

The core function of every clinical laboratory is the test or tests performed. Test procedures establish your laboratory's quality of testing. The patient and the clinician expect all test results to be performed to the same standard of quality. The correct use of a well written procedure will reduce mistakes, ensure that shortcuts are not passed on as legitimate procedures, and maintain standardized testing.

Every test your laboratory performs must have a separate procedure, uniformly written and organized and containing all pertinent information. These procedures must be consistent with the manufacturer's product information, established laboratory standards and actual practices in your facility. A good guide to determine what information needs to be included or excluded is to ask, "What information would a new lab tech, unfamiliar with the laboratory, need to know in order to perform the test?"

A good reference for developing clinical laboratory technical procedures is the current Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) publication, *Laboratory Documents: Development and Control*; Fifth Edition. Besides being a recognized standard, the publication states "GP2-A5 is a guideline for how to implement requirements that have been established by regulatory and accrediting organizations....for laboratory documents and procedure manuals."¹ A laboratory must have written test procedures and GP2-A5 "describes what laboratories need to do to meet published regulations and accreditation requirements."

The laboratory procedure should not be pages copied from an instrument manual or manufacturer's package insert. The manufacturer's information does not have facility specific information that a laboratory tech needs to know to perform the test such as: what controls to use and when to perform QC, action to take when a control fails, acceptable

specimen type, and abnormal/panic values. However, the manufacturer's product literature, such as operator manual and package inserts, are sources to reference when developing a laboratory procedure. Other sources may include published standards and guidelines, text books, unpublished information obtained from experts in the field, and applicable regulations.

A laboratory procedure should describe all activities performed for a single test; from the time the sample reaches the laboratory to the time the results are reported. The GP2-A5 guideline covers recommended elements to include in each type of test. Elements common to all testing procedures should include the following sections, as applicable and listed in the order which the reader would use the information.

- Title
- Purpose or Principle states the purpose of the document.
- Sample information lists the specimen type required for testing.
- Reagents and/or media lists all reagents or media used in performing the test. Only include instructions for preparing reagents when the reagents are prepared each time the test is performed. Instructions for preparation and handling of reagents that are prepared at times other than performance of the actual test should be written into separate procedures. A separate procedure is also needed for the proper handling and evaluation of reagents and kits, when a shipment is received and prior to using them for testing.
- Supplies lists materials needed to perform the test. There should also be a separate procedure for the proper handling and evaluation of supplies and materials, when a shipment is received and prior to their use for testing.
- Equipment calibration and maintenance instructions should be included in the procedure only when these activities are performed every time the test is run. When calibration and

maintenance are done other than at the time of testing, a separate procedure should be written.

Calibration should include the schedule for performing calibration and calibration verification, source and specifications of calibration materials, preparation of calibration materials, step-by-step instructions for calibration, instructions for troubleshooting calibration problems, and documentation of performance.

Maintenance should include the equipment maintenance schedule, step-by-step instructions, troubleshooting maintenance problems, and documentation of performance.

- Special safety precautions - All laboratory testing uses biologic samples. Since handling biohazardous substances should be part of required safety training, repeating this standard information in all procedures is unnecessary. If no special precautions are needed, the procedure may refer to the safety manual for general safety. If special precautions are indicated, this section must include engineering controls, personal protective equipment and work control practices.
- Quality Control (QC) includes the frequency of testing controls, the number of control levels tested, type and brand of control material, instructions for preparation and handling, criteria for acceptable control results, corrective action to take when controls fail, documentation of corrective action, and alternate measures to implement.
- Instructions for performing the test presents the step-by-step instructions for the test based on the manufacturer's package insert, operator manual, and/or reference method.
- Method performance specifications includes analytic sensitivity, specificity, bias, precision, reportable range, and appropriate dilution or concentration protocol if the reportable range is exceeded.
- Calculations (quantitative procedures only) include the equation, step-by-step instructions and examples.
- Expected values include the range of expected values for the test result based on sample type and local patient population variations.
- Interpretation of results provides guidelines for interpreting test results. This section includes comparison of results, follow-up for indeterminate results, and recognition of results

that exceed critical/panic values or that fall outside the reportable range.

- Related documents (if used) describe and list other procedures and forms that are referenced in this procedure.
- References include manufacturer's product literature, text books, published standards and guidelines, laboratory policy manuals, applicable regulations, unpublished information obtained from experts in the field, and laboratory computer system manuals. References should be written using American Medical Association format.
- Appendixes can include sample forms, labels, tables, or lists too extensive to include in the body of the procedure.
- Author of the document
- Approval signatures - regulatory agencies require evidence that the document has been reviewed and approved by the appropriate responsible personnel. The laboratory director must review and sign each procedure before it is put into use and annually thereafter. The entire manual should be read annually by all members of the laboratory staff and documentation should reflect this activity.

Good laboratory practice incorporates examining the manufacturer's product information each time a new lot/shipment is received, comparing it for any changes with the current product information. A good way to quickly determine if changes were made to the current product insert is to check the revision date listed and compare it to the revision date of the previous product insert. If revisions have been made, the laboratory procedure should be amended with the date of change noted. Following the director's documented review of the amended procedure, the lab staff should be trained and documentation should reflect this activity

Good laboratory procedures are essential for a laboratory to produce accurate patient test results. By vigilantly updating and following all established procedures the highest quality of patient care can be achieved.

Georgena Millar

References

¹CLSI. *Laboratory Documents: Development and Control*. Approved Standard GP2-A5, Wayne, Pa; 2006

Stewart, C. *Basic Quality Assurance Practices*. New York, NY: Van Nostrand Reinhold, 1989

