I have an obligation to protect data from loss, misuse, or unauthorized access or disclosure. The obligation to maintain confidentiality of information extends beyond work time to include personal time as well.
2. I acknowledge that patient information including demographics, patient care and results, are confidential, and are protected by legal and regulatory guidelines. Further, this data should not be shared without appropriate consents, authorizations or considerations. Accordingly, I understand that I am not allowed to share my password/ID access with others and that I have an obligation to close any computer session I open so that my access cannot be used by others.
3. I understand that improper access or disclosure of data may subject me to disciplinary and legal action. Similarly, if I exceed my computer system access authority or engage in conduct outside of the scope of my duties, I may be subject to disciplinary action.
4. I understand and agree to behave in a professional, ethical manner at all times regarding patient and organizational confidentiality.

Employee Signature

Date

Printed Name



TRAINING CHECKLIST INSTRUCTIONS

Purpose:

All employees need to understand their role in the organization as a whole, learn the expectations of their supervisor, and practice the basic elements of their job. Their experience in the first few weeks will have a significant effect on the level of commitment and ability to become productive quickly.

Checklists provide a structured approach to training new employees. Checklists allow new employees to work through the training agenda at their own pace, spending less time on issues with which they are already familiar, and more time on those issues that are new or unfamiliar to them.

A well-designed training checklist can serve as a guide for new arrivals as they learn all the elements of their job.

Contents:

There are many ways to document training. A blank checklist is included for your use, along with an example checklist that demonstrates how to correctly enter site specific information.

1. Example Training Checklist Completed.
2. Blank Training Checklist.

Instructions for Completing the Training Checklist:

1. The employee should read the procedure that they will be trained to perform.
2. The trainer should review the procedure before beginning the training.
3. The trainer will demonstrate the procedure explaining each step as they perform it.
4. The trainee will perform the procedure and be able to explain key steps.
5. Upon completion, the trainer and trainee will document the training with the checklist and address any issues or concerns that arise. If re-training is necessary, this should be documented on the checklist.
6. The checklist should be filed with the employee's other records.

EXAMPLE

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 5555

Training Checklist

Trainee: Colleen Olson

Date: 05/06/2015 Trainer: Sara Smith

Test: ABC Test Kit

Trainer should review all material listed below and verify that the trainee has read the appropriate procedures or manufacturer instructions involved and understands them. File completed form appropriately.

Checklist	Date Completed	Trainee Initials	Trainer Initials
1. Trainee reads and understands procedure	05/03/2015	CO	SS
2. Trainer discusses principle of test procedure so that trainee understands scope and purpose of the test.	05/04/2015	CO	SS
3. Trainer identifies materials to perform test and trainee knows location of materials needed.	05/03/2015	CO	SS
4. Trainee observes proper sample collection and handling.	05/03/2015	CO	SS
5. Trainee observes test procedure performed by trainer.	05/03/2015	CO	SS
6. Trainee performs the procedure and should be able to: a. Identify proper sample type, use of the appropriate collection device, labeling, and handling of samples b. Organize work area for testing c. Perform quality control (QC) samples & training panel prior to performing patient samples. d. Set up timer and follow incubation times per the procedure e. Interpretation of results 1) positive 2) negative 3) invalid f. Decontaminate and clean work area, including proper disposal of hazardous waste and sharps	05/06/2015	CO	SS
7. Data entry/Computer. a. Test order and accessioning b. QC and interpretation of results c. Report results and log QC data	05/06/2015	CO	SS

Trainee Comments: Sara was very clear in her explanations and knew all the answers to my questions

Trainee Signature: Colleen Olson Date: 05/06/2015

Trainer Comments: Colleen was attentive and followed directions

Trainer Signature: Sara Smith Date: 05/06/2015

Facility:

Location:

Training Checklist

Trainee: _____

Date: _____ **Trainer:** _____

Test: _____

Trainer should review all material listed below and verify that the trainee has read the appropriate procedures or manufacturer instructions involved and understands them. File completed form appropriately.

