

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: Core Lab, QA

Date Distributed: 2/5/2019
Due Date: 2/28/2019
Implementation: 2/12/2019

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
QC Responsibilities and Review SGAH.QA39 v2
Description of change(s):
<p>This SOP is revised to remove some Quest term that do not apply to our labs. The actual content that applies to staff (Testing Personnel responsibilities) and group leads/designees (General Supervisor responsibilities) has NOT changed. The SOP is provided as a review of our QC process and practice.</p> <p>Header: updated facility Section 1: removed QD Section 3 & 7: added technical consultant Section 4: added CV & SD, removed job titles Section 8: updated titles Section 9: added new BPT SOP</p> <p>This revised SOP will be implemented on February 12, 2019</p>

Document your compliance with this training update by taking the quiz in the MTS system.

Non-Technical SOP

Title	QC Responsibilities and Review	
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Owner	Robert SanLuis, Cynthia Bowman-Gholston	Date: 12/12/2016

Laboratory Approval		
Print Name and Title	Signature	Date
<i>Refer to the electronic signature page for approval and approval dates.</i>		
Local Issue Date:		Local Effective Date:

Review:		
Print Name	Signature	Date

TABLE OF CONTENTS

1. PURPOSE.....	2
2. SCOPE.....	2
3. RESPONSIBILITY.....	2
4. DEFINITIONS.....	3
5. TESTING PERSONNEL QC RESPONSIBILITIES.....	3
6. GENERAL SUPERVISOR QC RESPONSIBILITIES.....	5
7. TECHNICAL SUPERVISOR QC RESPONSIBILITIES.....	6
8. RELATED DOCUMENTS.....	7
9. REFERENCES.....	7
10. REVISION HISTORY.....	8
11. ADDENDA AND APPENDICES.....	8

1. PURPOSE

The performance, review, and maintenance of Quality Control are the responsibility of each person working in the laboratory. The purpose of this document is to define the roles of the Testing Personnel, the General Supervisor, and the Technical Supervisor to make sure that standards for Quality Control are understood and implemented every time patient samples are tested.

2. SCOPE

This document applies to all QC procedures in the laboratory. There are many aspects to managing an effective Quality Control program, some of which require daily, weekly, or monthly actions. Each of these is very important and essential to the ongoing success in our QC program's ability to identify those changes in the quality of testing that could adversely affect patient results. The overall review of QC is a shared responsibility that features unique roles as described below.

3. RESPONSIBILITY

Testing Personnel have primary responsibility for adhering to QC procedures on a **daily basis**, with every batch, worklist, or group of patient samples. See details in Section 5.

The **General Supervisor** has primary responsibility for the **weekly review** of QC records and information, while being available on a daily basis to assist in problem solving. See details in Section 6.

The **Technical Supervisor/Consultant** has primary responsibility for **monthly review** of QC information. See details in Section 7.

4. DEFINITIONS

Term	Definition
Coefficient of Variation (CV)	The ratio of the standard deviation to the mean. The CV reflects the extent of variability in relation to the mean of the population.
Imprecision	The variation of a process. This is measured by the standard deviation of the values.
Standard Deviation (SD)	A statistic used to describe the distribution or spread of data in a population that is shown to have the shape of a normal or Gaussian curve.
Trend	A general change that may increase or decrease in magnitude over time.

5. TESTING PERSONNEL QC RESPONSIBILITIES

A. QC Material Management

1. Ensure that QC materials are prepared properly (including use of current lot numbers)
2. Ensure that QC materials are placed properly in the batch or worklist per the assay SOP.
3. Ensure that QC checks are completed on new lots before use.
4. Ensure that QC samples are tested in the same manner as patient samples.

