

TRAINING UPDATE

Lab Location: GEC, SGMC & WAH
Department: Core

Date Distributed: 7/1/2015
Due Date: 7/29/2015
Implementation: 7/29/2015

DESCRIPTION OF REVISION

Name of procedure:

Bio-Rad Unity Real Time 2.0 GEC.C40, SGAH.C136, WAH.C129 v1

Description of change(s):

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

This revised SOP will be implemented on July 29, 2015.

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

Approved draft for training (version 1)

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

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

5. PROCEDURE

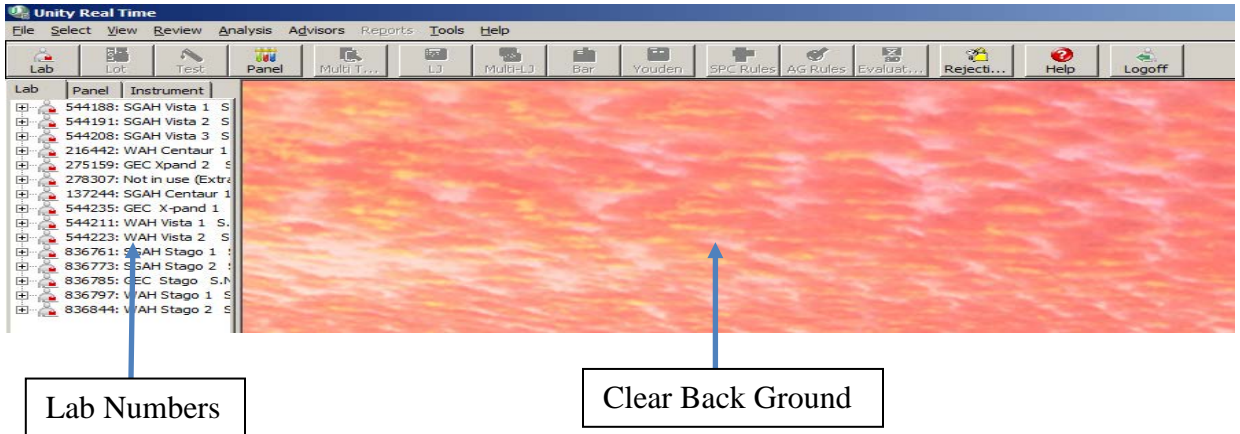
5.1 User Log In:

Log in using 6 digit Quest Diagnostics employee ID number.

5.2 Describing the system:

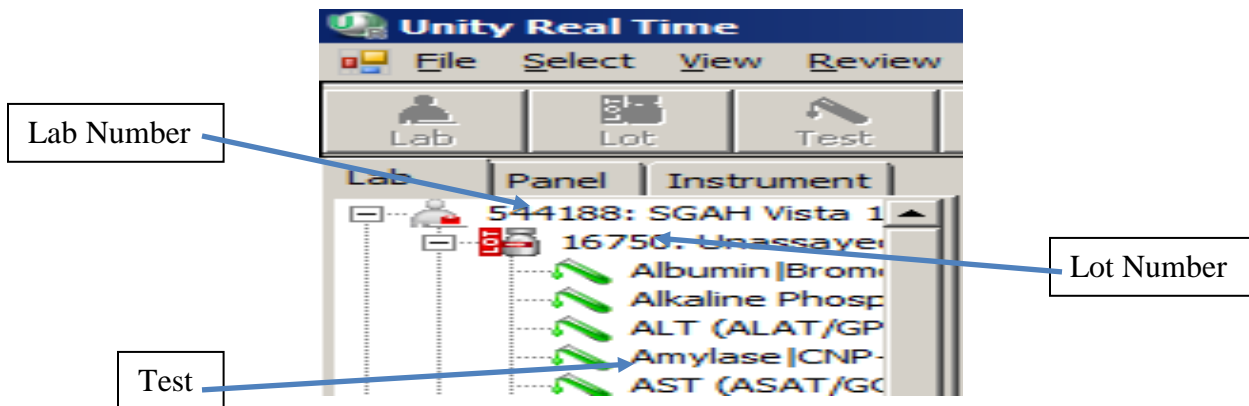
A. Main Page:

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.



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

The screenshot displays a QC data table with columns for Date & Time, Value, Y/N, Rules, z, Level 1, Level 2, and Action Log. Below the table is a Summary Statistics section with columns for Month and Cumulative for both Actual and Expected values.

