To Test or Not to Test?

Considerations for **Waived Testing**

https://www.cdc.gov/labquality/waived-tests.html

CDC

Introduction

Background

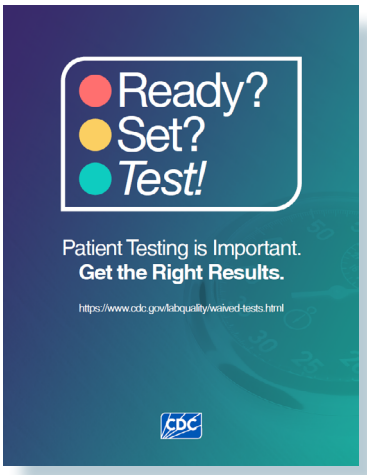
Test results help healthcare providers diagnose disease, determine prognosis, and monitor a patient's treatment or health status. Current practice shows that simple tests performed at the point of care play an increasingly prominent role in vital medical decisions.

Many of these tests can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS). These "waived tests" include test systems cleared by the Food and Drug Administration (FDA) for home use and those approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) criteria.

The FDA continually revises its list as new tests become eligible for approval. The most current information on FDA-cleared waived tests can be found at the following website: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Purpose

This booklet describes practices that should be considered when deciding whether to provide testing or not and may assist laboratory directors, supervisors, or leaders who want to implement and oversee waived testing or offer a new test under a CLIA Certificate of Waiver. You can use it alone or in combination with these additional CDC resources and training options:



- 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 Self-Assessment Checklist emphasizes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver. It can be used as a voluntary tool to help ensure good testing practices and reliable, high-quality test results.
- The **Ready? Set? Test!** online training provides scenario-based training on recommended practices for waived testing and offers continuing education credit.

You can access these and other resources and training information here: https://www.cdc.gov/labquality/waived-tests.html

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 enhance patient safety.

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Overall Considerations

Overview

Suppose you are thinking about beginning waived testing at your facility or adding a new test to your test menu. Before making that decision, you should carefully consider the potential benefits and issues that could arise.

Benefits

Waived testing comes with many benefits:

- Rapid results while the patient is on-site allowing for immediate follow-up.
- Simple tests require minimal training.
- Many waived tests are portable and can be easily used in nontraditional settings.

Issues to Consider

Despite the benefits of waived testing, the following should be considered when deciding when to perform testing on-site versus sending samples to a reference laboratory.

- **Testing Oversight —** Every site needs to designate a person responsible for testing and quality assurance.
- **Regulatory Requirements —** Every site must follow applicable federal, state, and/or local requirements for testing, confidentiality, and privacy.
- **Testing Location —** Testing sites must have adequate space, an appropriate physical environment, and accommodations for proper disposal of biohazardous waste.
- **Laboratory Safety —** Every site must follow applicable federal and state safety requirements, and all personnel need to know what to do when incidents happen.
- **Test Selection —** Every test has unique characteristics, sample requirements, and costs.
- **Testing Personnel —** Personnel who perform testing must be trained and periodically assessed on their ability to perform quality testing.
- **Instructions and Procedures —** Testing personnel should have access to, understand, and follow the current manufacturer's instructions.
- **Quality Assessment —** Testing sites should continually monitor, evaluate, and look for ways to improve testing quality.

Testing Oversight

Overview

Maintaining a consistently high level of quality and service should be a priority for everyone involved in patient care. You can help to achieve this goal at your laboratory testing site by designating someone to oversee testing, advise, and support testing personnel.

Responsibility for Management

Each laboratory testing site should identify someone to oversee testing and decision-making. This might be a physician or someone in a senior management position with the appropriate background, knowledge, and authority to make decisions about laboratory testing. The person overseeing testing should also:

- ✓ Understand how to comply with applicable regulatory requirements.
- ✓ 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. You can support testing personnel at your facility in many different ways:

- Post a list of emergency telephone numbers in a manner that is easily accessible to testing personnel.
- Identify a resource person or expert (e.g., a consultant or the test manufacturer's technical representative) available, either on- or off-site, to assist personnel and answer their questions.
- Post the manufacturer's technical assistance telephone numbers.
- Maintain all equipment and purchase service contracts for equipment maintenance requirements beyond your staff's abilities.
- Designate one person to discuss new tests and other testing materials with sales representatives or test distributors. This person should understand the requirements and impacts 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 laboratory testing site is subject to federal, state, and local regulations for testing and protecting confidential, personal information.

Waived Tests

Waived tests include test systems cleared by FDA for home use and those tests approved for waiver under the CLIA criteria. The FDA list of waived tests is continuously updated. Refer to the following website for the most current information on FDA-cleared waived tests and to verify if tests performed by your laboratory or testing site are categorized as waived. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm.

