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WAIVED TESTING

What are Waived Tests?
Waived tests are laboratory tests that:

- Are simple to use

- Have easy to follow procedures

- Provide accurate results

The Food and Drug Administration (FDA) determines which tests are approved as waived. The list of waived tests continues to grow as new tests are developed and approved.

Can Anyone Perform Waived Tests?
There are no personnel requirements to perform waived tests, but your facility must obtain a CLIA certificate before performing any testing. If you plan to perform only waived tests, then get a CLIA Certificate of Waiver. Laboratories with a Certificate of Waiver are not required to participate in proficiency testing and are not routinely inspected. However, the CLIA regulations do allow inspections of waived laboratories under certain circumstances.

If you already have a CLIA Certificate of Compliance, Certificate of Accreditation, or Certificate of Provider Performed Micrsocopy Procedures (PPMP), then waived testing is included.

What are the Requirements for Waived Testing?
The most important requirement that applies to waived testing is:

YOU MUST FOLLOW THE MANUFACTURER'S INSTRUCTIONS!

It is extremely important that you follow the test kit or instrument manufacturer's instructions for performing any test. If you do not follow the instructions exactly, then you may not get an accurate result. Also, the test may no longer be considered waived if the procedure is changed in any way.

What are Good Laboratory Practices?
Any test worth doing deserves your best effort. The results of the test may be used to make decisions about treatment for the patient. We already mentioned the importance of following all manufacturer's instructions exactly. The good laboratory practices below are additional steps you can take to make sure the tests performed in your office are accurate and reliable:

- Ensure employees have proper training.

- Perform quality control (also following the manufacturer's instructions).

- Focus on quality assessment (quality assurance) by monitoring laboratory activities, evaluating how things are done, and making improvements whenever needed.

- Consider enrolling in proficiency testing (PT) as an extra check for test accuracy. It is not required, but economical PT modules are available for waived tests.

- Keep organized records of training, test results, and quality control results.

- Report any problems with the test to the manufacturer.

Resources
- Take COLA's LabUniversity course on Best Practices for Performing Waived Tests at www.labuniversity.org/ labtesting/bestpractices.asp

- List of currently waived tests – www.cms.hhs.gov/clia/downloads/ cr4136.waivetbl.pdf
  Or, try
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/ cfClia/testswaived.cfm

- Information for waived laboratories – www.cms.hhs.gov/clia/08_waived_ppmp_laboratory _project.asp

- How to Apply for a CLIA Certificate – www.cms.hhs.gov/clia/06_how_to_apply_for_a_cli a_certificate,_including_foreign_laboratories.asp (Includes a link to a printable CMS-116 application form.)

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