COLA
Clinical Laboratory Accreditation

COLA Primers
Accreditation

COLA PRIMER 70

Quality Assessment

•Quality Assessment•

An effective quality assessment (QA) plan is the key to improving laboratory quality and efficiency and can also ensure that your laboratory will remain survey-ready at all times. A comprehensive QA plan will address the entire laboratory process, from specimen collection to result reporting, and will include a detailed description of what is to be reviewed, how and when.

COLA has developed tools, guides and templates to help your laboratory develop a suitable quality assessment plan to fit your laboratory's specific needs. A well-designed laboratory QA plan will include written policies and procedures for monitoring and assessing all phases of testing, and a means of correcting problems that are identified. Quality assessment reviews should be performed and documented throughout the year, and should thoroughly evaluate each quality system. To simplify the process, a schedule or calendar should be established, outlining when specific system reviews are to be performed. Documentation of QA reviews should include the area assessed, data collected, the names of the individuals performing the review, the results of the review and any investigations and corrective action plans implemented as a result of the review's findings.

All non-waived laboratories are required to perform regular quality assessments.

COLA's Quality Assessment criteria can be divided into three equally important areas: preanalytic, analytic, and postanalytic. The sections and examples below are not all-inclusive; they represent all required areas of quality assessment and suggest possible assessment activities that can be performed to monitor and improve laboratory quality. Please refer to the COLA Accreditation manual's Quality Assessment section for more information about specific QA criteria.

• Preanalytic Assessment •

The preanalytic stage of laboratory testing is perhaps the most critical of all where laboratory quality is concerned. It is impossible to produce quality results when the specimens are inappropriate, incorrectly procured or mislabeled. Below are some examples of laboratory activities that should be regularly monitored under a robust quality assessment program, and some examples of the types of reviews that may be appropriate.

1. **Patient preparation, specimen collection, handling, labeling, transport and acceptability.**
   This can include assessments such as:
   - *Examination of a random selection of patient specimens to confirm that all are correctly labeled*
   - *A study of coolers or other specimen transport containers to ensure they are maintaining correct temperatures over the duration of their expected use*
   - *Direct observation of phlebotomists during specimen collection*

2. **Monitoring the integrity of all specimens received for testing, specifically for specimen age, and storage and transport temperature.**
   Assessments in this area can include:
   - *A review of specimen rejection logs, looking for patterns or sudden increases in rejections*
   - *A periodic review of specimen collection and transportation requirements sent out to the laboratory's customers to confirm that any changes in the requirements are being communicated, such as when new tests are brought on board or a new transport media is adopted*

3. **Assessing requisitions for completeness and relevance of content, including inconsistencies of age, gender and, when available, diagnosis or pertinent clinical data, and relationship with the requests and/or results of other tests.**
   This can include:
   - *A periodic review of a random sample of requisitions to see if all required fields are being appropriately completed by the ordering provider(s)*
   - *Confirming that requisitions are retained for the required period of time and can be easily accessed, whether in physical form or electronic*

4. **Evaluating communication between ordering providers and laboratory staff.**
   This can include:
   - *A review of all complaints reviewed by the laboratory to confirm that all issues were promptly resolved with meaningful corrective actions*
   - *A review of complaints received by the laboratory to look for patterns that may indicate a systemic problem*

• Analytic Assessment •

Ensuring quality over the analytic phase requires a regular review of the testing itself, including the performance of the laboratory's personnel and instrumentation.

1. **Reviewing quality control data and any corrective actions taken by laboratory personnel when quality controls or calibrations are out of range or instruments are out of calibration.**
   In most cases, quality control data should be evaluated daily prior to beginning patient testing, and examined for trends over the short term. However, a more thorough review can pinpoint patterns worth investigating. This can include:
   - *Periodic review of QC reports to confirm they have been reviewed, signed and dated by appropriate individuals at the frequency dictated by the laboratory's quality control procedures*
   - *A review of all outlying results requiring corrective action to ensure that any outlier was noted, and corrective action taken and documented*
   - *A review, at least annually, of any Individualized Quality Control Plans (IQCP) that have been implemented in the laboratory, to ensure that the laboratory's data*

supports the continued use of the IQCP and that any quality failures were addressed with changes to the QC plan

- *A review of instrument calibration and calibration verification documentation to confirm that the procedures were performed on time and results were acceptable and approved by appropriate supervisory personnel*

2. **Evaluation of instrument performance and review of instrument maintenance logs.**
   Assessments in this area can include:
   - *Review of instrument maintenance logs and troubleshooting logs to identify patterns and to ensure that corrective action has been taken and documented*
   - *Review of any new performance verification studies that have been performed to ensure that they were acceptable and approved by the laboratory director or designee prior to patient testing*

3. **Review of Proficiency Test results and of corrective actions taken for unsatisfactory results.**
   Assessments in this area can include:
   - *Reviewing all proficiency testing records to check for documentation of review by the Laboratory Director and testing personnel*
   - *Review of all unsatisfactory PT results to determine root cause and to develop a plan of action*
   - *A review of any previously-implemented PT action plans to determine whether they have been successful*

4. **Review of personnel records, training records and competency assessment documentation.**
   Assessments in this area can include:
   - *A review of the laboratory's personnel files to ensure that they are up-to-date and include documentation of the education and experience that qualify individuals for their roles in the laboratory*
   - *Review of staff training records and competency assessment records to ensure that they were done on time and were approved and signed by the laboratory director or designee*

• Postanalytic Assessment •

Laboratory testing does not end when a result is obtained; the documenting and reporting of those results is also a critical part of laboratory workflow and should be assessed regularly.

1. **Assess test reports for completeness and relevance, distribution of results to the appropriate parties and maintenance of original or exact duplicate reports for the required time periods.**
   Assessments in this area can include:
   - *Review of patient test reports to ensure all applicable units of measurement, reference ranges and flags are present*

- *Random review of data that is manually entered into an electronic system to confirm accuracy*
- *Review of critical value notification logs to ensure that any critical results were communicated to the ordering provider or designee within the timeframe established by the laboratory*
- *Confirming that test reports are retained for the required period of time and can be easily accessed, whether in physical form or electronic*

2. **Test turnaround times must be evaluated to ensure results are obtained in a clinically useful timeframe.**
   This assessment can include a review of a selection of specimens to confirm that the test results were reported within the timeframe established by the laboratory.

• Review •

It is not an accident that the examples of QA activities in this Primer are very similar to the types of reviews that a surveyor would be performing over the course of an on-site laboratory survey. Establishing a comprehensive QA plan and performing regular reviews of all areas is a way to essentially pre-survey your laboratory a little at a time. It is an essential tool for finding areas for improvement in your processes and will end up saving the laboratory time and energy.

A sample Quality Assessment plan is available for download in COLAcentral's Solutions Library and can be modified to suit the particular needs of your laboratory. Remember that it must define what will be assessed, how those assessments should be performed and when the assessments will be performed. The assessments must cover all areas of testing, and both the assessments and any corrective actions that result from them must be documented and shared with the entire laboratory team. Quality assessment records, like most other laboratory documentation, should be retained for a minimum of two years.

See the Quality Assessment Plan template located on COLA Central for suggestions to organize and evaluate your laboratory's plan at the link below:

https://www.colacentral.com/TemplateLibrary/Quality%20Assessment%20Plan.docx