CASE-BASED LEARNING (CBL)

THE FAILED QC MYSTERY

In-House Committee for Quality Assurance (IHCQA) – PG Microbiology

1. Learning Outcomes

- Explain the role of Quality Assurance (QA), Quality Control (QC) and IHCQA in a microbiology laboratory.
- Identify laboratory quality problems and non-conformities.
- Analyse QC observations and laboratory records using evidence.
- Differentiate immediate causes, contributing factors and root causes.
- Apply Fishbone and 5-Why approaches to root-cause analysis.
- Assess the potential risk associated with a QC failure.
- Develop appropriate correction, corrective action, preventive action and effectiveness checks.
- Communicate and defend an evidence-based quality decision.

2. Essential Concepts

Quality Assurance (QA): Planned and systematic activities used to ensure reliable, consistent and fit-for-purpose laboratory performance.

Quality Control (QC): Operational techniques used to monitor whether a test system is performing within established acceptable limits.

IHCQA: An institutional mechanism for monitoring, evaluating and improving quality within the laboratory/department.

Non-conformity: Failure to meet a specified requirement.

Root cause: The underlying reason responsible for a quality problem.

Corrective Action: Action taken to eliminate the cause of an identified non-conformity and prevent recurrence.

Preventive Action: Action taken to eliminate or reduce the likelihood of potential problems or recurrence.

3. Case Scenario

A microbiology laboratory performs routine antimicrobial susceptibility testing (AST) using the Kirby–Bauer disc diffusion method. An appropriate reference QC strain is used to monitor AST performance.

During the weekly quality review, one antimicrobial QC result is found to be repeatedly outside the laboratory's established acceptable range.

Day	QC zone diameter	Acceptable range	Interpretation
Day 1	16 mm	18–24 mm	Out of range
Day 2	15 mm	18–24 mm	Out of range
Day 3	16 mm	18–24 mm	Out of range

The analyst states that the test was performed according to the SOP. However, the quality review identifies several findings that may be relevant to the repeated QC failure.

4. Evidence Cards

Evidence 1 – Incubator: Recorded temperature: 37.8°C. The laboratory SOP specifies 35 ± 2°C.

Evidence 2 – Culture Medium: A newly prepared batch of Mueller–Hinton agar was used. The batch preparation record is incomplete and final QC documentation is missing.

Evidence 3 – Antimicrobial Discs: A new lot of antimicrobial discs was opened. The storage record indicates that the discs were temporarily kept outside the recommended storage conditions.

Evidence 4 – Inoculum Standardization: Inoculum turbidity was estimated visually. No documented instrument-based verification was performed.

Evidence 5 – QC Strain: The routine QC strain was used, but stock-culture maintenance documentation and the date of the last verification are incomplete.

Evidence 6 – Equipment Records: The incubator maintenance record is incomplete and the date of the last preventive maintenance is unclear.

Evidence 7 – Personnel Competency: The analyst has experience in AST, but recent competency reassessment has not been documented.

Evidence 8 – Documentation: Several QC records contain missing signatures, missing dates and incomplete observations.

5. Investigation Tasks

Analyse the case using the available evidence. Distinguish between possible causes, contributing factors and the most probable root cause. Do not identify a root cause without considering what evidence would be required for confirmation.

6. Team Roles and Assigned Tasks

Team	Role	Task
Team 1	Problem Identification Team (15,4,13,32,6,50,51)	Identify the primary problem, observations indicating quality failure, non-conformities and potentially affected stages.
Team 2	Root-Cause Analysis Team (9,1,14,27,47,25,5)	Prepare a Fishbone diagram and identify possible, contributing and most probable root causes. State evidence needed for confirmation.
Team 3	Internal Audit Team (30,42,10,23,24,12,40)	Review personnel, equipment, materials, methods and documentation. Identify non-conformities and recommend actions.
Team 4	CAPA Team (28,26,31,36,37,3,21)	Develop immediate correction, corrective action, preventive action and effectiveness monitoring.
Team 5	Risk Assessment Team (22,34,44,45,35,17,29)	Assess the potential impact on sample/patient results and

		recommend actions for potentially affected results.
Team 6	IHCQA Decision-Making Team (20,7,16,46,38,49, 41,39)	Integrate the findings and make a final evidence-based recommendation on continuation or temporary suspension of testing.

7. Problem Identification

- What exactly is the quality problem?
- What observations indicate a quality failure?
- What are the non-conformities?
- Which stages of the laboratory process may be affected?

8. Root-Cause Analysis

Use a Fishbone (Ishikawa) framework:

Personnel | Equipment | Method | Material | Environment | Measurement

- What are the possible causes?
- Which factors may be contributing factors?
- Which factor is the most probable root cause?
- What additional evidence is required to confirm the root cause?

9. Internal Audit Review

- Personnel: training and competency records
- Equipment: calibration, maintenance and temperature monitoring
- Materials: media preparation, reagent/disc storage and lot records
- Methods: SOP and inoculum preparation procedure
- Documentation: records, dates, signatures and traceability

Record findings using the following format:

Finding	Evidence	Classification	Recommendation

10. CAPA Plan

Prepare a CAPA plan under the following headings:

- Immediate correction – What should be done immediately?
- Corrective action – How will the identified cause be addressed?
- Preventive action – How will recurrence be prevented?
- Effectiveness check – How will effectiveness be demonstrated?

Immediate Correction	Corrective Action	Preventive Action	Effectiveness Check

11. Risk Assessment

- Could the QC failure have affected sample/patient results?
- Were samples tested during the period of QC failure?
- Should potentially affected results be reviewed?
- Should testing be temporarily suspended?
- Is repeat testing or additional verification required?

12. IHCQA Final Decision

Based on the evidence, determine whether testing should continue or be temporarily suspended until the QC failure is resolved. Support the decision using QC data, evidence, risk assessment, root-cause analysis and CAPA.

Final recommendation:

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13. Presentation Format

- Problem – What happened?
- Evidence – What evidence supports the conclusion?
- Analysis – What are the possible causes?
- Root cause – What is the most probable root cause and why?
- Risk – What could be the impact?
- CAPA – What should be done?
- Recommendation – What should IHCQA decide?

14. Cross-Questioning

- What evidence supports your conclusion?
- Could there be another root cause?
- How would you verify the proposed root cause?
- Which finding represents the greatest quality risk?
- How will you demonstrate that CAPA was effective?