LabGuide 11
General Information on Waived Tests

WHAT ARE WAIVED TESTS?
The Clinical Laboratory Improvement Amendments (CLIA) define waived tests as simple tests with a low risk of error.

WHICH TESTS ARE WAIVED?
Waiver determinations are made by the Food and Drug Administration (FDA). There is a list of tests granted waived status on the Centers for Medicare and Medicaid Services (CMS) website at www.cms.gov/CLIA/downloads/waivetbl.pdf or, visit the FDA website at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm for a searchable list of waived tests sorted by analyte name.

Waived tests are easy, simple to use tests with a low risk of error.

HOW CAN I PERFORM WAIVED TESTS?
To perform one or more waived tests, each waived testing location must:

- Obtain and maintain a valid CLIA certificate of waiver; and
- Follow all manufacturer instructions for the tests.

ARE THERE REQUIREMENTS FOR PERSONNEL WHO PERFORM WAIVED TESTS?
Any person may perform waived tests – there are no minimum education, training, or experience requirements. However, waived labs must designate a laboratory director. There are no education or experience requirements to be the director of waived testing, but the designated director should be responsible and accountable for oversight of the waived testing.

WHAT ARE THE REQUIREMENTS FOR WAIVED TESTS?
A laboratory with a certificate of waiver can perform ONLY waived tests. Waived tests must be used in the exact manner specified by the manufacturer. Any modification to the test procedure or to the specimen used would mean that the test is no longer CLIA waived, and all the additional regulatory requirements associated with nonwaived testing would apply.

CLIA does not require Proficiency Testing (PT) for waived tests, but participation in PT is encouraged as a means of ensuring the quality and accuracy of the tests. Many PT providers offer low cost modules specifically for waived tests.

Waived labs are not routinely inspected by CMS, but there is growing concern about the quality of testing in some labs that may lead to more frequent inspections in the future.

Accrediting agencies or your state may have stricter requirements for waived tests.

Labs performing waived tests are expected to follow the manufacturer's instructions and good laboratory practices.

Original: 06/2005
Revised: 10/2012
Next scheduled review: 11/2014

WHAT ARE GOOD LABORATORY PRACTICES?

The risk of error is only truly "low" for waived testing if the test is performed exactly as the manufacturer instructs, and if good laboratory practices are followed. Good laboratory practices encompass a variety of activities and procedures designed with the common goal of achieving accurate and reliable test results. CMS has developed a list of good laboratory practices for waived testing (see the link at the end of this LabGuide), but we would like to expand that list to further reduce the risk of errors and ensure quality test results. The results of laboratory tests are used to make patient treatment decisions, so these practices should be performed by all labs, regardless of complexity level.

To follow good laboratory practices, at a minimum, labs should have:

- A procedure manual that contains procedures for all tests performed in the laboratory. The current manufacturer's package insert may be used for the procedure. Ensure that the test procedure is followed exactly, every time the test is performed.

  Note: It is important to check each lot number of kits for new or revised manufacturer's instructions to ensure that the most current package insert is being followed as the procedure. An easy way to determine whether or not a package insert has been updated or changed is to check the revision date. This will save you from having to reread the entire package insert in order to determine if changes have been made. If there is a change in revision date from the package insert you received with a previous lot, something in that package insert has been changed and/or updated.

- A system to train all testing personnel and ensure their ongoing competence to perform the tests.
- A system to ensure that patient preparation and specimen collection, identification, accessioning, handling, and storage policies and procedures are in place and followed.
- A recordkeeping system to ensure that all patient test results are documented and accurately reported in a timely manner, including critical values, confidentiality of results, and retention of the results.
- General policies and procedures for laboratory safety, including the use of Universal Precautions, and the prohibition of eating, drinking, or storage of food in the laboratory.
- A system to monitor the proper storage of kits, reagents, and controls as required by the manufacturer, and to ensure that they are properly disposed of when expired.
- A quality control system that, at a minimum, meets the manufacturer's recommendations, and includes ongoing monitoring of built-in controls (also called procedural, internal, or onboard controls) and external quality control material to ensure that the test system is operating correctly before reporting patient results.

