TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	4/8/2019
Department:	Core Lab	**Due Date:**	4/30/2019
		Implementation:	**4/22/2019**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Quality Control Program SGAH.QA40 v5
Bio-Rad Unity Real Time 2.0 SGAH.C136 v3

Description of change(s):

Notes:

- *It is **essential** that QC review & actions be documented in Bio-Rad Unity (not in DI). Why? – You can't see L J charts in DI to properly assess your QC trends.*
- ***Use** 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 SanLuis	Date: 8/18/2011
Owner	Cynthia Bowman-Gholston	Date: 8/18/2011

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

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.
L. 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-to-day 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 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	R SanLuis	C Bowman
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 Footer: version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L Barrett R SanLuis	C Bowman
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 Codes	AC. Control: repeated level 1-Accept
	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. Calibrated with new lot. QC issue resolved
	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 Codes	QC: reviewed for day
	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.

Form revised 3/31/00

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**
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

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

$$Z = \frac{\text{Observed Result} - \text{Expected Result}}{SD}$$

5. PROCEDURE

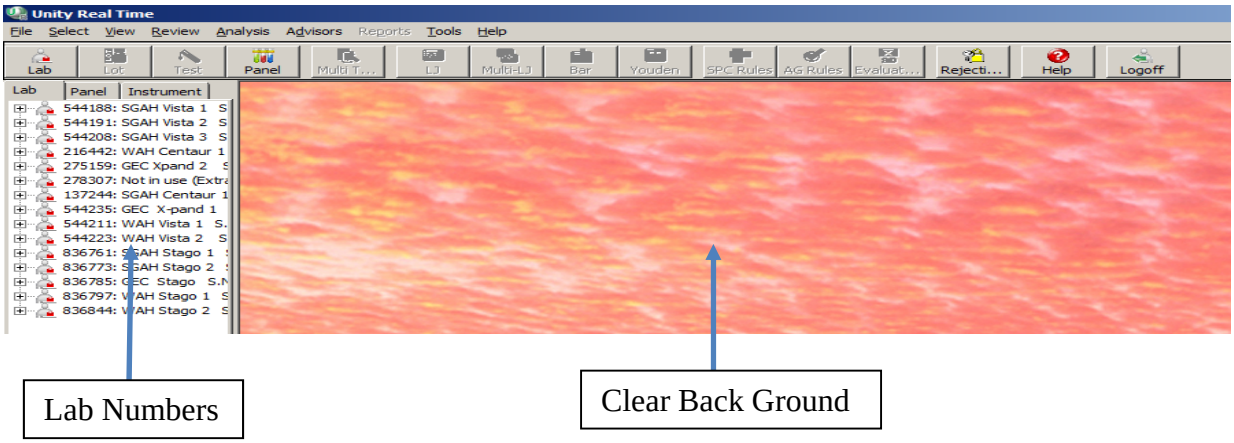
5.1 User Log In:

Log in using 6 digit Quest Diagnostics employee ID number.

5.2 Describing the system:

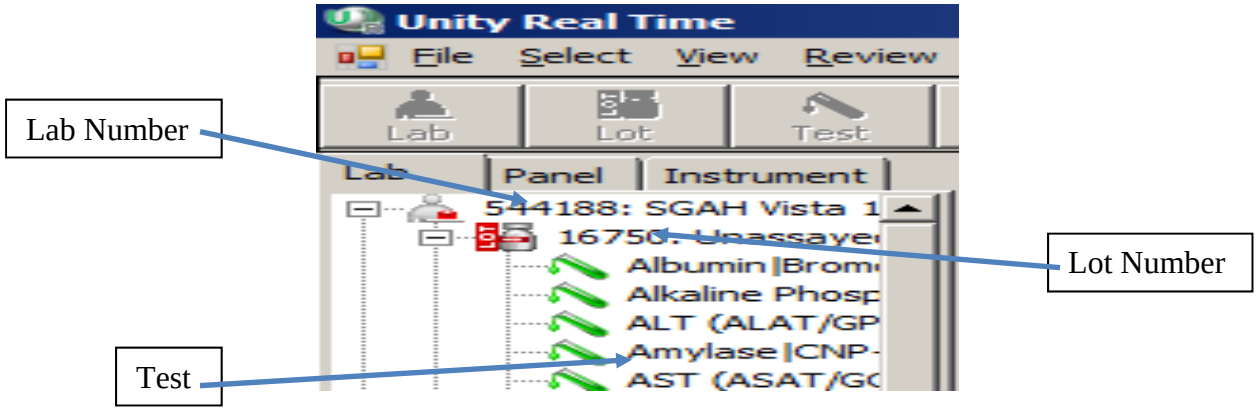
A. Main Page:

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.



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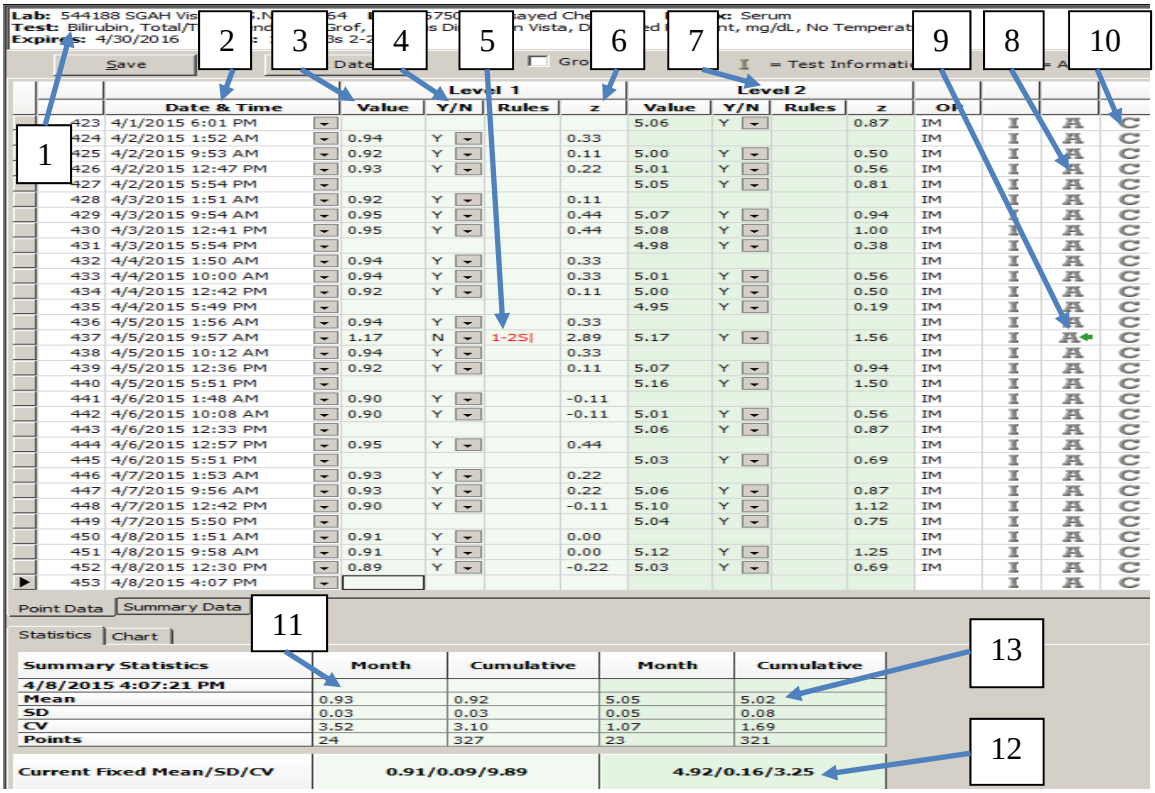
When a test page is opened the following information will be displayed:

