Ready?
Set?
Test!

Patient Testing is Important.
Get the Right Results.

https://www.cdc.gov/lab-quality/php/waived-tests

CDC

Introduction

Background

Healthcare providers use test results to diagnose disease, determine prognosis, and monitor a patient's treatment or health status. In current practice, medical decisions are increasingly made based on the results of simple tests conducted close to the site of patient care where treatment is provided. Many of these point-of-care tests are "waived tests" and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS). 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 list of waived tests is continually revised as new tests are waived. The most current information on FDA-cleared waived tests can be found here: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Purpose

This booklet describes recommended practices for physicians, nurses, medical assistants, pharmacists, and others who perform patient testing under a CLIA Certificate of Waiver.

CLIA requires waived tests to be simple and have a low risk of an incorrect result. While no test is completely error-proof, you can greatly reduce the likelihood of incorrect waived test results by cultivating an environment where trained personnel follow good testing practices.

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

- If a complaint is made
- To determine if the testing site performs tests not permitted with a Certificate of Waiver
- If there is a risk of patient harm from inaccurate testing
- To collect information about waived tests

The CLIA requirements for testing under a Certificate of Waiver can be found here: https://www.cdc.gov/clia/php/about/.

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

Contents

Overview

Before you are ready to start a testing process, you should take all necessary steps to prepare to ensure your results are accurate. The most important resource you will have to properly prepare for every step of the testing process is the manufacturer's instructions. Studies show most problems found at sites that perform waived testing result from failing to follow and understand the information found in this critical resource.

Preparing for Testing

When preparing to start testing, there are several pretesting tasks you should follow. Select a testing area that provides adequate space to safely conduct testing while maintaining patient privacy. You should evaluate and monitor your testing and storage areas to ensure they meet any environmental requirements described in the manufacturer's instructions. Maintain and calibrate testing equipment, as directed in the manufacturer's instructions. See Appendix A for a pretesting task checklist.

Some best practices to follow when preparing for testing are:

- ✓ Routinely clean and dry work surfaces before and after testing.
- ✓ Perform testing in a well-lit, clean, and dry area. Placing test strips on a moist or newly cleaned surface may damage the strip and cause incorrect results.
- ✓ Check and record temperatures of the testing, reagent, and test kit storage areas. See Appendix B for examples of daily temperature logs.
- ✓ Check inventory regularly to ensure you have enough reagents, test kits, and supplies for testing.
- ✓ Check and record expiration dates of reagents and test kits. Discard any expired reagents or test kits.
- ✓ Ensure all test kit component reagents are from the same kit lot. Do not mix or combine reagents between different lot numbers.
- ✓ Inspect reagents or vials for damage, discoloration, or contamination, and discard if found.
- ✓ Prepare reagents according to the manufacturer's instructions.
- ✓ Allow time for refrigerated reagents, test kits, and patient samples to come to room temperature before testing.
- ✓ Inspect equipment and electrical connections to be sure they are working.
- ✓ Perform equipment calibration checks, as needed, following the manufacturer's instructions.
- ✓ Consider the biological safety risks for the testing location. Information on risk management can be found here: https://www.cdc.gov/laboratory-systems/php/biological-risk-management/.

Performing a self-assessment before starting and throughout the testing process can be used as a voluntary tool to help ensure good testing practices. A self-assessment checklist and other helpful resources can be found here: https://www.cdc.gov/lab-quality/php/waived-tests/.

Following the Manufacturer's Instructions

The CLIA Certificate of Waiver requires that all testing sites follow the most current version of the manufacturer's test instructions. Manufacturers may update or change their guidance periodically, and instructions from different manufacturers for the same type of testing (e.g., glucose) may differ. To ensure that the most current and appropriate test instructions are being used:

- ✓ Keep a copy of the manufacturer's instructions on hand for easy reference.
- ✓ Check the manufacturer's instructions with each new lot and shipment of reagents or test kits to ensure they are unchanged from previous lots and shipments.
- ✓ Replace and file the old manufacturer's instructions when you discover changes.
- ✓ Communicate all changes in the manufacturer's instructions to other testing personnel and to the person who directs or supervises testing.

Some manufacturers provide quick-reference instructions to post in the testing area. These instructions are intended to supplement the current manufacturer's complete instructions. If the manufacturer's instructions are updated, the quick-reference instructions may also need to be updated. If changes to manufacturer's instructions affect any site-specific procedure manual at your testing site, those procedures must be updated.

See Appendix C for an explanation of components commonly found in manufacturer's instructions.

Doing the Test the Right Way

- ✓ Read and understand the manufacturer's instructions and any relevant site-specific procedure.
- ✓ Contact the manufacturer if any information is unclear.
- ✓ Follow safety precautions, including Occupational Safety and Health Administration (OSHA) guidelines: https://www.osha.gov/bloodborne-pathogens.
- ✓ Practice all tests while an experienced person watches before testing patient samples and reporting patient results. All training should be documented in your staff personnel file.

Understanding "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 modify an FDA-cleared or approved test system. This means using a test system in a way other than as described for intended use in the manufacturer's instructions. This kind of modification is considered an "off-label use" of a test system because the manufacturer's clinical data do not support it, and these test modifications were 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. This categorization requires sites using modified test systems to meet all applicable CLIA requirements for high complexity testing. These include meeting requirements for proficiency testing (PT), establishing test performance characteristics, quality control (QC), 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.

Performing Quality Control Testing

Quality control (QC) testing ensures the test performs as expected, alerts users when problems occur, and is required when indicated in the current manufacturer's instructions. The manufacturer's instructions explain when, why, and how to perform QC testing. Incorrect QC test results alert users about potential problems with the test or testing process (e.g., reagent or test kit deterioration, equipment failure, environmental conditions, or human error).

What are the Types of Controls?

Waived tests include two types of controls:

- Internal controls (also referred to as built-in or procedural controls) determine whether:
  - The test is working as it should.
  - The test sample amount used was adequate for the test to perform properly.
  - The sample is moving through the test strip correctly.
  - Electronic functions of the instrument are working correctly.
- External controls determine whether:
  - The entire testing process is performed correctly, from sample application to interpretation of results.
  - The control results are within the expected ranges or values printed on the controls or provided in the control manufacturer's instructions.

External controls may be provided as liquids or other materials that are similar to patient samples. External controls may be included with the test kit system, or they may need to be purchased separately.

Who Should Perform QC Testing and How Often Should it be Done?

The same personnel who routinely perform patient testing should perform QC testing. You should treat and test QC controls just as you would a patient sample. Your site should perform QC testing at least as often as specified in the manufacturer's instructions and should test controls with:

- Each new shipment of reagents or test kits
- Any change in lot numbers
- Each new testing personnel

Additional considerations to help determine when and how often your site should perform QC testing:

- Stability of the test (i.e., based on expiration dates and storage requirements)
- Environmental changes (e.g., power outages, mechanical breakdowns, and extreme temperature changes can cause QC or testing material to spoil)
- Competency and skills of the testing personnel (i.e., based on if personnel are newly trained versus experienced)

Tracking of QC results

Documenting and tracking QC results can help determine if a test is being performed correctly and if the test is working properly. Periodic reviews of QC records can provide information about QC result changes and trends over time. You can then use this information to identify and address any problems that may affect patient testing. See Appendix D for examples of QC logs and testing result logs.

Actions for Unexpected QC Results

If controls do not give the expected results, you should wait until the problem is identified and corrected before reporting patient results. This applies to both external and internal controls.

- ✓ Check to see if the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error, such as outdated reagents, test kits, or control materials.
- ✓ Check whether reagents, test kits, and control materials were stored correctly.
- ✓ Ensure controls and reagents were not cross contaminated by accidentally switching caps.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site-specific procedure.
- ✓ Contact the manufacturer, technical representative, or the person who directs or supervises the testing for additional assistance.

Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient sample(s) and report the final results.

