COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 11

Waived Testing

• Overview •

The Clinical Laboratory Improvement Amendments (CLIA) of 1988 established oversight of all clinical laboratories by the federal government. To perform patient specimen laboratory testing, clinical laboratories are required to obtain a CLIA certificate. There are several different types of CLIA certificates and the complexity of the laboratory testing being performed in a facility determines which certificate is needed. Laboratories performing only waived testing must obtain a Certificate of Waiver (COW) from the Centers for Medicare and Medicaid Services (CMS).

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCertificateofWaiver.pdf

The Food and Drug Administration (FDA) determines which test devices are approved for waived testing. Waived tests are defined by CLIA to be "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result." Approximately 120 different analytes can be performed with a waived testing platform and the FDA publishes a listing of those analytes and the waived test systems that are applicable for their performance.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

Federal Requirements for Laboratories Only Performing Waived Testing

- Enroll in the CLIA program to obtain a CLIA COW.
- Designate a Laboratory Director.
- Pay the certificate fee every two years.
- Follow the manufacturer's instructions for waived tests being performed.
- Permit inspection of the laboratory by a CMS agent:
    - When CMS has reason to believe lab poses patient harm.
    - To evaluate complaints from the public.
    - On a random basis to determine compliance with COW regulations.
- Notify the State Agency of any changes in ownership, laboratory name, address, or Laboratory Director within 30 days.

State and Local Regulations

In addition to following federal regulations, laboratories also must follow all applicable state and local regulations. Some states may require licensure for laboratories performing only waived testing or licensure for individuals performing specimen collection and testing. Enrollment in proficiency testing and specific frequencies for performing quality control are other possible requirements that must be followed per state regulations. Whenever state or local regulations are more strict than federal regulations, they must be followed.

• Getting Started •

CLIA Certificate of Waiver

To enroll in the CLIA program, you must complete an application (Form CMS-116) which is available on the CMS CLIA website or your local state agency. A Laboratory Director must be designated as part of the application. This individual is responsible for oversight of the laboratory testing. After the completed application and the required fee is received, the laboratory will receive the COW. The COW is valid for two years, and a renewal fee must be paid every two years to keep the COW current.

Train Personnel to Perform Testing

Proper training of the individuals who will be performing the testing is essential to obtaining quality results. Personnel must follow all manufacturer's instructions for the tests performed. Failure to follow these instructions or changing the manufacturer's instructions changes the classification of the test and it will no longer be considered waived.

Proficiency Testing

Proficiency testing (PT) is not required by federal regulations for any test that is waived; however, some accreditation organizations and state regulations may require PT. Participation in PT is a good laboratory practice and can help the laboratory feel confident in the quality of testing performed.

PT serves as an outside check of the accuracy of test results by providing unknown samples for the lab to test. The results are submitted to the PT provider to determine if the obtained results are correct.

To perform PT, enroll with a PT program and pay the necessary fees for the year. Economical options are available specifically for waived testing. The PT provider will then guide you through the process for participation in their program.

NOTE: PT samples must never be sent to another laboratory – the samples are only to be tested in the laboratory listed on the paperwork included with the samples. Additionally, the laboratory cannot discuss the PT results with another laboratory until the graded results are received for the specific samples.

A list of approved PT programs is available from CMS.

https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers

• Best Practices for Waived Testing •

The term, "best practice," is used in many different work environments. By definition, a best practice is an evidence-based, standardized method for achieving the best possible outcomes. From bakeries to burgers, it is how all types of businesses consistently produce the best product over time. Best practices can be techniques, processes, systems, or protocols.[1] In laboratory testing, following best practices can ensure that we are generating the most accurate test result possible each time we perform a test.

Due to the lack of government oversight in waived testing, laboratorians are responsible for ensuring that best practices are followed. It is important to remember, "guidelines do not implement themselves."[2]

Best practices exist for all phases of laboratory testing: *pre-analytic* (preparation for testing), *analytic* (the actual performance of the test) and *post-analytic* (after the test has been performed). One of the most common deficiencies found in waived testing is a failure to follow the instructions in the manufacturer's package insert. A good understanding of the components of the manufacturer's package insert is helpful in identifying which sections of the package insert apply to the different phases of testing.

