TRAINING UPDATE

Lab Location:	SGMC, WAH & GEC	**Date Distributed:**	1/3/2017
Department:	Core Lab	**Due Date:**	1/31/2017
		Implementation:	**1/31/2017**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

QC Responsibilities and Review SGAH.QA39 v1

Monthly QC Summary Report AG.F368.0

Note: this has been converted to a system SOP

Description of change(s):

SOP -

Section 5: add other QC software and Bio-Rad SOP, replace PI with QV form

Section 6: change summary due date to 12th

Section 7: add note about blood bank

Section 8: update SOP list, add summary form

FORM –

Placed under document control, and added drop down selections (on excel working copy) for "Lab", "Comments and/or Action Taken" and Sections I – V at bottom. *Note: the actual excel form contains more rows than what is shown on the attached copy.*

The revised SOP and FORM will be implemented on January 31, 2017

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

Non-Technical SOP

Title	**QC Responsibilities and Review**	
Prepared by	Robert SanLuis	Date: 8/1/2011
Owner	Robert SanLuis, ~~Jean Buss~~	Date: 12/12/2016

Laboratory Approval

Print Name and Title	Signature	Date
Refer to the electronic signature page for approval and approval dates.		

Local Issue Date: Local Effective Date:

Review:

Print Name	Signature	Date

Form revised 3/31/00

TABLE OF CONTENTS

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 Quest Diagnostics standards for Quality Control are understood and implemented every time patient samples are tested.

2. SCOPE

This document applies to all QC procedures in ~~every department in every~~ 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** has primary responsibility for **monthly review** of QC information. See details in Section 7.

4. DEFINITIONS

General Supervisor	"An individual, who under the direction of the Laboratory Director and supervision of the Technical Supervisor, provides day-to-day supervision of the testing personnel and reporting of test results." From CLIA 88 regulations, Section 493.1459, 1461 and 1463.
Imprecision	The variation of a process. This is measured by the standard deviation of the values.
Technical Supervisor	"An individual who is qualified by education and either training or experience to provide technical supervision for each of the specialties or subspecialties…" From CLIA 88 regulations, Section 493.1447, 1449 and 1551.
Testing Personnel	"Individuals who meet the qualification requirements … and perform the functions of specimen processing, test performance, and for reporting test results." From CLIA 88 regulations, Section 493.1487, 1489 and 1495.
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) Verifies 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 ~~LIS~~ 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.

Form revised 3/31/00

- 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 local QC rule policy (QC failure).

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) ~~PI~~ 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:
   - Does it affect only this batch?
   - Does it affect only part of this batch?
   - Have there been warnings in the previous batch?
   - Note all such information.
4. Determining cause of the out of range result.
5. Taking appropriate corrective action.
6. Retesting the affected patient samples, ONLY after showing acceptable performance has been restored.
7. Reviewing the situation with the supervisor or designee for the test area.

8. Making 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 ~~LIS procedure Quality Control Monthly Report~~ 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 ~~PI~~.
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 ~~15~~ 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 ~~PIs~~ 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 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

QC Responsibilities, QC Best Practice Team, QDQC714v1.0, 8/14/00.
~~Quality Control Monthly Report, LIS procedure~~
Quality Control Program, 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]

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 12th 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

11. ADDENDA AND APPENDICES

N/A

Month:

Monthly QC Summary Report for Quest Diagnostics at Adventist Healthcare

Date	Test	Control Lot #	Lot # / Date	Shift / Trend	Device ID/ Instrument	LAB	Tech	DAILY QC ISSUES	Comments and/or Action Taken

Instructions: Group Lead / designee completes sections I. - V. below. For each section below select the appropriate comment from the drop down menu. When the response is other than acceptable a QV form must be completed.

I. Control records for all **QUALITATIVE TESTS** have been checked and documentation was found to be _____**.**

If unacceptable, please explain below.

		Acceptable
1	Action:	
2	Action:	
3	Action:	

II. Any control records found to be unacceptable have been discussed with the responsible tech and the problem has been resolved. The discussions are documented and placed in the employee's training files.

		Acceptable
1	Action:	
2	Action:	

3	Action:	

III. Temperature charts for all water baths, refrigerators, freezers or other equipment have been checked. Records are _____

The chart(s) for the following instrument(s) was found INCOMPLETE:

		Acceptable
1	Action:	
2	Action:	
3	Action:	

IV. Records of instrument maintenance and function checks for all instruments have been checked.

The records for the following instrument(s) are incomplete:

		Acceptable
1	Action:	
2	Action:	
3	Action:	

V. Expiration dates on all reagents, kits, controls, etc., have been checked and found to be….

Items found to be unacceptable have been replaced.

Acceptable

Group Lead	Date	
		Acceptable
Medical Director or Designee (Technical Supervisor)	Date	

EXAMPLES OF APPROVED RESPONSES FOR UNACCEPTABLE CONTROL VALUES	Responses for section I - V
Run not accepted. All patients repeated.	Acceptable
Run accepted. Patients in control range repeated.	Unacceptable, see QV form for corrective action
Run accepted. No patients in this range.	
Data entry error. Control result is_____.	
Transposition error. Control result is_____.	
Control repeated-new result acceptable.	
Control repeated after _____(action) and new result is acceptable.	
Instrument recalibrated. Patients and control repeated.	
New lot of reagent on _____(date). Shift not clinically significant.	
Projected range. Will monitor until_____(date).	
Run reviewed. Abnormal and borderline patients repeated.	
Lab accident. all other controls in.	
Instr. repaired/serviced/replaced_____(date). Need to establish new range.	
Control aging. New control lot in parallel.	
Documented shift caused by _____. Will monitor until_____(date).	
Run reviewed and approved by supervisor_____.	
Other:	