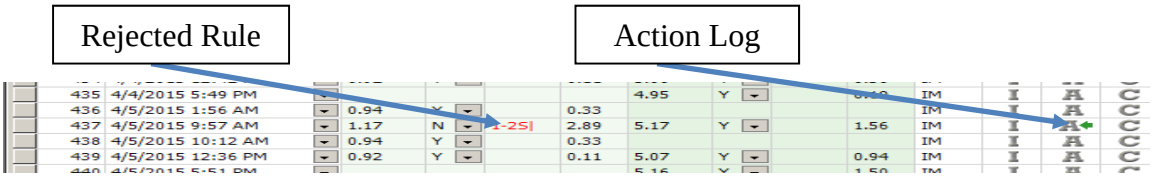
1. Lab, Lot and Test information
2. Date and Time QC was run
3. Value of QC
4. Y stands for Accept; N stands for Reject
5. QC Rule (QC warning or rejection rule)
6. Z-score
7. Level of QC
8. Action Log **WITHOUT** a statement
9. Action Log **WITH** a statement (**Green Arrow** beside the "A")
10. Comment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



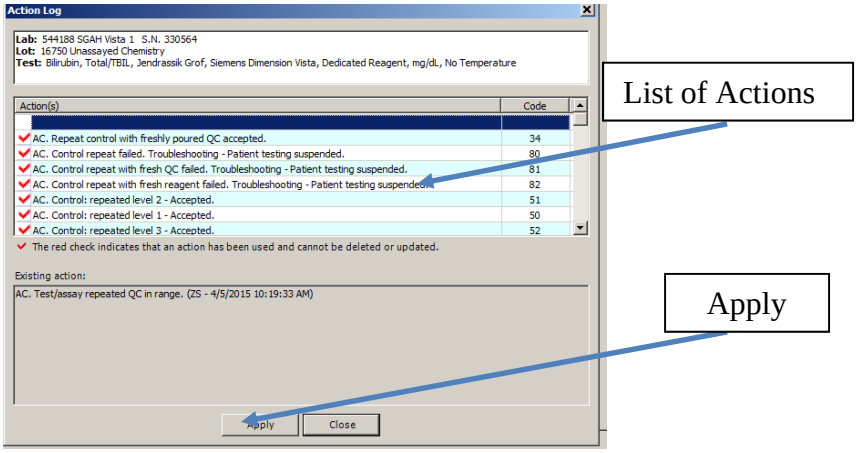
C. Action and Comment:

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:

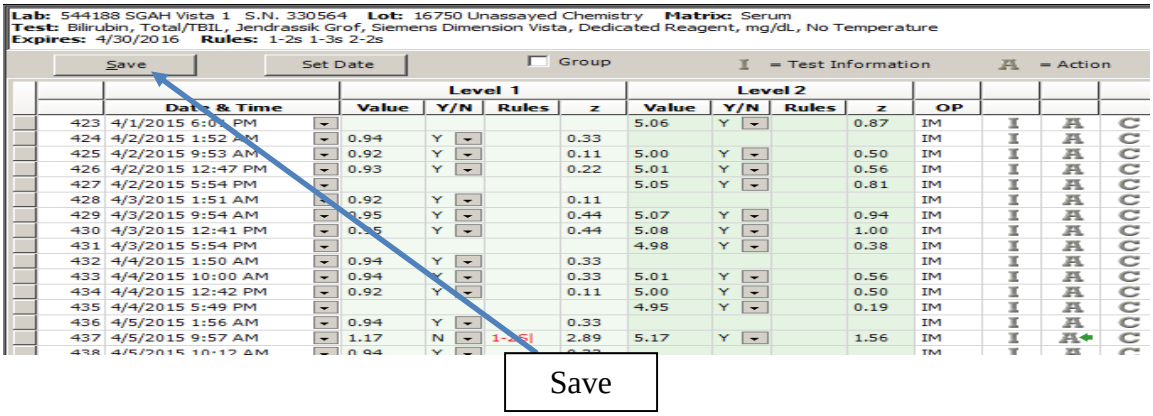
1. Adding an Action



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



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.



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.