CLIA Certificate of Waiver

Before testing patient samples, laboratory testing sites must have a CLIA certificate issued by CMS. Locations performing one or more waived tests must file a Certificate of Waiver application. Each of your testing locations must obtain a separate certificate ***unless*** they qualify for one of the following exceptions:

- If your testing location changes (e.g., mobile units providing laboratory testing, health screening fairs, or other temporary testing locations), the location may be covered under the certificate of the designated primary site or home base, using its address.
- For limited public health testing, you may file a single application to cover multiple locations. Limited public health testing includes not-for-profit or federal, state, or local government laboratories that engage in limited testing (not more than a combination of 15 waived tests per certificate).
- For testing locations that are within contiguous buildings under common direction on a hospital campus, you may file a single application for the laboratory sites at the same physical location or street address.

To obtain a CLIA Certificate of Waiver, complete Form CMS-116 found at: https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms012169.

Send your completed Form CMS-116 to the address of your site's local CMS state agency. You should contact the state agency for additional forms that may be necessary to complete the registration process. CMS state agency contacts can be found at: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/contacts.

You can use the Laboratory Quick Start Guide to CMS CLIA Certification for assistance with your CLIA certification application. A printable version of the guide can be found here: https://www.hhs.gov/guidance/document/laboratory-quick-start-guide-cms-clia-certification.

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

- ✓ Your site may only perform waived tests.
- ✓ Your testing personnel must follow the current manufacturer's instructions for any waived tests being performed.
- ✓ Your site must pay the certificate renewal fee every two years.

- ✓ You must notify the applicable CMS state agency of any changes in site ownership, name, address, or director within 30 days.
- ✓ You must notify the applicable CMS state agency if you wish to add tests that are not waived to your test menu.
- ✓ You must allow CMS representatives on-site for announced or unannounced inspections.

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 performing tests not permitted with a Certificate of Waiver
- ✓ If there is a risk of harm to a patient due to inaccurate testing
- ✓ To collect information about practices being used at waived testing sites

For additional CLIA training (e.g., foundational information, the history and importance of CLIA, and regulatory implications for clinical laboratories and facilities that perform testing), refer to CDC's Introduction to Clinical Laboratory Improvement Amendments of 1988 (CLIA) online course: https://www.cdc.gov/labtraining/training-courses/Introduction-Clinical-Laboratory-Improvement-Amendments-1988.html.

"Off-Label Use" of Waived Tests

Based on a testing site's need and unique patient population, instances may arise where the site chooses to use an FDA-cleared or approved test system in a way other than the intended use per the manufacturer's instructions. This is considered an "off-label use" of a test system because it is not supported by the manufacturer's clinical data and was not part of the FDA-cleared or approved instructions.

Any off-label use of a test system is considered high-complexity testing under CLIA regulations, so any site performing off-label testing must meet CLIA requirements for high complexity testing. These include meeting requirements for proficiency testing (PT); establishing performance characteristics, quality control (QC), and quality assessment; and adhering to personnel qualification requirements. Laboratories or testing sites with a CLIA Certificate of Waiver will need to upgrade to a CLIA Certificate of Compliance or a CLIA Certificate of Accreditation to use a modified waived test.

Example of Off-Label Use of Waived Tests

The manufacturer's instructions of a waived blood glucose monitoring test system requires that the patient's hematocrit or oxygenation level falls within a specific range. Testing a patient whose levels fall outside the specified range would be an off-label use of this system. The manufacturer's clinical data do not support using the test in this situation. Test results could be inaccurate and lead to clinical interventions that cause patient harm.

State and Local Requirements

State and local jurisdictions vary in how they regulate laboratory testing. Some jurisdictions have requirements governing testing, personnel licensure, and phlebotomy. The person overseeing testing should ensure that the site meets all state and local requirements. When state, local, and federal requirements differ, the strictest requirement that applies to the laboratory testing site should be followed.

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. Laboratory testing sites are required to establish policies and procedures to protect the confidentiality of health and personal information about their patients, including patient identification and all testing results and records. All personnel should receive training on maintaining the confidentiality of patient information.

Several states have medical privacy laws that apply to laboratories and testing sites. Refer to the U.S. Department of Health and Human Services website for more information on HIPAA: https://www.hhs.gov/hipaa/index.html

See Appendix B for an example Security and Confidentiality Agreement form.

Testing Locations

Overview

Providing the appropriate physical environment for testing is vital to achieving reliable test results. Your testing personnel should have a clean work area to perform testing. This area should have space to ensure patient privacy and safety throughout the process. Each laboratory testing site should arrange for the proper disposal of hazardous waste.

Environment

If you are contemplating beginning testing or adding tests to your menu, consider the following physical environmental factors. These factors, in conjunction with the test manufacturer's instructions, will help you determine the best conditions for test performance and storage of reagents, test kits, controls, and patient samples for your laboratory testing site.