Date & Time	Value	Y/N	Rules	z	Level 1		Level 2		Action Log	Comment
					Value	Y/N	Rules	z		
423 4/1/2015 6:01 PM					5.06	Y		0.87	IM	
424 4/2/2015 1:52 AM	0.94	Y		0.33	5.00	Y		0.50	IM	
425 4/2/2015 9:53 AM	0.92	Y		0.11	5.01	Y		0.56	IM	
426 4/2/2015 12:47 PM	0.93	Y		0.22	5.05	Y		0.81	IM	
427 4/2/2015 5:54 PM										
428 4/3/2015 1:51 AM	0.92	Y		0.11	5.07	Y		0.94	IM	
429 4/3/2015 9:54 AM	0.95	Y		0.44	5.08	Y		1.00	IM	
430 4/3/2015 12:41 PM	0.95	Y		0.44	4.98	Y		0.38	IM	
431 4/3/2015 5:54 PM										
432 4/4/2015 1:50 AM	0.94	Y		0.33	5.01	Y		0.56	IM	
433 4/4/2015 10:00 AM	0.94	Y		0.33	5.00	Y		0.50	IM	
434 4/4/2015 12:42 PM	0.92	Y		0.11	4.95	Y		0.19	IM	
435 4/4/2015 5:49 PM										
436 4/5/2015 1:56 AM	0.94	Y		0.33	5.17	Y		1.56	IM	
437 4/5/2015 9:57 AM	1.17	N	1-2S	2.89	5.16	Y		1.50	IM	
438 4/5/2015 10:12 AM	0.94	Y		0.33						
439 4/5/2015 12:36 PM	0.92	Y		0.11	5.07	Y		0.94	IM	
440 4/5/2015 5:51 PM					5.16	Y		1.50	IM	
441 4/6/2015 1:48 AM	0.90	Y		-0.11						
442 4/6/2015 10:08 AM	0.90	Y		-0.11	5.01	Y		0.56	IM	
443 4/6/2015 12:33 PM					5.06	Y		0.87	IM	
444 4/6/2015 12:57 PM	0.95	Y		0.44						
445 4/6/2015 5:51 PM					5.03	Y		0.69	IM	
446 4/7/2015 1:53 AM	0.93	Y		0.22						
447 4/7/2015 9:56 AM	0.93	Y		0.22	5.06	Y		0.87	IM	
448 4/7/2015 12:42 PM	0.90	Y		-0.11	5.10	Y		1.12	IM	
449 4/7/2015 5:50 PM					5.04	Y		0.75	IM	
450 4/8/2015 1:51 AM	0.91	Y		0.00						
451 4/8/2015 9:58 AM	0.91	Y		0.00	5.12	Y		1.25	IM	
452 4/8/2015 12:30 PM	0.89	Y		-0.22	5.03	Y		0.69	IM	
453 4/8/2015 4:07 PM										

Summary Statistics	Month		Cumulative	
	Mean	SD	Mean	SD
4/8/2015 4:07:21 PM	0.93	0.03	5.05	0.05
CV	3.52	3.10	1.07	1.69
Points	24	327	23	321

Current Fixed Mean/SD/CV	Month	Cumulative
	0.91/0.09/9.89	4.92/0.16/3.25

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

The screenshot shows a table of QC results. A callout box labeled 'Rejected Rule' points to the 'Rules' column of row 437, which contains '1-2S'. Another callout box labeled 'Action Log' points to the 'Action' column of the same row, which contains 'A'. The table includes columns for Date & Time, Value, Y/N, Rules, z, Level 2 Value, Y/N, Rules, z, OP, and Action.

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

The 'Action Log' dialog box is shown. It contains a list of actions with checkboxes and codes. A callout box labeled 'List of Actions' points to the list. Another callout box labeled 'Apply' points to the 'Apply' button at the bottom of the dialog. The dialog also shows an 'Existing action' section with a red checkmark and a description: 'AC. Test/assay repeated QC in range. (2S - 4/5/2015 10:19:33 AM)'.

- 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.

The screenshot shows the test page with a 'Save' button at the top left. A callout box labeled 'Save' points to this button. The main table is the same QC data table as in the previous screenshot, with row 437 highlighted in red. The 'Save' button is located above the table.