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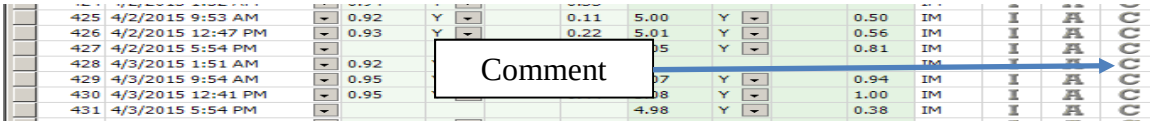
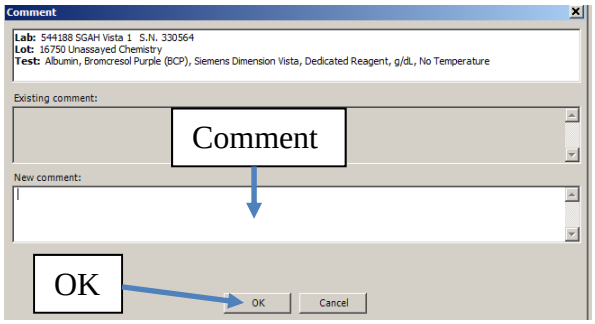
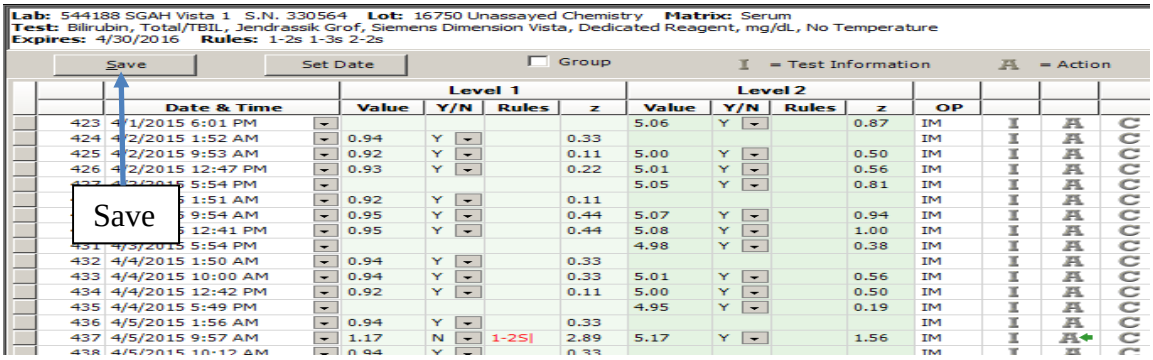
2. Adding a Comment
   a. Click on **C** (Comment).



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

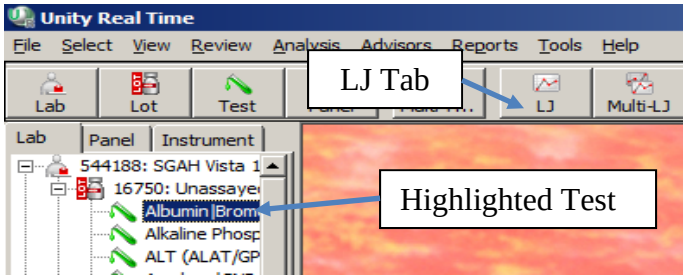


   c. The screen will return to the test page. Click on **Save** to store the data.



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



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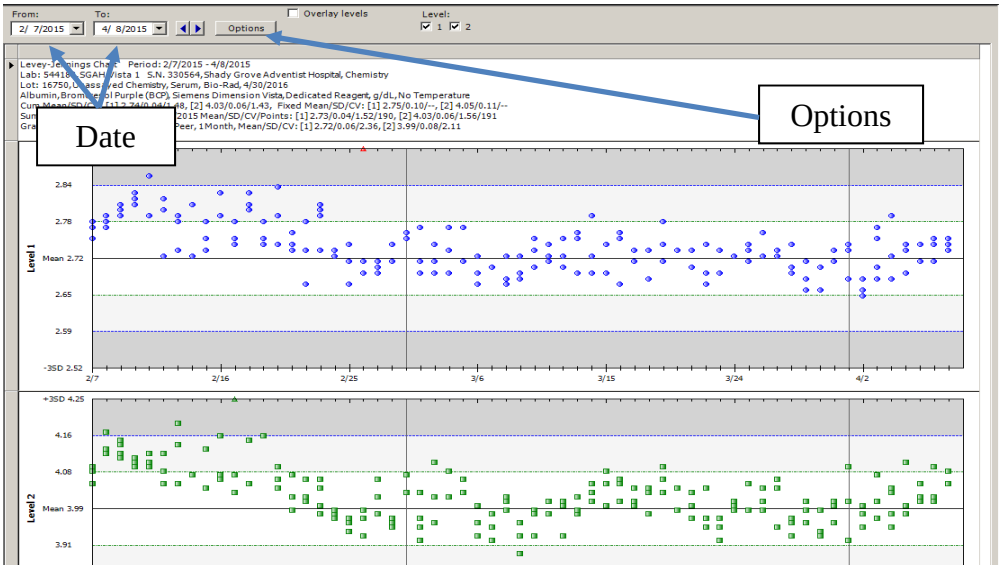
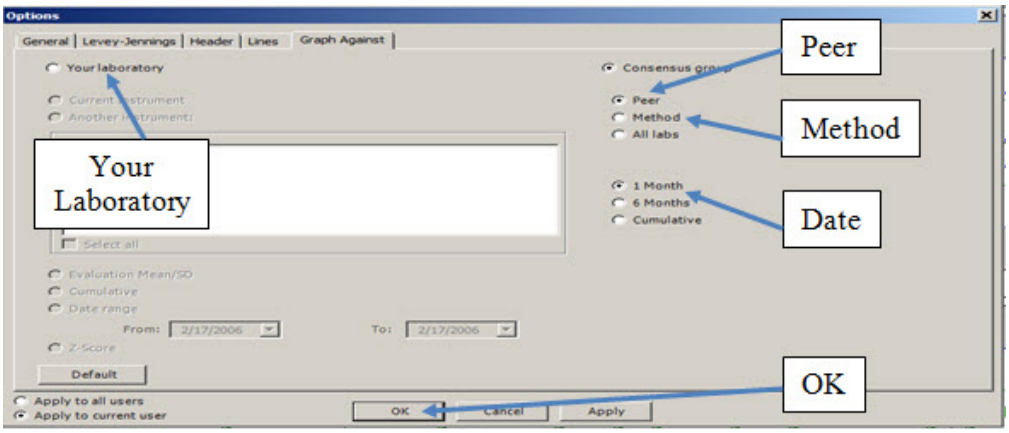
5. Adjust the date as desired
6. To include or exclude peer group on the Levey Jennings Chart:
   a. Click on **Options**



   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**.



