TRAINING UPDATE

Lab Location: Department: GEC, SGMC & WAH Core Lab
 Date Distributed:
 4/8/2019

 Due Date:
 4/30/2019

 Implementation:
 4/22/2019

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Control Program Bio-Rad Unity Real Time 2.0

SGAH.QA40 v5 SGAH.C136 v3

Description of change(s):

Notes:

- It is <u>essential</u> that QC review & actions be documented in Bio-Rad Unity (<u>not</u> in DI). Why? – You can't see L J charts in DI to properly assess your QC trends.
- <u>Use</u> the pre-defined QC Action codes. Remember an 'action' describes what you DID, use the Comment area if you want to add other info(example: reagent lot#)
- The separate Micro QC Program SOP has been retired and some details added to overall QC policy.

QC Program SOP

Section 2.2: added micro specific info Section 4: added Action & Comment Codes and exception for look-back

Section 5.4: added exception for look-back Attachment A: added new codes

Bio-Rad SOP

Section 5: added note in 5.2.C,

removed Edit Action Log from employee setup in 5.2.I

These revised SOPs will be implemented on April 22, 2019

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

Non-Technical SOP

Title	Quality Control Program					
Prepared by	Robert SanLuisDate: 8/18/20					
Owner	Cynthia Bowman-Gholston	Date: 8/18/2011				

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				

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1. PURPOSE

This procedure establishes the guidelines for implementation and management of the laboratory's Quality Control (QC) program. Deviation from these guidelines must be approved by the Laboratory's Medical Director and must be documented in the standard operating procedure for the particular procedure.

2. SCOPE

Both qualitative and quantitative laboratory tests require quality control. This procedure provides guidelines for the frequency and any corrective actions necessary in the event of failed or out of range quality control.

2.1 QUANTITATIVE

- A. QC materials provide objective assessment of method accuracy and precision and laboratory techniques. They also contribute an integral part of good laboratory practice.
- B. QC testing ensures that laboratories report accurate and reliable test results. These materials best represent actual patient specimens and contain analytes with concentrations that approximate realistic values.
- C. QC testing provides a performance check on the entire testing system: instrument function, operator competence, inventory management, and environmental conditions; all contribute to a successful quality control system. These attributes should be considered when quality control testing is questionable.
- D. The quantitative QC assessment at Quest Diagnostics at Adventist HealthCare Laboratories relies upon the verification of each new lot of control material against the manufacturer's ranges or the peer group performance.
- E. The Laboratory QC Module, functions through a series of rules which are applied to QC results to evaluate acceptable, using the two standard deviation range that falls within the manufacturer's published range or compares with a peer group on the same system. Technologists document all corrective actions in the Laboratory QC Module (LIS, Data Innovation [DI], or Bio-Rad Unity Real Time).

F. The supervisors evaluate QC statistics for assay specific controls from data gathered under similar operating conditions as patient testing, or based upon the manufacture's specifications.

2.2 QUALITATIVE

- A. For kits that have internal and external qualitative control requirements, the frequency of control is in accordance with the manufacturer's guidelines, unless otherwise stated within the respective operating procedure for the assay. An Individualized Quality Control Plan (IQCP) is performed when necessary (refer to Quality Management Plan for detailed information). The external material will be as close in nature as the patient sample.
- B. If external material ships with the kit, this material will be the primary control.
- C. For kits or assays without accompanying external material, the QC material will still reflect the consistency of the patient sample, i.e. the control for the urine pregnancy will be a urine control material.
- D. For microbiology, quality control materials such as ATCC strains of bacteria are selected to best represent (as possible) actual patient specimens and to approximate realistic results. The QC program also includes testing and monitoring of media.

3. **RESPONSIBILITY**

3.1 General Guidelines

- A. Each testing person for qualitative or quantitative testing must ensure that quality control adheres to the specified requirements for control frequency as specified in the SOP for each test.
- B. Each testing person will ensure that the QC met the acceptable performance limits prior to reporting patient results. No patient results can be reported until the method has been validated using the established QC rules.
- C. Each testing person will ensure QC material will be analyzed at established intervals and in the same manner as patient samples.
- D. Each testing person will ensure that all unacceptable QC results are investigated and appropriate actions documented electronically or on the QC/Action Log as appropriate.
- E. Each testing person will ensure the recording of all control results on the worksheet (paper), in the instrument (automatic process), LIS, or DI/Bio-Rad Unity Real Time. Where applicable, instrument printouts and manual control records will be retained for 2 years (5 years for Blood Bank QC records).
- F. THE TESTING PERSON WILL VERIFY THAT THE LOT NUMBER AND EXPIRATION DATE OF ALL QC MATERIAL IS CURRENT AND WITHIN DATE PRIOR TO RELEASING PATIENT RESULTS.
- G. The testing person will ensure the documentation of control results in accordance with the guidelines for the particular test being performed. (See test-specific procedure)
- H. Refer to the procedure QC Responsibilities and Review for additional details.

4. **DEFINITIONS**

- A. Action Codes standard remedial / corrective descriptions for failed QC established in Sunquest, DI, and Bio-Rad Unity, refer to attachment A.
- B. Analytical Run the interval within which the accuracy and precision of the measuring system is expected to be stable.
- C. Assayed controls the manufacturer has tested the control material in replicate and provided lot-specific mean values (along with upper and lower limits). Individual laboratory means should fall within the manufacturer's calculated limits. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by modification of the manufacturer's test method.
- D. Comment Codes descriptions used to explain rationale for repeating QC. May be used in conjunction with an Action Code but never used solely to describe remedial action.
- E. Control Limits the upper and lower values for acceptable control performance. Any test value outside of these limits must be considered a QC failure.
- F. Bracketing the placement of control materials at the beginning and the end of a batch of patients' specimens. When runs are performed sequentially in continuous processing placing control material in the first cup of the next batch can be considered as the control for the end of the previous batch. Note this applies only for continuous processing.
- G. Peer Group any group of laboratories, using the same instrumentation and reagents, and testing the same lot number of quality control material.
- H. Unassayed controls the control material has not been tested by the manufacturer to establish mean values. Each laboratory must test the material to establish its own mean values and statistically acceptable limits. All of the same analyzers within this laboratory system contribute values to the determination of the internal mean value.
- I. Quantitative Results numeric values that correspond to the actual amount of analytes present.
- J. Qualitative Results indicate only the presence or absence of a substance.
- K. TEa Total Allowable Error; TEa is the amount of error that can be tolerated without invalidating the medical usefulness of the analytical result.
- Look Back the term used for the process to determine the accuracy of prior reported test results, after discovery of an "out of control" analytical run (1:3S or 2-levels >2SD). Qualitative methods require look back when QC falls outside of the acceptable range.
- M. Standard Deviation (SD) is a mathematical calculation that measures the average distance to the mean for a given set of values, based upon instrument performance. A small SD indicates that most of the values, within a set of data, fall close to the mean. A large SD indicates that most values are farther away from the mean.
- N. Unacceptable QC results (for Quantitative Assays) any QC that exceeds 1:2S requires investigation and resolution before continuation of testing.
- O. "Out of control" QC results for quantitative methods 2-Levels >2SD or 1:3S; Perform Look Back. Exception: certain scenarios do not require Look Back, refer to action codes in attachment A.
- P. "Out of control" QC results (for Qualitative Assays) any value less than 100% compliance with manufacturers expected results.

Q. Acceptability Limits (AL) – the points beyond which an assay qualifies as out of control.

5. **PROCEDURE**

5.1 PERFORMING QUALITY CONTROL

- A. General Guidelines
 - Performance of QC is specific to the testing procedure. The applicable SOP should always be reviewed for specific quality control guidelines regarding:
 - 1. the type, name, and product number of QC material used
 - 2. preparation and handling instructions
 - 3. levels to be run and their frequency
 - 4. documentation of QC results and corrective action
 - 5. reagent preparation
 - 6. instrument maintenance
- B. Establishment of Quality Control Acceptability Limits (QC-AL) General Considerations
 - 1. QC-AL must be established on the analyzers within "the system" or the manufacturer's limits must be verified for each new lot of control material.
 - 2. When establishing in-house AL ranges for assayed controls, the in-house mean should fall within the manufacturer's published range
 - 3. When establishing an in-house range for unassayed controls, the QC-AL should be compared to a peer group using the same test system.
 - 4. Quality control material should mimic patient specimens and be focused at the clinical decision levels whenever possible.
 - 5. If quality control testing is performed on multiple shifts, then establishment of QC–AL will include testing from multiple shifts.
 - 6. New lots of QC will be tested against existing lots of QC material before being placed into service.
 - 7. QC material will not be used beyond its expiration date, including the open vial stability.
 - 8. Control material should also be purchased in sufficient volumes to minimize changes in lot numbers (purchase of quality control lots in yearly increments is recommended). In general, lot numbers for quality control material should not be changed at the same time as reagent lot numbers.

Note: In chemistry, where reagent lots change in 30-40 day cycles, the supervisors may need to establish QC ranges over two or more lots.

9. Mishandling of control material, i.e. improper long term storage (freezer outside the manufacturer's recommended storage temperature) or day-today mishandling through prolonged exposure to room temperature, will affect the stability and performance of the control material. These storage and handling practices should be controlled to ensure successful QC performance.