- **Workspace —** Testing workspaces should be stable and level, protect patient confidentiality, and allow for proper disinfection, sample collection, testing, and storage of supplies and records.
- **Lighting —** Sample collection and testing areas should be well-lit.
- **Ergonomics —** Tasks performed by employees should be considered and evaluated for ergonomic stressors that could manifest into injuries or repetitive stress disorders. Major ergonomic issues in the laboratory setting include static or awkward postures and repetitive motions. The environment should also be free from trip hazards.
- **Safety labels —** Clearly label all equipment and testing areas that present safety hazards.
- **Temperature range —** Follow the manufacturer's instructions for storage and testing and avoid temperature extremes, which can affect patient samples, reagents, components, reaction times, and test shelf-life.
- **Humidity levels —** Can affect reagents and test components, the rate of chemical reactions and sample interaction, and test endpoints. If applicable, acceptable humidity levels will be indicated in the manufacturer's instructions.
- **Utilities —** Some testing devices and equipment may require a source of electricity or water.
- **Housekeeping —** Testing areas should be clean, organized, and free of clutter. If applicable, ensure housekeeping staff are trained on the potential hazards of 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 laboratory testing site should have site-specific procedures that follow local, state, and federal requirements to safely dispose of biohazardous waste generated from sample collection and testing. Local hospitals or clinics may be able to provide information about regulated waste disposal.

Laboratory Safety

Overview

Every laboratory testing site must comply with applicable federal and state safety regulations to ensure a safe environment for staff and patients.

Federal Regulations for Safety

The Occupational Safety and Health Administration (OSHA) requires employers to provide employees with a safe and healthy workplace. The OSHA brochure, Medical & Dental Offices— A Guide to Compliance with OSHA Standards (https://www.osha.gov/publications/publication-products?publication_title=3187) lists regulations applicable to most laboratory testing sites. In addition, all laboratory testing sites must:

- ✓ Treat all human blood (and certain human tissues and body fluids) as infectious. Strictly enforce the use of universal precautions and compliance with the bloodborne pathogens standard: http://www.osha.gov/SLTC/bloodbornepathogens/index.html
- ✓ Provide safety training to employees on handling blood and other infectious materials. This training should include guidance on what to do when safety incidents happen.
- ✓ Ensure the use of safer, engineered needles, sharps containers, and personal protective equipment (PPE), such as gloves and protective eyewear: https://www.osha.gov/personal-protective-equipment/hazards-solutions
- ✓ Implement a sharps injury prevention program. Establish and maintain a sharps injury log to record any injuries from contaminated sharps. CDC provides a Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program: https://www.cdc.gov/infection-control/hcp/sharps-safety/program-workbook.html
- ✓ Offer hepatitis B vaccination at no cost for employees with possible occupational exposure.
- ✓ Provide equipment for safe handling and disposal of biohazardous waste.
- ✓ Have a written plan for exposure control: https://www.osha.gov/sites/default/files/CPL_2-2_69_APPD.pdf
- ✓ Maintain records of occupational injuries and illnesses: https://www.osha.gov/recordkeeping/entry-faq

State Regulations for Safety

Many U.S. states and territories provide OSHA-approved State Plans for workplace safety and health programs. Laboratory testing sites in one of these states or territories must comply with regulations outlined for their state: https://www.osha.gov/stateplans

General Safety Practices

In addition to applicable federal and state regulations, laboratory testing sites should incorporate the following practices into their standard operating procedures:

- ✓ Do not eat, drink, or apply makeup in sample collection or testing areas.
- ✓ Do not store food in refrigerators where testing supplies or samples are stored.

- ✓ Provide sinks for hand-washing or antiseptic hand-washing solutions. Staff should clean hands and change gloves between patients. Follow appropriate guidelines to ensure hand hygiene: https://www.cdc.gov/handhygiene/index.html
- ✓ Post safety information for employees and patients.

Safety Plan

All laboratory testing sites should develop a site-specific safety plan describing policies, procedures, and work practices to protect employee safety. The safety plan should provide testing personnel and staff with information about good laboratory practice and the health hazards associated with testing.

See Appendix A for an example Safety Plan, including an example Safety Training Checklist and Incident Report.

Risk Management

Another way to ensure the safety of your staff and patients is to perform a biological risk assessment of the biological safety risks at your testing location and how to reduce them. Information on risk management and risk assessments can be found at the following website: https://www.cdc.gov/csels/dls/point-of-care-testing.html

Test Selection

Overview

Selecting the appropriate test is crucial for both the laboratory testing site and the patients. Implementing the best test for your patient population and testing needs assists in accurate diagnoses and proper treatment plans while ensuring efficient testing processes. Before deciding to perform waived testing, you should consider the test characteristics, the types of samples required for testing, and the cost of each test.

Test Characteristics

You can find information on a test in the manufacturer's instructions or by contacting the manufacturer's customer service or technical support representative.

When choosing your test, consider the following test characteristics to ensure the test offered will meet your needs:

- **Intended use —** Review this component of the manufacturer's instructions to determine 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 manufacturer's data on the test's accuracy, precision, sensitivity, specificity, and potential interferences.
- **Patient population —** Some tests do not work for, or are less reliable for, certain age groups. (e.g., pediatric patients). In addition, the predictive value of results can vary in different populations.
- **Supplemental testing —** Some tests are used for screening and will need additional follow-up testing before a final, confirmatory result can be reported or used for patient treatment.
- **Patient follow-up —** Some tests (e.g., HIV tests) may benefit from post-test counseling about the meaning of the test result.
- **The test system —** Consider the complexity 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 (e.g., HIV tests) may require special training, development of a quality assurance program, or processes to provide information to patients.