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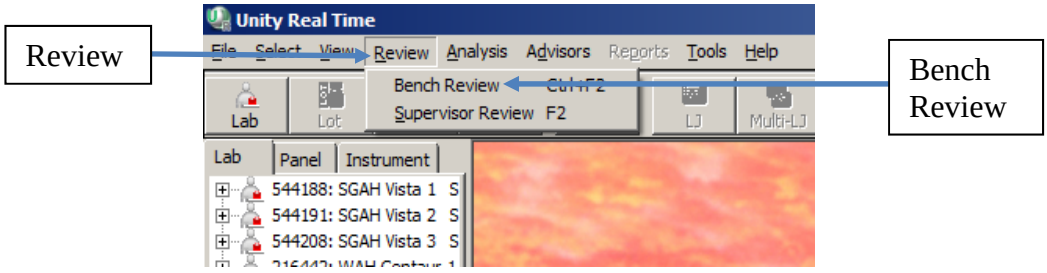
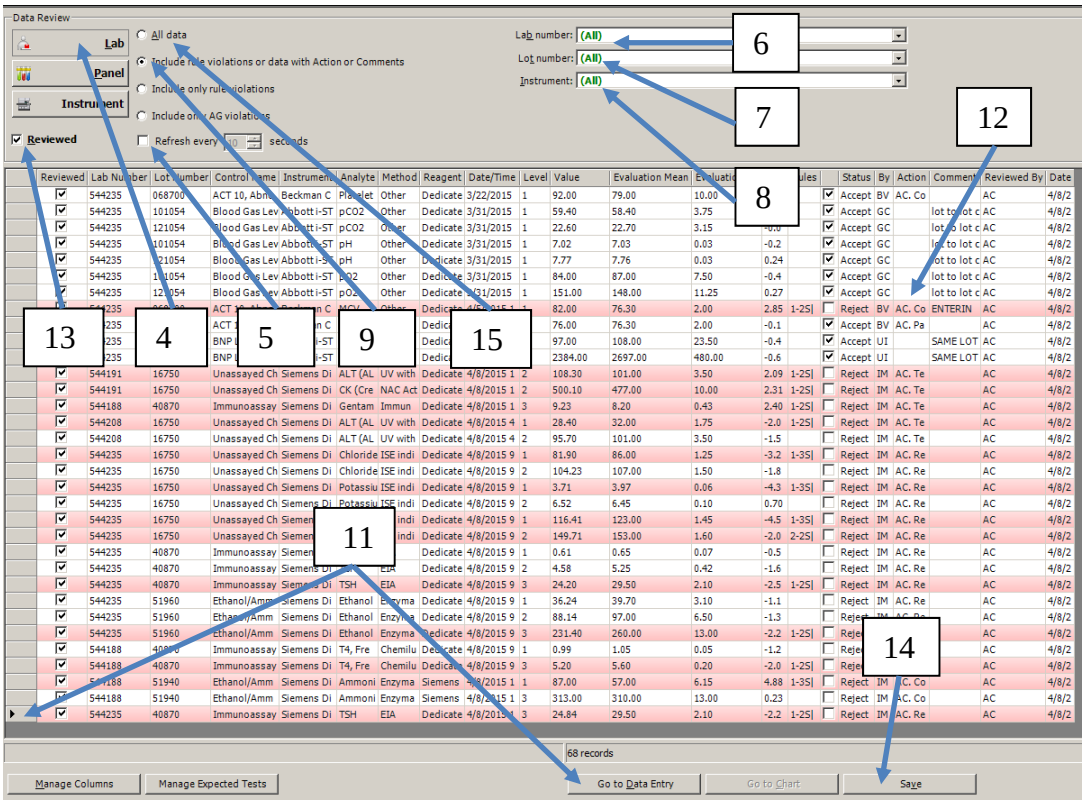
E. Bench Review:

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**



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**.



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**.

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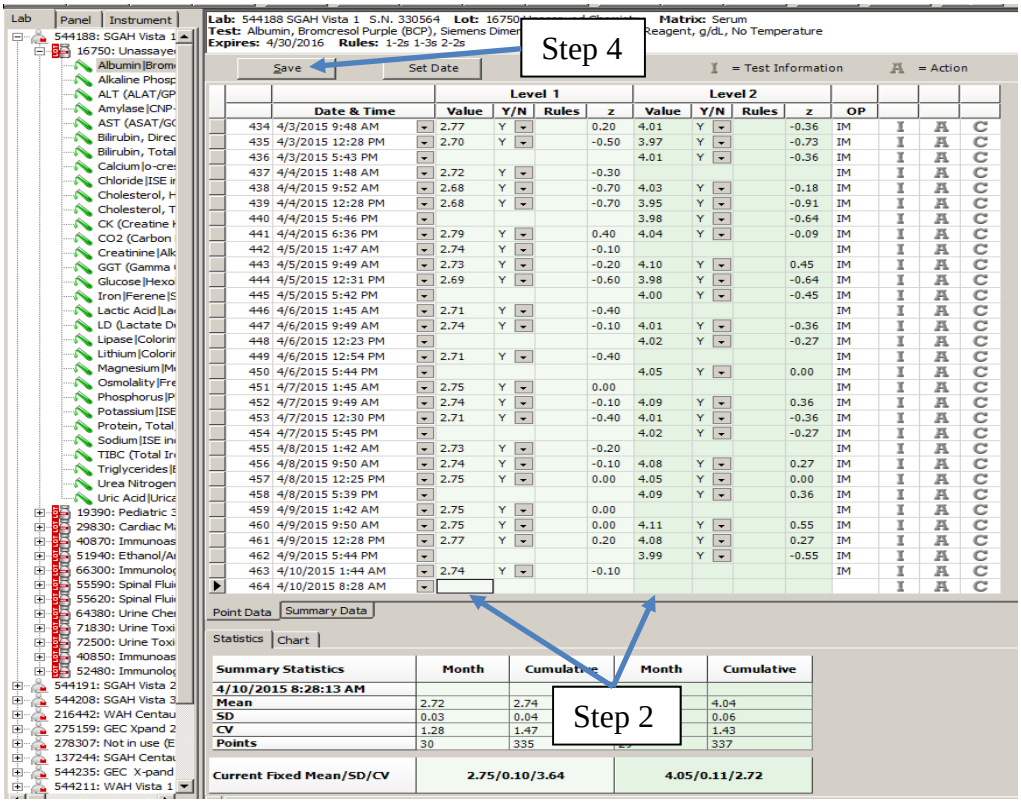
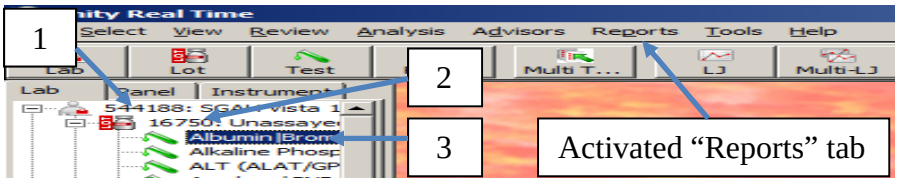