Quality Control helps ensure the test system is working properly before patient results are reported.

WHAT IS QUALITY CONTROL AND WHY SHOULD I USE IT?

Quality control is the process of testing materials that have a known value (or range of values) before you test patient specimens to make sure that your test system is working properly. Follow the manufacturer's instructions for performing quality control. The results of waived tests may be used to make patient treatment decisions, so quality control is important to ensure that the test results are accurate.

Original: 06/2005
Revised: 10/2012
Next scheduled review: 11/2014

Most kit tests (such as urine pregnancy kits) contain built-in controls which are part of the test device and run automatically each time you perform a test. These controls are a fast and easy way to perform quality checks for some, but not necessarily all, aspects of the test system. The manufacturer will also recommend the frequency for performing external controls, which are tested like a patient specimen and will give an expected result if the test system is functioning properly.

"Recommended" or "suggested" external control testing by the manufacturer is interpreted by COLA as "must be performed." External control samples may be included in the kit, or may need to be purchased separately. For good laboratory practice, and to meet the requirements of regulatory agencies, the manufacturer's recommended frequency should be interpreted as the minimum requirement for performing external controls for waived tests.

WHERE DO I GET QUALITY CONTROL MATERIAL?

The type of quality control materials available for waived tests will depend on the test. Examples include:

- For dipstick urinalysis, controls are purchased separately. There are three types:
  - Lyophilized (freeze-dried) controls to which you must add an exact quantity of deionized or distilled water to reconstitute for use;
  - Ready-to-use controls;
  - Chemical strips that you place in a tube and add an exact amount of deionized water to reconstitute.
- Most urine pregnancy kits, ovulation kits, and occult blood kits have built-in controls.
  - External quality controls may be included or may need to be purchased separately; and
  - They are required at the frequency specified by the manufacturer.
- Most rapid strep test kits have built-in controls.
  - External quality controls may be included or may need to be purchased separately; and
  - They are required at the frequency specified by the manufacturer.
- Obtain appropriate quality control materials from the manufacturer of your glucose, hemoglobin, hematocrit, and/or cholesterol meters or instruments.

The types of Quality Control material available varies according to the test system.

HOW OFTEN SHOULD I PERFORM QUALITY CONTROL?

If your test system includes built-in controls, they run automatically every time you run a test. In addition to the internal controls, the manufacturer's package insert will specify how often to run external quality control samples. This frequency would be considered the minimum requirement. Remember that statements like "manufacturer suggests performing external QC" and "manufacturer recommends performing external QC" is interpreted by COLA to mean "you MUST perform external QC."

External controls are usually two levels – for example, a positive and negative control for qualitative tests or a normal level and an abnormal level of control for quantitative tests, such as glucose meters. Some states may have their own requirements for waived tests, so be sure to follow your state's requirements if they are more stringent.

Original: 06/2005
Revised: 10/2012
Next scheduled review: 11/2014

WHAT IF MY BUILT-IN CONTROLS DON'T WORK?

Built-in controls are procedural checks by the manufacturer designed to ensure that:

- The reagents and test device function correctly;
- The test kit was not damaged during shipping or storage; and
- The proper volume of patient sample has been added.

If your built-in control does not work (i.e., the correct dot, bar, or color change does not appear), the test is invalid and you must not report the patient result. Instead, investigate the cause, repeat the test, and report the patient result only if the control for the new test works correctly. If the new control also fails to work correctly, contact the manufacturer of the kit for further instructions.

WHAT DO I DO IF THE RESULTS FROM MY QUALITY CONTROL SAMPLES DO NOT FALL WITHIN THE ACCEPTABLE RANGE?

It is the laboratory director's responsibility to ensure that there are policies and procedures in place that explain what to do if the external control sample results are not acceptable. When you use external quality control materials to make sure that your test system is working properly, you should be testing the controls BEFORE you test any patient samples. If the results of the external quality control samples are not within the acceptable range, then there may be something wrong with your test system. Don't begin to test patient samples unless you have acceptable control results. Follow your laboratory's policy for unacceptable quality control results.