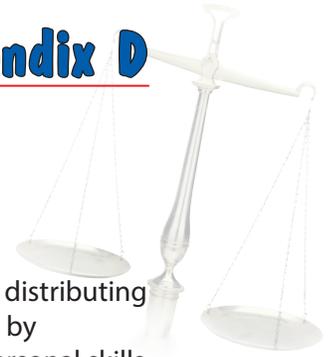
Checklist	Date Completed	Trainee Initials	Trainer Initials
1. Trainee reads and understands procedure			
2. Trainer discusses principle of test procedure so that trainee understands scope and purpose of the test.			
3. Trainer identifies materials to perform test and trainee knows location of materials needed.			
4. Trainee observes proper sample collection and handling.			
5. Trainee observes test procedure performed by trainer.			
6. Trainee performs the procedure and should be able to: a. Identify proper sample type, use of the appropriate collection device, labeling, and handling of samples b. Organize work area for testing c. Perform quality control (QC) samples & training panel prior to performing patient samples. d. Set up timer and follow incubation times per the procedure e. Interpretation of results 1) positive 2) negative 3) invalid f. Decontaminate and clean work area, including proper disposal of hazardous waste and sharps			
7. Data entry/Computer. a. Test order and accessioning b. QC and interpretation of results c. Report results and log QC data			

Trainee Comments: _____

Trainee Signature: _____ Date: _____

Trainer Comments: _____

Trainer Signature: _____ Date: _____



TRAINING EVALUATION INSTRUCTIONS

Purpose:

The individual overseeing testing acts as an advocate for employees by gathering and distributing the resources needed by employees in order for them to be able to do a good job and by providing positive encouragement for a job well done. They should display the interpersonal skills required to engage employees and enhance their self-confidence.

Feedback from employees on the training experience provides valuable information to employers seeking to improve or identify gaps in their training programs. This method also opens an avenue of communication between the employee and employer.

Many training programs fail to deliver the expected organizational benefits. Having a well-structured measuring system in place can help you determine where the problem lies.

Contents:

There are many ways to evaluate training. A blank evaluation form is included for your use, along with an example evaluation form that demonstrates how to correctly enter site specific information.

1. Example Training Evaluation Completed.
2. Blank Training Evaluation.

Instructions for Completing the Training Evaluation:

1. After training is completed, the trainee should complete the Training Evaluation.
2. The trainee should be honest and open about the training experience without fear of remedial action or other adverse reactions as a result of the evaluation.
3. Management should review and compile the results to assess the training program's effectiveness and make improvements and changes to the program as necessary.

EXAMPLE

Facility: *Dr. Smith's Office*

Location: *123 Main Street
Atlanta, GA 5555*

Training Evaluation

Date: 2/16/2015

Trainee: Colleen Olson

Item	Circle Y (Yes) or N (No)	Comments	Score <i>1= unsatisfactory 2= satisfactory 3= very good</i>
Was the process clearly explained?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
Was (were) the procedure(s) clearly demonstrated?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
Were you shown where to get supplies and equipment?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
Were you given enough time to practice?	Y <input checked="" type="radio"/> N	<i>I felt rushed and it seemed that Sarah was too busy while training me.</i>	1
Was the trainer approachable?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
Did you feel comfortable asking questions?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
If the trainer did not know the answer, could he/she find the information?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
When you did the procedure(s), were you corrected respectfully?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
Did you get constructive, timely feedback?	<input checked="" type="radio"/> Y <input type="radio"/> N		3
Did you feel comfortable performing the procedure(s) on your own?	Y <input checked="" type="radio"/> N	<i>I felt like I needed a few more times running the test with Sarah observing me prior to testing patient samples.</i>	1
Were you asked questions to gauge your knowledge and understanding of the process or procedure(s)?	<input checked="" type="radio"/> Y <input type="radio"/> N		3

Trainer(s) being evaluated: Sara Smith

Facility:

Location:

Training Evaluation

Date: _____ Trainee: _____

Item	Circle <i>Y (Yes) or N (No)</i>	Comments	Score <i>1= unsatisfactory 2= satisfactory 3= very good</i>
Was the process clearly explained?	Y N		
Was (were) the procedure(s) clearly demonstrated?	Y N		
Were you shown where to get supplies and equipment?	Y N		
Were you given enough time to practice?	Y N		
Was the trainer approachable?	Y N		
Did you feel comfortable asking questions?	Y N		
If the trainer did not know the answer, could he/she find the information?	Y N		
When you did the procedure(s), were you corrected respectfully?	Y N		
Did you get constructive, timely feedback?	Y N		
Did you feel comfortable performing the procedure(s) on your own?	Y N		
Were you asked questions to gauge your knowledge and understanding of the process or procedure(s)?	Y N		