Sample Characteristics

Choosing the right test includes considering the following sample characteristics, as these factors directly impact the accuracy and reliability of test results.

- Consider the type of sample. Remember, only unprocessed samples can be used for waived tests. Tests that require the use of samples that have had any processing (e.g., centrifugation, dilution, or extraction) are no longer considered waived tests.
- Check the 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, it is important to assess financial sustainability by considering various factors that contribute to testing costs. This ensures resources are allocated effectively to support essential testing services.

- **Personnel —** including labor and training
- **Consumables —** including test kits, supplies, reagents, disposables, controls, and calibration materials
- **Frequency of testing —** including cost per test, and for infrequent testing, the number of tests that may become outdated before being used

- **Equipment and related costs —** including repairs or maintenance contracts
- **Safety and biohazard supplies —** including sharps containers and personal protective equipment
- **Record keeping —** including office supplies and recording keeping software or services
- **Resources needed for additional activities —** including supplemental or referral testing, licenses, and fees

Testing Personnel

Overview

To ensure safe and reliable laboratory testing at your facility, you must prioritize workforce development. This means attracting and selecting employees with the requisite skills, competencies, and commitment required to do the work, but that is only the first step. You should commit to an employee training and assessment program to ensure that all testing personnel remain qualified to do the work.

Choose the Right Employee

No CLIA requirements exist for personnel qualifications to perform waived testing; however, testing sites must meet all applicable state or local personnel regulations. As you evaluate prospective employees, several factors could positively or negatively affect performance:

- ✓ Different tests may have different skill and time requirements, which should be considered if personnel have other duties or responsibilities.
- ✓ Some tests require personnel to differentiate between colors to interpret results; you might consider evaluating staff for color vision deficiency.
- ✓ Maintaining the competency to perform tests correctly may be difficult for temporary or part-time staff who perform infrequent testing.
- ✓ The staff turnover rate at your facility will affect the frequency and time required to train new employees.

Employee Training

Well-trained, skilled personnel are essential for quality testing and patient care. The person overseeing testing must ensure personnel receive adequate training before performing testing or reporting patient results. In cases where the person overseeing testing will not be conducting the training, a qualified person (e.g., an experienced staff member or an outside consultant) must be delegated.

This person should understand:

- ✓ The test procedure
- ✓ How to accurately demonstrate the performance of the test
- ✓ Good laboratory practices
- ✓ Safety practices

Many resources are available to complement your employee training program, including test manufacturers and distributors, professional organizations, state health departments, and government agencies. As a minimum, your on-the-job training program 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 the trainee's test performance, provides feedback, and follows up if additional instruction is needed.
5. Both the trainer and trainee document the training.

See Appendix C for an example Training Checklist and Appendix D for an example Training Evaluation form.

Performance Assessment

The person overseeing testing must ensure testing is consistent and accurate by periodically checking the performance of testing personnel and recommending additional training when needed. Be conscious of testing personnel who perform testing infrequently, they may lose competency overtime. Complete employee competency and performance assessments in a positive, non-punitive manner that emphasizes education and promotes good testing practices. See Appendix E for an example Competency and Performance Assessment form.

Employee competency and performance can be evaluated by:

- Watching the person do the test
- Giving the employee mock samples for testing (these can be control samples or previously tested patient samples)
- Checking post-testing documents completed by the employee for accuracy and completeness
- Participating in external assessment activities (e.g., proficiency testing programs)

Instructions and Procedures

Overview

Reliable laboratory test results depend on testing personnel who perform tests correctly. This means reviewing, understanding, and following the test system's current manufacturer's instructions. It is vital that you make these instructions available and accessible to anyone who performs laboratory testing to ensure that they know how to perform the test before they start.

Manufacturer's Instructions

Every test manufacturer provides precise instructions for testing personnel on properly using their test system. These instructions may be found in a product insert, on the manufacturer's website, or in a manufacturer-provided testing manual. For every test your facility offers, make the current manufacturer's instructions or a written procedure containing information from the current manufacturer's instructions readily available and accessible in the testing area.

For each new lot of testing kits or supplies, check the manufacturer's instructions for any changes by referring to the instruction's revision date. If changes have been made to the manufacturer's instructions, ensure all testing personnel follow the updated instructions.

Quick-Reference Instructions

Some manufacturers provide quick-reference instructions outlining the essential steps for the test, often on a card or small sign containing diagrams or flow charts. These instructions are not a substitute for a complete written test procedure. Facilities that use quick-reference instructions should clearly post them so that they are easily visible where testing is performed. As with the current manufacturer's instructions, you should routinely review quick-reference instructions for revisions and update them as necessary.

Caution: When using quick-reference instructions, use the current version and ensure they are for the manufacturer and test you are performing. The specific test system name should be on these instructions to avoid confusion.

Procedures

You may choose to use the current manufacturer's instructions to develop written procedures that include specific instructions for your laboratory testing site. When writing procedures, using a general template with standard headings is helpful. See Appendix F for Procedure Contents and Tips.

