COLA Clinical Laboratory Accreditation

COLA Primers Accreditation

COLA PRIMER 53

Individualized Quality Control Plans (IQCP)

•Overview •

Individualized Quality Control Plan (IQCP) is a risk-based quality control (QC) option available to laboratories. The purpose of IQCP is to identify the ***optimal*** QC plan for a specific test within a specific laboratory. Use of an IQCP is optional. If a laboratory chooses not to implement an Individualized Quality Control Plan then they must, at minimum, follow regulatory requirements for QC for that test. IQCP applies to **non-waived** testing; the QC requirement for waived testing is to follow manufacturer requirements at a minimum.

In most cases, the standard regulatory requirement for non-waived tests is two levels of QC each day of patient testing. If manufacturer QC requirements are **more** stringent than the regulatory requirements, the laboratory must comply with the manufacturer requirements. If the manufacturer requirements for QC are **less** stringent than the regulatory requirements, the laboratory must choose one of two options:

1. Follow regulatory requirements for the test
   OR
2. Implement an IQCP that supports the suitability, in this particular laboratory, of the performance of QC per the manufacturer's requirements, including number, type, and frequency of QC testing.

IQCP may not be a feasible option for some laboratory tests, but can be useful in some cases where the manufacturer QC requirements are less stringent than the applicable regulatory requirements.

Please note that COLA requires that all Laboratory Developed Tests adhere to performing at least two levels of external QC each day of patient testing.

Each laboratory must develop appropriate IQCPs using the laboratory's own testing personnel and data. A manufacturer can provide information to help with the risk assessment, but cannot write the IQCP for the laboratory. Please refer to the links provided in this Primer for additional suggestions to develop, maintain and evaluate your laboratory's IQCP.

•Microbiology•

Laboratories must follow regulatory requirements for media QC, multiple reagent ID systems and susceptibility testing unless an IQCP has been implemented.

Regulatory QC requirement for media: Perform QC on each lot/shipment to ensure that the media is sterile, and supports, selects and inhibits growth as required. IQCP does not apply to non-exempt media such as chocolate agar, Campylobacter media, or selective media for the isolation of Neisseria species.

Regulatory QC requirement for multiple reagent ID systems: Perform QC on each lot/shipment. *Each substrate* must be checked for positive and negative reactivity. The laboratory must challenge the system with the organisms suggested by the manufacturer.

Regulatory QC requirement for susceptibility testing: Perform susceptibility QC each day of patient testing using the appropriate organisms suggested by the manufacturer.

• 3 Required Components Of IQCP•

IQCP consists of three components: **a risk assessment, QC plan and a plan for ongoing quality assessment.**

Risk assessment

A risk assessment identifies potential errors that may occur in the testing process and lead to erroneous results. Five areas are evaluated as part of the risk assessment. These include:

- Specimen
- Environment
- Personnel
- Reagents
- Test system

The assessment must evaluate possible sources of risk in preanalytic, analytic and postanalytic processes. Manufacturer inserts or user manuals may be helpful in defining possible risks for each test, but the laboratory must also review its own historical data to determine the likelihood and severity of any identified risks and to identify and assess processes for risk mitigation. For example, the laboratory must review data from method verification studies, QC and proficiency testing data, competency assessments, environmental monitoring and quality assessment reviews.

When the laboratory has multiple devices of the same make and model, a single risk assessment may be performed that covers them as a group. However, if there are any differences among these devices, including but not limited to environmental conditions or personnel, then these must be taken into consideration and there may be a need to customize the QC plan for each device.

Multiple analytes that are tested on the same analyzer but have variations in procedure, such as a sample pre-treatment, must be evaluated and addressed *separately* in the QC plan.

For assistance with the construction of the risk assessment portion of an IQCP, please refer to the Risk Assessment Template with IQCP Instructions in the COLAcentral Solutions Library.

QC plan

The laboratory must develop a written Quality Control plan for the test that is supported by the data reviewed during the risk assessment. The QC plan will include the number, type and frequency of Quality Controls to be run, as well as define acceptable limits for QC results. The QC plan must at a minimum meet manufacturer's requirements.

The QC plan must also reference the activities and practices of the laboratory that are in place to mitigate any risks to the test that were identified during the risk assessment. These may include training and competency assessment of personnel, specimen collection and handling, instrument calibration and maintenance, pipette calibration, function checks and monitoring of environmental conditions.