Trainer(s) being evaluated: _____



COMPETENCY AND PERFORMANCE ASSESSMENT INSTRUCTIONS

Purpose:

The ability of each person to perform their duties should be assessed following training and periodically thereafter. Retraining and reassessment of employee performance needs to be done when problems are identified with employee performance. The training and assessment program should be documented and specific for each job description. Activities requiring judgment or interpretive skills need to be included in the assessment.

Performance assessment can

- identify key training areas,
- identify processes that need improvement,
- provide supervisors and managers with data on employee performance, and
- provide evidence to customers and management that the laboratory assures quality with trained staff.

Some elements of performance assessment include:

- observing routine patient test performance, including sample handling, processing and testing;
- monitoring recording and reporting of test results;
- reviewing intermediate test results or worksheets, QC records, proficiency testing results, and preventive maintenance records;
- observing performance of instrument maintenance and function checks;
- assessing test performance through testing previously analyzed samples, internal blind testing samples, or external proficiency testing samples; and
- evaluating problem-solving skills.

Contents:

There are many ways to assess testing competency. A blank assessment is included for your use, along with an example assessment that demonstrates how to correctly enter site-specific information.

1. Example Performance Assessment Completed.
2. Blank Performance Assessment.

Instructions for Completing the Performance Assessment:

1. Record the facility name and location.
2. Record the employee's name and the procedure being observed.
3. Have the employee perform the procedure.
4. Record whether the steps completed were satisfactory or unsatisfactory, note any comments, and document any corrective action needed.
5. Sign and date the form.
6. Have the employee sign and date the form and provide comments.

EXAMPLE

Facility: Dr. Smith's Office

Location: 123 Main Street
Atlanta, GA 5555

Performance Assessment

Employee Name: Colleen Olson

Procedure to be Observed: ABC Test Kit

Instructions to the Employee:

1. Review the procedure and package insert.
2. Perform the procedure, including collecting the sample, equipment maintenance, and records management, while being observed.
3. Your performance will be based on how well you follow the procedure. You may refer to the written procedure during the performance of the procedure. If the evaluation of your performance is unsatisfactory, you will be given instructions for corrective action.
4. If you find that the written procedure is unclear or missing necessary information, please make a note in the employee comments section below.

Instructions to the Observer:

1. Select previously analyzed samples or samples with known results for the employee to demonstrate the procedure.
2. Directly observe the employee perform each step of the procedure. If any step of the procedure is performed incorrectly, please note this in the observer comments section.
3. Test the employee's problem solving skills with a question or observe the employee resolving a problem.
4. If procedure is followed correctly, mark as satisfactory. If there are steps that are not followed, then mark unsatisfactory and describe the corrective action necessary to obtain a satisfactory rating.
5. Record your name and date on the 'observed by' line.
6. Ask the employee to sign and date the form and file appropriately.

Assessment of Sample Handling Satisfactory Unsatisfactory

Assessment of Test Performance Satisfactory Unsatisfactory

Assessment of Quality Control Satisfactory Unsatisfactory

Assessment of Data Management Satisfactory Unsatisfactory

Assessment of Problem Solving Satisfactory Unsatisfactory

Observer Comments: Colleen did not know where to file completed result forms.

Corrective Action Needed (if applicable): We discussed the proper procedure and I showed her where the forms are filed

Observed By: Sara Smith

Date: 4/27/2015

Reviewed by Employee: Colleen Olson

Date: 4/27/2015

Employee Comments: Sarah was very polite and explained the procedure clearly.

Facility: _____

Location: _____

Performance Assessment

Employee Name: _____

Procedure to be Observed: _____

Instructions to the Employee:

1. Review the procedure and package insert.
2. Perform the procedure, including collecting the sample, equipment maintenance, and records management, while being observed.
3. Your performance will be based on how well you follow the procedure. You may refer to the written procedure during the performance of the procedure. If the evaluation of your performance is unsatisfactory, you will be given instructions for corrective action.
4. If you find that the written procedure is unclear or missing necessary information, please make a note in the employee comments section below.