5.2 HANDLING QUALITY CONTROL MATERIAL

- A. Quantitative Controls
 - 1. Establishing QC-AL for a new lot number of controls with expiration dates greater than 2 months.
 - a) Analyze the new lot of QC material in conjunction with the current lot number.
 - b) Collect at least 30 data points (for each level) from at least 20 separate runs over 5 to 30 days. (*Each instrument can be considered a separate run*). Calculate the mean for the new control lot. Establish and accept the new mean if it falls within the assay range (for assayed controls) or peer group range (unassayed controls).
 - 2. Establishing ranges for a new lot number of assayed controls with short expiration dates, e.g., hematology controls.
 - a) Analyze each level of control simultaneously with the current lot of controls once per shift for 3 days.
 - b) After the 3 days, compare the in-house derived mean and SD to the manufacturer's assigned mean and SD.
 - c) If the mean is within the manufacturer's range, accept the manufacturers mean and SD as the established mean and SD.
 - d) If the mean is outside the manufactures range, then **do not proceed** with patient testing, test a level of a current QC lot to ensure analyzer accuracy and notify the supervisor on duty. Proceed with instrument troubleshooting, when applicable.
 - 3. Verifying new shipment of a current lot.
 - a) When a new shipment of a current lot number is received, the control name, lot number and date of receipt will be logged in the reagent inventory log. (*Complete all sections on the log*)
 - b) Each level of the control will be analyzed simultaneously with the current in-house control, as soon as practical.
 - c) All results must be within the laboratory's AL for all the analytes for it to be acceptable.
 - 4. Establishing control ranges, when no current control lot is available.
 - a) Analyze each level of new control 10 times and calculate the mean.
 - b) If the new control lot is an assayed control, compare the calculated mean to the manufacturer's published range. If this value is within manufacturer's range, use the calculated mean along with the historic SD to calculate the new acceptability limits. If the calculated range is outside the manufacturer's range, **do not proceed with patient testing and notify the supervisor on duty**.
 - c) If the new control lot is an unassayed control, compare the in-system calculated mean to the peer group control performance on the same test system. If the mean is within the peer group AL, use the calculated mean and our historic SD to establish the new AL. If the calculated mean is outside of the peer group AL, do not proceed with patient testing and notify the supervisor on duty.

- 5. If commercial control material is unavailable through any means, notify the supervisor on duty immediately. The following methods may be employed to verify the reliability of patient results.
 - Split samples and send to a reference laboratory (accuracy).
 - Exchange specimens with another accredited laboratory (accuracy).
 - For labile specimens, have multiple technologists perform analysis (precision).
 - With the guidance of the supervisor, selected patient samples can be re-tested using a comparison of obtained results to total allowable error as a method of validating new patient testing in the absence of available control material.
 - Any of these methods will not be used without written documentation and approval of the supervisor.
- B. Qualitative Controls

General Considerations

- 1. For tests in which numerical values are not generated, at minimum, the analytic run and external QC frequency is defined per procedure. In addition, tests with internal QC will require documentation of said internal QC before reporting patient results per procedure.
- 2. For specific details on microbiology media, refer to the procedure Media Quality Control.
- C. Other Methods of Assessing Test Quality
 - 1. Instrument Comparison
 - a) In situations where multiple analyzers are used for the same analytes (at the same site) patient specimens are run on both analyzers and the results are compared based on TEa of the given analyte. Specimens are chosen to represent the clinically appropriate range. Alternatively, specimens may be purchased from a qualified vendor that utilizes traceable testing material.
 - b) Instrument comparison testing must be performed at least twice a year, but can be performed at more frequent intervals as determined by the section supervisor, Medical Director, or designee. Refer to Comparison of Intra-laboratory Test Results procedure for details.
 - 2. Primary versus Secondary Modes
 - a) On instruments that have multiple-sampling modes, specimens will be analyzed through each mode and the results are compared.
 - Tea/4 is accepted and requires no additional approval.
 - Tea/3 is acceptable with Medical Director Approval.
 - b) This is performed during instrument correlations. See the appropriate SOP for complete details.

5.3 **REVIEWING QC RESULTS**

Refer to QC Responsibilities and Review SOP

5.4 ACTION FOR UNACCEPTABLE QC RESULTS

Note: All unacceptable and "Out of Control QC" results must be investigated and acceptable QC results must be obtained.

- All corrective action must be documented in the QC module (LIS, DI or Unity Real Time) and in the Look-Back Binder, before testing patient samples or reporting patient results.
- "Out of Control" QC result will initiate the patient Look-Back process, after acceptable QC results have been obtained. Exception: certain scenarios do not require Look-Back, refer to action codes in attachment A.
- For qualitative methods Look-Back is required when QC exceeds the acceptable limits.
- An evaluation of results already reported from the affected run must be documented by recording either 'no patient impact' or 'reports corrected'.
- A. Quantitative or Semi-quantitative Determinations (with numerical values)1. Discontinue patient testing on the analyzer.
 - **Note**: Valid patient results are a priority. Immediately perform patient look-back on another instrument, if available, before beginning QC failure investigation. Refer to step 7.
 - 2. Check to make sure reagents are not expired and there are no obvious signs of reagent contamination.
 - 3. Use the freshest control material, re-pour and reanalyze the control. If the QC result is within the AL, document your actions in the appropriate QC Module along with the acceptable control value and initiate the patient look-back procedure prior to resuming patient testing, as applicable. If the QC issue persists, go to step 4.
 - 4. Repeat testing using fresh reagent. If the QC result exceeds the AL, then go to step 5. If the QC result is in range, go to step 6.
 - 5. Evaluate the method for systematic errors by reviewing the following as applicable:
 - a) Instrument maintenance logs, changes in reagent or control lots, instrument function checks and operator competency.
 - b) Check parameters of instrument function as is appropriate, i.e., up to date maintenance, check/correct temperature, timer correct, etc. If any deviation from the acceptable practice is noted, correct the situation and document all corrective action in the appropriate manner: LIS manual QC log, or instrument maintenance log. Be sure to include your initials, date/time, problem identification, actions taken, persons notified, and resolution, if any. Repeat the QC. If the QC result is still outside of the AL, call Hotline and notify the section supervisor/designee.
 - 6. If the repeat QC is acceptable, proceed with patient testing. Proceed to step 7 (unless look-back was already completed on another instrument).
 - 7. Patient Look-Back
 - a) Repeat the last three patient samples that were reported before the QC failure. Record the instrument, test and results (original and repeat) on

the Patient Look-Back Log and indicate if the results are within the TEa.

- b) All three repeated results must be within the TEa for the assay. If acceptable, proceed to step H for documentation guidance.
- c) If one or more results exceed the TEa, select and repeat testing on the lesser number of patients from either the 10 next most recent patient samples or all patient samples that have been tested since the last successful QC result.
- d) If nine out of the above 10 samples fall within the TEa of the original assay values, further look back will not be necessary.
 - If 90% of the look back is acceptable, within the TEa range, collect data and attach to the daily bench log for the supervisor or designee to review and file in the Patient Look Back Binder.
- e) Patient results outside of the TEa must be corrected. (See the Corrected Results procedure)
- f) If two (2) or more patient values fall outside of the TEa, perform an extended patient look-back.
 - If less than 90% is acceptable continue patient look back with 20 additional patients or the entire run, whichever is fewest.
 - If 95% match within the TEa, collect the data and present to the supervisor.
 - If less than 95% of the values fall within the acceptable range, perform a full look-back of all patient samples tested from the last successful QC. Correct any report where the repeat value differs from the original reported value by greater than the TEa.
- g) Document all actions taken on the corrective action log.
- h) Using the "-" function in the LIS, append the comment LOOKB "Repeat/Look Back performed and satisfactory" to the previous corrective action documentation on the within-limit QC result. If no patient samples were tested prior to this failed QC, use the "-" and append NPTR "No patients run between successful and failed QC run." For assays processed through DI/Unity Real Time select the appropriate code / description from the remedial actions listed (Attachment A).
- i) Staple and place all documentation of the QC printouts to the Patient Look-Back Log and attach to the daily bench log for the supervisor or designee to review and file in the Patient Look Back Binder.
- B. Qualitative or Semi-Quantitative Determinations (no numerical values)
 - 1. Repeat control. If control value is acceptable, accept run and proceed with patient testing. If control value is unacceptable proceed to step 2.
 - 2. Ensure that the reagent/test kit and controls are within date, and that the test kit components have not been inappropriately combined. Verify the selection of the appropriate lot and control material. Check parameters of testing system as appropriate, i.e., up to date maintenance, correct temperature, timer correct, etc. If everything is in order, obtain new

control material and repeat control. If control is unacceptable, proceed to step 3.

