Troubleshooting Quality Control (QC) Failures in a Clinical Laboratory

Step 1: Identify the QC Failure

Review QC results for trends, shifts, or out-of-range values.

Determine if the failure is isolated or recurring.

Step 2: Stop Testing & Notify Supervisor

Cease patient testing until the issue is resolved.

Inform the lab or section supervisor or quality control manager.

Step 3: Check for Clerical & Procedural Errors

Ensure correct QC material, lot number, and expiration date.

Verify proper storage and handling of QC materials.

Confirm correct instrument calibration and settings.

Check for transcription or data entry errors.

Step 4: Repeat QC Testing

Re-run QC using the same sample to confirm failure.

Use a new QC sample from the same lot.

Step 5: Evaluate Equipment & Reagents

Inspect the instrument for errors, maintenance issues, or calibration problems.

Verify reagent integrity, expiration, and preparation.

Ensure proper instrument function with maintenance logs.

Step 6: Review Environmental Factors

Check temperature, humidity, and storage conditions.

Ensure no power surges or mechanical disruptions occurred.

Step 7: Perform Corrective Actions

If an error is identified, take corrective steps (e.g., recalibration, reagent replacement, fresh quality control, instrument maintenance).

Document corrective actions and re-run QC.

Step 8: Validate & Resume Testing

If QC is within acceptable limits, resume patient testing.

If QC remains out of range, escalate to technical support or manufacturer.

Step 9: Document & Report Findings

Record all troubleshooting steps, corrective actions, and outcomes.

Report persistent issues to laboratory management.

Following this structured approach ensures accurate and reliable laboratory results while maintaining compliance with regulatory standards.