



LABORATORIES, START YOUR INSTRUMENTS

Finally! Your new instrument has been delivered and you can hardly wait to get it up and running. Just as you're about to plug it in, you stop to think about what you need to have in place before you can start testing patient specimens . . .

The Clinical Laboratory Improvement (CLIA) amendments of 1988 as well as the COLA Criteria for Quality Laboratory Performance list specific requirements for new instrument startup. These requirements are based upon the complexity level of the instrument and the tests it performs. The possible complexity levels are waived, moderate, and high.

Your sales representative or the manufacturer should be able to provide you with this information. You may also determine the complexity of a test by using the searchable CLIA test complexity database at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>.

Note: Deviation from the manufacturer's written procedure changes the complexity of any waived or moderate instruments. It automatically becomes high complexity and is subject to high complexity requirements.

Waived Instruments

- Follow manufacturer's instructions for installation and operation. This includes calibration, performance of quality control (QC), maintenance and any other function checks, etc., as outlined in the instrument manual.

Moderate Complexity Instruments

- Determine reportable and patient normal ranges (manufacturer's stated ranges may be used).
- Calibration - COLA criteria #50-52 state the minimum requirements for calibration. Manufacturer's requirements must be followed if they are more stringent than COLA's.
- Quality Control - QC requirements differ based upon the specialty/subspecialty of testing. See COLA criteria #139-260. Adhere to the manufacturer's QC requirements if they are more stringent than COLA's requirements.
- Enroll in proficiency testing for regulated analytes, or perform split specimen analysis for all unregulated analytes.

High Complexity Instruments

Subject to the same requirements as moderate instruments outlined above with these additions.

- Calibration - Follow additional COLA criteria #56-60 specific for high complexity instruments.
- Quality Control - See additional COLA criteria #261-278. You must verify and document accuracy, precision, reportable patient range, linearity, sensitivity, specificity and other performance characteristics required for test performance.

**Other Requirements for All New Instruments
Regardless of Complexity**

- Notify HCFA of the addition of any tests in a specialty/subspecialty that you have not been previously certified for by CLIA within the last six months.
- Notify COLA of the new instrument and/or tests within 60 days. A COLA "Change Form" may be used for this purpose.
- You must have a written policy and procedure for performance of the test and use of the instrument. See COLA criteria #65-84.
- You must perform and document all maintenance and function checks required by the manufacturer. See COLA criteria #38-41 and #44-46.
- Monitor your new instrument for quality assurance purposes and follow up on any corrective action that is necessary.
- Instrument correlation studies are considered to be good laboratory practice. They are only required if you have another instrument that will act as a back up for your new instrument. Evaluate the differences between the two instruments at least twice a year (see COLA criterion #290). If correlations are performed, a statistically sound study should consist of 20 specimens.

We hope these guidelines will help assist with your new instrument setup. If you require clarification of these requirements, or a COLA Change Form, please contact COLA's Information Resource Center at (800) 981-9883.