- 3. Check reagent/test kit and QC for obvious signs of contamination. Take the reagent/test kit out of service and document findings. Open a new reagent/test kit, run QC, if acceptable, repeat testing using new reagent/kits and assess the need to perform a patient look-back. If control value is unacceptable, proceed to step 4.
- 4. Have another trained staff member review your work and repeat controls. If controls are acceptable assess the need to perform a patient look-back. If control values are still unacceptable notify supervisor/manager that testing is suspended and the problem is unresolved. Follow up with technical support to determine if there are reports of reagent/test kit problem or product recall, proceed to step 5. (Upon resolution of the "out of control" event assess the need to perform a patient look-back).
- 5. Document all corrective action in the appropriate log: LIS, DI/Unity Real Time, manual QC log, or instrument/equipment maintenance log. Be sure to include your initials, date/time, problem identification, actions taken, persons notified, and resolution.

C. Unresolved QC Issues

- 1. If the QC problem does not resolve after all actions are performed, the section supervisor/designee must be notified.
- 2. Run patient samples using an alternate method, if available. If an alternate method is unavailable, patient testing must be suspended until QC problem is resolved.

6. **RELATED DOCUMENTS**

QC Responsibilities and Review, QA procedure Quality Management (QM) Plan, QA procedure Comparison of Intra-laboratory Test Results, QA procedure Corrected Results, LIS procedure Data Innovations Instrument Manager, Laboratory policy Bio-Rad Unity Real Time 2.0, Chemistry procedure Reagent Parallel Testing, QA procedure Media Quality Control, Microbiology procedure Vista QC Schedule, SGAH (AG.F208) Vista QC Schedule, WAH (AG.F209) XPAND QC Schedule (AG.F210) Patient Look-Back Log (AG.F187)

7. **REFERENCES**

A. Clinical and Laboratory Standards Institute. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Third Edition. CLSI document C24-A3 [ISBN 1-56238-613-1]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.

- B. Tietz, Textbook of Clinical Chemistry, 6th Edition, Carl A Burtis, Edward R Ashwood & David E Bruns, 2008
- C. College of American Pathologists, CAP Accreditation Program, section specific checklists, www.cap.org
- D. Guidelines for Troubleshooting Quality Control Issues, QDQC707 v1.0, Quest Diagnostics intranet
- E. QC Frequency for Batch, Random Access and STAT Testing, QDQC705 v1.2, Quest Diagnostics intranet

8. **REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
		Supersedes SGAH-WAH L002.003		
000	4/23/2013	Section 2.1, 3.1: update programs for corrective action documentation Section 5.2.A: add each instrument as separate run	R SanLuis	C Bowman
		Section 5.2.B: add internal QC		
		Section 5.2.C: revise TEa acceptability approval Section 5.4: update program, add Look-Back log Section 6: add DI, Unity Real Time and Reagent		
		Parallel Testing SOPs Section 9: add attachments C-F, revised A		
001	8/11/2015	Section 2: remove Nichols Institute Section 6: move schedules & forms from section 9 Section 9: retitle description column to include DI and Bio-Rad	L Barrett R SanLuis	C Bowman
		Footer: version # leading zero's dropped due to new EDCS in use as of $10/7/13$.		
2	1/19/2017	Header: add other sites Section 2.2: add IQCP Section 3.1.C: update reference to QC charts Section 5.4.A: add immediate look-back testing on another instrument	L Barrett R SanLuis	C Bowman
3	9/28/2017	Section 3.1: remove reference to QC chart, specify action documentation, add QC responsibility SOP Section 3.2: delete (duplicates QC responsibility SOP) Section 5.2.C: remove comparison approval and reference SOP Section 6: delete QC frequency chart	L Barrett R SanLuis	C Bowman- Gholston
4	1/31/19	Header: updated facility Section 4: added Action & Comment Codes and exception for look-back Section 5.4: added exception for look-back Attach A: added new codes	L Barrett	C Bowman- Gholston

9. ADDENDA AND APPENDICES

Attachment A: QC Action Codes and Comment Codes

ATTACHMENT A

QC Action Codes and Comment Codes

	Sunquest / DI / Bio-Rad Unity Description
Action	AC. Control: repeated level 1-Accept
Codes	AC. Control: repeated level 2-Accepted
	AC. Control: repeated level 3-Accepted
	AC. Instrument problem identified detail on QC summary report, issue resolved
	AC. Patient Lookback not indicated.(No patients tested since last acceptable QC)
	AC. Patient Lookback performed and acceptable
	AC. Patient testing suspended
	AC. Patient testing suspended/hotline called, supervisor/TIC informed
	AC. Reagent change, lookback not indicated.(No patients tested since last acceptable QC)
	AC. Reagent change, lookback performed and acceptable
	AC. Repeat control with freshly poured QC accepted
	AC. Repeat control with new QC vial accepted
	AC. Test recalibrated, lookback performed and acceptable
	AC. Test recalibrated, lookback not indicated, no patients tested since last acceptable QC
	AC. Test/assay repeated QC in range
	AC. Wrong Control Level-QC Repeated and Accepted.(No lookback indicated)
	AC. New lot calibration done, reagent lot suspended for QC range adjustment
	AC. Control repeat with fresh QC failed. Troubleshooting - Patient testing suspended.
	AC. Control repeat with fresh reagent failed. Troubleshooting - Patient testing suspended.
	AC. Establishing range for new lot of QC not in use, no lookback indicated
	AC. Troubleshooting by FSE
Comment	
Codes	CC. Calibrator changed. QC issue resolved
	CC. Instrument calibrated
	CC. Instrument serviced see summary report
	CC. Instrument: bleached
	CC. Instrument: electrode/cartridge/IMT change
	CC. New mean established
	CC. QC vial QNS, no patient lookback indicated
QC	QC: reviewed for day
Codes	QC: reviewed for month
	QC: reviewed for week

Note: Utilize only the above defined Action Codes to document corrective / remedial action taken for QC failures.

Non-Technical SOP

Title	Bio-Rad Unity Real Time 2.0	
Prepared by	Ashkan Chini	Date: 3/12/2013
Owner	Robert SanLuis	Date: 3/12/2013

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						

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1. PURPOSE

This procedure describes the process for using Unity Real Time software.

2. SCOPE

Unity Real Time 2.0 is a software program used to review, evaluate and study Quality Control results. This software is also used to submit the monthly QC results to Bio-Rad Company for cumulative evaluation against the peer group.

This SOP is written for both technical and administrative staff.

3. **RESPONSIBILITY**

Technical staff is responsible for performing and complying with this procedure. The Technical Supervisor is responsible for content and review of this procedure.

4. **DEFINITIONS**

Mean: The mean is defined as the arithmetic average of a set of data points.

Standard Deviation (SD): The standard deviation quantifies the degree of dispersion of data points about the mean and is used to set limits upon which control result acceptability is determined.

Standard Deviation Index (SDI): is used to compare a laboratory's results to its consensus group. The target SDI is 0.0, which indicates there is not any difference between the laboratory mean and the consensus group mean.

Bias: Bias measures how far your observed value is from a target value.

Coefficient of Variation (CV): a measure of variability

Z score: The number of standard deviations a control is from the mean $Z = \underline{Observed Result} - \underline{Expected Result}$

SD

5. **PROCEDURE**

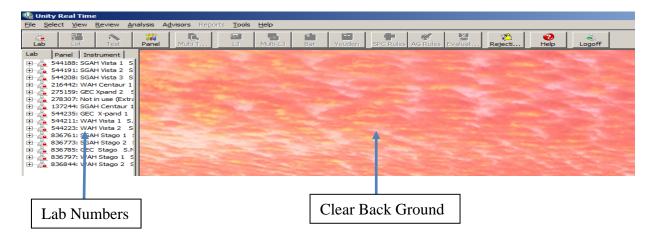
5.1 User Log In:

Log in using 6 digit Quest Diagnostics employee ID number.

5.2 Describing the system:

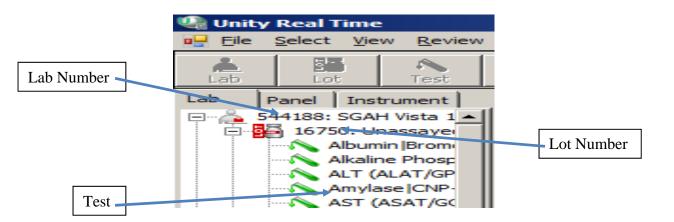
A. Main Page:

Before doing any activities on Unity Real Time the main page always needs to be clear, that means nothing but the lab numbers (on the left) should be visible on the screen.



B. Navigate the test page:

Start by selecting the Lab number, Lot number and the test.