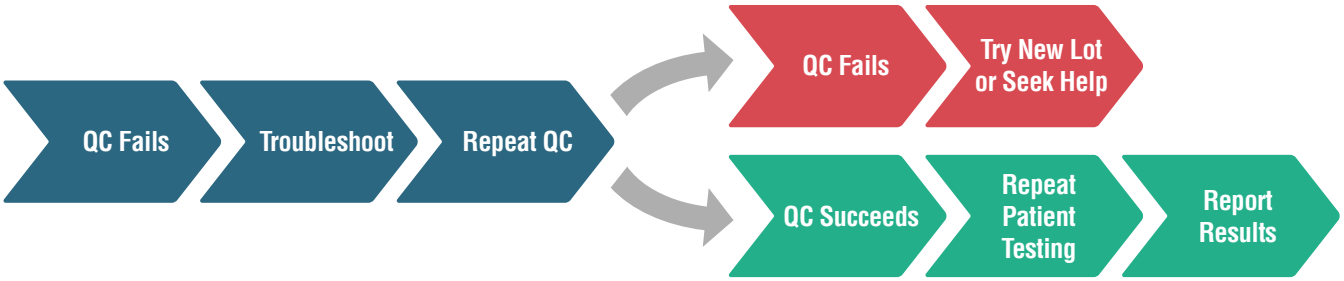


Figure 1. *Actions for unexpected QC results.*

Overview

How you prepare for patient testing can be as important to the testing process as performing the test. Closely examining test orders, properly identifying, and preparing the patient, collecting a quality sample, and setting, and maintaining a testing area that reduces occupational and biohazard safety risks all contribute to accurate test results.

Considering the Test Order

Before collecting a sample, confirm:

- ✓ The test order: If there is any question about whether the order is correct, check with the individual who requested the test.
- ✓ Patient identification: Patient names can be similar, which can lead to confusion. Using at least two unique patient-specific identifiers (e.g., patient name and date of birth) is good practice to ensure the test is ordered for and collected from the correct patient.

Preparing the Patient

Enhancing patient awareness regarding any information that may impact their health or the accuracy of the test is an essential aspect of the testing process. Consult with the patient regarding:

- ✓ Pretest instructions: Some tests require preparation by the patient (e.g., fasting for a glucose test). Verify that any recommended patient instructions were followed before collecting the sample.
- ✓ Pretest information: Discuss factors such as medical indications, medications, or other interfering substances that could affect test results. This information can often be found in the Limitations section of the manufacturer's instructions.
- ✓ The test: Make sure the patient understands the purpose of the tests being ordered and what the results will mean to their health.
- ✓ Patient counseling: Some test results (e.g., HIV tests) may benefit from counseling on what the results will mean for the patient.

Collecting the Sample

Quality patient samples are critical for accurate and reliable test results. The sample collector should understand the type of sample needed for the test and the proper collection process. The manufacturer's instructions provide all necessary sample collection, handling, and storage information. Do not test samples that are improperly collected or handled.

When a test is approved for both waived and non-waived testing use, the manufacturer's instructions may include instructions for testing that could be performed using more than one sample type. However, waived tests may only be performed using unprocessed samples. Examples of unprocessed samples include:

- Whole blood (fingerstick or anticoagulated blood collected by venipuncture)
- Urine
- Throat swab, nasopharyngeal swab, nasal wash, or aspiration
- Stool
- Saliva or oral fluid
- Gastric biopsy

Using Collection Devices

Collection devices are essential to sample collection, and sample collectors must use them in accordance with the current manufacturer's instructions. This means only using the swabs that come in the sample collection kit or the test kit. Swabs can be made of different materials, so substituting them may interfere with the test result. Fingerstick and venipuncture collection devices are for one-time use only and should never be reused.

Be sure to use a device that is appropriately sized for your patient. Fingerstick devices come in various sizes, from pediatric to adult. Some collection devices ensure the delivery of the correct sample volume, while some contain additives that are needed for the test to work correctly.

Labeling Samples

Always label the sample immediately after collection with at least two unique patient identifiers (e.g., name and date of birth) to prevent sample mix-up. Sample labels may also include the date and time of collection and who collected the sample. When a test requires the sample to be applied directly to the test device (e.g., test strip or cassette), label the test device with a patient identifier *before collecting the sample*.

Safety Issues

- ✓ Follow OSHA safety guidelines for occupational exposure to bloodborne pathogens: https://www.osha.gov/bloodborne-pathogens.
- ✓ Wear appropriate personal protective equipment (PPE).
- ✓ Clean hands and change gloves between patients. For hand hygiene educational resources and training, visit CDC's Hand Hygiene in Healthcare Settings website: https://www.cdc.gov/handhygiene/index.html.
- ✓ See Appendix E for information about blood and body fluid exposure and gloves.
- ✓ Keep an updated copy of each reagent or test kit's Safety Data Sheet (SDS) to refer to in the event of an exposure. SDSs can be obtained from the test manufacturer. For more information about SDSs visit: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200AppD.

Follow work practices that reduce the risk of exposure, including:

- Handle all blood and body fluids as if they are infectious.
- Use required PPE and safety devices.
- Do not eat, drink, or apply cosmetics in the testing area.
- Be cautious of exposure to mucous membranes (i.e., eyes, nostrils, and mouth.)
- Wear goggles or face shields to protect against aerosol and droplet exposure.
- Avoid using needles and lancets if safe and effective alternatives are available.
- Never re-use single-use devices (i.e., needles and lancets.)
- Avoid recapping needles, transferring a body fluid between containers, or opening blood tubes.
- Properly dispose of used sharps in puncture-proof sharps containers.
- Report all occupational exposures promptly to your supervisor or to the person who oversees or directs testing to ensure you receive appropriate follow-up care.
- Report any real or potential hazards you observe to the person who oversees or directs testing.
- Participate in training related to infection control and prevention, https://www.cdc.gov/Infectioncontrol/index.html.
- Get hepatitis B vaccination.

Disposing of Biohazardous Waste

You must comply with local, state, and federal requirements for the safe disposal of biohazardous waste generated from sample collection and testing. Hazardous waste cannot be disposed of with regular trash. You must use proper biohazard waste disposal bags and containers. During the testing process, the biohazard bags and containers used for disposal of contaminated materials should be:

- ✓ As close to the immediate testing area as possible
- ✓ Upright throughout use
- ✓ Routinely replaced and never overfilled
- ✓ Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, and shipping
- ✓ Labeled or color-coded to indicate biohazard material
- ✓ Closed before removal to prevent spillage or protrusion of contents during handling

Each testing site should have site-specific procedures that comply with local, state, and federal requirements for safe disposal of biohazardous waste. Local hospitals or clinics may be useful resources for information about regulated waste disposal. Helpful OSHA resources include:

- OSHA Occupational Safety and Health Standards: https://www.osha.gov/healthcare/standards
- OSHA-approved workplace safety and health programs operated by individual states or U.S. territories: https://www.osha.gov/stateplans

Disinfecting Work Surfaces

Disinfect surfaces before performing any test procedure, whenever contamination is visible, and before leaving the testing area. Bacteria and viruses can be present in very high concentrations in just a few drops of blood. Some remain infectious for at least one week in dried blood on countertops and doorknobs. Use the appropriate disinfectant for decontaminating your work area.

See Appendix F for information about common disinfectants and antiseptics.

Overview

Once the sample is collected, the testing phase begins. Navigating this part of the process means knowing how to perform the test; being able to identify and resolve problems; and interpreting, recording, and reporting the test results.

Performing the Test

When performing a test, be sure to:

- ✓ Follow the proper testing steps according to the current manufacturer's instructions and in the exact order as they are listed.
- ✓ Ensure QC is acceptable.
- ✓ Have the manufacturer's instructions, the site-specific procedure, or a quick-reference guide in the testing area.
- ✓ Remember that quick reference guides or color charts can be useful resources when performing a test or interpreting results, but they are not a substitute for the current manufacturer's instructions.
- ✓ Use timers, if indicated, and follow the required timing intervals before reading test results.
  - Reading the results too soon can cause invalid or false negative results due to incomplete reaction of the sample and reagents.
  - Reading a test after the time given in the manufacturer's instructions can lead to:
    - » False-positive results – due to over-development of color
    - » False-negative results – fading of the reaction or color
    - » Invalid results – the reaction moves beyond a visible area

- ✓ Consider any test limitations outlined in the manufacturer's instructions.