H. Printing Reports:

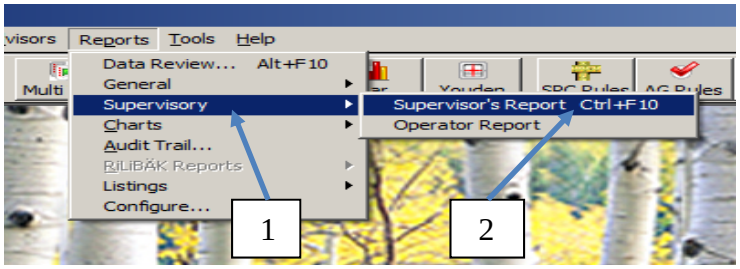
This software provides the following reports:

- **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.

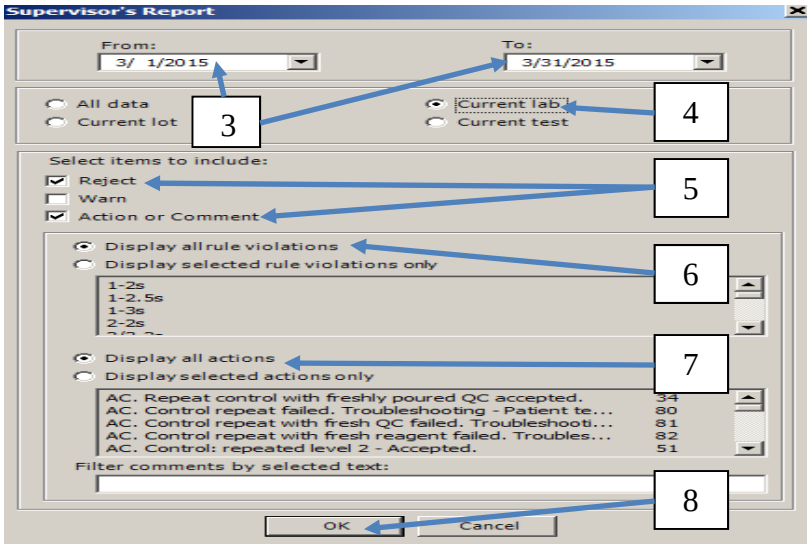
1. **To print any report**, first the "Reports" tab needs to be activated.
   a. Go to desired lab number
   b. Select desired or a random lot number
   c. High light desired or a random test



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



   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**



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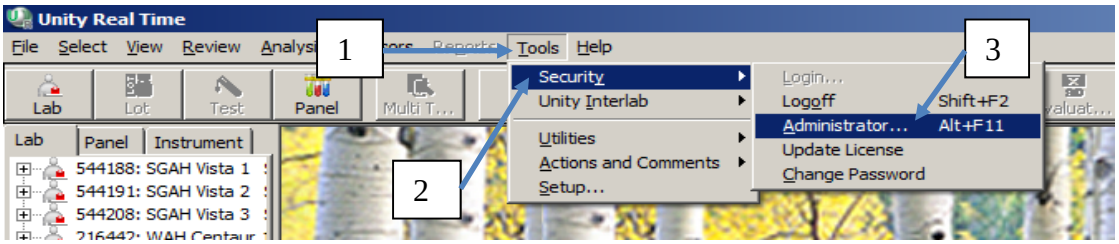
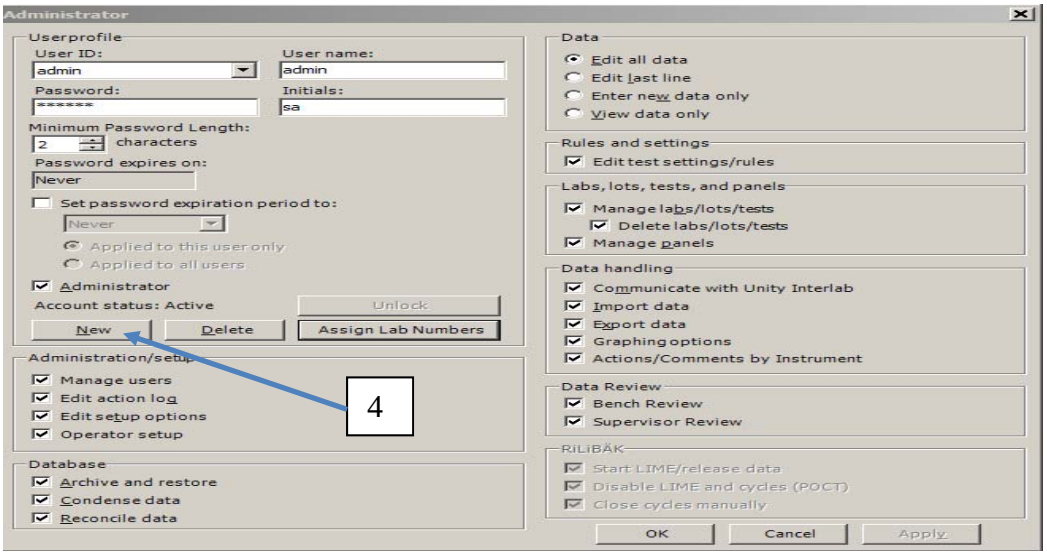
I. To add or edit employee information: (Supervisors Only)

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**



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**
12. ~~Select **Edit Action Log**~~
13. Select **Apply**
14. Select **Assign Lab Numbers**