Form revised 3/31/00

When a test page is opened the following information will be displayed:

- 1. Lab, Lot and Test information
- 2. Date and Time QC was run
- 3. Value of QC
- 4. Y stands for Accept; N stands for Reject
- 5. QC Rule (QC warning or rejection rule)
- 6. Z-score
- 7. Level of QC
- 8. Action Log **WITHOUT** a statement
- 9. Action Log WITH a statement (Green Arrow beside the "A")
- 10. Comment
- 11. Actual Mean, SD & CV
- 12. Expected Mean, SD & CV
- 13. Cumulative Mean, SD & CV

Test: Bili	4188 SGAH Vis Irubin, Total/T 4/30/2016	54 Grof, 3s 2-2 Date	s Di	5	6 🗂 7	c: Serum nt, mg/dL, No I = Test	Tempera	9	8	1	0
		L.		1 1		Level 2					
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1	24 4/2/2015 1:52 AM	• 0.94	Y -		.33			IM	I	A	C
	25 4/2/2015 9:53 AM	• 0.92	Y -		.11 5.00	Y -	0.50	IM	I.	A	C
	26 4/2/2015 12:47 PM	• 0.93	Y -	0	.22 5.01	¥ 🖵	0.56	IM	I	A	C
_	27 4/2/2015 5:54 PM	-			5.05	¥ 🖵	0.81	IM	I	A	C
	28 4/3/2015 1:51 AM	• 0.92	Y -	-	.11			IM	E.	A	C
	29 4/3/2015 9:54 AM	▼ 0.95	Y -	-	.44 5.07	¥ -	0.94	IM		A	C
_	30 4/3/2015 12:41 PM	• 0.95	Y -) 0	.44 5.08	Y 🖵	1.00	IM		A	C
	31 4/3/2015 5:54 PM	-			4.98	Υ 🖵	0.38	IM	I	A	C
	32 4/4/2015 1:50 AM	• 0.94	¥ -		.33			IM	I	A	C
	33 4/4/2015 10:00 AM	• 0.94	Y -	-	.33 5.01	Y 🖵	0.56	IM	I	A	C
	4/4/2015 12:42 PM	▼ 0.92	Y -	0	.11 5.00	Y 🖵	0.50	IM	I	A	C
	35 4/4/2015 5:49 PM	-			4.95	Y 🖵	0.19	IM	I	A	C
_	36 4/5/2015 1:56 AM	▼ 0.94	Y -		.33			IM	I	A.	C
	37 4/5/2015 9:57 AM	1.17	N 👻		.89 5.17	Y 🖵	1.56	IM	I	A +	C
	38 4/5/2015 10:12 AM	▼ 0.94	Y -		.33			IM	I	A	C
43	39 4/5/2015 12:36 PM	0.92	Y -	0	.11 5.07	Y 🖵	0.94	IM	I	A	C
44	4/5/2015 5:51 PM	-			5.16	Y 🖵	1.50	IM	I.	A	C
44	1 4/6/2015 1:48 AM	- 0.90	¥ 🖵] -0	0.11			IM	I	75.	C
44	4/6/2015 10:08 AM	0.90	Y -] -(0.11 5.01	Y 🖵	0.56	IM	II.	<i>.</i>	C
44	4/6/2015 12:33 PM	-			5.06	Υ -	0.87	IM	I	A.	C
44	44 4/6/2015 12:57 PM	 0.95 	Y -	0	.44			IM	I	A.	C
44	4/6/2015 5:51 PM	-			5.03	Y 🖵	0.69	IM	I	A	C
44	4/7/2015 1:53 AM	· 0.93	Y -	0	.22			IM	I	75.	C
44	4/7/2015 9:56 AM	▼ 0.93	¥ -	0	.22 5.06	Y -	0.87	IM	I	75.	C
44	48 4/7/2015 12:42 PM	- 0.90	Y -	-(0.11 5.10	Y -	1.12	IM	I	A.	C
44	4/7/2015 5:50 PM	-			5.04	Y -	0.75	IM	I	A	C
	50 4/8/2015 1:51 AM	- 0.91	Y -	0	.00			IM	I	75.	č
45	1 4/8/2015 9:58 AM	- 0.91	Y -	0	.00 5.12	Y	1.25	IM	I	A	č
	52 4/8/2015 12:30 PM	0.89	Y		0.22 5.03	Y	0.69	TM	Ĩ	A	č
	53 4/8/2015 4:07 PM	-							T	A	č
Point Da Statistics	11	Month		umulative	Month	Cumula	ting		13		
		Fionth		unuative	Fionth	Cumula	tive				
	015 4:07:21 PM	-								1	
Mean		0.93	0.9		5.05	5.02					
SD		0.03	0.0		0.05	0.08		-		1	
Points		3.52	3.1		23	1.69			10		
	Fixed Mean/SD/CV	1	91/0.09		i.	2/0.16/3.25			12		

C. Action and Comment:

Failed QC results should arrive with an action comment from Instrument Manager / Data Innovation. For manual tests or if a failed QC result does not have an Action statement, enter the appropriate Action and/or Comment as follows:

1. Adding an Action

Rejected Rule				Action	Log					
435 4/4/2015 5:49 PM				4.95	Y	0.10	IM	T.	A	č
436 4/5/2015 1:56 AM	▼ 0.94	× •	0.33				IM	Ť	A	č
437 4/5/2015 9:57 AM	· 1.17	N - 1-25	2.89	5.17	Y -	1.56	IM	I	A+	C
438 4/5/2015 10:12 AM	▼ 0.94	Y 🖵	0.33				IM	I	<i>.</i>	C
439 4/5/2015 12:36 PM	 0.92 	¥ -	0.11	5.07	Y 🖵	0.94	IM	I	AL.	C
440 4/5/2015 5-51 PM				5.16	× 🗖	1 50	TM		375	~

a. Click on A (Action Log), shown above, for the specific failed QC and the following page opens up.

Code	List of Actions
80	
80	
81	
82	
51	
50	
52 💌	
	Apply
	50

- b. Select the appropriate Action
- c. Click on **Apply**
- d. The screen will return to the test page. Click on Save to store the data.

		Save		Set	Date	ate Group					I = Test Information					A	= Actio	n
						Level 1						Lev	el 2		1			
		Da	t & Tim	ie	Value	Y/	/N	Rules	z	Value	Y	/N	Rules	z	OP		i i	
1	423	4/1/2015	6:0. PM	-						5.06	Y	-		0.87	IM	I	A	<
	424	4/2/2015	1:52 AM	-	0.94	Y	-		0.33						IM	I	A.	<
	425	4/2/2015	9:53 AM	-	0.92	Y	-		0.11	5.00	Y	-		0.50	IM	I	A.	<
	426	4/2/2015	12:47 PM		0.93	Y	-		0.22	5.01	Y	-		0.56	IM	I	A	<
ĺ	427	4/2/2015	5:54 PM	-						5.05	Y	-		0.81	IM	I	A	
	428	4/3/2015	1:51 AM	-	0.92	Y	-		0.11						IM	I	A.	<
	429	4/3/2015	9:54 AM	-	9.95	Y	-		0.44	5.07	Y	-		0.94	IM	I	A	<
	430	4/3/2015	12:41 PM	-	0.5	Y	-		0.44	5.08	Y	-		1.00	IM	I	A	
	431	4/3/2015	5:54 PM	-						4.98	Y	-		0.38	IM	I	A.	4
i	432	4/4/2015	1:50 AM	-	0.94	Y	-		0.33						IM	I	<i>1</i> 4.	
	433	4/4/2015	10:00 AM	1 👻	0.94	X	-		0.33	5.01	Y	-		0.56	IM	I	A.	
	434	4/4/2015	12:42 PM	-	0.92	Y	-		0.11	5.00	Y	-		0.50	IM	I	A.	<
i	435	4/4/2015	5:49 PM	-						4.95	Y	-		0.19	IM	I	<i>1</i> 4.	<
	436	4/5/2015	1:56 AM	-	0.94	Y	-		0.33						IM	I	<i>7</i> 5.	<
	437	4/5/2015	9:57 AM	-	1.17	N	-	1-25	2.89	5.17	Y	-		1.56	IM	I	A +	<
i	438	4/5/2015	10-12 AM	1 -	0.94	×	-		0.00						TM	T.	375	

Note: The list of Action Codes is specified in the procedure *Quality Control Program*. Any changes to these codes must go through the document control process. Only technical supervisors and technical specialists have access to edit action codes.

Adding a Comment a. Click on C (Comment).

425 4/2/2015 9:53 AM	· 0.92	Y - 0.11	5.00	Y -	0.50 IM	I	AC
426 4/2/2015 12:47 PM	· 0.93	Y - 0.22	5.01	Y -	0.56 IM	I	A C
427 4/2/2015 5:54 PM	-		05	Υ -	0.81 IM	II.	A C
428 4/3/2015 1:51 AM	÷ 0.92	Comment			TM		
429 4/3/2015 9:54 AM	▼ 0.95	Comment	07	Y 🖵	0.94 IM	I	A C
430 4/3/2015 12:41 PM	÷ 0.95		8	Υ 🖵	1.00 IM	II.	A C
431 4/3/2015 5:54 PM	-		4.98	Y 🖵	0.38 IM	I	A C

b. Type the appropriate comment. Then click on **OK**.

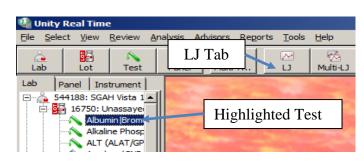
Internet X Lab: 544188 SGAH Vista 1 S.N. 330564								
Existing comment:	Cr), siemens Dimension vista, Deuicate	o Reagent, g/oL, no remperature						
	Comment							
New comment:		-						
		<u></u>						
OK	OK Canc	el						

c. The screen will return to the test page. Click on Save to store the data.

