PROGRAM Standard Operating Procedure – Laboratory Services	
Title: **QC10100 Quality Control Troubleshooting**	Policy Number: 15-171-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date: 19/06/2024	Next Review Date: 19/06/2026
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved: 19/06/2024
Accreditation Canada Applicable Standard: NA	

GUIDING PRINCIPLE:

Quality Control is run for each test performed by the laboratory to ensure the analyzers, reagents and processes are allowing accurate results to be measured and reported and provide the best patient care possible.

Westgard rules are a multi-rule tool used to statistically detect errors by detecting trends and shifts in quality control results. Quality control materials are used to determine random and systematic error in instrument analysis.

PURPOSE/RATIONALE:

To ensure that appropriate remedial and corrective actions are taken in response to incidents of quality control flags or failures. This procedure provides instructions for troubleshooting Quality Control and documenting actions taken utilizing Quality Control Troubleshooting Checklist.

DEFINITIONS:

- **QC** – Quality Control
- **QC flag or failure** – A warning or indicator of a quality control problem such as inappropriate analyte result, and incorrect quality control result
- **LJ graph** – Levey-Jennings graph
- **LIS** – Laboratory Information System
- **STAT samples** – Results required less than 55 minutes

SCOPE/APPLICABILITY:

This procedure applies to Medical Laboratory Technologists (MLTs) and Combined Laboratory and X-ray Technologists (CLXTs) performing Quality Control.

SPECIAL SAFETY PRECAUTIONS:

- Ensure proper PPE is used such as gloves, lab gowns and eye protection, when possible exposure to splashes
- Ensure all samples are treated following universal precautions and assume all products as potentially infectious

PROCEDURE INSTRUCTIONS:

<table>
<tr><th>Step</th><th colspan="2">Action</th></tr>
<tr><td colspan="3">Preparing to troubleshoot</td></tr>
<tr><td>1</td><td colspan="2">Discontinue patient testing for affected analytes until QC issue is resolved</td></tr>
<tr><td>2</td><td colspan="2">Print a copy of the QCM10101 Quality Control Troubleshooting Checklist</td></tr>
<tr><td>3</td><td colspan="2">Gather related information that may help with troubleshooting
Review other levels of QC for the same test
If this QC is run on another instrument, review the results
Review other tests and consider related factors they have in common (ie QC material, reagent, mode of detection)</td></tr>
<tr><td rowspan="2">4</td><td colspan="2">Determine type of error based on LJ graph and LIS SoftTQC rules</td></tr>
<tr><td>Systematic Error</td><td>Random Error</td></tr>
<tr><td></td><td>Deterioration of QC material
Reagent deterioration
Calibrator deterioration
Calibration problem
Lack of calibration following major maintenance
Reagent lot switch
Change in technique between operators</td><td>Improper QC/reagent reconstitution
Improper QC/reagent handling
Instrument pipetting error
Bubbles in reagent or QC cups
Periodic maintenance not performed</td></tr>
</table>

<table>
<tr><th>Step</th><th colspan="2">Action</th></tr>
<tr><td colspan="3">Performing Troubleshooting Corrective Actions</td></tr>
<tr><td rowspan="3">1</td><td colspan="2">Complete the first 4 steps of the QCM10101 QC Troubleshooting Checklist to rule out any issues with the QC product.</td></tr>
<tr><td>If the issue was resolved by:</td><td>Then:</td></tr>
<tr><td>• Utilizing the correct QC product
• Using fresh QC bottle/vial</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Proceed with patient testing</td></tr>
<tr><td></td><td>• Switching to a new QC lot number</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Follow steps to activate new QC lot in TQC
• Proceed with patient testing</td></tr>
<tr><td rowspan="4">2</td><td colspan="2">Complete Steps 5 – 8 of the QCM10101 QC Troubleshooting Checklist to rule out any reagent issues.</td></tr>
<tr><td>If the issue was resolved by:</td><td>Then:</td></tr>
<tr><td>• Replacing reagent with the current lot number</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Proceed with patient testing</td></tr>
<tr><td>• Performing successful calibration
Note: It is not recommended to calibrate without identifying the source of the problem</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Proceed with patient testing</td></tr>
<tr><td></td><td>• Replacing reagent with new lot number and validation has been approved</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Follow steps to activate new reagent lot in TQC
• Notify supervisor to adjust mean if required
• Proceed with patient testing</td></tr>
<tr><td>3</td><td colspan="2">If these steps have not resolved the issue, contact the vendor’s technical support team to notify them of the issue.</td></tr>
</table>

<table>
<tr><td rowspan="3">4</td><td colspan="2">Perform corrective actions recommended by the vendor’s technical support team and document further intervention on the QUA40690 Laboratory Instrument Troubleshooting Form.</td></tr>
<tr><td>If the issue was:</td><td>Then:</td></tr>
<tr><td>Resolved</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Proceed with patient testing</td></tr>
<tr><td>Not resolved</td><td>• Add comment in LIS indicating corrective actions (Refer to QCM10300 Entering QC comments in LIS procedure)
• Discontinue patient testing
• “STAT” and Time-sensitive samples should be tested with back up method. If this is not available, refer samples to Referral Lab for testing.
• Notify wards about the delay in testing
• Routine samples can be stored until issues are resolved.
• Notify supervisor.</td></tr>
<tr><td>5</td><td colspan="2">If the above steps have resolved the issue, investigate if previously reported patient results were affected. Determine at what point patient results may have been affected.
• Retested results must fall within a 10% difference.
• If results fall outside the 10% difference, amend results, and notify healthcare provider.
• Submit an RL6 if required.</td></tr>
<tr><td>6</td><td colspan="2">Submit all troubleshooting documentation to supervisor for review.</td></tr>
</table>

CROSS-REFERENCES:

QCM 10101Quality Control Troubleshooting Checklist
QUA40690 Laboratory Instrument Troubleshooting Form
QCM10300 Entering QC comments in LIS

REFERENCES:

CLSI C24-ED4:2016 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th Edition

APPROVAL:

June 19, 2024
Date

Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	15 Feb 2024	Initial Release	L. Howlett