2. 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	A	C
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	0.95	Y	0.44	5.05	Y	0.81	IM	I	A	C
428	4/3/2015 1:51 AM	0.92	Y	0.11	5.07	Y	0.94	IM	I	A	C
429	4/3/2015 9:54 AM	0.95	Y	0.44	5.08	Y	1.00	IM	I	A	C
430	4/3/2015 12:41 PM	0.95	Y	0.33	4.98	Y	0.38	IM	I	A	C
431	4/3/2015 5:54 PM	0.94	Y	0.33	5.06	Y	0.87	IM	I	A	C

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

Comment

Lab: 544188 SGAH Vista 1 S.N. 330564
 Lot: 16750 Unassayed Chemistry
 Test: Albumin, Bromocresol Purple (BCP), Siemens Dimension Vista, Dedicated Reagent, g/dL, No Temperature

Existing comment:

New comment:

OK

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

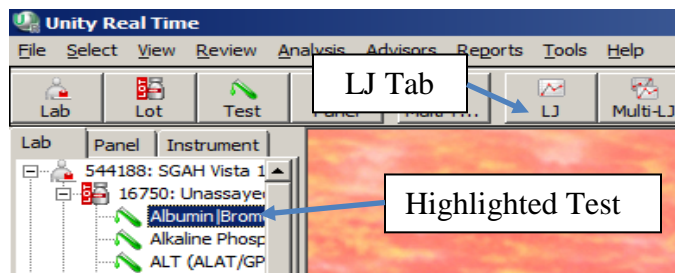
Lab: 544188 SGAH Vista 1 S.N. 330564 Lot: 16750 Unassayed Chemistry Matrix: Serum
 Test: Bilirubin, Total/TBIL, Jendrassik Grof, Siemens Dimension Vista, Dedicated Reagent, mg/dL, No Temperature
 Expires: 4/30/2016 Rules: 1-2s 1-3s 2-2s

Save Set Date Group I = Test Information A = Action

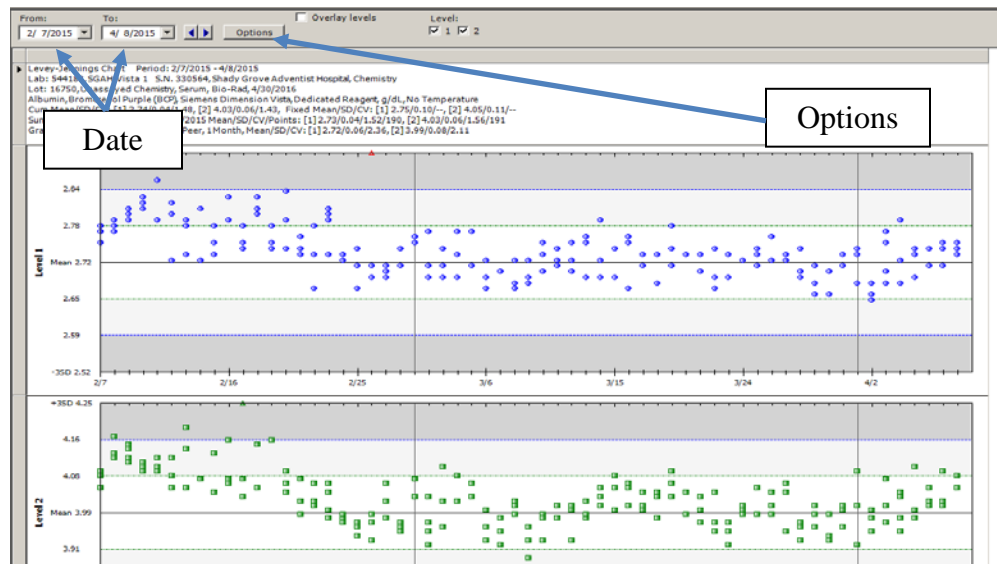
	Date & Time	Level 1			Level 2			OP			
		Value	Y/N	Rules	Value	Y/N	Rules				
423	4/1/2015 6:01 PM	0.94	Y	0.33	5.06	Y	0.87	IM	I	A	C
424	4/2/2015 1:52 AM	0.92	Y	0.11	5.00	Y	0.50	IM	I	A	C
425	4/2/2015 9:53 AM	0.92	Y	0.11	5.00	Y	0.56	IM	I	A	C
426	4/2/2015 12:47 PM	0.93	Y	0.22	5.01	Y	0.56	IM	I	A	C
427	4/2/2015 5:54 PM	0.95	Y	0.44	5.05	Y	0.81	IM	I	A	C
428	4/3/2015 1:51 AM	0.92	Y	0.11	5.07	Y	0.94	IM	I	A	C
429	4/3/2015 9:54 AM	0.95	Y	0.44	5.08	Y	1.00	IM	I	A	C
430	4/3/2015 12:41 PM	0.95	Y	0.33	4.98	Y	0.38	IM	I	A	C
431	4/3/2015 5:54 PM	0.94	Y	0.33	5.06	Y	0.87	IM	I	A	C
432	4/4/2015 1:50 AM	0.94	Y	0.33	5.01	Y	0.56	IM	I	A	C
433	4/4/2015 10:00 AM	0.94	Y	0.33	5.00	Y	0.50	IM	I	A	C
434	4/4/2015 12:42 PM	0.92	Y	0.11	4.95	Y	0.19	IM	I	A	C
435	4/4/2015 5:49 PM	0.94	Y	0.33	5.17	Y	1.56	IM	I	A	C
436	4/5/2015 1:56 AM	1.17	N	1-2S	2.89	Y	1.56	IM	I	A	C
437	4/5/2015 9:57 AM	0.94	Y	0.33	5.17	Y	1.56	IM	I	A	C
438	4/5/2015 10:12 AM	0.94	Y	0.33	5.17	Y	1.56	IM	I	A	C