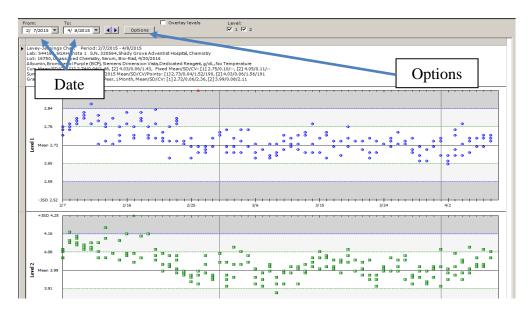
Save		Set [Date			Group		I = Test Information						A = Action			
				Le	vel 1			L	eve	12							
1	Date & Tim	e	Value	Y/1	I Rules	; z	Value	Y/	N I	Rules	z	OP	1	i — — — — — — — — — — — — — — — — — — —			
423 4/1/201	L5 6:01 PM	-					5.06	Y [-		0.87	IM	I	A	<		
424 4 2/201	L5 1:52 AM	-	0.94	Y	-	0.33						IM	II.	A			
425 4 2/201	L5 9:53 AM	-	0.92	Y	-	0.11	5.00	Y [-		0.50	IM	II.	<i>.</i>			
426 4 2/201	L5 12:47 PM	-	0.93	Y	-	0.22	5.01	Y [-		0.56	IM	I	A.			
427 4 2/201	5 5:54 PM	-					5.05	Y [-		0.81	IM	II.	A			
	5 1:51 AM	-	0.92	Y	-	0.11						IM	II.	<i>.</i>			
Save	5 9:54 AM	-	0.95	Y	-	0.44	5.07	Y [-		0.94	IM	I	A.	4		
Juic	5 12:41 PM	-	0.95	Y	-	0.44	5.08	Y [-		1.00	IM	I	A.	4		
431 4/3/201	5 5:54 PM	-					4.98	Y [-		0.38	IM	I	A	4		
432 4/4/201	L5 1:50 AM	-	0.94	Y	-	0.33						IM	I	A.			
433 4/4/201	L5 10:00 AM	-	0.94	Y	-	0.33	5.01	Y [-		0.56	IM	I		<		
434 4/4/201	L5 12:42 PM	-	0.92	Y	-	0.11	5.00	Y [-		0.50	IM	I	A			
435 4/4/201	L5 5:49 PM	-					4.95	Y [-		0.19	IM	I	A			
436 4/5/201	15 1:56 AM	-	0.94	Y	-	0.33						IM	I	A.			
437 4/5/201	L5 9:57 AM	-	1.17	N	1-25	2.89	5.17	Y	-		1.56	IM	I	A +	<		
438 4/5/201	15 10-12 AM	-	0.94	YE	-	0.33						TM	10	375			

D. To pull up Levey Jennings Chart:

- 1. Go to main page (refer to section 5.2.A)
- 2. Click on the lab number and the desired QC lot number.
- 3. Highlight the desired test by clicking on it just once
- 4. Click on LJ Tab



- 5. Adjust the date as desired
- To include or exclude peer group on the Levey Jennings Chart:
 a. Click on **Options**



- b. The Options page provides users the tool to view the levey jennings chart in different ways.
 - Peer will put the data against all the labs which use the same QC material on the same type of instrument. To include peer group select "Peer".
 - Method will put the data against all labs which use the same QC material on the same method of measurement.
 - To exclude both Peer group and Method, select "Your Laboratory"
- c. After selecting the options, click on **OK**.

Options	×
General Levey-Jennings Header Lines Graph Against	Consensus group Peer
Your Laboratory	C All labs Miethod
C Evaluation Mean/SD Comulative Deterange Prom: 2/17/2006 T C 2/5core	
C Apply to all users C Apply to all users C Apply to current user OK Cancel	Apply

E. Bench Review:

Technologists are required to do a review at the end of each shift. Bench review will provide a summary of all the QC which was run during a shift and day. It will indicate whether a failed QC was repeated or not and if every QC failure has the right Action and/or Comment.

- 1. Go to main page (refer to section 5.2.A)
- 2. Select **Review**
- 3. Select Bench Review

	l		Real Tim	e					
Review		<u>File</u> Sele	ct View	-		A <u>d</u> visors	 <u>T</u> ools	Help	Bench
		🔔 Lab	Lot		n Review <		in an	Multi-LJ	Review
			Panel Ins 14188: SGA 14191: SGA 14208: SGA	AH Vista 2 AH Vista 3	s s s		12.12		

- 4. On the Data Review select Lab
- 5. Turn the **Refresh** page off by unchecking it.
- 6. For Lab Number, either select All or a specific Lab.
- 7. For Lot Number, either select All or a specific Lot.
- 8. For Instrument, either select All or a specific instrument.
- 9. For Data, first select Include rule violations or data with Action or Comments.
- 10. When the data appears on this page, there will be three different colors: **White**, **Pink** and **Orange**.
 - a. Data in White: Shows the QC which is within acceptable ranges, however, it has been rejected since the other level or levels failed. Put a check mark next to **Reject** and it will automatically change to **Accept**.
 - b. Data in Pink: Shows the **quantitative** QC failure Ensure failed QC has an appropriate action and/or comment indicated.
 - c. Data in Orange: Shows the **qualitative** QC failure. Ensure failed QC has an appropriate action and/or comment indicated.
- 11. When reviewing the failed QC, check mark the left side of the test which is desired to review in detail, then click on **Go to Data Entry** tab. This will pull up the test page where tech can see both repeated QC and the action/comment.
- 12. When reviewing the Action and/or Comment, just position the mouse on the **Action** column of the failed QC without clicking, then the action or comment added appears.
- 13. After making sure that all failed QC have appropriate comments and/ or actions, check mark **Reviewed**.
- 14. Click on Save.
- 15. To review the rest of the data, select **All Data**. This will pull all QC which was run since the last review was performed. Check mark **Reviewed**, then click on **Save**.

	leview		C <u>A</u> ll data							.a <u>b</u> numbe	er: (All	1 4		~			•			
<u>ě</u>		Lab								Lot numb				6	_		-			
		Panel	Include role	violations or da	ata with Actio	in or Com	ments			-										
			C Include only	y rule violations						Instrumer	nt: (All				-		•	_		
	Ins	truinent	C Include on	AC violations										7					12	
_														/					12	
Rev	viewed		Refresh ev	ery 10 🕂 si	ecunds								L							i i
1										la allas		1			.	let i l	- 1	1 -		
- F	Reviewed			Control ame				-				Evaluation Me		0	ules				Reviewed	
		544235 544235	068700	ACT 10, Abn Blood Gas Lev			Other		3/22/2015 3/31/2015		2.00 9.40	79.00 58.40	10.00 3.75	8		 Accept Accept 		lot to ot e	AC	4/
	· ·	544235	121054	Blood Gas Lev Blood Gas Lev			Other		3/31/2015		2.60	22.70	3.15			Accept		lot o lot e		-1/ 4/
- 1	1	544235	101054	Blood Gas Lev			Other		3/31/2015			7.03	0.03	-0.0		Accept		let to lot a		4/
		544235	21054	Blood Gas Lev Blood Gas Lev			Other		3/31/2015			7.05	0.03	0.24		Accept Accept		ot to lot		4/
	Ţ	544235	1 1054	Blood G is Lev		рп 1.92	Other		3/31/2015		,,00	87.00	7.50	-0.4		Accept Accept		lot to lot a		4/
	-	544235	12,054	Blood Gas Lev			Other		3/31/2015		1.00	148.00	11.25	0.27		Accept		lot to lot o		4
_		544235	000 00	ACT 10 AL	Abbotti-Si	MOV	Other	Dedicate	A/EA 01E 1		2.00	76.30	2.00	2.85				ENTERIN		4
		235		ACT 1	in C			Dedica			.00	76.30	2.00	-0.1		Accept			AC	4
	13	235	4	BNPI 5	I-ST	9		Dedica	15		7.00	108.00	23,50	-0.4		Accept		SAME LOT		4
	15	235	-	BNPI	i-ST			Dedica	15		84.00	2697.00	480.00	-0.6		Accept		SAMELOT		4
-	~	544191	16750	Unassaved Ch			LIV with		4/8/2015 1		18.30	101.00	3.50	2.09			IM AC. Te		AC	4
		544191	16750	Unassayed Ch							0.10	477.00	10.00	2.03			IM AC. Te		AC	4
		544188	40870	Immunoassay								8.20	0.43				IM AC. Te		AC	4
		544208	16750	Unassaved Ch							2.5 3.40	32.00	1.75			Reject			AC	4
	1	544208	16750	Unassayed Ch								101.00	3.50	-1.5		Reject			AC	4
		544235	16750	Unassayed Ch							.90	86.00	1.25	-3.2			IM AC. Re		AC	4
	1	544235	16750	Unassaved Ch							4.23	107.00	1.50	-1.8			IM AC. Re		AC	4
		544235	16750	Unassaved Ch								3.97	0.06		1-351		IM AC. Re		AC	4
	1	544235	16750	Unassayed Ch								6.45	0.10	0.70		Reject			AC	4
	v	544235	16750	Unassaved Ch					4/8/2015 9		16.41	123.00	1.45		1-351		IM AC. Re		AC	4
		544235	16750	Unassaved Ch		11			4/8/2015 9		9.71	153.00	1.60				IM AC. Re		AC	4
	1	544235	40870	Immunoassav		11			4/8/2015 9			0.65	0.07	-0.5			IM AC. Re		AC	4
		544235	40870	Immunoassay			610		4/8/2015 9			5.25	0.42	-1.6		Reject			AC	4
	v	544235	40870	Immunoassay			EIA		4/8/2015 9		1.20	29.50	2.10	-2.5	1-25		IM AC. Re		AC	4
	1	544235	51960	Ethanol/Amm					4/8/2015 9		.24	39.70	3.10	-1.1			IM AC. Re		AC	4
	~	544235	51960	Ethan Amm					4/8/2015 9		1.14	97.00	6.50	-1.3	Ī	Rejer	M AC D	4	AC	4
	1	544235	51960	cthanol/Amm			Enzyma		4/8/2015 9		1.40	260.00	13.00		1-25				AC	4
	~	544188	4000	Immunoassay	Siemens Di	T4, Fre	Chemilu	Devicate	4/8/2015 9	1 0.9	99	1.05	0.05	-1.2	[Reje	14		AC	4
	~	544188	40870	Immunoassay	Siemens Di	T4, Fre	Chemilu	Dedica	4/8/2015 9	3 5.2	20	5.60	0.20	-2.0	1-25	Reje			AC	4
		5 1188	51940	Ethanol/Amm	Siemens Di	Ammoni	Enzyma	Siemens	4/8/2015 1	1 87	7.00	57.00	6.15	4.88	1-35	Reject	IM C. Co		AC	4
		544188	51940	Ethanol/Amm	Siemens Di	Ammoni	Enzyma	Siemens	4/8/2015 1	3 31	3.00	310.00	13.00	0.23	[Reject	IM AC. CO	0	AC	4
4		544235	40870	Immunoassay			EIA		4/8/2015 1		1.84	29.50	2.10	-2.2	1-25	Reject	IM AC. Re		AC	4
											68 reco	rds								
											1						-			
M	lanage Ci	olumns	Manage E	xpected Tests							-	Go to <u>D</u> ata Entry		Go to <u>C</u> h	art		Sa <u>v</u> e			