Procedure Manual

Laboratory testing sites often choose to compile procedure manuals to provide a single location for all documents, forms, and instructions in use at the site. The individual overseeing testing should review and sign the procedure manual annually and whenever changes occur. Whenever a procedure is revised, remove the old procedure from the active manual, label it as "inactive," and keep it on file.

Procedure manuals should have instructions and forms for:

- ✓ Preparing the test and reagents
- ✓ Performing tests

- ✓ Performing QC procedures
- ✓ Interpreting and reporting the test results
- ✓ Troubleshooting testing problems
- ✓ Training new personnel
- ✓ Recording temperatures of refrigerators, storage, and testing areas
- ✓ Keeping inventories and lot numbers of kits and reagents
- ✓ Maintaining equipment
- ✓ Handling hazardous waste
- ✓ Adhering to all safety policies, including needle stick protocols
- ✓ 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
- ✓ Referring testing to outside laboratories

Quality Assessment

Overview

Assessing the quality of testing requires planned and systematic monitoring and evaluation of the testing process. By conducting these activities, you can reduce errors, improve patient outcomes, improve patient and employee safety, and reduce costs.

Assessments

Depending on your facility's needs, resources, and practices, you may use internal or external mechanisms for quality assessment. Examples are listed below.

Internal assessments are processes for staff performing and overseeing testing to evaluate their current practices. These may include:

- Performing and documenting 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
- Documenting and reviewing injury/incident reports

External assessments are typically performed by an outside party to evaluate current practices and offer educational opportunities. 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
- Exchanging samples with other laboratories or testing sites using the same test methods to compare results
- Subscribing voluntarily to proficiency testing (PT) programs
    - PT is a tool laboratories use to verify the accuracy and reliability of testing and to monitor the entire testing process, including the competency of testing personnel.
    - PT programs periodically send samples to the participating laboratory or test site. The laboratory or test site then tests these samples in the same manner as patient samples and submits their results to the PT program. The program then compares the reported results with an assigned value or expected result and reports an assessment of the results back to the participating laboratory or test site.

      The CLIA regulations do not require PT for waived testing. However, there are many benefits to participating in a PT program:

        - Regular, external checks on the quality of testing
        - Motivation to improve performance
        - Comparison of performance with that of other participating sites
        - Feedback and technical advice from PT programs

- Assistance in evaluating methods and instrumentation
- Assistance with staff education, training, and competence monitoring
- Opportunities to identify areas needing improvement

For information on programs that offer PT, refer to: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/proficiency-testing.

Each CLIA Certificate of Waiver (CoW) laboratory location is assigned an individual (and unique) CLIA identification number and proficiency testing must only be performed at the laboratory location assigned to that individual (and unique) CLIA identification number. If a laboratory location with a different CLIA number is found to perform testing on proficiency testing samples not intended for that location, CMS may impose sanctions against all the CLIA certificates involved, including those performing waived tests.

For additional information and resources on PT and PT Referral, refer to:

- CLIA Brochure - PT and PT Referral: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures
- CLIA PT Referral Categories: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-18-07
- CLIA PT Related to Analytes and Acceptable Performance: https://www.federalregister.gov/documents/2022/07/11/2022-14513/clinical-laboratory-improvement-amendments-of-1988-clia-proficiency-testing-regulations-related-to
- CLIA Fees; Histocompatibility, Personnel, and Alternative Sanctions for Certificate of Waiver Laboratories: https://www.federalregister.gov/documents/2023/12/28/2023-28170/clinical-laboratory-improvement-amendments-of-1988-clia-fees-histocompatibility-personnel-and

Tips

The following checklist summarizes the steps that should be taken when implementing and overseeing waived testing or when deciding to offer 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 before offering testing.
- ☐ Renew the Certificate of Waiver every two years.
- ☐ Ensure only waived tests are performed.
- ☐ Follow test instructions 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 CMS representatives on-site for announced or unannounced inspections.
- ☐ Follow all applicable state and local requirements.
- ☐ Follow regulations for confidentiality and patient privacy.

Testing Locations

- ☐ 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.

Laboratory Safety

- ☐ Follow all applicable federal and state requirements.
- ☐ Consider general safety practices, such as hand hygiene.
- ☐ Post safety information for staff and patients.
- ☐ Develop a safety plan.
- ☐ Consider the biological safety risks for the testing location and how to reduce risks by performing a risk assessment.

Test Selection

- ☐ 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.
- ☐ Ensure all testing personnel understand and can perform the test correctly before reporting patient results.
- ☐ Periodically assess the performance of testing personnel.