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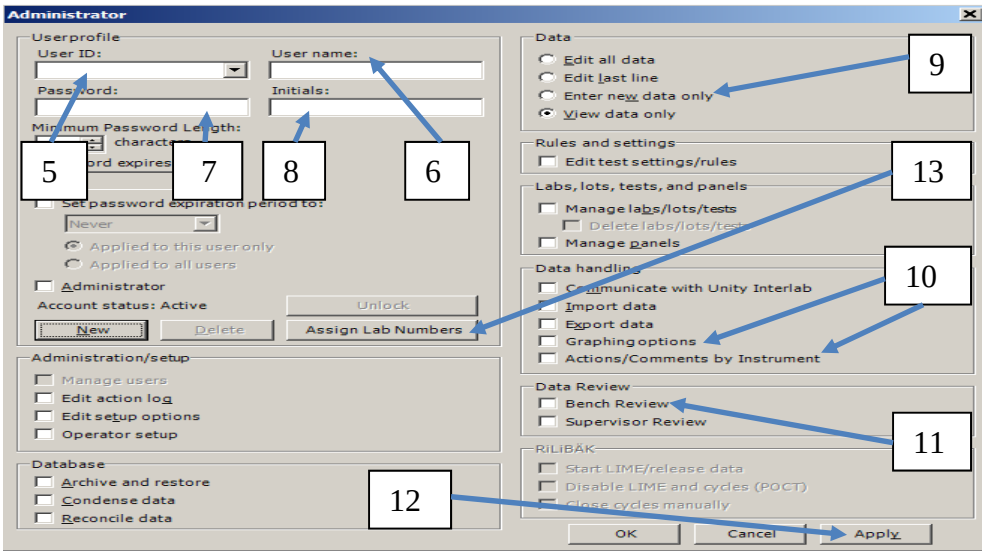
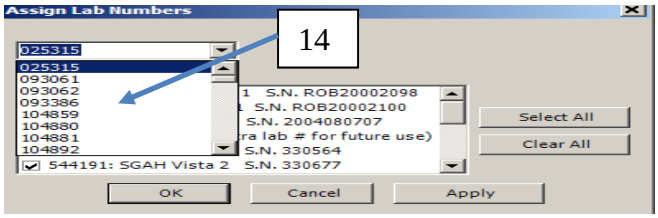
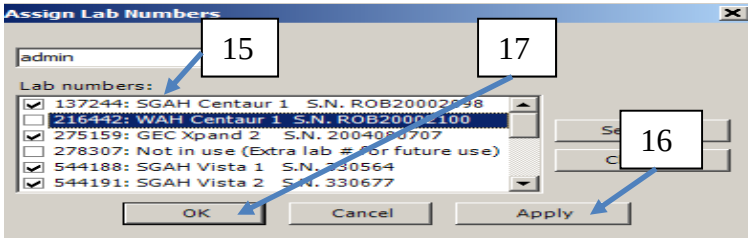


14. Select the employee number of the individual to be edited

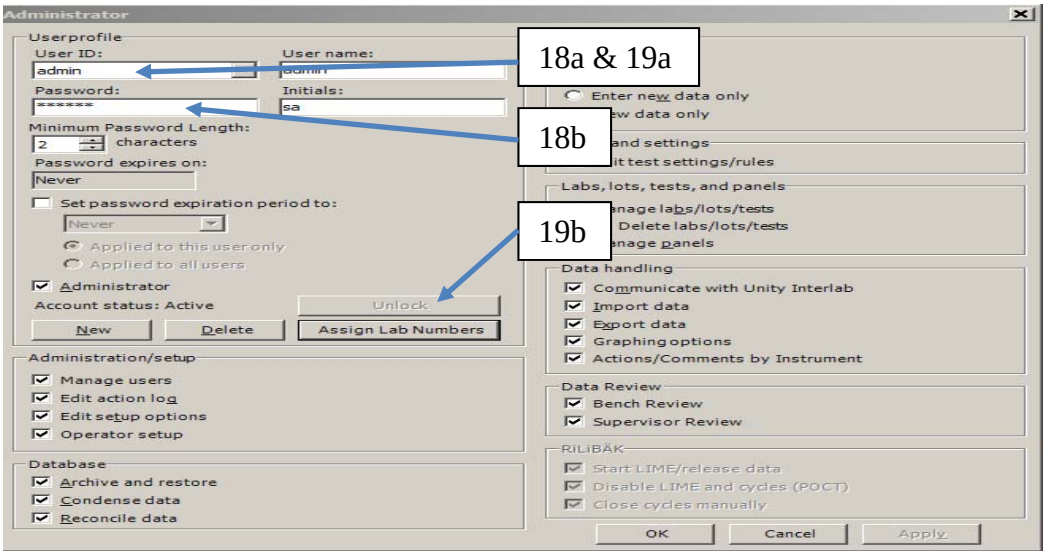


15. Assign desired **Lab numbers**
16. Select **Apply**
17. Select **OK**



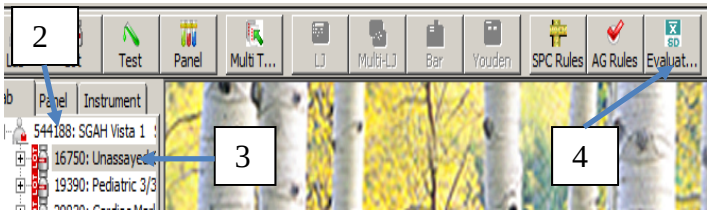
18. If an employee forgets his/her password and cannot log into Unity Real Time:
    a. Repeat steps 1-3 and select the correct employee
    b. Provide a temporary password to the employee
    c. Select **OK** (When the employee logs back in the Unity Real Time, it will ask them to reset their password)

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.