Instructions to the Observer:

1. Select previously analyzed samples or samples with known results for the employee to demonstrate the procedure.
2. Directly observe the employee perform each step of the procedure. If any step of the procedure is performed incorrectly, please note this in the observer comments section.
3. Test the employee's problem solving skills with a question or observe the employee resolving a problem.
4. If procedure is followed correctly, mark as satisfactory. If there are steps that are not followed, then mark unsatisfactory and describe the corrective action necessary to obtain a satisfactory rating.
5. Record your name and date on the 'observed by' line.
6. Ask the employee to sign and date the form and file appropriately.

Assessment of Sample Handling _____ Satisfactory _____ Unsatisfactory

Assessment of Test Performance _____ Satisfactory _____ Unsatisfactory

Assessment of Quality Control _____ Satisfactory _____ Unsatisfactory

Assessment of Data Management _____ Satisfactory _____ Unsatisfactory

Assessment of Problem Solving _____ Satisfactory _____ Unsatisfactory

Observer Comments: _____

Corrective Action Needed (if applicable): _____

Observed By: _____ **Date:** _____

Reviewed by Employee: _____ **Date:** _____

Employee Comments: _____

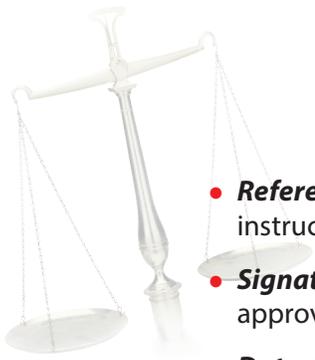


PROCEDURE CONTENTS AND TIPS

Procedure Contents:

Written procedures can be developed from the manufacturer's instructions to include specific instructions for your testing site. When writing procedures, it is helpful to use a general template with standard headings. Headings that are often used for writing procedures are:

- **Title (Test Name)**— the title should clearly state the intent of the procedure.
- **Purpose**— states what the test measures and clinical use of the result.
- **Materials**— lists all materials, reagents, supplies, equipment needed and how to prepare them.
- **Sample**— describes the type of sample, how to collect it, how to store it, and patient pre-test information or preparation instructions.
- **Special Safety Precautions**— indicates any safety requirements that are unique to this procedure or need to be highlighted.
- **Quality Control (QC)**— describes the types of controls for the test, steps to perform QC, how often to test, interpreting the results, and how to recognize and correct problems.
- **Procedure**— use the manufacturer instructions for:
 - Step by step test instructions, including QC,
 - The order of adding reagents, mixing and timing.
- **Method Performance Specifications**— this section should include information about precision, accuracy, and specificity as well as the reportable range for the test. Information on interfering substances, or conditions that can affect the test result should also be included in this section.
- **Expected Values**— the reference range for the test based on sample type, age, sex, or race, if applicable.
- **Interpreting, Recording, and Reporting Results**
 - How to read and interpret test results (photos or diagrams from the manufacturer instructions are especially useful)
 - Comparison of the results to the expected values or diagnostic findings to determine if the result is normal, abnormal, or indeterminate
 - Follow-up for indeterminate results
 - Criteria for referral of samples including procedures for sample submission and handling
 - How to report results
 - Actions to take if results cannot be reported (invalid or out of range values). Include contact information for the manufacturer, individual overseeing testing or other consultants
 - Follow-up for results that exceed critical limits and are considered life-threatening results or panic (critical) values



- **References**— list any references used in writing the procedure such as the manufacturer instructions for the test.
- **Signature**— the individual overseeing testing should sign and date after reviewing and approving the contents.
- **Date procedure put into use**— record the date the procedure became effective or the date each revision was made.

Tips for a Useful Procedure Manual

- ✓ Use a three-ring or similar binder to maintain the manual in a format that is easily reviewed and updated.
- ✓ Provide electronic versions, if available.
- ✓ Use tabs or a table of contents for easy reference.
- ✓ Use plastic sheet protectors to extend the “shelf-life” of the manual.
- ✓ Write each procedure at a level that all personnel who perform testing can understand.
- ✓ Keep a copy of the manual in the work area.
- ✓ If there is more than one copy of the manual, ensure they are all current and include the same information.
- ✓ Include a page at the front of the manual where personnel can “sign-off” when they have read the manual.
- ✓ All staff who oversee and perform testing should review the manual annually.