D. To pull up Levey Jennings Chart:

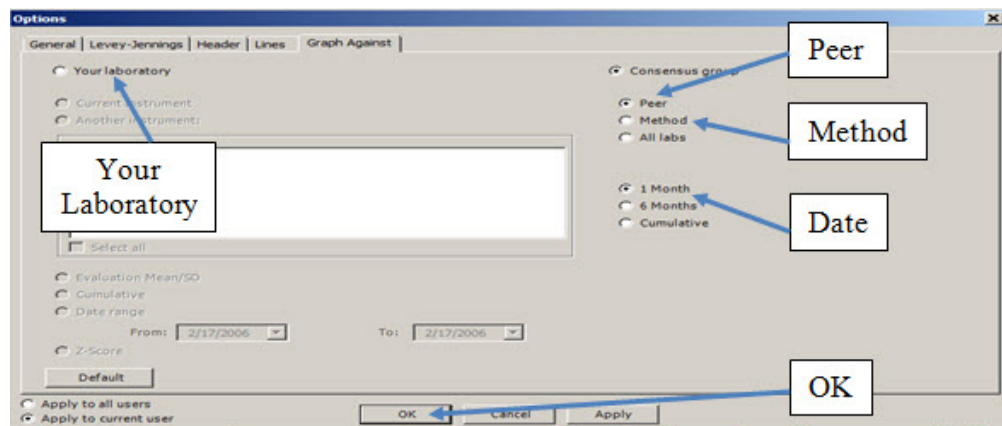
1. Go to main page (refer to section 5.2.A)
2. Click on the lab number and the desired QC lot number.
3. Highlight the desired test by clicking on it just once
4. Click on LJ Tab



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



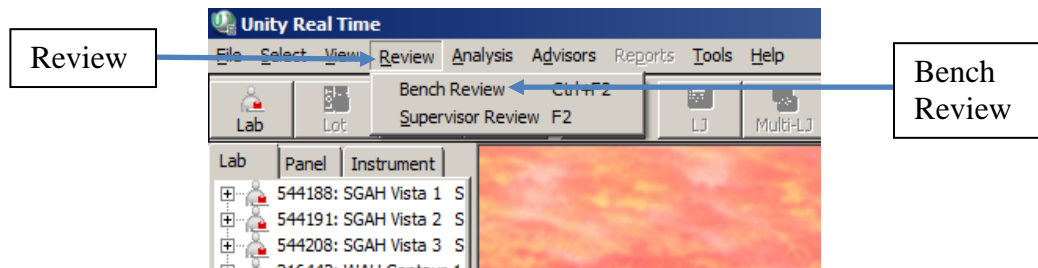
- b. The Options page provides users the tool to view the levey jennings chart in different ways.
 - Peer will put the data against all the labs which use the same QC material on the same type of instrument. To include peer group select “Peer”.
 - Method will put the data against all labs which use the 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.



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 Red: 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**.