Reading the Results

Interpreting test results is a vital component of the testing process, and your most reliable and comprehensive resource to ensure you correctly read and understand a patient's test results is the manufacturer's instructions. You may also find it useful to keep quick-reference guides or color charts available to help interpret results.

Test results are either quantitative, qualitative, or a combination of the two, in which a numerical result is interpreted as a non-numeric result.

- Quantitative results are the numerical results a test produces. These results indicate the amount of the measured substance reported in specific measurement units.
- Qualitative results are interpreted as positive, negative, reactive, non-reactive, or invalid. These results identify the presence or absence of a particular substance, condition, or microbial organism.

Resolving Problems

Problems can occur during the testing process that may involve testing, equipment, or testing material and could affect the test results. These problems should be documented, reported to the person who oversees or directs testing, and corrected. Some examples include:

- Improperly labeled samples
- Freezer or refrigerator failure
- QC failure
- Defective collection devices

By effectively capturing and tracking this information, you can identify trends that may reveal problems in the testing process at your site.

Actions for Invalid or Questionable Test Results

If the test system gives an invalid result or you read the test results as invalid, compromised, or disagreeing with the patient's clinical information, you should perform the test again. Repeating the test may require a new sample. Other instances where you should repeat testing include:

- Quantitative (numerical) result values are less than or greater than the reportable (measurable) range of the instrument
- The test system prevents the display of the result

The manufacturer's instructions for test performance should include steps for handling higher or lower than reportable range results that cannot be accurately measured. You should wait to report test results after all problems are identified and corrected.

Recording Results

Record test results accurately and according to the testing site's policy for reporting results. Results should be kept as a permanent record. These records should have enough detail for easy retrieval of information. Guidelines for recording results include:

- Quantitative (numerical) results should be recorded in the appropriate units of measurement, and as described in the manufacturer's instructions.
- Qualitative results should be recorded using words or abbreviations rather than symbols. For example, use:
  - » "Positive" or "Pos", "Reactive" or "R" instead of "+"
  - » "Negative" or "Neg", "Non-reactive" or "NR" instead of "-"

Be sure to record any invalid or unacceptable results. If you need to repeat a test, record the first result (invalid or unacceptable), resolve the problem, retest, and then record the repeated result. Only report the final acceptable result. See Appendix D for examples of QC logs and testing result logs.

Issuing Test Results

Guidelines for Issuing Test Reports:

- ✓ Patient test reports should be legible, standardized, and promptly issued according to site-specific procedures.
- ✓ Reports from on-site tests should be easily distinguishable from referral laboratory test reports.
- ✓ Only give patient test reports to authorized persons, in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA). https://www.hhs.gov/hipaa/for-professionals/index.html
- ✓ Verbal communication of test results should be documented and followed by a written test report.
- ✓ Follow site-specific policies and procedures when using electronic medical record systems or laboratory information systems to issue test reports.

Guidelines for Critical Values:

Critical values are test results that require immediate treatment or evaluation by the physician. The testing site should establish a system to ensure critical values are addressed by:

- ✓ Defining which tests have critical values
- ✓ Ensuring that staff are aware of the critical values and know how to alert the physician promptly
- ✓ Documenting when and to whom critical values are reported

Confirmatory or Supplemental Testing

The manufacturer's instructions should explain when additional testing is required. Each testing site should have written site-specific procedures to ensure confirmatory or additional testing is performed or referred, when needed. Instructions should include how to:

- ✓ Order additional tests with examples of completed request forms.
- ✓ Contact the referral laboratory, if necessary.
- ✓ Collect and label the sample.
- ✓ Transport or ship samples safely. (http://www.phmsa.dot.gov/hazmat and http://www.iata.org/publications/dgr/Pages/index.aspx)

Sites should maintain records of referred tests that:

- ✓ Link the referred sample to the original patient sample
- ✓ Document the referral laboratory, test name, and date referred
- ✓ Document when test results are received and the date of the final test report

Public Health Reporting

Public health agencies require testing sites to report confirmed positive test results for certain infectious diseases. Diseases identified for reporting can change over time, and state requirements may vary. Check with local public health agencies for the most current information on mandated reporting procedures.

The National Notifiable Disease Surveillance System (NNDSS) plays a crucial role in monitoring, controlling, and preventing over 120 diseases. These diseases are considered nationally significant and require continuous monitoring. Public health departments rely on the data collected through NNDSS to safeguard their local communities. To learn more about NNDSS and access its educational resources, visit https://www.cdc.gov/nndss/index.html.

Record Keeping

Document all steps of the testing process to ensure quality testing. Logbooks or electronic files can be used to maintain records. The person overseeing testing and operations should periodically review all records. Good record-keeping is necessary to:

- ✓ Retrieve and verify information
- ✓ Assess test performance
- ✓ Identify and resolve problems that could affect test results
- ✓ Maintain patient and personnel information
- ✓ Check with your local/state public health department for record keeping requirements

Records

Examples of records to maintain for easy access and retrieval of information include:

- Test orders, test results, confirmatory or additional testing results
- Quality control results
- Reagents, test kits, quality control material lot numbers, dates received and used, and expiration dates
- Daily temperature checks, test system or equipment function checks and maintenance
- Test system failures, troubleshooting, and corrective action taken when problems have been identified
- Test or product recall notices
- Personnel training and competency assessments
- Results of proficiency testing (PT) or other external quality assessment activities

Proficiency Testing

Proficiency Testing (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 testing 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/downloads/survey-and-cert-letter-18-07.pdf
- 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

Quality Assessment

Assessing testing quality requires planned and systematic monitoring and evaluation of the testing process. Conducting these activities can lead to reduced errors, improved patient outcomes, improved patient and employee safety, and reduced costs. Depending on your site's needs, resources, and practices, you may perform quality assessment using a combination of internal and external processes.

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

- 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 education 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
- Subscribing voluntarily to PT programs
- Exchanging samples with other testing sites using the same test method(s) to compare results

Reminders, Resources, and Links

Reminders

- ✓ Have a CLIA Certificate before testing patients.
- ✓ If you have a Certificate of Waiver, use only waived tests or test kits.
- ✓ If a test is modified by the testing laboratory or test site in any way, it is no longer considered waived and cannot be used under a CLIA Certificate of Waiver.
- ✓ The most important resource you have for every step of the testing process is the manufacturer's instructions.

Resources

- Appendix A: Pretesting Task Checklist
- "Self-Assessment Checklist for Good Testing Practices" https://www.cdc.gov/lab-quality/php/waived-tests/
- 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
- CDC CLIA Home Page: https://www.cdc.gov/clia/php/about/index.html
- CMS CLIA Home Page: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments
- How to Apply for a CLIA Certificate, including International Laboratories: https://www.cms.gov/medicare/quality/clinical-laboratory-improvement-amendments/apply
- CMS CLIA Application for Certification: https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf
- 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
- Health Insurance Portability and Accountability Act (HIPAA): https://www.hhs.gov/hipaa/for-professionals/index.html
- For additional information: https://www.cdc.gov/lab-quality/php/waived-tests/

Safety Links

- The Centers for Disease Control and Prevention (CDC) Biosafety Information for Laboratories and Testing Sites: https://www.cdc.gov/safe-labs/php/about/ and https://www.cdc.gov/labsafety/
- List of OSHA publications and links: https://www.osha.gov/publications
- OSHA Occupational Safety and Health Standards: https://www.osha.gov/healthcare/standards
- OSHA state plans: https://www.osha.gov/stateplans
- Safety Data Sheets: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1200AppD
- Hand Hygiene in Healthcare Settings: https://www.cdc.gov/handhygiene/index.html

Reminders, Resources, and Links

Training Links

- CDC Laboratory Training: https://www.cdc.gov/labtraining/
- OneLab REACH™: https://reach.cdc.gov/home
- **Ready? Set? Test!** Patient Testing is Important. Get the Right Results. Online training course: https://www.cdc.gov/lab-training/php/courses/ready-set-test.html

Pretesting Task Checklist

Prepare Work Area

- ☐ Are your work surfaces clean? Routinely clean using an EPA-registered disinfectant and dry work surfaces before and after testing.
- ☐ Is your work area well-lit? Ensure adequate lighting. Always perform testing in a well-lit area.
- ☐ Remove clutter or trash.