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**

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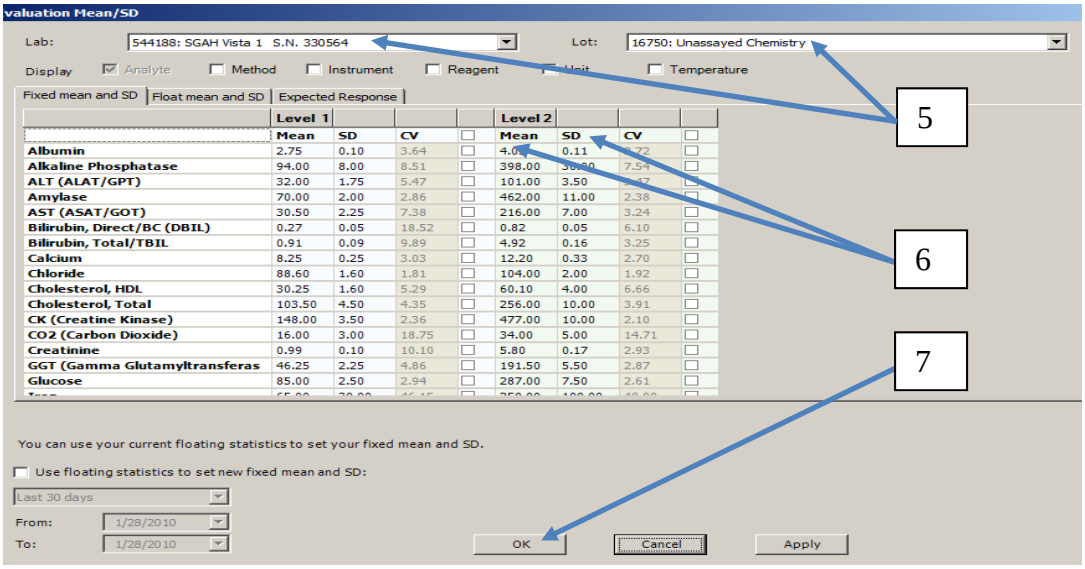
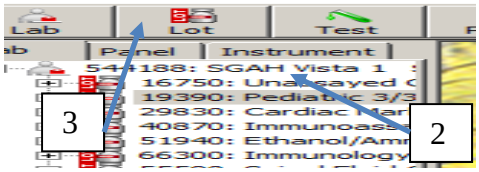


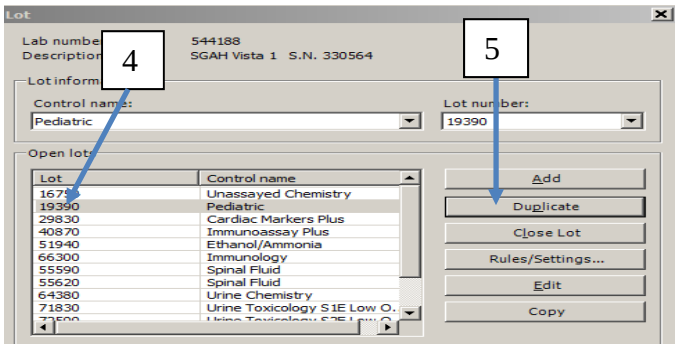
K. Managing (adding and closing) lot numbers

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.**

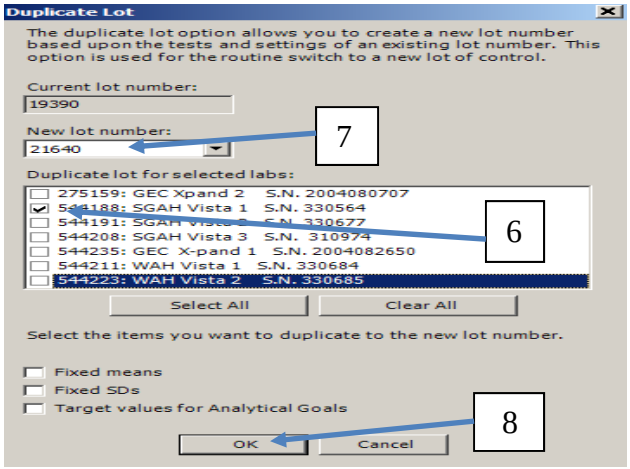
1. Go to main page (refer to section 5.2.A)
2. Select the desired lab
3. Select **Lot** tab



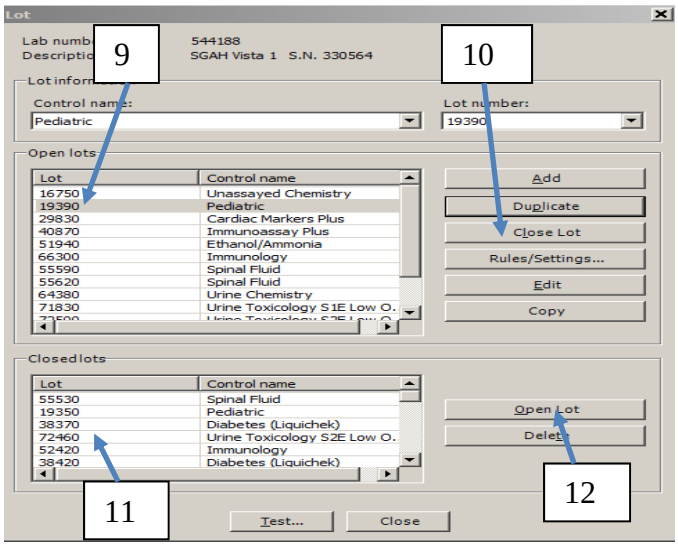
4. To open a new lot, select the current lot of QC in use
5. Select **Duplicate**



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



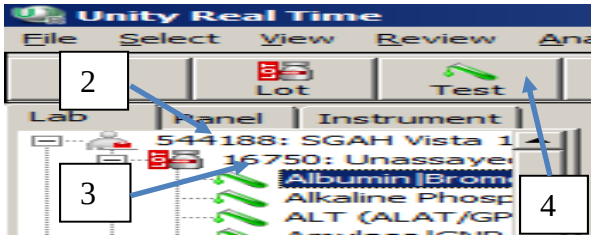
9. To close a lot, select the desired lot
10. Select **Close Lot**
11. To reopen a closed lot, select the desired lot
12. Select **Open Lot**