B. QC Results Review (daily/weekly)

1. Verify that all QC data are entered into the appropriate database (LIS or other QC software system) or appropriate QC tracking log, as defined in the testing SOP.
 - a) Verify that all acceptable and unacceptable QC data points are recorded and captured.
 - b) Verify compliance with specific QC frequency requirements.
 - c) Verify that each QC data point designated as acceptable is within the defined tolerance limits for the assay tested.
 - Acceptable QC points require no further documentation
 - Unacceptable QC should be followed by an acceptable run prior to performing testing
 - d) Verify that all QC warnings are identified and appropriately documented on the QC Summary Report (Spreadsheet).
 - e) Verify that all QC failures are identified and appropriately documented in the QC software system and on QC Summary Report.
 - Data points appearing as gross outliers may be dispositioned (excluded from statistical analysis), but must remain in the QC record.
 - Verify appropriate corrective action was taken and documented including the need and/or result of Look Back when indicated (1:3S)
 - Notify supervisor and manager if Look Back failed or was not performed to determine extent of failure, necessary corrective action and potential for RQI report.

- For testing that does not allow appropriate Look Back, assess if testing was performed and submit data for supervisor/manager review. An assessment of patient impact may be required by the medical director or designee.
- f) Verify that NO patient results were released when controls exceed acceptable limits as defined by the QC Program.
2. Review patient results: checking for critical values, need for dilutions and repeats, “impossible/absurd” results that might indicate sampling errors, and population trends.
 3. Evaluate the documented corrective action for each QC failure. Written corrective action must include:
 - a) the control level(s) affected
 - b) the QC rule(s) violated
 - c) the cause of the out of range QC result (or adequate review of a warning)
 - d) corrective action
 - e) an evaluation of patient results already reported from the affected run
 - f) evidence of retesting patient samples as defined in local policy, ONLY after showing acceptable QC performance has been restored
 - g) signature/initials/tech ID and date, recorded by hand or electronically
 4. Document that any problems or areas of concern have been discussed with the appropriate testing personnel. The corrective action tool is the laboratory Quality Variance (QV) form.

C. QC Results Out of Range

1. Ensure that NO results are released when controls do not meet acceptable limits.
2. Ensure that all unacceptable control results are identified and documented.
3. Take appropriate action for each QC result that is out of limits, as defined in the assay SOP. These actions include:
 - Checking the other control results.
 - Determining the scope of the problem and note such information:
 - Does it affect only this batch?
 - Does it affect only part of this batch?
 - Have there been warnings in the previous batch?
4. Determine the cause of the out of range result.
5. Take appropriate corrective action.
6. Retesting the affected patient samples, ONLY after showing acceptable performance has been restored.
7. Review the situation with the supervisor or designee for the test area.
8. Make sure that all corrective actions are fully documented.

D. Release Process

1. Make sure that **all** QC data (both good and bad) are reviewed and entered into the data base or appropriate QC tracking log, defined in the testing SOP.
2. Sign and date all runs and QC records for each batch, or run, or worklist.
3. Secondary review as designated by the supervisor is strongly recommended.
4. Ensure that action items not completed in your shift are
 - Documented in writing for the next shift.
 - Discussed with your supervisor (or designee).

6. GENERAL SUPERVISOR QC RESPONSIBILITIES

(Or designated technically responsible person)

A. QC Material Management

1. Review the status of availability of QC materials and plan for crossover testing of a new lot, if necessary.
2. Review data for checkout of new lots of QC material before they are put in use (sign and date to document review).

B. Daily QC Assistance and Review

1. Be aware of the status of all testing during the shift.
2. Provide problem solving assistance to the tech as problems arise.

C. Weekly QC Results Review

1. Review to be performed every 7-10 days
2. Examine qualitative and quantitative QC data and/or patient data on a weekly basis.
 - a) Perform a 1-2 week look back of all QC points for each assay using Levy-Jennings graphs, when available. Refer to Bio-Rad Unity Real Time 2.0 Chemistry procedure for details.
 - 1) Identify and document trends or shifts for each control level on the QC summary log.
 - 2) Note whether more than one control level is similarly affected.
 - 3) Investigate unexpected findings.
 - 4) Document causes and any follow-up corrective action resulting from the weekly review.
 - b) Perform a 1-2 week look back of patient means, % abnormal, etc. for each assay, if defined in the assay SOP.
 - 1) Identify and document trends or shifts.
 - 2) Investigate unexpected findings.
 - 3) Document causes and any follow-up corrective action resulting from the weekly review.