TERMS AND ABBREVIATIONS

Accuracy	True or target value determined by comparing results to accepted correct results or by comparing to results from another laboratory using a comparable method.
Biohazard	A biologic substance that can have harmful effects on humans.
Biohazardous waste	Biohazard or sharps waste and waste that is generated or produced as a result of the diagnosis, treatment, or immunization of humans. Environmental laws dictate appropriate, safe disposition of hazardous waste. Refer to applicable federal, state, and local laws.
Biosafety	The application of practices, procedures and safety equipment when working with infectious materials to prevent infection.
Bloodborne pathogens	Microorganisms that, when present in human blood, can cause disease in humans. Examples are hepatitis B and C viruses, and human immunodeficiency virus (HIV).
CDC, The Centers for Disease Control and Prevention	A federal agency under the department of Health and Human Services (HHS) that works with partners throughout the nation and world by collaborating to create the expertise, information, and tools that people and communities need to protect their health— through health promotion, prevention of disease, injury and disability, and preparedness for new health threats.
CLIA, The Clinical Laboratory Improvement Amendments of 1988	United States federal regulatory standards that set forth the conditions that all laboratories must meet to be certified to perform testing on human samples.
CMS, The Centers for Medicare and Medicaid	A federal agency under HHS that has the administrative responsibility for the CLIA program.
Certificate of Waiver	A certificate issued or reissued by the Centers for Medicare & Medicaid Services to a testing site performing only waived tests.
Compliance	The act of adhering to, and demonstrating adherence to, a standard or regulation.
Contamination	The accidental introduction of “foreign” material that can seriously distort the results of experiments where small samples are used.
Control	A device or solution used to monitor a test system to ensure proper test performance and correct results.
Corrective action	A method used to remedy a situation, remove an error, adjust a condition, or prevent recurrence of a problem.
Decontamination	The removal or neutralization of toxic agents or the use of physical or chemical means to remove, inactivate, or destroy living organisms on a surface or item so that the organisms are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.
Disinfectant	An agent that destroys microorganisms that may cause disease.
Disinfection	A process by which viable biohazardous agents are reduced to a level unlikely to produce disease in healthy people, plants, or animals.
EPA, The Environmental Protection Agency	The United States government agency with the mission of protecting human health and the environment.
Engineering Controls	Controls (e.g., sharps containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.
Ergonomics	The science of fitting workplace conditions and job demands to the capabilities of the working population.
Exposure	Contact with blood or other potentially infectious materials that result from the performance of an employee’s duties.
External assessment	A review that is typically performed by an outside party to evaluate current practices and offer opportunities for education.
FDA, The Food and Drug Administration	A federal agency under HHS that is responsible for regulating and supervising the safety of biological and medical products and devices as well as categorization of tests under CLIA, including waiver.