Check and Record Temperatures

- ☐ Check and record temperatures of the refrigerators, freezers, and any rooms used to store testing materials daily.
- ☐ Check and record temperatures of the room where testing is performed before using the room.

Maintain Equipment

- ☐ Wear gloves and thoroughly clean the surface of the testing equipment using a manufacturer-recommended or EPA-registered disinfectant before and after each use to prevent cross-contamination. Make sure that the machine is dry before using it. Be sure to wash your hands after removing gloves.
- ☐ Inspect equipment and electrical connections to be sure they are working.
- ☐ Perform calibration checks if required by the manufacturer's instructions.

***Portable equipment, if moved, might be subject to inaccurate results.**

To verify proper test system functioning, perform control testing or calibration check procedures after moving the equipment, even if not required by the current manufacturer.

Prepare Materials for Testing

- ☐ Regularly check inventory to ensure you have enough reagents (testing solutions) and supplies for testing.
- ☐ Check and record expiration dates of reagents and test kits.
- ☐ Discard any reagents or tests that have expired or have been opened for longer than recommended by the current manufacturer's instructions.
- ☐ Check and record lot numbers of all reagents and test kits; be sure all reagents come from the same lot. **NOTE: DO NOT mix reagents from different products or lot numbers**
- ☐ Visually inspect reagents or vials for damage, discoloration, or contamination.
- ☐ Prepare reagents according to the current manufacturer's instructions.
  (If opening a new reagent, write the date opened on the outside of the vial or test kit.)
- ☐ Allow refrigerated reagents and samples to reach room temperature before testing.
- ☐ Perform quality control testing, as recommended in the current manufacturer's instructions.

Temperature Log Instructions

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test being performed. This includes instructions for reagents, test kits, controls, and patient sample storage.

The manufacturer's instructions will indicate the acceptable temperature range for storing reagents, test kits, controls, and patient samples. Some products have the option to be stored at multiple temperature conditions. Each testing site should consider environmental factors and equipment availability to determine the best storage condition for reagents, test kits, controls, and patient sample storage.

Refrigerators and freezers are essential for cooling or freezing the test reagents or test kits, controls, and patient samples for preservation. Typically, a refrigerator used to store patient samples is kept between 2 and 8 degrees Celsius (between 36 and 46 Fahrenheit). A freezer used for sample storage is often kept between -25 and -15 degrees Celsius (between -13 and 5 Fahrenheit). The proper temperature range for a freezer or refrigerator should be determined by considering the acceptable temperature range indicated for the reagents or test kits, controls, and patient samples that will be stored in it.

Room temperature is essential for testing conditions and storing some reagents or test kits, controls, and patient samples. Typically, rooms used for testing and storage are kept between 15 and 30 degrees Celsius (between 59 and 86 Fahrenheit). Always refer to the manufacturer's instructions before storing patient samples and products at room temperature.

To ensure that a refrigerator, freezer, or room maintains the proper temperature, it is important to check and record the temperature daily and before using the room. This applies whether the refrigerator or freezer has a temperature alarm, a chart recorder thermometer, a digital data logger thermometer, or a continuous temperature monitoring system.

Contents:

There are many ways to log the temperature of a refrigerator, freezer, or room. Blank logs are included for your use, along with example logs that demonstrate how to enter site-specific information correctly.

1. Example Refrigerator/Freezer Temperature Log Completed
2. Blank Refrigerator/Freezer Temperature Log
3. Example Room Temperature Log Completed
4. Blank Room Temperature Log
5. Example Minimum/Maximum Temperature Log Completed
6. Blank Minimum/Maximum Temperature Log
7. Example Temperature Log for Multiple Instruments Completed
8. Blank Temperature Log for Multiple Instruments

Instructions for Recording Temperatures:

1. Post a temperature log in the room or on the refrigerator or freezer door.
2. Read the thermometer(s) in the room, refrigerator, or freezer daily.
3. Optionally, use a digital data logger thermometer with minimum and maximum temperature reading capabilities to monitor temperature on weekends and/or during testing site closures if reagents or test kits will be continuously stored during that time. The display should be reset or cleared after each reading, restarting the clock for the timeframe being monitored.
4. If a continuous temperature monitoring system is in use, the daily temperature should still be reviewed. If applicable, alerts and alarms messages can be used to notify key personnel when temperatures are out of range.
5. Check for separated columns, gas bubbles, and cracks each time the thermometer is read, as applicable.
6. Record the temperature(s) of the room, refrigerator, or freezer.
7. Date and initial/sign the temperature log.
8. If a temperature reading is missed, and there is no available temperature data for that time frame, the entry log should remain blank. Do not make up or guess what the temperature was for that reading.
9. If the temperature falls outside of the recommended range for storage of test reagents or test kits, controls, and patient samples or the testing room for any amount of time, stop testing and contact the person who directs or supervises the testing for guidance and next steps, including if all impacted reagents or test kits should be discarded and when to resume testing. Document all corrective actions.
10. The person who directs or supervises the testing should review and sign when the temperature log is complete for the month.

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

TEMPERATURE LOG

Refrigerator/Freezer Location Lab refrigerator **Month/Year** June 2024
Acceptable Temperature Range 4-8°C

Date	Temperature	Checked By	Date	Temperature	Checked By
1	4°C	Sara	17	#	#
2	#	#	18	4°C	Sara
3	#	#	19	4°C	Sara
4	4°C	Sara	20	4°C	CO
5	4°C	Sara	21	4°C	Sara
6	8°C	CO	22*	24°C	Sara
7*	15°C	Sara	23	#	#
8	4°C	Sara	24	#	#
9	#	#	25	4°C	Sara
10	#	#	26	4°C	Sara
11	4°C	Sara	27	4°C	CO
12	4°C	Sara	28	4°C	Sara
13	4°C	CO	29	4°C	Sara
14	4°C	Sara	30	#	#
15	4°C	Sara	31	#	#
16	#	#			

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
*6/7	Refrigerator door was ajar. Closed door, check in 30 minutes. Temp at 6°C - OK	Sara
*6/22	Refrigerator not staying in range. Called for service. Door seal replaced. QC'd kits stored in refrigerator. Continue to QC and monitor for problems.	Sara

Reviewed By: Janice Smith, office mgr. **Date:** 6/29/2024

Facility:
Location:

TEMPERATURE LOG

Refrigerator/Freezer Location _____ **Month/Year** _____
Acceptable Temperature Range _____

Date	Temperature	Checked By	Date	Temperature	Checked By
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed By: _____ **Date:** _____

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

ROOM TEMPERATURE LOG

Room Location Lab **Month/Year** June 2024
Acceptable Temperature Range 15-30°C

Date	Temperature	Checked By	Date	Temperature	Checked By
1	20°C	Sara	17	#	#
2	#	#	18	19°C	Sara
3	#	#	19	18°C	Sara
4	20°C	Sara	20	18°C	CO
5	18°C	Sara	21	19°C	Sara
6	20°C	CO	22	21°C	Sara
7*	40°C	Sara	23	#	#
8	18°C	Sara	24	#	#
9	#	#	25	18°C	Sara
10	#	#	26	19°C	Sara
11	18°C	Sara	27	20°C	CO
12	19°C	Sara	28	20°C	Sara
13	18°C	CO	29	20°C	Sara
14	19°C	Sara	30	#	#
15	20°C	Sara	31	#	#
16	#	#			

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
*6/7	Unexpected power outage. Temp rechecked when power restored. Temp at 20°C - OK. QC'd room temp kits. Continue to QC and monitor for problems.	Sara

Reviewed By: Janice Smith, office mgr. **Date:** 6/29/2024

Facility:
Location:

ROOM TEMPERATURE LOG

Room Location _____ **Month/Year** _____
Acceptable Temperature Range _____

Date	Temperature	Checked By	Date	Temperature	Checked By
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed By: _____ **Date:** _____

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

MINIMUM/MAXIMUM TEMPERATURE LOG

Refrigerator/Freezer Location Lab refrigerator **Month/Year** June 2024
Acceptable Temperature Range 4-8°C