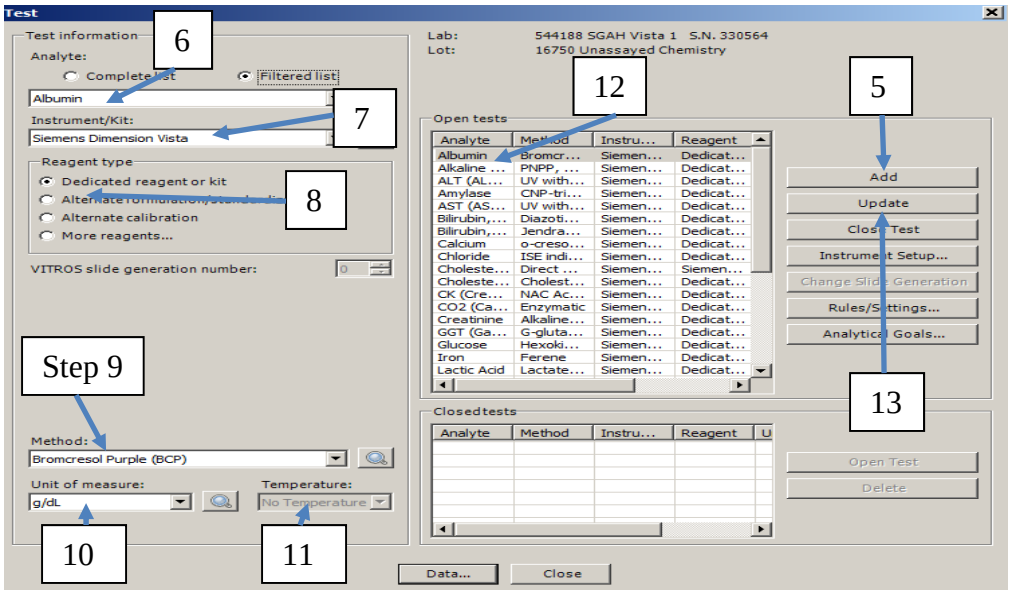
L. Managing Tests

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



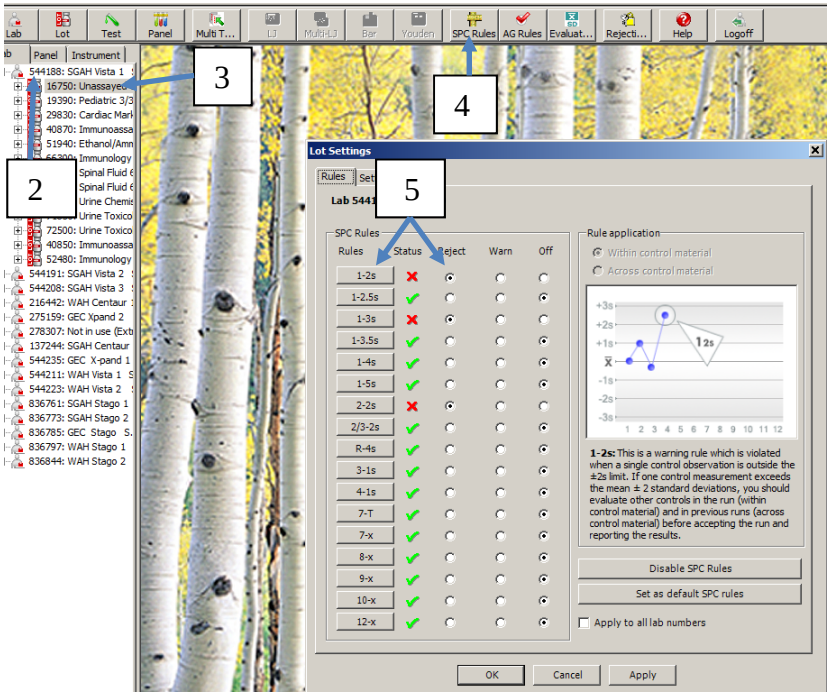
5. To add a new test, Select **Add**
6. Select desired Test
7. Select desired Instrument
8. Select desired Reagent
9. Select desired Method
10. Select desired Units of Mesure
11. Select desired Temperature
12. To update a current test, highlight the desired Test
13. Select Update and repeat steps 7 through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

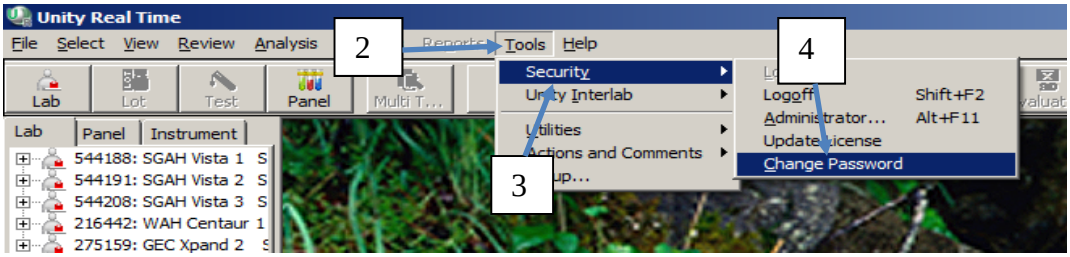
1. Go to main page (refer to section 5.2.A)
2. Open the desired **Lab**
3. High light the desired **Lot**
4. Select **SPC Rule** tab
5. Select the desire rules



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**



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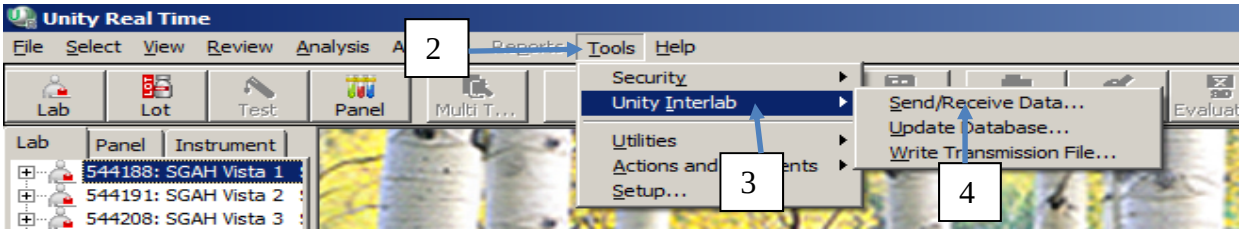
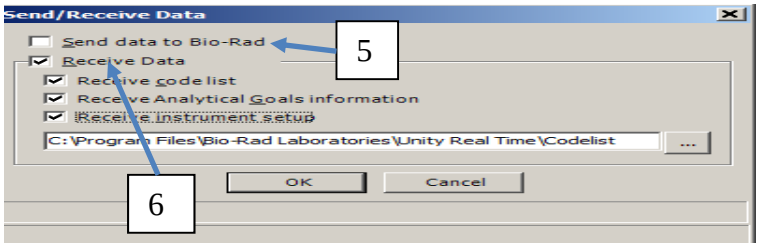
5.3 Communication with Bio-Rad:

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**



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.



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 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.	A Chini	R SanLuis
1	6/28/17	Header: add other sites	L Barrett	R SanLuis
2	4/1/19	Header: update parent facility Section 5: add note in 5.2.C, remove Edit Action Log from employee setup in 5.2.I	L Barrett	R SanLuis

9. ADDENDA AND APPENDICES

N/A