F. Supervisor Review:

Supervisor review steps are exactly the same as bench review with only one exception; instead of selecting **Bench Review** select **Supervisory Review**. It is performed by Supervisor or designee on a daily basis. This review enables the reviewer to double check the technologists' review one last time before saving it as reviewed; once the data is saved it can no longer be edited.

G. Entering QC manually:

Unity Real Time automatically downloads data from the instruments which it communicates with. For manual tests and in the event of LIS downtime or software problems, QC data must be entered in Unity Real Time manually. To enter data manually:

- 1. Go to test page (use instructions in section 5.2.B)
- 2. The last row is always blank; pay extra attention to the lot numbers and enter the data in the appropriate column.
- 3. Unity Real Time automatically calculates the Z-score and flags if there is a failure.
- 4. If there is a failure, trouble shoot and add the appropriate Action and/or Comment. Press **Save**.

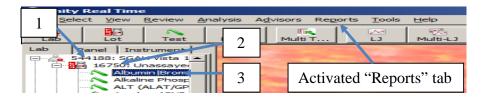
<u>_</u> 5	Panel Instrument 544188: SGAH Vista 1 • 16750: Unassayer	Test: Albu	88 SGAH Vista 1 S.N. umin, Bromcresol Purple 4/30/2016 Rules: 1-	(BCP) 2s 1-3	, Siemens s 2-2s			р4	Reagen	t, g/	′d∟, №	No Tempe					
	Albumin Brom Alkaline Phosp		Save	Set	Date		. ·	-	_		1 =	= Test In	formati	on	A	= Actio	on
	ALT (ALAT/GP					L	evel 1				Leve	el 2					
	Amylase CNP-		Date & Time		Value	Y/1	N Rules	z	Value	Y,	/N	Rules	z	OP			
	AST (ASAT/GC	434	4/3/2015 9:48 AM	-	2.77	Y	•	0.20	4.01	Y	-		-0.36	IM	I	A	(
	Bilirubin, Direc	435	4/3/2015 12:28 PM	-	2.70	Y	-	-0.50	3.97	Y	-		-0.73	IM	I	A	0
		436	4/3/2015 5:43 PM	-	1				4.01	Y	-		-0.36	IM	I	A	0
	Calcium lo-cre:	437	4/4/2015 1:48 AM	-	2.72	Y	-	-0.30						IM	I	A	0
	Chloride ISE ir	438	4/4/2015 9:52 AM	-	2.68	Y	-	-0.70	4.03	Y	-		-0.18	IM	I	A	0
	Cholesterol, H	439	4/4/2015 12:28 PM	-	2.68	Y	-	-0.70	3.95	Y	-		-0.91	IM	I	A	0
	Cholesterol, I	440	4/4/2015 5:46 PM	-	ĺ				3.98	Y	-		-0.64	IM	I	A	0
	CO2 (Carbon	441	4/4/2015 6:36 PM	-	2.79	Y	-	0.40	4.04	Y	-		-0.09	IM	I	A	(
	Creatinine Alk	442	4/5/2015 1:47 AM	-	2.74	Y	•	-0.10						IM	I	A	(
	GGT (Gamma	443	4/5/2015 9:49 AM	-	2.73		-	-0.20	4.10	Y	-		0.45	IM	I	A	
	Glucose Hexo		4/5/2015 12:31 PM	-		Y		-0.60	3.98	Y	-		-0.64	IM	Ĩ	A	1
	Iron Ferene IS		4/5/2015 5:42 PM	-	1				4.00		Ē		-0.45	IM	ĩ	A	1
	Lactic Acid La	446			2.71	Y	-	-0.40						IM	î	A	1
	LD (Lactate D		4/6/2015 9:49 AM	-	2.74	Y	_	-0.10	4.01	Y	-		-0.36	IM	Î	A	
	Lipase Colorin	448		-	1		•	0.10	4.02		÷		-0.27	IM	î	A	
	Lithium Colorir		4/6/2015 12:54 PM	-	2.71	Y	_	-0.40	1.02		-		0.27	IM	Î	A	
	Magnesium M		4/6/2015 5:44 PM	-	2./1	1	•	-0.40	4.05	×	-		0.00	IM	Î	A	
	Osmolality Fre		4/7/2015 1:45 AM	-	2.75	Y	_	0.00	4.05		-		0.00	IM	Î	A	
	Phosphorus P				2.75				4.00	~			0.00		Ĩ	A	
	N Potassium ISE		2 4/7/2015 9:49 AM	-		Y	-	-0.10	4.09	Y	-		0.36	IM	I	A	
	Protein, Total		4/7/2015 12:30 PM	-	2.71	ΥL	•	-0.40	4.01				-0.36		1 I	A	
	Sodium ISE ini		4/7/2015 5:45 PM	-]		_		4.02	Y	-		-0.27	IM			1
	TIBC (Total In		5 4/8/2015 1:42 AM	-	2.73		-	-0.20			_			IM	I	A	1
	Triglycerides [t		4/8/2015 9:50 AM	-			-	-0.10	4.08	Y	-		0.27	IM	I	A	1
	🔨 Urea Nitrogen		4/8/2015 12:25 PM	-	2.75	Υ	-	0.00	4.05	Y	-		0.00	IM	I	A	1
	Uric Acid Urica		4/8/2015 5:39 PM	-]				4.09	Y	-		0.36	IM	I	A	-
9	19390: Pediatric 3		4/9/2015 1:42 AM	-		Y		0.00			_			IM	I	A	-
2	29830: Cardiac Mi	460		-			-	0.00	4.11	Y	-		0.55	IM	I	A	4
9	🗧 40870: Immunoas	461		-	2.77	Y	-	0.20	4.08	Y	-		0.27	IM	I	A	
5	🗃 51940: Ethanol/Aı		2 4/9/2015 5:44 PM	-					3.99	Y	-		-0.55	IM	I	A	
2	66300: Immunolog		4/10/2015 1:44 AM	-	2.74	Υ	-	-0.10						IM	I	A	1
2	55590: Spinal Flui	▶ 464	4/10/2015 8:28 AM	-											I	A	
2	55620: Spinal Flui		Summary Data						_								
2	64380: Urine Cher	Point Data	Summary Data														
2	71830: Urine Toxi 72500: Urine Toxi	Statistics	Chart														
ľ	40850: Immunoas		[Chart]														
Ē	52480: Immunoloc	Summa	ry Statistics		Month		Cumulati	-	Month		0	umulativ	ve l				
P	544191: SGAH Vista 2						cumulati			_							
	544208: SGAH Vista 3		015 8:28:13 AM	-		-											
	216442: WAH Centau	Mean SD		2.			1.04	ton	. ว ⊢		4.04						
	275159: GEC Xpand 2			1.			.47	Step		-	1.43		_				
	278307: Not in use (E	Points		30			35	-			337		_				
	137244: SGAH Centa					_	557										
5	544235: GEC X-pand	Current	Fixed Mean/SD/CV		2.7	5/0 1	0/3.64		4.00	5/0	11/	2.72					
	544211: WAH Vista 1 💌	Current	inco rican/30/CV		2./:	10.1			4.03	-10							

H. Printing Reports:

This software provides the following reports:

- **Point Data Report** is useful for reviewing all point data for a specific date range such as a month or quarter.
- **Summary Report** shows Level, Mean, SD, CV, number of data points for each test in the selected data set and active rules.
- **Statistical Report** shows the percentage of point data that did not violate any active SPC (Statistical Process Control) rule or analytical goal. It provides a helpful overview of how well the laboratory is meeting its performance goals. The report shows Cumulative statistics for the test and statistics for each calendar month.
- **Supervisor's Report** shows data points that violate a SPC rule set to Reject, violate a SPC rule set to Warn and have an action or comment attached.
- **Operator's Report** shows the following statistics for each test entered by operator: Operator, Mean, SD, CV and Number of data points.
- Data Review Report documents the review of point data from the Bench Review and Supervisor Review. It contains the following information for each data point: Date and time the data was generated, Operator initials, Value for each level, Associated actions and comments (if any), Accept/reject status, Initials of the person performing the Bench Review or Supervisor Review, and Date and time of the Bench Review or Supervisor Review.