Date	Min Temperature	Max Temperature	Checked By:	Date	Min Temperature	Max Temperature	Checked By
1	2°C	6°C	Sara	17	2°C	6°C	Sara
2*	#	9°C	Sara	18	2°C	6°C	Sara
3	2°C	6°C	CO	19	2°C	6°C	CO
4	2°C	6°C	Sara	20	2°C	6°C	Sara
5	2°C	6°C	Sara	21	2°C	6°C	Sara
6	2°C	8°C	CO	22	2°C	6°C	CO
7	2°C	8°C	Sara	23	2°C	6°C	Sara
8	2°C	8°C	Sara	24	2°C	6°C	Sara
9	2°C	8°C	CO	25	2°C	6°C	CO
10	2°C	8°C	Sara	26	2°C	6°C	Sara
11	2°C	8°C	Sara	27	3°C	6°C	Sara
12	2°C	8°C	Sara	28	3°C	8°C	Sara
13	2°C	8°C	Sara	29	3°C	8°C	Sara
14	2°C	8°C	CO	30	3°C	8°C	CO
15	2°C	8°C	Sara	31	3°C	8°C	Sara
16	2°C	8°C	Sara				

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials
*6/2	Refrigerator not staying in range. Called for service. Door seal replaced. QC'd kits stored in refrigerator. Continue to QC and monitor for problems.	Sara

Reviewed By: Janice Smith, office mgr. **Date:** 6/29/2024

Facility:
Location:

MINIMUM/MAXIMUM TEMPERATURE LOG

Refrigerator/Freezer Location _____ **Month/Year** _____
Acceptable Temperature Range _____

Date	Min Temperature	Max Temperature	Checked By:	Date	Min Temperature	Max Temperature	Checked By
1				17			
2				18			
3				19			
4				20			
5				21			
6				22			
7				23			
8				24			
9				25			
10				26			
11				27			
12				28			
13				29			
14				30			
15				31			
16							

* Enter # for weekends and holidays when temperature is not monitored.

Corrective Action for Out of Range Temperature

Date	Action Taken	Initials

Reviewed By: _____ **Date:** _____

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

Temperature Log for Multiple Instruments

Month July **Year** 2024

Temp/ Acceptable Range	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Room temp/ (18 to 30°C)	25	26	24	22	27	#	#	26	22	20	19	29	#	#	22	23	25	26	22	#	#	23	27	28	25	22	#	#	24	22	26
25°C Incubator (23 to 27°C)	25	25	25	25	25	#	#	25	26	25	25	25	#	#	25	25	26	25	25	#	#	25	25	24	25	25	#	#	26	25	25
37°C Incubator (35 to 39°C)	37	38	37	36	37	#	#	37	38	38	36	37	#	#	38	35	30*	36	35	#	#	36	37	38	35	36	#	#	38	37	37
Refrigerator (2 to 8°C)	5	6	4	5	6	#	#	6	5	4	6	5	#	#	6	6	6	5	5	#	#	6	6	5	6	4	#	#	5	5	6
Freezer (-25 to -35°C)	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30	-30	-30	#	#	-30	-30	-30
Initials	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO	CO	CO	#	#	CO	CO	CO

Temperatures should be read first thing in the morning.
Record temperature in degrees Celsius for all equipment requiring temperature monitoring. Enter # for weekends and holidays when temperature is not monitored.

Report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate corrective action.

Comments: *Incubator door left open. Closed door and checked temperature prior to using for testing purposes. Temp was 35°C.

Reviewed By: Joe Smith, MD **Date:** 8/01/2024

Facility:
Location:

Temperature Log for Multiple Instruments

Month _____ **Year** _____

Temp/ Acceptable Range	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Room temp/ (18 to 30°C)																															
25°C Incubator (23 to 27°C)																															
37°C Incubator (35 to 39°C)																															
Refrigerator (2 to 8°C)																															
Freezer (-25 to -35°C)																															
Initials																															

Temperatures should be read first thing in the morning.
Record temperature in degrees Celsius for all equipment requiring temperature monitoring.
Enter # for weekends and holidays when temperature is not monitored.

Report all problems, difficulties, or abnormalities concerning equipment to the supervisor and document the appropriate corrective action.

Comments: _____

_____

_____

_____

_____

Reviewed By: _____ **Date:** _____

Common Components of a Manufacturer's Instructions

Component	Information Provided
Intended Use	Describes the test purpose, substance detected or measured, test methodology, appropriate specimen type and FDA cleared conditions for use. Additionally, it might include if the test is diagnostic or for screening a target population and if it is intended for professional use or self-testing.
Summary	Explains what the test detects; a short history of the methodology, the disease process or health condition detected or monitored; the response to disease, symptoms and severity and disease prevalence and appropriate references.
Test Principle	A description of the test methodology, chemical process of the test.
Precautions	Alerts the user of practices or conditions affecting the test, potential hazards, and safety precautions (toxic reagents, handling infectious samples or biohazardous waste). Warnings to not mix components from different lot numbers or use products beyond the expiration date are often included.
Storage and Stability	The recommended conditions for storing reagents or test kits; temperature ranges and other physical requirements (humidity, exposure to light) affecting the stability of reagents or test components.
Reagents and Materials Supplied	A list of reagents and materials included in the test kit, the concentration, and major ingredients in reagents.
Materials Required but Not Provided	A description of materials that are not included in the test kit that will be required to perform the test.
Sample Collection and Preparation	A detailed procedure for collecting the appropriate sample, including storage and handling instructions. Conditions affecting the acceptability of the sample may be described.
Test Procedure	Step-by-step instructions and information critical to correctly performing the test are provided in this section.
Interpretation of Results	An explanation of how to read or interpret the test results, often includes visual aids. Instructions for dealing with invalid results, precautions against reporting results when supplementary or confirmatory testing is required.
Quality Control	Instructions for performing QC, what aspects of the test are monitored by internal and/or external QC, and when to perform QC testing.
Limitations	Describes the conditions that can affect test results, or circumstances for which the test was not intended, such as: interference from medical conditions, drugs or other substances; limitations for testing with certain samples or populations; more specific testing may be required; warnings that the test does not differentiate between active infection and carrier states, or warnings that test results should be considered with clinical signs, history and other information.
Expected Values	Describes the test results normally expected, how results can vary with disease prevalence or seasonality. Studies leading to the expected results might be included.
Performance Characteristics	Describes studies performed by the manufacturer to evaluate test performance.

Note: Manufacturer's instructions vary in format and some information may be found in different sections than those described here. Testing site directors and testing personnel should read the information provided in the manufacturer's instructions for an understanding of the test and update their procedures, as needed, based on manufacturer's instructions updates.

Appendix D

Quality Control Log Instructions

Purpose:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer's instructions provided with the test including instructions for quality control (QC).

QC is designed to detect problems arising from reagent or test kit deterioration, instrument malfunction, improper environmental conditions, or operator error. Performing QC testing procedures assures that the test performs as expected and alerts the user when problems occur. QC procedures should describe the type of controls to be used, how to perform QC testing, frequency of QC testing, and actions to be taken when QC results are unacceptable.

QC material should be treated the same as patient samples by being tested in the same way that patient samples would be tested. QC is usually performed with:

- Each new operator
- After an instrument is serviced
- When reagent or test kit lots are changed
- When reagent or test kit temperatures exceed the manufacturer's acceptable temperature range
- After calibration
- When patient results seem questionable

Refer to the manufacturer's instructions for specific QC requirements for each test your testing site performs. Each testing site should determine the appropriate QC frequency for each test system. Remember that the frequency of QC testing cannot be less than what is specified in the manufacturer's instructions.

Contents:

There are many ways to log QC results. A blank QC log is included, along with an example log demonstrating how to enter site-specific information correctly.

1. Example Quality Control-Qualitative Test Log Completed
2. Blank Quality Control-Qualitative Test Log
3. Example Quality Control-Quantitative Test Log Completed
4. Blank Quality Control-Quantitative Test Log

Note: Qualitative tests are interpreted as positive, negative; reactive, non-reactive; or invalid. Quantitative tests give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.