Fingerstick	A procedure in which a finger is pricked to obtain a small quantity of capillary blood for testing. Also called a finger prick.
Good laboratory practices	A technique, method, process, activity, incentive or reward that is believed to be more effective at delivering a particular outcome than any other technique, method, or process.
HHS, The Department of Health and Human Services	The United States government's principal agency for protecting the health of all Americans and providing essential human services.
HIPAA, Health Insurance Portability and Accountability Act of 1996	The Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes.
Infectious materials	Materials containing viable microorganisms including bacterium, virus, rickettsia, parasite, fungus, or recombinant, hybrid or mutant that is known or reasonably believed to cause disease in humans or animals.
Interfering substance, Interferences	Any substance in a sample, other than the one being measured or detected, whose presence affects the result of the test.
Internal assessment	A review that staff performing and overseeing testing perform to evaluate their current practices. The process of critical review of the laboratory.
Kit	A packaged set containing test devices, instructions, reagents and supplies needed to perform a test and generate results.
Limitations	Describes conditions that might influence the test results or for which the test is not designed.
Log	A record documenting the performance of a machine, the progress of an undertaking, or the results of a task.
Lot	A specific group of articles in a kit. Each article may have a number that can be used as a reference for manufacturing information.
Manufacturer's instructions	Written product information usually supplied by the manufacturer with each test kit or test system containing instructions and critical details for performing the test.
Occupational Exposure	Reasonably anticipated skin, eyes, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
OSHA, The Occupational Safety and Health Administration	The United States government agency with the mission to assure safe and healthful working conditions for all men and women. Workplace standards established and enforced to prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules for workplace safety and health.
POC, Point of Care	The analysis of clinical samples as close as possible to the patient.
Pathogen	Any biohazardous agent that is capable of producing disease in healthy people, plants, or animals.
Performance assessment	The evaluation of a person's ability to perform a test and to use a testing device; this includes all aspects of testing, from sample collection to results reporting.
Phlebotomy	The practice of collecting venous blood samples.
PPE, Personal protective equipment	Specialized clothing or equipment worn by an employee for protection against a hazard. Examples of PPE are gloves, respirators, lab coats, and safety glasses.
Precision	Also called reproducibility or repeatability, the degree to which further measurements or calculations show the same or similar results.
Procedure	A fixed, step-by-step sequence of activities or course of action (with definite start and end points) that must be followed in the same order to correctly perform a task.
Processing (sample)	Any type of treatment a sample undergoes before testing such as spinning of whole blood.
Prophylaxis	A preventive measure. A prophylactic is a medication or a treatment designed and used to prevent a disease from occurring.

PT, Proficiency testing	An external quality assessment program in which samples are periodically sent to testing sites for analysis. Proficiency testing involves a group of laboratories or analysts performing the same analyses on the same samples and comparing results. The key requirements of such comparisons are that the samples are homogenous and stable, and also that the set of samples analyzed are appropriate to test and display similarities and differences in results.
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.
Qualitative test	A test that detects the presence or absence of a substance or condition in a sample.
Quantitative test	A test that measures the concentration or amount of a substance present in a sample. Results are numerical.
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.
Quick reference instructions	Cards or small signs containing diagrams or flow charts with essential steps for conducting a test that is often included with waived test systems.
Reagent	A substance that produces a chemical or biological reaction with the patient sample to detect or measure the substance or condition determined by the laboratory test.
Record	Anything (such as a document, form, log book) providing permanent evidence of or information about past events.
Referral testing	Sending a sample from a CW site (or other laboratories) to another site or laboratory to perform additional testing, often for follow-up confirmatory testing. The majority of referral laboratories perform nonwaived testing.
Report (test)	A document describing the result or findings of a test.
Sample	A specimen of fluid, blood or tissue collected for analysis on the assumption that it represents the composition of the whole.
Screening (tests)	Tests used to detect a disease in individuals without signs or symptoms of that disease.
Sensitivity (analyte)	The lowest concentration of an analyte that can reliably be detected or measured by a test system.
Sharps	Instruments, tools, or items that have rigid, acute edges, protuberances or corners capable of cutting, piercing, ripping or puncturing such as syringes, blades, and broken glass. Items that have the potential for shattering or breaking are also considered sharps.
Specificity (analyte)	The ability of a test to detect a particular substance or constituent without interference or false reactions by other substances.
Test system	The instructions and all the instrumentation, reagents and supplies needed to perform a test and generate results.
Testing site	The location where testing is actually conducted. In some instances, laboratories do not stay at a fixed location (e.g., mobile units providing laboratory testing, health screening fairs, or other temporary testing locations). In these cases, the testing site for the laboratory is where the test is performed.
Universal Precautions	An approach to infection control where all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bacteria and viruses.
Unprocessed samples	Samples that are not subjected to any type of treatment prior to testing such as centrifugation of whole blood.
Waived testing	Test systems, assays or examinations that have been cleared by the FDA for home use, or have been determined to meet the CLIA criteria of being a simple test with an insignificant risk for an erroneous result.

Notes



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Notes

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For additional information go to: <http://wwwn.cdc.gov/clia/Resources/WaivedTests/>
Contact the Division of Laboratory Science and Standards at WaivedTesting@cdc.gov
or by calling 404-498-2290.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

July 2015