3. Prepare a summary of the daily and weekly issues utilizing the QC summary report log incorporating all the information outlined above for Daily and Weekly QC Review.
4. Address issues regarding quality in general with the Department Supervisor, Manager, Director and/or staff as appropriate, documenting date of communication on the QC Summary Report and create QV.
5. Weekly QC will be completed by Tuesday-Wednesday of each week and e-mailed to Supervisor/Manager for review.

D. Monthly QC responsibilities

1. Consolidate the weekly reviews for a comprehensive monthly QC Summary Report. Present the QC Summary in a binder to the Supervisor/Manager no later than 12th of the following month. The binder will contain the following:
 - Executive Summary from the LIS
 - The end-of-month QC Summary Report (all areas must be completed)
 - The Monthly LJ with areas of note tabbed for review
 - A copy of QV forms listed on the end-of-month QC Summary Report
 - QAP data to be added to binder when available (Chemistry QAP ready on the 17th of the month).
 - Maintenance records

7. TECHNICAL SUPERVISOR / CONSULTANT QC RESPONSIBILITIES (Or designated technically responsible person for the department)

A. Management of Technical QC Issues

1. Ensure that each SOP contains the correct QC information, including frequency, limits and QC rules.

B. Review of QC information

1. Monthly review to be performed by the 21st of the following month.
2. Ensure that weekly QC review is being performed and documented.
3. The Supervisor/Manager will review the monthly QC Binders.
 - Document any additional corrective action needed on the monthly summary report.
4. Verify that the performance of each assay is consistent with the previous month's performance.
 - a) Examine Levy-Jennings Charts, SDs, CVs, and achieved Sigma scores if available for month to month trends and imprecision.
 - Document each performance issue and a plan for improvement on the Monthly QC Summary Report.
 - b) Review the previous month's documented performance issues. Evaluate the success of their improvement plans on the Monthly QC Summary Report.

5. Evaluate and compare Peer Group QC data with interlab lab QC data, if applicable (SDIs, CVRs, etc.).
 - a) Document each performance issue and plan for improvement on the Monthly QC Summary Report.
 - b) Review the previous month's documented performance issues.
 - Evaluate the success of their improvement plans.
6. Review appropriateness of QC ranges.
 - Document causes / reasons for changes of QC ranges, including the fact that new ranges are based on more data on the Monthly QC Summary Report.
7. Review frequency of failures to determine the:
 - a) need for fundamental problem solving and resolution or
 - b) need for staff re-training or
 - c) need for repair or replacement of equipment
8. Review other incident reports, such as:
 - a) revised reports
 - b) client-requested repeat testing
 - c) Document unexpected findings and improvement plans.
9. Assemble all QC documentation for final approval signature(s) by medical director or designee.

Note: The delegated blood bank General Supervisor or designee performs applicable duties in this section.

8. RELATED DOCUMENTS

Quality Control Program, QA procedure
Policy for Delegation of Responsibilities, QA procedure
Quality Control Program, Transfusion Service, Blood Bank procedure
Bio-Rad Unity Real Time 2.0, Chemistry procedure
Monthly QC Summary Report (AG.F368)

9. REFERENCES

- CLIA 88 Regulations
- CAP checklists (both Lab General and Specialty Checklists)
- NCCLS guideline "Statistical Quality Control for Quantitative Measurements: Principles and Definitions: C24-A (1999). [obtain from the Corporate Medical Library, Teterboro]
- QC Responsibilities, QC Best Practice Team, QDQC714v1.0, 8/14/00.
- Policy for QC Responsibilities, QC Best Practice Team, QDMOQ718v2, 12/3/18.

10. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes GEC/SGAH/WAH.QA35.000		
000	12/12/16	Update owner Header: add other sites Section 5: add other QC software and Bio-Rad SOP, replace PI with QV form Section 6: change summary due date to 12 th Section 7: add note about blood bank Section 8: update SOP list, add summary form Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett Z Morrow J Negado	R SanLuis
1	1/24/18	Header: updated facility Section 1: removed QD Section 3 & 7: added technical consultant Section 4: added CV & SD, removed job titles Section 8: updated titles Section 9: added new BPT SOP	L Barrett	R SanLuis

11. ADDENDA AND APPENDICES

N/A