The QC plan must indicate which QC requirement is being replaced by the IQCP. For example, the default regulatory requirement for a serum HCG test is a positive and negative control performed each day of patient testing. This is covered by COLA's QC 17 criterion, so the laboratory's QC plan for this test must state that the IQCP is replacing criterion QC 17.

The laboratory director must review and approve the QC plan, indicated with a signature and date, prior to implementation of the IQCP.

Quality Assessment

A quality assessment (QA) review of the IQCP must be performed and documented at least annually to determine the effectiveness of the QC plan and to identify whether adjustments are necessary. A QA review of the IQCP must also be performed and documented after any quality failures occur for the test. This can include failed proficiency testing events, QC failures, complaints or inconsistent patient results.

The assessment may include review of personnel records, competency assessments, test systems, reagents, proficiency testing results, specimen collection, specimen storage and transport, specimen rejection, maintenance records, complaints and environmental monitoring. The review is intended to identify any areas where risk for the test is not being appropriately mitigated; problems discovered during this QA review may indicate that changes to the IQCP are required. Any changes to the IQCP must be reviewed and approved by the laboratory director prior to implementation, and the laboratory must also document training of laboratory personnel on any changes to the plan.

Please see the COLAcentral Solutions Library for a sample QA review form that can be used for the annual review of an IQCP.

•Documentation•

The written IQCP risk assessment, copies of supporting data, written QC plan, and QA review documentation must be maintained by the laboratory for the entire time the IQCP is in use, plus two years after it is discontinued. Several states require longer documentation retention; please consult your state requirements.

For additional guidance in developing an IQCP specific to the QC of microbiology media, please see the IQCP for Microbiology Media Template in the COLAcentral Solutions Library.

•Sample IQCP and QC Plan•

The following is a fictitious example of what a risk assessment and resulting QC plan might look like. This example is abbreviated for demonstration purposes; it is likely that the laboratory's risk assessment will include additional potential sources of error.

Main Street Laboratory
Company X HCG Combo Test – Risk Assessment
Replacing QC 17 with IQCP for this test

	Potential Error	**Can this be detected by the system controls or current lab practice?**	**Risk level**	**QC Plan**
Specimen	Plasma is not an acceptable specimen type	No	Unacceptable	We will test only primary serum tubes.
	Improper storage – must be stored at 2-8 degrees for up to 48 hours if not tested immediately.	Yes	Acceptable	We run all HCG tests within one hour of collection
Environment	Do not perform or store in direct sunlight	No	Unacceptable	We will keep the blinds closed in the lab at all times.
Reagents	Expired reagents	No	Unacceptable	Record lot number and expiration date on log each day of testing
	Improper storage – requires storage at 15-30 degrees	Yes	Acceptable	We monitor room temp daily. Consistently in range.
Test system	Reading at incorrect time	No	Unacceptable	Timers to be placed on each counter where testing occurs
	No sample or insufficient sample added	Yes	Acceptable	Internal QC run with each test – internal QC line will not show up with insufficient sample

	Potential Error	Can this be detected by the system controls or current lab practice?	Risk level	QC Plan
Testing personnel	Staff not trained and/or not competent	No	Unacceptable – turnover among nursing staff is a problem.	Competency evaluations done as required – plus each newly trained nurse will undergo additional direct observation and blind sample testing one month after training.
Postanalytic	Incorrect results transcribed in to computer	No	Unacceptable	Training and competency to include that test results must be entered directly from the test cartridge immediately after testing. Computer at each workstation.

QC Plan:

1. Internal QC with each test must be acceptable in order to report results.
2. External Pos and Neg controls run with each new lot/shipment and with each new untrained tester.
3. Test only primary serum tubes.
4. Run all HCG tests within one hour of collection.
5. Keep blinds closed in the testing area at all times.
6. Monitor room temp daily and take corrective action if out of range.
7. Timers placed on every counter where testing is performed.
8. Competency and training documentation done as required – plus direct observation and blind sample testing done one month after training for new nurses.
9. Test results are entered in to the computer directly from the labeled test cartridge immediately after reading result. Computer at each workstation.

Approval by Laboratory Director:
Date:
Implemented: