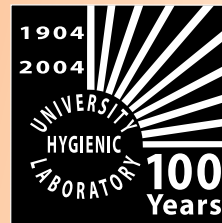


CLIA Corner

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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.

What are acceptable types of procedures for the laboratory to use?

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

- Procedures written by the laboratory: Procedures can be organized as a written manual or stored electronically in the computer system. Procedures stored in a computer system must be accessible to all laboratory personnel.
- Manufacturer's instructions, package inserts, or operator manuals: If used, the instructions or operator manuals must include all the required procedure information as listed under, "What are the procedure requirements for analytic testing?" Any required information not found in the instructions or 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.
- Procedures as reference: Procedures that are not used for test performance, but for reference use should be located in a "reference section" of the procedure manual.

What are the procedure requirements for pre-analytic testing?

- Patient preparation: These procedures must be available for all laboratory staff, including individuals (e.g. phlebotomists) who instruct patients on preparing for specific laboratory tests (e.g. fasting instructions for lipid profile and dietary restrictions prior to occult blood testing).
- Specimen collection: Again, specimen collection 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 containers (acceptable anti-coagulant, type sterile container used for culture specimens), etc.
- Specimen labeling: The specimen labeling 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 your laboratory's labeling requirements, keep in mind the minimum information needed to maintain the integrity and positive identification of the specimen throughout the testing process.
- Specimen storage and preservation: The laboratory is responsible for reviewing the manufacturer's instructions for the performance of each test method to ensure that specimens are being properly stored

(e.g. room temperature versus refrigerated) and that procedures reflect the specimen storage and preservation requirements.

- Conditions for specimen transportation: A procedure is required to be available to all laboratory staff indicating the correct specimen transportation conditions for specimens being 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: The laboratory is required to have procedures detailing specimen acceptability and rejection criteria for all testing performed by the laboratory. This procedure should also include how the laboratory plans to inform the authorized person when a specimen is rejected for not meeting the acceptability criteria and is unacceptable for testing.
- Specimen referral: The laboratory is required to have a current service manual available for each reference laboratory that it uses which contains the reference laboratory's specimen requirements for the test to be performed.

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.

What are the procedure requirements for analytic testing?

- 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 for all calibration and calibration verification procedures.
- Reportable range: This is required for all tests performed by the laboratory.
- Control Procedures: including the type of control (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 controls, control limits, and criteria to determine acceptable control results. *Reminder: The laboratory must have a written procedure describing, if applicable, the equivalent quality control procedures being performed by the laboratory.*
- 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 the 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 testing system becomes inoperable.

What is the laboratory director's responsibility concerning procedures/ procedure manuals?

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. This responsibility may be delegated, in writing, to the technical supervisor or technical consultant.

What is the laboratory personnel's responsibility concerning procedures/ procedure manuals?

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

What are the record retention requirements for procedure manuals?

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 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.