Instructions for Performing External Control Testing and Recording Results:

1. Obtain the QC material. Check the expiration date and check that the material has been stored and handled according to the manufacturer's requirements and instructions.
2. Record the initials of the person performing the test, test date, test name, lot number, and expiration date of the test on the QC Log.
3. Record the lot number for the QC material on the QC Log.
4. Test the QC material following the manufacturer's instructions and record the results on the QC Log.
5. If the results are acceptable, QC passes, and patient results can be reported.
6. If controls do not give the expected results, patient results should not be reported until the problem is identified and corrected.

- ✓ Check to see if the manufacturer's instructions were followed correctly.
- ✓ Look for possible sources of error, such as outdated reagents, test kits, or control materials.
- ✓ Check to see if reagents, test kits, and control materials were stored correctly.
- ✓ Make sure controls and reagents were not cross contaminated by accidentally switching caps.
- ✓ Follow the troubleshooting steps in the manufacturer's instructions or site-specific procedure.
- ✓ Contact the manufacturer, technical representative, and/or the person who directs or supervises the testing for additional assistance.

Once the problem is identified and corrected, repeat QC testing. If the QC results are acceptable, re-test patient sample(s) and report the final acceptable results.

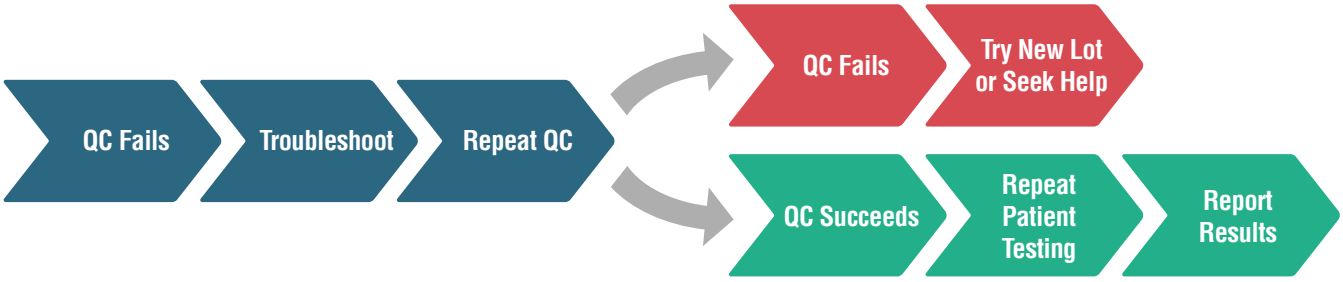


Figure D1. *Actions for unexpected QC results.*

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

Quality Control Log - Qualitative Test

	Tech Initials	Date	Test Name	Test Lot number/ Test Exp. Date	Negative Control	Positive Control	Mid-Range Control (if applicable)	Comments	Reviewed by Initials/Date
1	CO	5/5/2024	Occult Blood 1-2-3	BJZ-3 / 8/31/2025	lot #: 108-OCB result: Pos*	lot #: 108-OCB result: Pos	lot #: N/A result:	*possible sample mix-up, retest	Joe Smith 5/5/2024
2	CO	5/5/2024	Occult Blood 1-2-3	BJZ-3 / 8/31/2025	lot #: 108-OCB result: Neg	lot #: 108-OCB result: Pos	lot #: N/A result:	QC passed and ready to use	Joe Smith 5/5/2024
3					lot #: result:	lot #: result:	lot #: result:		
4					lot #: result:	lot #: result:	lot #: result:		
5					lot #: result:	lot #: result:	lot #: result:		
6					lot #: result:	lot #: result:	lot #: result:		
7					lot #: result:	lot #: result:	lot #: result:		
8					lot #: result:	lot #: result:	lot #: result:		
9					lot #: result:	lot #: result:	lot #: result:		
10					lot #: result:	lot #: result:	lot #: result:		

Facility:
Location:

Quality Control Log - Qualitative Test

	Tech Initials	Date	Test Name	Test Lot number/ Test Exp. Date	Negative Control	Positive Control	Mid-Range Control (if applicable)	Comments	Reviewed by Initials/Date
1					lot #:	lot #:	lot #:		
					result:	result:	result:		
2					lot #:	lot #:	lot #:		
					result:	result:	result:		
3					lot #:	lot #:	lot #:		
					result:	result:	result:		
4					lot #:	lot #:	lot #:		
					result:	result:	result:		
5					lot #:	lot #:	lot #:		
					result:	result:	result:		
6					lot #:	lot #:	lot #:		
					result:	result:	result:		
7					lot #:	lot #:	lot #:		
					result:	result:	result:		
8					lot #:	lot #:	lot #:		
					result:	result:	result:		
9					lot #:	lot #:	lot #:		
					result:	result:	result:		
10					lot #:	lot #:	lot #:		
					result:	result:	result:		

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

Quality Control Log - Quantitative Test

	Tech Initials	Date	Test Name	Test Lot number/ Test Exp. Date	Level 1 Control	Level 2 Control	Comments	Reviewed by Initials/Date
1	CO	5/5/2024	XYZ ALT	C843 / 4/31/2025	lot #: 91750566 range: 43-78 U/L result: 31 U/L*	lot #: 91750566 range: 132-242 U/L result: 203 U/L	*Level 1 Control value too low, Kit was expired. Discard Kit	Joe Smith 5/5/2024
2	CO	5/5/2024	XYZ ALT	C978 / 8/31/2025	lot #: 91750598 range: 43-78 U/L result: 55 U/L	lot #: 91750598 range: 132-242 U/L result: 221 U/L	New lot. QC passed and ready to use	Joe Smith 5/5/2024
3					lot #: range: result:	lot #: range: result:		
4					lot #: range: result:	lot #: range: result:		
5					lot #: range: result:	lot #: range: result:		
6					lot #: range: result:	lot #: range: result:		
7					lot #: range: result:	lot #: range: result:		
8					lot #: range: result:	lot #: range: result:		
9					lot #: range: result:	lot #: range: result:		

Facility:
Location:

Quality Control Log - Quantitative Test

	Tech Initials	Date	Test Name	Test Lot number/ Test Exp. Date	Level 1 Control	Level 2 Control	Comments	Reviewed by Initials/Date
1					lot #:	lot #:		
					range:	range:		
					result:	result:		
2					lot #:	lot #:		
					range:	range:		
					result:	result:		
3					lot #:	lot #:		
					range:	range:		
					result:	result:		
4					lot #:	lot #:		
					range:	range:		
					result:	result:		
5					lot #:	lot #:		
					range:	range:		
					result:	result:		
6					lot #:	lot #:		
					range:	range:		
					result:	result:		
7					lot #:	lot #:		
					range:	range:		
					result:	result:		
8					lot #:	lot #:		
					range:	range:		
					result:	result:		
9					lot #:	lot #:		
					range:	range:		
					result:	result:		

Instructions for Logging or Recording Results

Purpose:

Test results should be recorded legibly and completely. Filing all test result records in an organized, easy to find manner is a recommended practice for all testing.

Contents:

There are many ways to record results. A blank results log is included, along with an example log demonstrating how to enter site-specific information.

Instructions for Logging or Recording Results

Results Log – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Enter the test date, sample number, patient name or identification, test results, lot number, and expiration test date.
3. The person who performed the test should initial the results after verifying all information has been entered correctly.

Results Log – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Enter the test date, sample number, patient name or identification, test results, lot number, and expiration test date.
3. The person who performed the test should initial the results after verifying all information has been entered correctly.

Results Log with QC – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Record the QC material lot number, expiration date, and positive and negative control results.
3. If the results are acceptable, QC passes, and patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition, etc.), re-test the QC, and document the corrective action.

Results Log With QC – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Record the QC material lot number, reportable range, and result.
3. If the results are acceptable, QC passes, and patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition, etc.), re-test the QC, and document the corrective action.

Results Log for Multiple Tests

1. Record the facility information on the top of the form.
2. Record the date, sample number, patient identification, test name, reportable range (if applicable), test result, lot number, expiration date, and the initials of the individual performing the test.