If Quality Control results are not acceptable, do not report patient results.

HOW SHOULD I RECORD MY BUILT-IN CONTROL RESULTS?

Daily recording of quality control results should not be a hassle. For kit tests with built-in controls, document once each day that the control worked (or the actions you took if it didn't work). For acceptable built-in controls, a simple check mark on a chart that includes the test name, date (don't forget to include the year), and testing person is adequate.

HOW SHOULD I RECORD EXTERNAL QUALITY CONTROL RESULTS?

When you are testing external quality control materials, a simple chart that includes the test name, date, testing person, and the expected acceptable results for the control is sufficient. Each day, record the value obtained for each of the quality control levels tested. Compare your result to the acceptable result, and if acceptable, proceed to test patient specimens.

Here are some helpful hints:

- Record the lot number and expiration date of the kit on the QC sheet. This information is helpful (if you experience problems with a kit or test method) because you will have a written record of the kit or reagent that was used.
- Always write your initials on the QC sheet to identify who performed the QC.
- When a control is either not performing correctly or out of acceptable range, write a comment on the bottom of the QC sheet documenting the problem and the corrective action taken to fix the problem before testing patients. This information is very helpful when trying to identify the causes of repeated QC problems.
- To remind you to complete the QC record sheets, tape them on walls or cabinet doors so they're always visible at eye level.
- The laboratory director should review QC record sheets monthly.
- Keep QC record sheets for two years so that you can evaluate QC results over time.

Original: 06/2005
Revised: 10/2012
Next scheduled review: 11/2014

WE ARE A MODERATE COMPLEXITY LAB. WHAT ARE THE REQUIREMENTS FOR THE WAIVED TESTS WE PERFORM?

When waived tests are performed in a moderate or high complexity lab (labs that have a Certificate of Accreditation, Certificate of Compliance, or Provider Performed Microscopy certificate), the waived tests are still considered waived. All manufacturer's instructions must be followed and good laboratory practices are encouraged and expected. Accrediting agencies or your state may have stricter requirements for waived tests performed in nonwaived labs.

During a routine CLIA inspection or COLA survey, the focus is on the nonwaived testing, but any obvious problems with your waived testing, such as not following the manufacturer's instructions, will be brought to your attention for correction. If the surveyor sees a lack of good laboratory practices or perceives the possibility of immediate danger to a patient because of waived testing procedures, they might cite the lab for problems related to waived testing. And as stated earlier, the growing concern about the quality of waived testing in some labs that may lead to a greater focus on waived testing.

SUMMARY

Even though waived tests are simple tests to perform, they should not be taken lightly. Always follow the manufacturer's instructions exactly, including those for quality control. To ensure accurate results, always use good laboratory practices when performing waived tests. Accurate results are important for patient care!

When performing waived testing, always follow manufacturer's instructions and good laboratory practices.

Waived Testing Resources

MMWR Report regarding Good Laboratory Practices for Waived Testing:
www.cdc.gov/mmwr/PDF/rr/rr5413.pdf

Educational materials from the CDC, including the *Ready? Set? Test!* program:
www.cdc.gov/dls/waivedtests/

LabUniversity® Online course: *Best Practices for Waived Testing:*
www.labuniversity.org/?page_id=1066

CMS Information from the CLIA program website:

CLIA Brochure #6: How to Obtain a Certificate of Waiver
:www.cms.gov/CLIA/downloads/HowObtainCertificateofWaiver.pdf

List of waived tests: www.cms.gov/CLIA/downloads/waivetbl.pdf

The Certificate of Waiver Laboratory Project: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certificate_of_-Waiver_Laboratory_Project.html

Good Laboratory Practices: www.cms.gov/CLIA/downloads/wgoodlab.pdf

CMS Fact Sheet: Visiting CLIA Certificate of Waiver Laboratories:
www.cms.gov/CLIA/downloads/wfact.pdf

Original: 06/2005
Revised: 10/2012
Next scheduled review: 11/2014