Instructions and Procedures

- ☐ Understand and follow the current manufacturer's instructions for each test you perform.
- ☐ Consider writing procedures developed from the manufacturer's instructions, including specific instructions for your laboratory 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. https://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." https://stacks.cdc.gov/view/cdc/23032
- 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 How to Apply for a CLIA certificate, Including International Laboratories: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/apply
- CMS How to obtain a Certificate of Waiver brochure: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/brochures
- CLIA CW Application: https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms012169
- CLIA State Agency Contacts: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/contacts
- FDA's CLIA Waived Test List: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfclia/analyteswaived.cfm
- HIPAA regulations: https://www.hhs.gov/hipaa/index.html
- National Notifiable Diseases Surveillance System: https://www.cdc.gov/nndss/index.html
- CDC's Waived Testing website: https://www.cdc.gov/labquality/waived-tests.html

Safety Links

- The Centers for Disease Control and Prevention (CDC) Biosafety Information for Laboratories and Testing Sites: https://www.cdc.gov/safelabs/ and https://www.cdc.gov/labsafety
- List of OSHA publications and links: https://www.osha.gov/publications
- OSHA Occupational Safety and Health Standards: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- Medical & Dental Offices – A Guide to Compliance with OSHA Standards at: https://www.osha.gov/publications/publication-products?publication_title=3187
- Bloodborne Pathogens Standard: http://www.osha.gov/SLTC/bloodbornepathogens/index.html

- OSHA's PPE Fact Sheet: https://www.osha.gov/personal-protective-equipment/hazards-solutions
- CDC Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program https://www.cdc.gov/infection-control/hcp/sharps-safety/program-workbook.html
- WHO patient safety website: http://www.who.int/patientsafety/en/
- Resources to transport or ship samples safely: http://www.phmsa.dot.gov/hazmat and http://www.iata.org/publications/dgr/Pages/index.aspx
- Infection Prevention during Blood Glucose Monitoring and Insulin Administration link: https://www.cdc.gov/injection-safety/hcp/infection-control/
- Preventing Needlestick Injuries in Health Care Settings link: https://www.cdc.gov/niosh/docs/2000-108/default.html

Appendix A

Example

Safety Plan

I. INTRODUCTION

The safety plan describes policies and procedures to ensure the safety of the testing personnel. 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 should 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 should be available in each testing area. Some useful safety documents can be found here: https://www.cdc.gov/safelabs/ and https://www.cdc.gov/labsafety/

III. RESPONSIBILITIES

Implementation of the safety plan is a shared responsibility. The individual providing testing oversight and all testing personnel 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 the completion of safety training for all employees, including housekeeping staff, and maintain training records.
6. Provide appropriate personal protective equipment (PPE) and engineering controls to ensure work is performed safely. Ensure equipment is used correctly, maintained properly, and kept in working order.
7. Identify all appropriate immunizations for the testing being performed and offer it to employees.
8. If unsafe work practices are identified or reported, ensure all findings are corrected 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 testing site safety training.
3. Ensure 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. Always maintain professionalism.
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 before operating ANY equipment. *Do not use damaged equipment.
3. Be aware of potential hazards in the testing area.
4. Wear the appropriate PPE.
5. Report ALL exposures immediately to the individual overseeing testing or your supervisor.

C. Personal Hygiene

1. Smoking, drinking, eating, chewing gum, applying or removing contact lenses, and applying 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 and when visibly soiled.
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 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 appropriately from work area and floors. Notify the individual overseeing testing of any spills immediately.
3. Do not impede or use doorways and walkways for storage.
4. Keep all exits, emergency equipment, and safety controls accessible.
5. Flush eyewash stations, if available, weekly; flush emergency showers every six months. Keep documentation records of the maintenance history.

E. Ergonomics

1. Perform an ergonomic assessment of the entire work area, including chairs, workstations, desks, and computer stations.
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 at laboratory testing sites. 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 (e.g., needles, glass pipettes, etc.) should be used only when no alternative is available.

B. Needles (do not resheath; recapping of needles is prohibited), syringes, slides, pipettes, capillary tubes, scalpels, and broken glass must be placed in a rigid puncture-resistant disposable container with a lid.

C. Do not touch broken glass. Remove it mechanically using forceps, brush, dustpan, etc. Deposit all glass into a 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. Laboratories and 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 the door and post with a warning sign.
3. Remove contaminated clothing, turn the exposed area inward, and place it 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 the 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 spilled material and discard these into a biohazard bag. Use fresh toweling to wipe up any residual material and discard it 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 by an application of bleach solution. Allow to air dry.
10. Remove disposable gloves and discard them as biohazardous waste. Discard any disposable protective clothing used during spill clean-up. Clean and disinfect utility gloves, face shields, 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 the individual overseeing testing and document the incident accordingly. 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 the 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 blood flow out of the wound.
    b. Wash needlesticks and cuts with soap and water.
    c. Report to the individual overseeing testing immediately for next steps including determining if prophylaxis is necessary.
    d. If applicable, follow the needle stick protocol for your organization and/or immediately seek medical treatment.