Components of a Manufacturer's Package Insert[3]*

Package Insert Headings	Phase of Testing	Information Found in This Section
Intended Use	Pre-Analytic	Name of the test, test method used, specimen type, and the use of the test result in the diagnosis process
Summary and Explanation	Pre-Analytic	Symptoms and signs of disease, the disease process, the history of testing for the disease
Principle of the Test	Pre-Analytic	Details regarding the methodology of the test and how it works to produce a result
Reagents and Materials Included	Pre-Analytic	The components that are found in the kit
Reagents and Materials Not Included	Pre-Analytic	Components you will need for testing that are not supplied
Warnings and Precautions	Pre-Analytic	A listing of what you should do (usually safety related) and those things you should NOT do (do not use after expiration date) and warnings regarding human specimens.
Storage and Stability	Pre-Analytic	Information on the storage of the kit and its components as well as the stability of the kit and its components
Specimen Collection and Preparation	Pre-Analytic	Explicit, detailed instructions on the type of sample to collect, what to collect the sample in, how to collect the sample, and how long the sample is stable under various conditions
Quality Control (QC)	Analytic	What the "external" control is, when it should be performed, and how to interpret these results. What the "internal" control is and how it should be interpreted.

Package Insert Headings	Phase of Testing	Information Found in This Section
Procedure Notes	Pre-Analytic, Analytic and Post- Analytic	Helpful information regarding all phases of the test that CAN BE VERY IMPORTANT
Test Procedure	Analytic	Step-by-step directions on how to perform the test including sample volume, timing of reagent addition, and timing to test completion
Interpretation of Results	Post-Analytic	Instructions and aids (e.g. color photos) for reading and interpreting the results of the tests
Performance Characteristics	N/A	Test accuracy, precision, sensitivity and specificity information from studies that were conducted using the product
Limitations	Post-Analytic	Details what can cause interference with the testing (e.g. hemolysis, Vitamin C, etc.), how negative results cannot always rule out disease, patient age limitations for detecting the analyte
Expected Results	Post-Analytic	For qualitative testing: Positive, Negative. For quantitative testing: a number (value) corresponding to the amount of the analyte being measured
*This is an example of a manufacturer's package insert. Most package inserts contain all of the information above; however, some information may be located under a different heading.		

Follow these *Best Practices* to help your laboratory consistently produce the best results possible

***Pre-Analytic Phase*/Best Practices**

1. Prior to performing any testing, ensure that the individuals performing the test are thoroughly trained. Training should include specimen collection, the actual performance of the test, result interpretation, and reporting. ***The package insert for the test must be read and reviewed thoroughly***. Those that perform the test should have their competency (ability to perform the test accurately) assessed annually. Competency assessment can be assessed using proficiency testing (PT) samples or previously tested patient samples.
2. Check the expiration dates on kits and reagents and discard any kit or reagent that has expired. Do not mix components of one kit with another kit. If a kit has been left out at room temperature too long or stored under the wrong conditions, run external quality control (QC) to ensure the test can still provide quality results.
3. Ensure all instrument function checks (calibration, temperatures, etc.), room temperature, storage temperature, and humidity levels (if applicable) are all acceptable and documented. All of these records should be maintained.
4. Verify that you will be using the most up to date package insert for the test. Test manufacturers print revision dates on the package inserts. Compare the revision date of the package insert from a newly opened kit to the previous kit that was used. A change

in the revision date will be your clue that something in the package insert has been changed or updated. Read and follow ALL instructions on the *latest* version of the insert.

