

CLIA Corner

State Hygienic Laboratory at the University of Iowa



State Hygienic
Laboratory

Fourth Quarter 2018

Iowa CLIA Surveyors:

Nancy Grove, BS, MT(ASCP)

Kristine Rotzoll, BS, MT(ASCP)

Melinda Bochmann, BA, MT(AMT)

In This Issue...

• **Procedures & Procedure Manuals**

This edition of the CLIA Corner will focus on laboratory procedures and procedure manuals; specifically, what must be included in the procedures, responsibilities of the laboratory director and personnel, and record retention requirements for procedures. Specific regulations pertaining to procedures can be found at D5401 through D5409, 493.1251. The CLIA Regulations and Interpretive Guidelines can be found online at the following web address: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf

Acceptable Types of Procedures

CLIA requires a written procedure manual be available to, and followed by, all laboratory personnel for all tests, assays, and examinations performed by the laboratory.

- **Procedures written by the laboratory:** Procedures can be organized as a paper-based manual or stored electronically in a computer-based system. Procedures stored in a computer-based system must be accessible to all laboratory personnel, even when the system is down.
- **Manufacturer's instructions, package inserts, and/or operator manuals:** If used, the instructions, package inserts, and/or operator manuals must include all the required procedure information listed under "Analytic Testing Procedure Requirements." Any required information not found in the instructions, package inserts, manuals, or information specific to your laboratory, must be added. For example, if the laboratory is using the hematology analyzer operator manual as the procedure, it must also include the laboratory's control procedures, critical values, laboratory's system for entering results, and course of action to take when the instrument is inoperable.
- **Textbooks:** Textbooks may supplement procedures, but cannot replace them.
- **Reference procedures:** Procedures that are not used for test performance, but for reference use, should be located in a "reference section" of the procedure manual.

Pre-Analytic Testing Procedure Requirements

The laboratory must establish and follow written policies and procedures for each of the following:

- **Patient preparation:** These procedures must be available for all laboratory staff, including individuals (e.g., phlebotomists) who instruct patients on preparation for specific laboratory tests (e.g., fasting instructions for lipid profile and dietary restrictions prior to occult blood testing).
- **Specimen collection:** Again, these procedures must be available for all laboratory staff, including staff collecting specimens at alternative sites (e.g., nursing homes, physician offices). Collection procedures should include collection technique (order and draw site), proper collection containers (acceptable anticoagulant, type of sterile container used for culture specimens), etc.
- **Specimen labeling:** This procedure needs to include the information (e.g., patient name, patient

identification number, time and date of collection, etc.) to be labeled on the collection containers for all types of specimens (urine, blood, etc.). When determining the laboratory's labeling requirements, include the minimum information needed to maintain the integrity and positive identification of the specimen throughout the entire testing process.

- **Specimen storage and preservation:** The laboratory is responsible for reviewing the manufacturer's instructions for each test method's performance to ensure that specimens are stored properly (e.g., room temperature versus refrigerated) and that specimen storage and preservation requirements are reflected in the laboratory's procedures.
- **Conditions for specimen transportation:** The laboratory must have a procedure available to all laboratory staff indicating the correct transportation conditions for specimens sent to a reference laboratory.
- **Specimen processing:** Specimen processing procedures may include, but are not limited to: receiving the specimen, accessioning the specimen, preparing the specimen for in-house analysis or to be sent to a reference laboratory for testing, preparing slides, and inoculating primary cultures.
- **Specimen acceptability and rejection:** A procedure detailing specimen acceptability and rejection criteria for all testing performed by the laboratory is required. This procedure should also include the laboratory's plan for informing the authorized individual(s) when a specimen is rejected for not meeting the acceptability criteria and is unacceptable for testing.
- **Specimen referral:** For each reference laboratory utilized, the laboratory is required to have a manual available or electronic access to specimen requirements for testing performance.

It is important to provide staff external to the laboratory (e.g., nursing homes, physician's office, etc.) a copy of the laboratory's current procedures to ensure that all pre-analytic procedures are being followed.

Analytic Testing Procedure Requirements

The procedure manual must include the following when applicable to the test procedure:

- Microscopic examination of specimens, including the detection of inadequately prepared slides.
- Step-by-step performance of the procedure, including (when applicable) any test calculations and the interpretation of test results.
- Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.
- Calibration and calibration verification procedures, including the frequency, type of material used, and the interpretation of results.
- Reportable range; this is required for all tests performed by the laboratory.
- Control Procedures, including type (e.g., manufacturer, assayed vs. unassayed, liquid vs. electronic, etc.), identity (e.g., normal vs. abnormal, level I vs. level II, etc.), number and frequency of testing, control limits, and criteria for control result acceptability.
 - *Reminder: When the manufacturers' instructions do not address quality control or those instructions are less stringent than the CLIA regulatory control procedures, the laboratory must follow the regulatory requirements or develop an Individualized Quality Control Plan (IQCP), which includes a Risk Assessment (RA), Quality Control Plan (QCP), and Quality Assessment Plan (QAP).*
- Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability: The laboratory is required to have procedures instructing laboratory personnel of the appropriate corrective actions to take when calibration and control results fail to meet the laboratory's criteria for acceptability. The laboratory should include a copy of the current forms used to document corrective action.
- Limitations in the test methodology, including interfering substances (e.g., lipemia, hemolysis, medications, etc.).
- Reference intervals (normal values). This is required for all tests performed by the laboratory.
- Imminently life-threatening test results, panic, or alert values.

- Pertinent literature references.
- The laboratory's system for entering results. The laboratory is required to have a procedure detailing the entry of patient test results, including panic or critical values, into patient test records.
- Description of the course of action to take if the test system becomes inoperable, including procedures instructing personnel on the course of action to take if the laboratory information system fails or if the laboratory's primary test system becomes inoperable.

Other Procedure Requirements

- The laboratory must have written policies and procedures that implement and monitor a quality system for all phases of the testing process, including pre-analytic, analytic, post-analytic, and general laboratory systems. A quality assessment component must be included that ensures continuous identification, evaluation, and resolution of problems within the laboratory through an on-going monitoring process.
- The laboratory must have written policies and procedures to assess employee and consultant competency.

Laboratory Director Responsibilities

All procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use; this includes the manufacturer's instructions and operator manuals. A coversheet may be used for the director to approve the manual. An annual review of the procedures is not required as long as there have been no changes in the procedure manual.

Laboratory Personnel Responsibilities

Laboratory personnel are required to follow all laboratory procedures. The laboratory must have a mechanism in place to communicate to personnel when changes have been made to the procedures.

Record Retention Requirements

The laboratory is required to maintain a copy of each procedure for the period of time the laboratory uses the test system(s), but no less than two years. The laboratory is also required to retain a copy of each test procedure for at least two years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.

