



EDUCATIONAL RESOURCES

Creating A Successful Quality Assessment Program

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CLINICAL LABORATORY



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Objectives

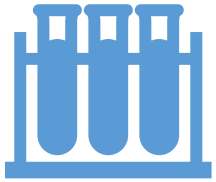
Upon completion of this presentation, the participant will be able to:

- List the three phases of a QA program.
- Understand the standards related to Quality Assessment.
- Implement improvements to their laboratory's current Quality Assessment Program.

Quality Assessment Program

- A successful Quality Assessment Program addresses the complete laboratory process, starting with the arrival of the patient or specimen in the laboratory until the results are reported to the health care provider.

A Quality Assessment Program should:



Evaluate the effectiveness of a laboratory's policies and procedures.



Identify and correct problems.



Assure the reliable, accurate, and timely reporting of patient results which are interpreted correctly.



Assure staff competency and performance.

The three
phases of a
QA program
are:

Pre-Analytic Phase

Analytic Phase

Post- Analytic Phase



Pre-Analytic Phase

- Patient Information and Test Requisitions
- Specimen Collection Instructions
- Specimen Collection, Labeling and Transport
- Specimen Processing, Handling, and Storage
- Storage of Testing Supplies
- Specimen Referral
- Selection of Testing Methodologies
- Staff Training
- Laboratory Safety



Analytic Phase

- Specimen Examination
- Policies and Procedures
- Reagent Preparation
- Maintenance and PMs
- Calibrations
- Quality Control
- Specimen Testing
- Proficiency Testing



Post-Analytic Phase

- Reviewing QC
- Result Reporting (to include Interpreting, Transcribing, and Entering Results)
- Turn Around Times
- Notification of Critical Values
- Corrected Reports
- LIS Issues
- Communication
- Complaints

Standard 05.04.00

Laboratory Quality Assessment



The laboratory must establish and follow written policies and procedures to monitor, assess, and when necessary, correct problems identified in the laboratory system.

Quality Assessment

- Is an ongoing review process.
- Includes all facets of a laboratory's technical and non-technical functions.
- Includes all locations where specimens are collected, or testing is performed.
- Covers the laboratory's interactions and responsibilities to its patients, health care providers, non-laboratory areas or departments within the institution and other laboratories.
- When an error or issue is identified, corrective action must occur to address the issue.

Corrective Action Should Include:

- Identification of the Problem.
- Resolution of the Problem.
- Development of policies to prevent reoccurrence.
- Monitoring of the process put in place.

QA of the General Laboratory System includes:

Patient
Confidentiality

Specimen
Identification

Specimen
Integrity

Complaint
Investigation

Communication

Personnel
Competency

Proficiency
Testing
Performance

05.04.01

Effectiveness of Corrective Actions for QA



The General Laboratory Systems QA Program must include:

- A review of the effectiveness of Corrective Actions to resolve issues.
- Revision of policies and procedures to prevent reoccurrence of issues.
- Discussion of QA issues with appropriate staff.

The laboratory must document all general laboratory QA activities.

05.05.00

Pre-Analytic Systems

 The laboratory must monitor and evaluate the overall quality of the pre-analytic systems and correct identified problems for each specialty and subspecialty of testing performed.

This is a CLIA condition requirement.

Pre-Analytic System QA must include?

Test Requests

Specimen Submission,
Handling and Referral

Pre-analytic Systems
Quality Assessment

05.06.00

Pre-analytic Systems QA/ Corrective Action



The laboratory must establish and follow written policies and procedures to monitor, assess, and when indicated, correct problems identified in the pre-analytic systems.

05.07.00

Post-Analytic Systems



The laboratory must monitor and evaluate the overall quality of the post-analytic systems and correct identified problems for each specialty and subspecialty of testing performed.

This is a CLIA condition level requirement.

05.08.00


Post-Analytic Systems QA



The laboratory must establish and follow written policies and procedures to monitor, assess and, when indicated, correct problems identified in the post-analytic systems specified in the requirements.

05.08.01

Corrective Actions



The post-analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve the problem, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of post-analytic systems quality assessment reviews with appropriate staff.

?

How do I create or modify a
Quality Assessment Plan to
achieve continuous
improvement and create a
culture of quality?

Quality Assessment Continuous Improvement

- Keep detailed analytics or logs for specimen issues (including rejection, labeling, transport, and processing issues), complaints, communications, and corrective actions to identify patterns and trends.
- Share the responsibility, include all staff in QA activities.
- Brainstorm.
- Make this a continuously changing process.
- Monitor if the changes that have been made have resulted in improvements.

References:

- Laboratory Quality Assurance and Standardization Programs-CDC
- CLIA And Quality Assurance- AAFP
- Quality Assessment in the Laboratory- COLA Lab Guide 70

Any Questions?





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Thank you

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