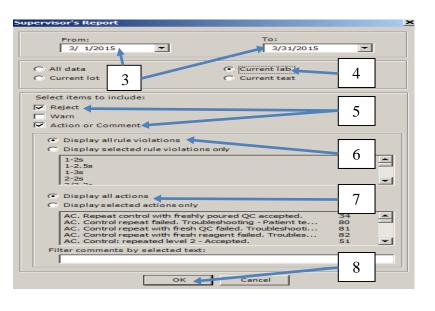
- 1. To print any report, first the "Reports" tab needs to be activated.
 - a. Go to desired lab number
 - b. Select desired or a random lot number
 - c. High light desired or a random test



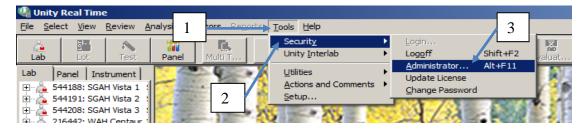
- 2. To print the Supervisory Report:
 - a. Under Reports tab, select Supervisory
 - b. Then select **Supervisor's Report**

visors	Reports	Tools	<u>H</u> elp		
Multi	Data F Gener		. Alt+F10	•	ar Vouden SPC Pules AC Pules
100	Super	visory	ь.	•	Supervisor's Report Ctrl+F10
Carlon -	Charts	;		•	Operator Report
	<u>A</u> udit ⁻	Trail			NUMBER OF STREET, STRE
-	<u>R</u> iLiBĂ	K Repor	ts	►	7.5
	Listing	s		►	1 / JA / LONG 2 F
	Config	ure			
0.1			1	K	2

- c. Select the desired date
- d. Always select Current Lab
- e. Check both Reject and Action or Comment
- f. Select **Display all rule violations**
- g. Select **Display all actions**
- h. Select OK



- I. To add or edit employee information: (Supervisors Only) To add a new employee to Unity Real Time, assign/unassign labs, or to edit a current employee's file (including changing or unblocking an employee's password):
 - 1. Select Tools tab
 - 2. Select Security
 - 3. Select Administrator



4. To add a new employee information select New

ministrator	>					
Userprofile User ID: User name:	Data					
admin 👻 admin	Edit all data					
Password: Initials:	C Edit last line					
****** sa	Enter new data only					
Minimum Password Length:	C ⊻iew data only					
2 characters	Rules and settings					
Password expires on:	Edit test settings/rules					
Never	Labs, lots, tests, and panels					
Set password expiration period to:	Manage labs/lots/tests					
Never 👻	✓ Delete labs/lots/tests					
Applied to this user only	Manage panels					
C Applied to all users	Data handling					
Administrator	Communicate with Unity Interlab					
Account status: Active Unlock	I Import data					
New Delete Assign Lab Numbers	Export data					
New Delece Assign Lab Numbers	Graphing options					
Administration/setup	Actions/Comments by Instrument					
Manage users	Data Review					
Edit action log	Bench Review					
Edit setup options	Supervisor Review					
Operator setup	RILIBÄK					
Database	Start LIME/release data					
Archive and restore	Disable LIME and cycles (POCT)					
Condense data	Close cycles manually					
Reconcile data	Tel close cycles manually					
	OK Cancel Apply					

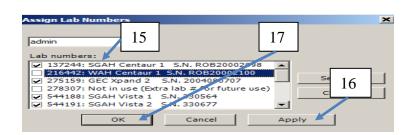
- 5. Enter employee's six digit QD Employee number for User ID
- 6. Enter employee's first and last name under User Name
- 7. Provide a temporary password
- 8. Enter employee's Initials
- 9. Select Enter new data only
- 10. Select both Graphing Options and Action/Comments by Instrument
- 11. Select Bench Review
- Select Edit Action Log
- 12. Select Apply
- 13. Select Assign Lab Numbers

Administrator	×
Userprofile User name: Password: Minimum Password Leight:	Data C Edit ali data C Edit Last line C Enter new data only C View data only
5 ord expires 7 8 6	Rules and settings Edit test settings/rules Labs, lots, tests, and panels Manage labs/lots/tests
Never	Indiage rags/rots/test Delete labs/rots/test Manage ganels
C Applied to all users Administrator Account status: Active Unlock	Data handling 10
Account status: Active Onioce	Import data Export data Graphing options Actions/Comments by Instrument
Manage users Edit action log Editsetup options	Data Review
Database Archive and restore	RILIBÄK 11
Condense data	Disable LIME and cycles (POCT) Cose cycles manually OK Cancel Apply

14. Select the employee number of the individual to be edited

ssign Lab Numb	14	×
025315 093061 093062	1. 5.N. ROB20002098	
093386 104859 104880	L S.N. ROB20002100 S.N. 2004080707 ra lab # for future use)	
104881 104892 544191: SGAH	Vista 2 S.N. 330564 ✓ S.N. 330677 ✓	
	K Cancel Apply	

- 15. Assign desired **Lab numbers**
- 16. Select Apply
- 17. Select **OK**



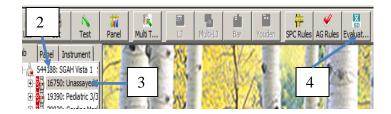
- 18. If an employee forgets his/her password and cannot log into Unity Real Time:
 - a. Repeat steps 1-3 and select the correct employee
 - b. Provide a temporary password to the employee
 - c. Select **OK** (When the employee logs back in the Unity Real Time, it will ask them to reset their password)

- 19. If an employee attempts to log into Unity Real Time five (5) consecutive times and yet fails to type in the right password, the system will automatically block that individual from logging in. To unblock the employee's password:
 - a. Repeat steps 1-3 and select the correct employee
 - b. The unblock tab is activated under this specific employee who is being worked on, Press the Unblock tab and if the employee still could not remember his/her password, reset the password if he/she wishes.

dministrator		×
Userprofile User ID: admin	User name:	18a & 19a
Password:	Initials:	Enter new data only
Minimum Password Len 2 Characters Password expires on:	igth:	18b and settings it test settings/rules
Never Set password expire Never Applied to this]	Labs, lots, tests, and panels Inage labs/lots/tests Delete labs/lots/tests nage ganels
C Applied to all us Administrator Account status: Active <u>New</u>		Data handling Communicate with Unity Interlab J Import data F Export data F Graphing options
Administration/setup		Actions/Comments by Instrument
 ✓ Manage users ✓ Edit action log ✓ Edit setup options ✓ Operator setup 		Data Review Sench Review Supervisor Review
Database ✓ Archive and restore ✓ Condense data ✓ Reconcile data	•	RLIDBAK Im Start LIME/release data Im Disable LIME and cycles (POCT) Im Close cycles manually
In <u>Reconcise data</u>		OK Cancel Apply

J. Adjusting QC ranges:

- 1. Go to main page (refer to section 5.2.A)
- 2. Select the desired Lab Number
- 3. Select the desired Lot Number
- 4. Select the **Evaluation** tab



- 5. Double check the Lab and Lot number
- 6. Adjust the QC ranges by simply typing the new Mean and SD
- 7. Select **OK**

	Level 1	d Respon	se	1	Level 2	1	1	1
	Mean	SD	CV		Mean	SD 🚤	Q	
Albumin	2.75	0.10	3.64		4.0	0.11	2.72	
Alkaline Phosphatase	94.00	8.00	8.51		398.00	30.00	7.54	
ALT (ALAT/GPT)	32.00	1.75	5.47		101.00	3.50	47	
Amylase	70.00	2.00	2.86		462.00	11.00	2.38	
AST (ASAT/GOT)	30.50	2.25	7.38		216.00	7.00	3.24	
Bilirubin, Direct/BC (DBIL)	0.27	0.05	18.52		0.82	0.05	6.10	
Bilirubin, Total/TBIL	0.91	0.09	9.89		4.92	0.16	3.25	
Calcium	8.25	0.25	3.03		12.20	0.33	2.70	
Chloride	88.60	1.60	1.81		104.00	2.00	1.92	
Cholesterol, HDL	30.25	1.60	5.29		60.10	4.00	6.66	
Cholesterol, Total	103.50	4.50	4.35		256.00	10.00	3.91	
CK (Creatine Kinase)	148.00	3.50	2.36		477.00	10.00	2.10	
CO2 (Carbon Dioxide)	16.00	3.00	18.75		34.00	5.00	14.71	
Creatinine	0.99	0.10	10.10		5.80	0.17	2.93	
GGT (Gamma Glutamyltransferas	46.25	2.25	4.86		191.50	5.50	2.87	
Glucose	85.00	2.50	2.94		287.00	7.50	2.61	
T	CE 00	20.00	40.40	-	250.00	100.00	40.00	

K. Managing (adding and closing) lot numbers

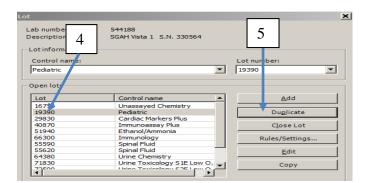
Use the following steps to open or close a lot number. Never Delete a lot number. To put a current lot out of use just close them.