5. Be sure to record the lot number and expiration date when a new kit is opened. Recording the lot number and expiration date on the patient testing log will allow this information to be traced back to specific patients in case of a recall or issue with the test kit.
6. Ensure there is a written order for the test and that all of the information is correct. Talk with the patient to be sure that any special instructions regarding testing (e.g. fasting specimen) have been followed and inform the patient of conditions that can affect testing.
7. Properly identify your patient using two forms of identification (e.g. name and date of birth). Be sure to label all patient specimens with the two identifiers. Label all testing components (cartridges, test strips, cassettes, tubes, etc.) with the identification information in case another person comes after you to read the results.
8. Collect the specimen exactly as the package insert states. Do not substitute serum if the package insert states to collect whole blood. (This will change the test complexity also!) Always collect your sample with the device stated by the manufacturer (e.g. EDTA, heparin, etc.). Be aware and avoid specimen issues stated in the package insert that can affect test results (e.g. hemolyzed samples, finger stick samples that require testing be performed immediately, etc.).

***Analytic Phase*/Best Practices**

1. Prior to the testing of patient samples, QC must be performed per the manufacturer's instructions and the results must be acceptable. Quality control requirements vary with different tests and manufacturers but the rule is simple: the laboratory **MUST** perform external QC as per the manufacturer's instructions listed in the package insert. Most waived tests also have built-in "internal" controls that are read when the patient result is read. Both external and internal QC must be recorded and these documents must be maintained.
2. Follow the manufacturer's instructions for the performance of the test exactly as they are written. Set a timer to ensure the timely addition of reagents or development time. These steps are often critical to the proper performance of the test.
3. For those tests that use a color indicator for test interpretation (a blue line, a red line, a black dot, etc.), it is a good idea for testing personnel to be checked for colorblindness to prevent errors in reading test results.
4. Know what to do if the test fails (e.g. if quality control fails, if the result is invalid, etc.). The package insert will usually provide options for problem resolution.
5. Record the result of the internal QC and the patient test interpretation immediately upon completion of the test. A patient testing log is the ideal location for all of this information.
6. Proficiency testing is NOT required for waived testing; however, it is a great tool for assessing personnel competency and ensuring that high quality testing is being performed consistently.

***Post-Analytic*/Best Practices**

1. Report the patient results exactly as the package insert states (including any units of measure). Some tests will require only a "positive" or "negative" result (this is qualitative testing) while others may require a more detailed result (positive for Flu A or 6.77 ug/mL). Your laboratory must have established panic values and procedures for the reporting of critical results, if applicable.
2. The package insert will also state if any confirmatory testing needs to be performed. For example, some manufacturers of Group A Streptococcus antigen kits require that a culture be done to follow up all negative antigen results. Your laboratory must have policies and procedures in place to facilitate any required confirmatory testing.
3. Ensure that any testing records (patient test log, temperature logs, humidity logs, instrument function checks, and maintenance logs, etc.) are maintained in an organized manner. Although waived laboratories are not subject to biennial inspections, CMS can inspect a waived laboratory if it chooses to do so. Having all of your waived testing documentation organized in good order will go a long way in providing a successful outcome.
4. Waived laboratories should have a Quality Assessment Program. Regular review of laboratory procedures, personnel training and competency, QC, temperature records, and instrument maintenance can help identify problems with testing and prevent a large-scale disaster.

• COLA's WAIVED TESTING MANUAL •

COLA's Waived Testing Manual, available on COLAcentral© under the "Waived Testing" tab, includes many templates that you may find useful, as well as a self-assessment for waived testing to help you monitor your waived testing practices.

References

1. Robert H. Christenson, Susan R. Snyder, Colleen S. Shaw, James H. Derzon, Robert S. Black, Diana Mass, Paul Epner, Alessandra M. Favoretto, Edward B. Liebow. (2011). Laboratory Medicine Best Practices: Systematic Evidence Review and Evaluation Methods for Quality Improvement. *Clinical Chemistry,* 57(6), 816-825.
2. Field MJ, Lohr KN, editors. Guidelines for Clinical Practice: From Development to Use Institute of Medicine. Washington DC: National Academy Press; 1992.
3. Centers for Disease Control. (2018). Test Complexities, retrieved December 31, 2019, from www.cdc.gov/clia/test-complexities.html.