D. Documentation Procedures

1. All spills and 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

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:

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. Train new employees on work practices, procedures, and 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 55555

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.	2/15/2024	CO	SS	
Received appropriate immunizations as determined by individual overseeing testing.	2/12/2024	CO	SS	
Discussed hazardous chemical inventory and safe use of hazardous chemicals at the laboratory testing site. Reviewed Safety Data Sheets (SDS).	2/15/2024	CO	SS	
Shown where First AID Kits and Automated External Defibrillator (AED) (if available) are located.	2/15/2024	CO	SS	
Shown where Biosafety and Chemical Spill Kits (if applicable) are located.	2/15/2024	CO	SS	
Reviewed procedures for obtaining supplies.	2/16/2024	CO	SS	
Discussed required use of personal protective equipment (PPE).	2/15/2024	CO	SS	
Provided appropriate PPE.	2/15/2024	CO	SS	
Shown where fire extinguishers are located.	2/15/2024	CO	SS	
Discussed ergonomics in the workplace.	2/15/2024	CO	SS	
Reviewed procedure on waste disposal:	2/16/2024	CO	SS	
Infectious	2/16/2024	CO	SS	
Non-infectious	2/16/2024	CO	SS	
Hazardous chemical	2/16/2024	CO	SS	
Sharps	2/16/2024	CO	SS	
Reviewed emergency response procedures:	2/15/2024	CO	SS	
Infectious material spill or release	2/15/2024	CO	SS	
Hazardous chemical spill or release	2/15/2024	CO	SS	
Fire or explosion	2/15/2024	CO	SS	
Medical emergency	2/15/2024	CO	SS	
Bomb threat	2/15/2024	CO	SS	
Shelter In Place	2/15/2024	CO	SS	
Active Shooter	2/15/2024	CO	SS	
Provided instructions on Incident Reporting.	2/15/2024	CO	SS	

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:** 2/16/2024
Employee Signature: Colleen Olson **Date:** 2/16/2024
Supervisor Review: Joe Smith, MD **Date:** 2/16/2024

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 at the laboratory testing site. Reviewed Safety Data Sheets (SDS).				
Shown where First AID Kits and Automated External Defibrillator (AED) (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 workplace.				
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				
Active Shooter				
Provided instructions on Incident Reporting.				

Comments: _____

_____

_____

Trainer Signature: _____ **Date:** _____

Employee Signature: _____ **Date:** _____

Supervisor Review: _____ **Date:** _____

Appendix A2

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 work area.

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

Contents:

There are many ways to document incidents. A blank incident report form is included, along with an example report demonstrating how to correctly enter site-specific information.

1. Example Incident Report form completed
2. Blank Incident Report form

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 always had ten or fewer employees during the last calendar year, you only need to keep OSHA injury and illness records if 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 because of a work-related incident. Reporting of the fatality/multiple hospitalizations may be done by telephone or in person to the OSHA office nearest the incident site.

Example

Facility: Dr. Smith's Office
Location: 123 Main Street
Atlanta, GA 55555

INCIDENT REPORT

Name of Person Involved in Incident: Sara Smith

Date of Incident: 6/30/2024 **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:

X 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. Initial training performed on 6/12/2018, 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: 6/30/2024

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: _____

Appendix B

Security and Confidentiality Agreement Instructions

Purpose:

The U.S. Department of Health and Human Services (HHS) issued the Privacy Rule to implement the requirements 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, and 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
- The past, present, or future payment for the provision of healthcare to the individual
- Any information that identifies the individual
- Any information that can reasonably be used or believed to be used in the past 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 in 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 demonstrating 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 55555

SECURITY AND CONFIDENTIALITY AGREEMENT

1. I understand that the patient and organization information I will be able to access online, 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.

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 consent, authorization, or consideration. 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 others cannot use my access.

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 my duties' scope, I may be subject to disciplinary action.

4. I understand and agree to always behave in a professional, ethical manner regarding patient and organizational confidentiality.

Colleen Olson
Employee Signature

6/30/2024
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 online, 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.

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 consent, authorization, or consideration. 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 others cannot use my access.

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 my duties' scope, I may be subject to disciplinary action.

4. I understand and agree to always behave in a professional, ethical manner regarding patient and organizational confidentiality.

_____ _____

Employee Signature Date

_____

Printed Name

Appendix C

Training Checklist Instructions

Purpose:

All employees need to understand their role in the organization as a whole and learn the expectations of their supervisor while performing 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 55555

TRAINING CHECKLIST

Trainee: Colleen Olson

Date: 05/06/2024 **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's instructions involved and understands them. File the completed form appropriately.

Checklist	Date Completed	Employee Initials	Trainer Initials
1. Trainee read and understood procedure.	05/03/2024	CO	SS
2. Trainer discussed the principle of the test procedure ensuring the trainee understood the procedure scope and purpose of the test.	05/04/2024	CO	SS
3. Trainer identified materials needed to perform the test, including their storage location. Trainee knows the location of materials needed to perform testing.	05/03/2024	CO	SS
4. Trainee observed the proper sample collection and handling.	05/03/2024	CO	SS
5. Trainee observed the trainer performing the test procedure.	05/03/2024	CO	SS
6. Trainee performed the procedure and is able to: a. Identify the proper sample type, the appropriate collection device, labeling, and handling of samples b. Organize the work area for testing c. Perform quality control (QC) samples and training samples prior to performing patient samples d. Set up timer and follow the incubation times per the procedure. e. Interpret Results: • Positive • Negative • Invalid f. Decontaminate and clean the work area, including proper disposal of hazardous waste and sharps	05/06/2024	CO	SS
7. Trainer discussed data entry/computer: a. Test order and accessioning b. QC and interpretation of results c. Report results and log QC data	05/06/2024	CO	SS

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

Trainee Signature: Colleen Olson **Date:** 05/06/2024

Trainer Comments: Colleen was attentive and followed directions

Trainer Signature: Sara Smith **Date:** 05/06/2024

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's instructions involved and understands them. File the completed form appropriately.