- 1. Go to main page (refer to section 5.2.A)
- 2. Select the desired lab
- 3. Select Lot tab

Lab	Lot	Test	F
ab P	anel Ins	trument	-
I 🐴 54	+188: SGA		
😑 · · 📴 🥁	16750: U	nal sayed (
1	19390: P	ediatic 3/3	
I 2 📝	29830: C	ardiac Mar	
E 3 🖉	40870: In	nmunoassa	2
E -	51940: E	thanol/Amr	
	66300: In	nmunology	
		· · · · · · · · · · · · · · · · · · ·	

4. To open a new lot, select the current lot of QC in use

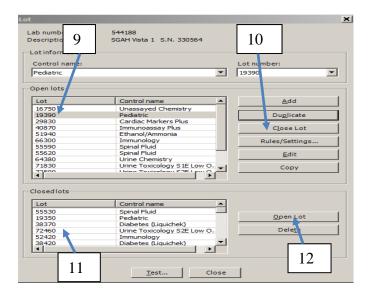
5. Select **Duplicate**



- 6. Select the Lab which the lot needs to be added on
- 7. Select the **new lot number**
- 8. Select OK

Duplicate Lot X
The duplicate lot option allows you to create a new lot number based upon the tests and settings of an existing lot number. This option is used for the routine switch to a new lot of control.
Current lot number:
19390
New lot number: 7
21640
Duplicate lot for selected labs:
□ 275159: GEC Xpand 2 S.N. 2004080707 ✓ 544188: SGAH Vista 1 S.N. 330564
544191: 59AH MENS 5 N 330677
544208: SGAH Vista 3 S.N. 310974 0
544235: GEC X-pand 1 S.N. 2004082650 544211: WAH Vista 1 S.N. 330684
544223: WAH Vista 2 S.N. 330685
Select All Clear All
Select the items you want to duplicate to the new lot number.
Fixed means
Fixed SDs
Target values for Analytical Goals
OK Cancel

- 9. To close a lot, select the desired lot
- 10. Select Close Lot
- 11. To reopen a closed lot, select the desired lot
- 12. Select **Open Lot**



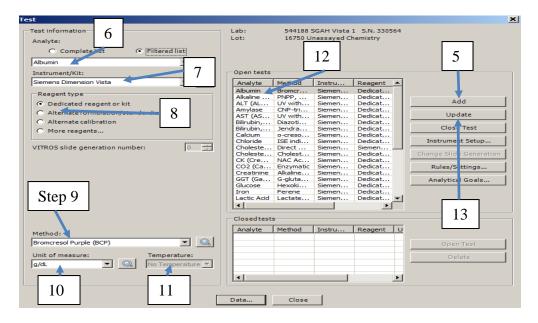
L. Managing Tests

Use the following information to add, update or close a test. Never Delete a test. To put a current test out of use just close them.

- 1. Go to main page (refer to section 5.2.A)
- 2. Select the desired Lab
- 3. Select the desired Lot
- 4. Select **Test** tab



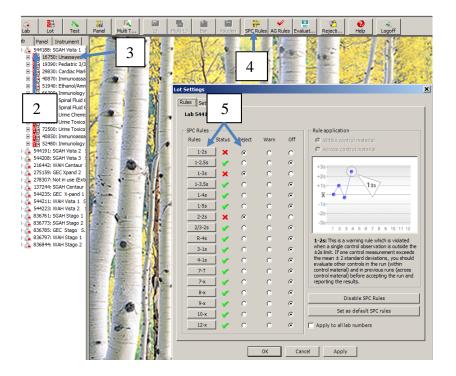
- 5. To add a new test, Select Add
- 6. Select desired Test
- 7. Select desired Instrument
- 8. Select desired Reagent
- 9. Select desired Method
- 10. Select desired Units of Mesure
- 11. Select desired Temperature
- 12. To update a current test, highlight the desired Test
- 13. Select Update and repeat steps 7 through 11



M. Managing Rules:

The Unity Real Time evaluates data points against 1 - 2s, 2 - 2s and 1 - 3s to determine whether to accept or reject the data. The 2 - 2s rule will only flag when the 2-2s rule is violated (when 2 levels of the same method fall outside the QC range at the same time.) To add or modify a rule:

- 1. Go to main page (refer to section 5.2.A)
- 2. Open the desired **Lab**
- 3. High light the desired Lot
- 4. Select SPC Rule tab
- 5. Select the desire rules



N. Managing Passwords:

The Unity Real Time password does not need to be changed on a regular basis, however, a user may change their password.

- 1. Go to main page (refer to section 5.2.1)
- 2. Select Tools
- 3. Select Security
- 4. Select Change Password



5.3 Communication with Bio-Rad:

The monthly QC must be submitted to Bio-Rad before midnight of the seventh day of each month. Data must be reviewed before submission to make sure that all QC failures are rejected and no data is missing. It is also recommended to receive data (code list, analytical goals, instrument set-up) from Bio-Rad several times a year to maintain up to date system files.

- 1. Go to main page (refer to section 5.2.A)
- 2. Select **Tools**
- 3. Select **Unity Inter lab**
- 4. Select Send/Receive Data

🍓 Unity Real Time			
<u>File Select View Re</u>	eview <u>A</u> nalysis A 2	Peperte Tools Help	
🔺 🖪 🗍	A 1 11	Securit <u>v</u>	
Lab Lot		ulti T Unity <u>I</u> nterlab	Send/Receive Data
	ument	<u>U</u> tilities	Update Database Write Transmission File
+ 544188: SGAH \	Vista 1	Actions and	ents
🗄 👗 544191: SGAH \	Vista 2	Setup	3 4 4
🗄 🚠 544208: SGAH \	Vista 3 🕴 🦰 👘	and the second	

- 5. Select **Send data to Bio-Rad** when submitting month QC. Then select **OK**
- 6. Select **Receive Data** when receiving information. When receiving data, make sure to check mark all three choices. Then select **OK**. This procedure takes about one (1) hour.

Send/Receive Data
Send data to Bio-Rad 5 Receive Data Receive code list Receive code list Receive Analytical Goals information Receive Linstrument setup
C: \Program Files \Bio-Rad Laboratories \Unity Real Time \Codelist
ок Cancel

5.4 Backup and Restore the Database:

LIS staff is responsible for monitoring the backups to ensure that they complete. Documentation of review can be found on the server hard drive (C:\Daily lab logs).

- 1. Daily Backup:
 - a. Runs automatically at 0100 and is saved to the C:\Backups by date/time on the BioRad server. File is BIORAD_SGAH_YYYMMDDHHMMSS.bak.
 - b. The C:\Backups directory is backed up on the network daily by IT.
 - c. The backup configuration can be found on the desktop or task bar on the BioRad server. The app is called 'Unity Backup/Restore Utility''.
- 2. Manual Backup:
 - a. Access the "Unity Backup/Restore Utility" located on desktop or taskbar.
 - b. You need to be in the tab called "Backup".

- c. Above the Database selection you will see "Database Disconnected". At the Database prompt, click on the drop down and then click on BIORAD_SGAH. You will now see that you are "Connected" and the next field "Required local full path of backup file" is now populated.
- d. Click on **Execute Backup** and backup will start up.

6. **RELATED DOCUMENTS**

Unity Real time 2.0 Reference Guide for Expert QC Data Management.

7. **REFERENCES**

Unity Real Time 2.0 Reference Guide for Expert QC Data Management. Version 1.0, revised 08/03/2009

8. **REVISION HISTORY**

Version	Date	Reason for Revision	Revised By	Approved By
000	6/9/15	Section 2: specify job roles that utilize SOP	A Chini	R SanLuis
		Section 4: add Z-score		
		Section 5: add screen shots, explanations and step		
		by step instructions, update back up process		
		Footer: version # leading zero's dropped due to new		
		EDCS in use as of $10/7/13$.		
1	6/28/17	Header: add other sites	L Barrett	R SanLuis
2	4/1/19	Header: update parent facility	L Barrett	R SanLuis
		Section 5: add note in 5.2.C, remove Edit Action		
		Log from employee setup in 5.2.I		

9. ADDENDA AND APPENDICES

N/A