COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 1

The Procedure Manual

•Introduction •

Procedure manuals are the road map to a high quality laboratory. They provide direction for all phases of testing, from the pre-analytic phase through the analytical and post-analytical phases. A good manual can also be an excellent resource for training of employees, ensuring that each test is performed in the same way, which ensures standardization.

• Responsibility •

One of the laboratory director's responsibilities defined by CLIA is to have an up-to-date manual that has been reviewed and approved by the laboratory director. The importance of approval is to ensure the test selected has the capability to provide quality results that meets the laboratory needs.

Each new procedure needs to be approved, signed and dated by the current laboratory director. This approval needs to take place *before* the procedure is implemented. Also any changes to procedures must be approved and dated before the change is implemented. **These responsibilities cannot be delegated**. If the laboratory has a new director, it is required that they review and approve all procedures as soon as they take responsibility for the position. Signatures can be electronic as long as they are password protected.

A biennial review of the procedure manual is required by COLA. This review can be delegated, such as to a technical consultant, as long as there have been no changes or new procedures.

• Creating a Procedure Manual •

A procedure manual can be created by organizing printed procedures into a binder. Operator manuals and product inserts are a valuable reference and can be used as a basis for a procedure. If they are used as your procedure or part of your procedure, make sure the laboratory director has reviewed and signed the manual or insert.

If you are writing your own procedures, follow the four "C's"**:**
A good procedure will be:

1. Clear- use terminology that staff can understand
2. Concise- stick to the basics, don't get too wordy
3. Consistent-use a similar format
4. Complete-include pre analytic, analytic and post analytic phases

Electronic procedures are also acceptable as long as the laboratory director is able to produce documentation of dated approval for each procedure. Electronic procedures also have to be readily available to staff and be available in some form if the computer system goes down.

• Required Elements of a Laboratory Procedure •

- **The test name**

- **Directions for patient preparation , specimen collection preservation, storage and handling**
  1. Any special preparation such as fasting
  2. Type and amount of specimen required
  3. Collection container required
  4. How specimen is handled and stored - room temperature, refrigerated, frozen

- **Written instructions for the collection and storage of specimens that patients would collect themselves**

  Have written instructions that patient can take home with them. Include a contact if they have questions.

- **Criteria for specimen acceptability and rejection of unacceptable specimen**

  This can include such things as patient not fasting, hemolyzed, lipemic, etc. Refer to product insert to see acceptable specimen criteria.

- **Instructions for patient and physician notification if a specimen is unacceptable**

  The reason for unacceptability should be documented, whether testing can still be performed but results might be compromised or testing cannot be performed. Document who was notified of the problem.

- **Directions for preparing and storing reagents, stains, standards and controls**

  All materials should be labeled as to content, date of preparation and expiration. See product inserts for expiration criteria. Some reagents or control materials may have a new expiration date upon opening.

- **Directions for calibration, calibration verification and corrective action failures**

  Need to include the following:
  - Type and concentration of materials to be used
  - Number of calibrators required
  - Step by step instructions for performing calibration or calibration verification
  - Acceptable limits or criteria for interpretation of results
  - Corrective action if calibration or calibration verification is unacceptable

- **Control procedures and criteria defining unacceptable control results**

  The frequency of quality control testing, the number and type of controls to be used, and the acceptable limits for control results must be defined.

  All procedures need to have a quality control section, including microscopic tests that do not have routine external control material. Quality control procedures for these tests are limited to the actions taken to control the quality of results (e.g., personnel training and competency assessment, proficiency testing, microscope maintenance).

- **Corrective actions to take when control limits are exceeded**
  Operator manual or product inserts can be very helpful suggesting corrective actions to take.

- **Step by step directions for performing the tests**
  Operator manuals or product inserts can be part of the procedure if the laboratory director has reviewed and approved the manual or product insert.

- **Directions for microscopic examinations and criteria for adequately prepared slides**
  Include how the slide is prepared, examined (what power of magnification, how many fields, etc.) and how results are reported.

- **Directions for calculations or interpretations of test results**
  Include any calculations that need to be performed. If the calculations are done by the LIS, these need to be checked for accuracy on a periodic basis.

- **Derivation of the test result**
  Explain how result is derived: by direct read out, calibration curve, calculation etc.

- **Reference ranges, reportable ranges and critical values and when to immediately notify the physician of critical values**
  It is essential that staff know what a critical value is, how to notify the physician, and document who the result was given to along with the date and time.

- **Limitations of the test method, including interfering substances**
  Examples would include lipemia, hemolysis. Product inserts can be a good reference.

- **Notes, special requirements, safety procedures, references, atlases**
  Include if they are applicable. All procedures should have safety procedures.

- **How the laboratory reports results**
  Include how reports are created, distributed and maintained for future reference.

- **Steps to take if test system is not working or laboratory is unable to perform a test**
  Often referred to as a downtime procedure. Include how patient samples will be handled, options available if results are needed immediately, and when to communicate the delay in testing to providers.

• Laboratory Information System •

If the laboratory has an LIS system, the laboratory needs to have procedures to include (as applicable):

- Start up and shut down of system
- Data Entry
- Generation of work lists
- Validation of accuracy of data entry and calculations
- Approval of data manually entered or electronically transmitted
- Data Retrieval
- Reporting of test results
- Maintenance and back up procedures