Checklist	Date Completed	Employee Initials	Trainer Initials
1. Trainee read and understood procedure.			
2. Trainer discussed the principle of the test procedure ensuring the trainee understood the procedure scope and purpose of the test.			
3. Trainer identified materials needed to perform the test, including their storage location. Trainee knows the location of materials needed to perform testing.			
4. Trainee observed the proper sample collection and handling.			
5. Trainee observed the trainer performing the test procedure.			
6. Trainee performed the procedure and is able to: a. Identify the proper sample type, the appropriate collection device, labeling, and handling of samples b. Organize the work area for testing c. Perform quality control (QC) samples and training samples prior to performing patient samples d. Set up timer and follow the incubation times per the procedure. e. Interpret Results: • Positive • Negative • Invalid f. Decontaminate and clean the work area, including proper disposal of hazardous waste and sharps			
7. Trainer discussed 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:** _____

Appendix D

Training Evaluation Instructions

Purpose:

The individual overseeing testing acts as an advocate for employees by gathering and distributing the resources needed by employees 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 form completed
2. Blank Training Evaluation form

Instructions for Completing the Training Evaluation:

1. After training is completed, the trainee should complete the Training Evaluation form.
2. The trainee should be honest and open about the training experience without fear of remedial action or other adverse reactions because 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 55555

TRAINING EVALUATION

Date: 02/16/2024 **Trainee:** Colleen Olson

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

Trainer(s) being evaluated: Sara Smith

Facility:
Location:

TRAINING EVALUATION

Date: _____ **Trainee:** _____

Item	Circle *Y (Yes) or N (No)*	Comments	Score *1 = unsatisfactory* *2 = satisfactory* *3 = very good*
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 they 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: _____

_____

Appendix E

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
- Provide evidence to customers and management that the laboratory testing site 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
- 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 form completed
2. Blank Performance Assessment form

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 55555

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 the 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):

Observed By: Sara Smith **Date:** 4/27/2024

Reviewed by Employee: Colleen Olson **Date:** 4/27/2024

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 the 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: _____

_____

Appendix F

Procedure Contents and Tips

Procedure Contents:

Written procedures can be developed from the manufacturer's instructions to include specific instructions for your laboratory or 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's 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 can 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's 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's instructions for the test.
- **Signature** — The individual overseeing testing should sign and date after reviewing and approving the contents prior to the start of a new procedure and after each procedure revision.
- **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. If electronic versions are available, ensure all manual copies are updated and consistent with the electronic version.
- ✓ 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.

Appendix G

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 the 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). CDC is the nation's leading science-based, data-driven, service organization that protects the public's health. In partnership with the Centers for Medicare & Medicaid Services and the Food and Drug Administration, CDC supports the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program and clinical laboratory quality.
CLIA, The Clinical Laboratory Improvement Amendments of 1988	The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease.
CMS, Centers for Medicare & Medicaid Services	CMS is the federal agency that provides health coverage to more than 100 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace. CMS works in partnership with the entire health care community to improve quality, equity, and outcomes in the health care system. CMS has administrative responsibility for the CLIA program including regulating all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
CoW, 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	HIPAA is a federal privacy rule that provides protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. HIPAA permits the disclosure of personal health 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 or 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 healthy working conditions for all people. OSHA establishes workplace standards to enforce and prevent work-related injuries, illnesses, and deaths by issuing and enforcing rules for workplace safety and health.
POC, Point of Care Testing	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 labors 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, stable, and that the set of samples analyzed are appropriate to test and display similarities and differences in results.
PT referral	An unauthorized process where PT test samples intended for one test site or laboratory are forwarded to a different laboratory or test site for testing. Sharing or discussing PT sample test results between laboratories or test sites is also considered PT referral.

QA, Quality assessment	A group of activities to monitor and evaluate the CW site's entire testing process to help ensure that test results are reliable, improve the testing process, and promote good quality testing practices.
QC, Quality control	The procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions, and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time.
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.
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	A document, form, or logbook that serves as permanent evidence of information about past events.
Referral testing	Sending a sample from a Certificate of Waiver site (or other laboratories) to another site or laboratory to perform additional testing, often for follow-up confirmatory testing. Most referral laboratories perform nonwaived testing.
Report (test)	A document describing the result or findings of a test.
Reportable (measurable) range	The span of test result values for which the instrument or test device can accurately measure.
Safety Data Sheet (SDS)	A document that lists information relating to occupational safety and health for the use of various substances and products.
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.
Temperature range	The numerical difference between the minimum and maximum values of temperature observed in a system.

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.
WT, 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

Notes

For additional information go to:
https://www.cdc.gov/labquality/waived-tests.html
Contact the Division of Laboratory Systems at WaivedTesting@cdc.gov

June 2024