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

Results Log - Qualitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2024	05052018	Donald Smith	NEG	Bd-0679/ 11/30/2025	CO
2	5/6/2024	05052019	Chris White	POS	Bd-0679/ 11/30/2025	CO
3	5/7/2024	05061930	Sam Jones	NEG	Bd-0679/ 11/30/2025	CO
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

Facility:
Location:

Results Log - Qualitative Test

Test Name: _____

	Date	Sample ID / Patient ID	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

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

Results Log - Quantitative Test

Test Name: XYZ Strep antigen **Reportable Range:** 5-400 U/L

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1	5/5/2024	05052018	Steve Smith	Male: 30 U/L	Bd-0679/ 11/30/2025	CO
2	5/6/2024	05052019	Chris White	Male: 22 U/L	Bd-0679/ 11/30/2025	CO
3	5/7/2024	05061930	Sam Jones	Female: 14 U/L	Bd-0679/ 11/30/2025	CO
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

*Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.

Facility:
Location:

Results Log - Quantitative Test

Test Name: _____ **Reportable Range:** _____

	Date	Sample Number	Patient Name	Test Result	Test Lot number / Test Exp. Date	Initials
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

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

Results Log With QC - Qualitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Lot / Exp. Date	Positive Control Results	Negative Control Results
1	5/5/2024	5/05/20 / Tom Jones	NEG	SH	Bd-0679/ 11/30/2025	108-OCB / 9/30/2025	POS	NEG
2	5/6/2024	5/05/22 / Mattie Dunn	NEG	CO	Bd-0679/ 11/30/2025	108-OCB / 9/30/2025	POS	NEG
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

Facility:
Location:

Results Log With QC - Qualitative Test

Test Name: _____

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Lot / Exp. Date	Positive Control Results	Negative Control Results
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

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

Results Log With QC - Quantitative Test

Test Name: XYZ Strep antigen

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1	5/5/2024	5/05/2018 / Steve Smith	Male: 30U/L	CO	C843 / 06-31-2025	Lot #: 91750566 Range: 43-78 U/L Result: 57 U/L	Lot #: 91750566 Range: 132-242 U/L Result: 203 U/L
2	5/6/2024	5/05/2019 / Chris White	Male: 22U/L	CO	C843 / 06-31-2025	Lot #: 91750566 Range: 43-78 U/L Result: 58 U/L	Lot #: 91750566 Range: 132-242 U/L Result: 221 U/L
3	5/7/2024	5/05/1930 / Sam Jones	Female: 14U/L	CO	C843 / 06-31-2025	Lot #: 91750566 Range: 43-78 U/L Result: 57 U/L	Lot #: 91750566 Range: 132-242 U/L Result: 221 U/L
4						Lot #: Range: Result:	Lot #: Range: Result:
5						Lot #: Range: Result:	Lot #: Range: Result:
6						Lot #: Range: Result:	Lot #: Range: Result:
7						Lot #: Range: Result:	Lot #: Range: Result:
8						Lot #: Range: Result:	Lot #: Range: Result:
9						Lot #: Range: Result:	Lot #: Range: Result:

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility:
Location:

Results Log With QC - Quantitative Test

Test Name: _____

	Date	Sample ID / Patient ID	Test Result	Initials	Test Lot number / Test Exp. Date	QC Level 1 Control	QC Level 2 Control
1						Lot #: Range: Result:	Lot #: Range: Result:
2						Lot #: Range: Result:	Lot #: Range: Result:
3						Lot #: Range: Result:	Lot #: Range: Result:
4						Lot #: Range: Result:	Lot #: Range: Result:
5						Lot #: Range: Result:	Lot #: Range: Result:
6						Lot #: Range: Result:	Lot #: Range: Result:
7						Lot #: Range: Result:	Lot #: Range: Result:
8						Lot #: Range: Result:	Lot #: Range: Result:
9						Lot #: Range: Result:	Lot #: Range: Result:

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

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

Results Log for Multiple Tests

	Date	Sample Number	Patient Name or ID	Test Name	*Reportable Range	Test Result	Test Lot Number / Test Exp. Date	Initials
1	5/5/2024	05052018	Donald Smith	XYZ Strep	NA	NEG	Bd-0679 / 11/30/2025	CO
2	5/5/2024	05052019	Chris White	XYZ Strep	NA	POS	Bd-0680 / 11/30/2025	CO
3	5/5/2024	05052020	Tom Jones	Occult Blood - 123	NA	NEG	Bjz-3 / 8/31/2025	SH
4	5/5/2024	05052021	Pam Roberts	Urine HCG-ABC	NA	NEG	Trp-23/11-30-2025	CO
5	5/6/2024	05052022	Mattie Dunn	Occult blood - 123	NA	NEG	Bjz-3/8-31-2025	CO
6	5/6/2024	05052023	Steve Smith	XYZ ALT	5-400 U/L	Male: 33 U/L	C843/6-31-2025	CO
7								
8								
9								
10								
11								
12								
13								
14								
15								

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Facility:
Location:

Results Log for Multiple Tests

	Date	Sample Number	Patient Name or ID	Test Name	*Reportable Range	Test Result	Test Lot Number / Test Exp. Date	Initials
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

** Reportable Range is the range of results for which a test system has been proven to yield accurate results. This is usually found in the manufacturer's instructions for the test.*

Safety: Blood and Body Fluid Exposure

It is important to use standard precautions when cleaning up blood or body fluids. **Always assume they are infectious and act accordingly**.

If a hand washing sink is available:

1. Wet hands with warm running water.
2. Apply soap and vigorously scrub all surfaces of hands and fingers, using large amounts of soap and water for at least 15 seconds.
3. Rinse hands and dry with disposable towels.
4. Use a disposable towel to turn off the faucet.

Before leaving the area, decontaminate the sink and faucet handles using 10% bleach, or an Environmental Protection Agency (EPA) registered disinfectant effective against HBV, HIV, and other bloodborne pathogens. See Appendix F: for Common Disinfectants and Antiseptics.

If mucous membranes or eyes have been exposed to blood or body fluids, follow the steps below.

1. Rinse mucous membranes (i.e., eyes, nostrils, and mouth) with large amounts of water or saline solution.
2. If running water is not readily available, use another water source, such as bottled water, to rinse.

If there is a puncture of skin from a sharp instrument or needle, follow the steps below.

1. Wash the puncture with soap and water while encouraging the puncture to bleed by gently squeezing it, if necessary.
2. Bandage the puncture when finished.

Report exposure

1. Report any exposures to those responsible for managing exposures. Prompt reporting is essential, as post-exposure treatment that might be recommended, in some cases, should be started as soon as possible.
2. Discuss the possible risks of acquiring hepatitis B, hepatitis C, and HIV and the need for post-exposure treatment with the provider managing your exposure.

Safety: Gloves

Disposable Gloves (latex, vinyl, nitrile)

Disposable gloves reduce hand contamination, prevent cross-contamination, and protect from infection. Gloves should fit properly, not restrict hand coordination, accommodate individual requirements such as allergy to latex, and meet the task's requirements. Rings, long fingernails, and fingernail jewelry can make it more challenging to put the gloves on properly and cause gloves to tear more easily.

To help prevent allergic reactions to latex gloves, use appropriate work practices.

- Do not use latex gloves. If you choose latex gloves, it is recommended to opt for powder-free gloves that have a lower protein content.
- Do not use oil-based hand creams or lotions when wearing latex gloves.
- After removing gloves, wash hands with a mild soap for at least 15 seconds, and then rinse and dry them thoroughly.
- Familiarize yourself with the signs of latex allergy, which may include symptoms such as a skin rash, hives, flushing, itching, nasal congestion, eye irritation, sinus problems, asthma, and in rare cases, even shock.

For more information on how to protect yourself from latex exposure and allergy in the workplace, visit: https://www.cdc.gov/niosh/docs/98-113/.

All employees using disposable gloves must observe the following precautions.

- Cover open sores, dermatitis, cuts, etc., with a dressing or bandage.
- Wash hands before putting on gloves.
- Never wash or reuse disposable gloves.
- Remove gloves after they become contaminated and before leaving the work area.
- Remove contaminated gloves using a procedure that avoids contact with the glove's outer surface.
- Dispose of contaminated gloves in infectious waste containers in the work area.
- Wash hands immediately or as soon as possible after removal of gloves.

