

# CLIA Corner

State Hygienic Laboratory at The University of Iowa

First Quarter 2011



Iowa CLIA Surveyors: Nancy Grobe, BS, MT(ASCP) & Kristine Rotzoll, BS, MT(ASCP)

## In This Issue...

**CLIA requirements for waived tests**

**The Manufacturer's instructions**

**Good laboratory practices for waived tests**

**WE MOVED! Our new address**

## CLIA requirements for waived tests

As defined by CLIA, **waived tests** are categorized as “simple laboratory examinations and procedures that have an insignificant risk of erroneous result”.

For a test system to be approved and categorized into one of three test complexities (waived, moderate or high), the manufacturer submits its application to the Food and Drug Administration (FDA) for evaluation. If the FDA determines that the test system meets the waived complexity criteria for being simple with a low risk of error, it is categorized as waived. Some test systems may be categorized as both waived and moderate complexity depending on the specimen type, testing methods, etc. It is not acceptable to make changes to a test system's manufacturer instructions. This could change the “intended use” of the test system as approved by FDA and result in a test that is no longer waived. An example of this would be if the test specifies a urine sample and a different body fluid is tested. To find a list of the waived tests, visit the FDA website: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm> sorted by analyte) or <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/testswaived.cfm> (sorted by test categorization date and by test system name).

Laboratories with any type of CLIA certificate (e.g. waiver, provider-performed microscopy procedures, registration, compliance and accreditation) may perform waived testing. However, laboratories with a certificate of waiver may only perform waived testing.

## Certificate of Waiver CLIA Requirements

- Enroll in the CLIA program by obtaining a certificate;
- Pay the certificate fee every two years;
- Follow the manufacturer's instructions for the waived tests you are performing;
- Notify, in writing, your State Agency of any changes in ownership, name, address (physical and/or mailing) or director within 30 days, or if you wish to add tests that are more complex; and
- Permit inspections by an agent from the Centers for Medicare and Medicaid Services (CMS), such as a surveyor from the State Agency. However, laboratories with a certificate of waiver are not subject to a routine survey or inspection. Currently, CMS is conducting a project whereby a small percentage of facilities that perform only waived testing may receive an educational visit at no additional fee.

If your laboratory is located outside of Iowa, check with your State Agency since some states have additional laboratory requirements. Iowa does NOT have additional state laboratory licensure requirements.



## ***The Manufacturer's Instructions***

The manufacturer's instructions can be found in the package (product) insert and/or operator's manual. Be sure the package (product) insert and/or quick reference guides are **current**. To ensure the use of the most current insert and/or instructions, obtain one from the test system or kit just opened or contact the manufacturer. Over time, the manufacturer may make modifications to the test system that results in changes to the instructions. Failure to use the current instructions could cause inaccurate results that may lead to misdiagnosis or delay in proper treatment.

Words like '**always**', '**require**', '**shall**', '**test**', '**perform**' and/or '**must**' mean the instruction is regulatory and must be performed. For *waived tests only*, '**should**' or 'recommend' mean the action is not regulatory. It is optional to follow the recommendations or suggestions of the manufacturer. However, adhering to the recommendations and suggestions help to assure accurate and reliable test results and is a good laboratory practice.

The laboratory must follow ALL instructions in the package (product) insert and/or operator's manual from "intended use" to "limitations of procedure." Before you begin testing for the first time or when evaluating a new test to perform in your laboratory, read the ENTIRE package insert and/or operator's manual while paying special attention to the following:

❖ Specimen collection and preparation

Follow instructions for obtaining the proper specimen for the test system. This includes: using the appropriate collection container; checking patient identification; informing the patient of any test preparation; labeling specimens to ensure positive patient identification; and adhering to guidelines for specimen preservation, storage and transport.

❖ Storage & Handling

Observe storage and handling requirements for the test system components and reagents; adhere to the expiration date of the test system and reagents, as applicable; and do NOT mix components or reagents of different kits and/or lot numbers.

❖ Procedure

Follow the step-by-step procedure as described by the manufacturer; perform each step in the proper order; adhere to timing requirements; and follow important warnings and disposal information.

❖ Quality Control

Perform quality control as required by the manufacturer, and perform function checks and maintenance of equipment as directed by the manufacturer.

❖ Interpretation & Reporting of Results

Understand and recognize when the test is finished. Record the patient's test results in the proper place (e.g. patient's chart, test report form or laboratory test log) and in the units as described in the manufacturer's instructions. If it's a qualitative test, spell out **positive/negative** or **pos/neg** because symbolic representations can be altered (the – can be altered to a +). In the test records, include name of test, date (month, day and YEAR) when the test was performed and initials of the testing personnel. If the same test is performed on a patient multiple times in one day, include the TIME of each test.

❖ Limitation of Procedures

Understand and recognize that the test only works within certain prescribed situations and that there may be limits to achieving accurate test results (e.g. certain factors, called interfering substances, can prevent the test from performing correctly; or certain circumstances will give false results). Ensure that the test results and testing procedures are within the manufacturer's specification.

❖ Manufacturer's Phone Number

Contact the manufacturer if you have problems with the test system requiring technical assistance. Train and evaluate testing personnel on the following:



## ***Good laboratory practices***

- Specimen collection, labeling and storage;
  - Understanding and following manufacturer's instructions for each test performed;
  - Test performance;
  - Documentation and communication of test results; and
  - Identification of inaccurate results and/or test system failures.
- ❖ Check the area where testing is conducted for extreme changes in such things as humidity, temperature or lighting as these may affect test results.
- ❖ Ensure patient specimens are handled properly from collection to test completion.

For more information concerning [waived testing](#), go to [www.cms.hhs.gov/clia](http://www.cms.hhs.gov/clia). Click on link for *CLIA Brochures*, then *Brochure #6*.

**WE MOVED!  
NEW ADDRESS:**

***Iowa CLIA Laboratory Program  
State Hygienic Laboratory  
UI Research Park-Coralville  
Iowa City, IA 52242  
Email your questions, comments or  
suggestions to Nancy Grove  
[nancy-grove@uiowa.edu](mailto:nancy-grove@uiowa.edu) or  
Kristi Rotzoll  
[kristi-rotzoll@uiowa.edu](mailto:kristi-rotzoll@uiowa.edu) or***

