

## WAIVED TESTING LABORATORY REGULATORY INFORMATION Clinical Laboratory Improvement Amendments (CLIA)

There are only a few requirements to be aware of to perform waived testing and be in compliance with CLIA.

- Perform only those tests that are approved as waived by the FDA. Be sure that you see the test complexity of a kit you are considering in writing.
- Notify Laboratory Compliance Section within 30 days if you have a change of owner, director, address, or name or the addition of tests beyond waived test complexity.
- When you receive your testing material (dip sticks, kits) review the manufacturers insert so that you make sure to follow the manufacturers instructions (your only requirement). See the attached example.
- Check the storage requirements and determine if the expiration date is shortened when stored at room temperature or when the kit is opened. Document the new expiration date on the box if applicable. Make sure that you store your supplies as the manufacturers stipulate being mindful of sunny windowsills.
- **Daily** monitor and document the temperature of the location where you are keeping your testing materials. Most offices use a log sheet to record their temperatures. It should include the acceptable range and actions taken when the temperature is not within acceptable range.
- Refrigerators are usually 2-8 degrees centigrade or 36-46 degrees Fahrenheit
- Freezers less than zero degrees centigrade or less than or equal to 32 degrees Fahrenheit

- Room temperature 15-32 degrees centigrade or 60-90 degrees Fahrenheit  
An example of a log sheet is included.

- Review the quality control (QC) requirements. Most dip sticks and kits require external control when opening a new kit/box or can of strips. Automated dipstick readers such as the Clinitek 50 or Chemstrip 101 require QC each day of patient testing. Note that some manufacturers require that each person testing from the kit perform QC each time a new kit/box is opened. Most offices use a log sheet to document the external quality control along with the lot number. An example of a log sheet is included.
- Check if there is a procedural/internal control with the test you are using. This tells you if the test is working correctly each time it is run. This should be documented each day of testing. Most offices find it easiest to document each time the test is run rather than have to keep track of what tests have been performed each day. This could be a box on the report form to check, which says Ainternal QC OK@, or a notation in the chart.
- Review the steps to run the test and make sure that each person performing testing is trained. Keep the procedure available in the area where testing occurs. If you change manufacturer remove the instructions from current procedures but keep on file for 2 years.
- Document the test results so that it is clear where the test was performed. If you document in the chart notes make sure that it is clear what office the notes are from. If you use a sticker or lab sheet it must include the name and address of your office.
- Establish a system to identify the specific individual performing each test. This can be a notation in the patient chart, initials on the report or a log in the laboratory.
- Maintain all laboratory records for a minimum of two years including quality control information, temperature records, lot numbers of kits or reagents, and logs showing which patients had testing.