Instructions on how to safely remove gloves:

https://www.cdc.gov/ebola/hcp/communication-resources/how-to-remove-gloves-safely.html

Common Disinfectants and Antiseptics

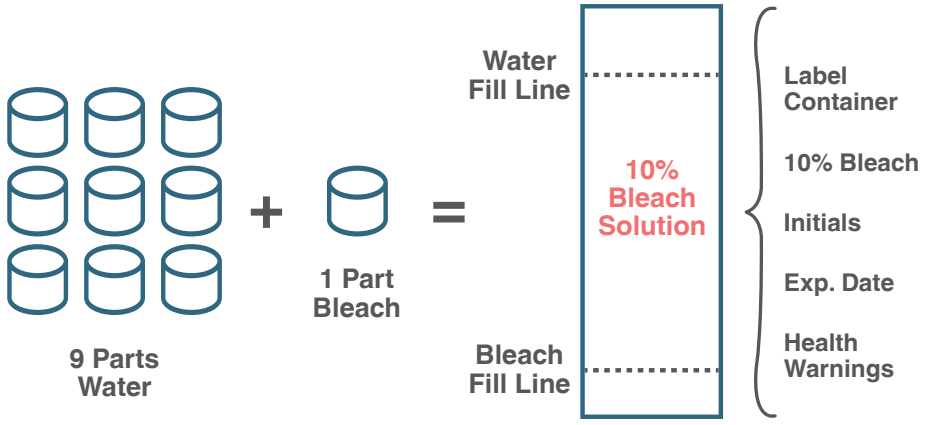
Note: Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services. Proprietary disinfectant products should be used in accordance with the manufacturer's instructions for concentration, contact time, or other conditions of use.

Disinfectants

Selected EPA-registered disinfectants: A list of EPA's registered sterilizers, tuberculocides, and antimicrobial products against certain bacteria and viruses can be found at: https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants.

Chlorine compounds are powerful disinfectants that are inexpensive and easy to obtain. Sodium hypochlorite or household chlorine bleach solutions possess intermediate-level disinfectant properties and are commonly used to disinfect lab surfaces. For maximum potency, the working solution should be prepared fresh at the time of use or daily as needed, but studies show that weekly preparations work, too. A 10% bleach solution is also called 1/10, 1:10, or 5,000 ppm bleach solution.

The directions for preparation are:



Note: Bleach will corrode some equipment. Refer to the manufacturer's instructions for alternatives and recommendations for cleaning and disinfecting procedures.

Commercial Products. The EPA lists registered commercial products that are effective against certain bacteria and viruses. Examples are 'Lysol' (cresol and soap solution) and 'Stericol' (xylenol-rich cresylic acid and soap solution).

Antiseptics

Alcohols are considered intermediate-level disinfectants. Alcohol solutions are often used as a skin antiseptic. Alcohols, such as isopropyl (rubbing) alcohol, are well suited to rapidly kill bacteria on the skin surface in preparation for fingerstick or venipuncture.

Terms and Abbreviations

Anticoagulated blood	Blood that has been treated with an anticoagulant. Anticoagulant solutions are used for the preservation of stored whole blood and blood fractions and to keep laboratory blood specimens from clotting.
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	Bloodborne pathogens are infectious microorganisms that, when present in human blood, can cause disease in humans.
Calibration check	The process of testing and adjusting an instrument or test system to provide a known relationship between the value of the substance being measured by the test and the test system's measurement response. A calibration check is a mechanism to be sure the test system has remained stable, and results remain accurate.
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 performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments of 1988 (CLIA).
Collection devices	A container or instrument used for the collection of samples for testing or analysis.
Competency 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.
Confirmatory test	An additional more specific test performed to rule out or confirm a preliminary test result to provide a final result.
Control	A device or solution used to monitor a test system to ensure proper test performance and correct results.

Corrective action	A method used to remedy a situation, remove an error, adjust a condition, or prevent recurrence of a problem.
Critical value	A test result requiring immediate notification to the clinician for patient evaluation or treatment.
CoW, Certificate of Waiver	A certificate issued or reissued by the Centers for Medicare & Medicaid Services to a testing site performing only waived tests.
Diagnostic test	Tests that are likely to provide information which aids in the making of a diagnosis.
Disinfectant	An agent that destroys microorganisms that may cause disease.
EPA, The Environmental Protection Agency	The United States government agency with the mission of protecting human health and the environment.
External control	Control materials that mimic patient samples and monitor the testing process from sample application to result interpretation.
External quality assessment	A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification, whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value and reported to the participating laboratories and others.
False negative test result	A false negative result is when the test says the patient does not have a disease or condition, but they do.
False positive test result	A false positive result is when the test says the patient does have a disease or condition, but they do not.
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.
Interfering substance	Any substance in a sample, other than the one being measured or detected, whose presence affects the result of the test being performed.

Internal control	Procedural or built-in controls; controls that are built into a testing device and designed to verify that the test system is working as expected.
Kit	A packaged set containing test devices, instructions, reagents, and supplies needed to perform a test and generate results.
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 test 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.
N, Neg, Negative	A result that indicates the absence of the substance a test is designed to detect.
Negative control	A device or solution used to monitor a test system for proper test performance and correct results. A negative control sample or reagent will produce a negative result on the test system.
NR, Non-reactive	A result that indicates the absence of the substance a test is designed to detect.
Order (test)	A written or verbal request by an authorized individual for a test or procedure to be performed on a patient.
OSHA, The Occupational Safety and Health Administration	The United States government agency with the mission to assure safe and healthful 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 specimens as close as possible to the patient.
P, Pos, Positive	A result indicating the presence of a substance a test is designed to detect.
Patient identifiers	Used to reliably identify the individual as the person for whom the service or treatment is intended, and to match the service or treatment to that individual. Acceptable identifiers may be the individual's name, date of birth, and other unique identification numbers such as an assigned identification number, and other unique person-specific identifiers.
Positive control	A device or solution used to monitor a test system for proper test performance and correct results. A positive control sample or reagent will produce a positive result on the test system.
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.
Pretest instructions	Information provided that should be read and followed before testing begins.
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 pretreatment a sample undergoes before testing examples include centrifugation or spinning down of whole blood.

PT, Proficiency testing	An external quality assessment program in which samples are periodically sent to testing sites for analysis. Proficiency testing involves a group of laboratories or analysts performing the same analyses on the same samples and comparing results. The key requirements of such comparisons are that the samples are homogenous, 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 testing site or laboratory are forwarded to a different laboratory or testing site for testing. Sharing or discussing PT sample test results between laboratories or testing sites is also considered PT referral.
Public health reporting	A system to notify public health agencies and to monitor the incidence and distribution of communicable, environmental, occupational, and other dangerous disease occurrences in populations, as well as factors determining that distribution.
QA, Quality assessment	A group of activities used to monitor and evaluate the CoW 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 provided by the test manufacturer containing diagrams or flow charts with essential steps for conducting a test.
R, Reactive	A result indicating the presence of a substance detected by a test.
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 or information about past events.
Referral laboratory	A laboratory that receives samples from CoW sites (and other laboratories) to perform additional testing, often for follow-up or confirmatory testing. Most referral laboratories perform non-waived 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.
Request (test)	A written or verbal order by an authorized individual for a test or procedure to be performed on a patient.
Safety Data Sheet (SDS)	A document that lists information relating to occupational safety and health for the use of various substances and products.
Sample (test)	A specimen of fluid, blood, or tissue collected for testing.
Screening test	Tests used to detect a disease in individuals without signs or symptoms of that disease.

Single-use device	A device intended by the manufacturer to be used on one patient during one procedure.
Supplemental testing	A test performed that increases the reliability of reported test results or provides additional information about the sample.
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. According to the concept of Universal Precautions, all human blood and certain human body fluids should be 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 or spinning down of whole blood.
Venipuncture	The puncture of a vein through the skin to withdraw blood for analysis.
Verbal report	An oral documentation describing the results of a test or assay.
Verification	A procedure intended to verify the accuracy of results over the entire measurement range of a test.
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 of an erroneous result.
Whole blood	Blood containing all cellular components that has not undergone centrifugation or had the plasma removed.

Notes

Notes

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

May 2025