Step 4

Date & Time	Level 1				Level 2				z	OP	I	A	C
	Value	Y/N	Rules	z	Value	Y/N	Rules	z					
434 4/3/2015 9:48 AM	2.77	Y		0.20	4.01	Y		-0.36	IM	I	A	C	C
435 4/3/2015 12:28 PM	2.70	Y		-0.50	3.97	Y		-0.73	IM	I	A	C	C
436 4/3/2015 5:43 PM					4.01	Y		-0.36	IM	I	A	C	C
437 4/4/2015 1:48 AM	2.72	Y		-0.30					IM	I	A	C	C
438 4/4/2015 9:52 AM	2.68	Y		-0.70	4.03	Y		-0.18	IM	I	A	C	C
439 4/4/2015 12:28 PM	2.68	Y		-0.70	3.95	Y		-0.91	IM	I	A	C	C
440 4/4/2015 5:46 PM					3.98	Y		-0.64	IM	I	A	C	C
441 4/4/2015 6:36 PM	2.79	Y		0.40	4.04	Y		-0.09	IM	I	A	C	C
442 4/5/2015 1:47 AM	2.74	Y		-0.10					IM	I	A	C	C
443 4/5/2015 9:49 AM	2.73	Y		-0.20	4.10	Y		0.45	IM	I	A	C	C
444 4/5/2015 12:31 PM	2.69	Y		-0.60	3.98	Y		-0.64	IM	I	A	C	C
445 4/5/2015 5:42 PM					4.00	Y		-0.45	IM	I	A	C	C
446 4/6/2015 1:45 AM	2.71	Y		-0.40					IM	I	A	C	C
447 4/6/2015 9:49 AM	2.74	Y		-0.10	4.01	Y		-0.36	IM	I	A	C	C
448 4/6/2015 12:23 PM					4.02	Y		-0.27	IM	I	A	C	C
449 4/6/2015 12:54 PM	2.71	Y		-0.40					IM	I	A	C	C
450 4/6/2015 5:44 PM					4.05	Y		0.00	IM	I	A	C	C
451 4/7/2015 1:45 AM	2.75	Y		0.00					IM	I	A	C	C
452 4/7/2015 9:49 AM	2.74	Y		-0.10	4.09	Y		0.36	IM	I	A	C	C
453 4/7/2015 12:30 PM	2.71	Y		-0.40	4.01	Y		-0.36	IM	I	A	C	C
454 4/7/2015 5:45 PM					4.02	Y		-0.27	IM	I	A	C	C
455 4/8/2015 1:42 AM	2.73	Y		-0.20					IM	I	A	C	C
456 4/8/2015 9:50 AM	2.74	Y		-0.10	4.08	Y		0.27	IM	I	A	C	C
457 4/8/2015 12:25 PM	2.75	Y		0.00	4.05	Y		0.00	IM	I	A	C	C
458 4/8/2015 5:39 PM					4.09	Y		0.36	IM	I	A	C	C
459 4/9/2015 1:42 AM	2.75	Y		0.00					IM	I	A	C	C
460 4/9/2015 9:50 AM	2.75	Y		0.00	4.11	Y		0.55	IM	I	A	C	C
461 4/9/2015 12:28 PM	2.77	Y		0.20	4.08	Y		0.27	IM	I	A	C	C
462 4/9/2015 5:44 PM					3.99	Y		-0.55	IM	I	A	C	C
463 4/10/2015 1:44 AM	2.74	Y		-0.10					IM	I	A	C	C
464 4/10/2015 8:28 AM									IM	I	A	C	C

Step 2

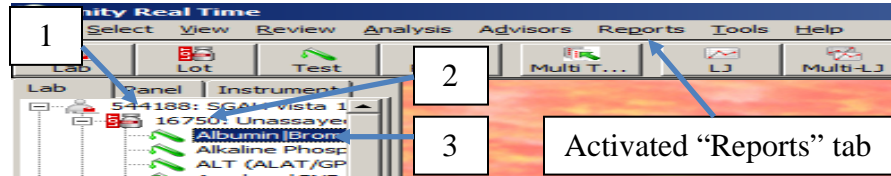
Summary Statistics	Month	Cumulative	Month	Cumulative
4/10/2015 8:28:13 AM				
Mean	2.72	2.74		4.04
SD	0.03	0.04		0.06
CV	1.28	1.47		1.43
Points	30	335		337
Current Fixed Mean/SD/CV	2.75/0.10/3.64		4.05/0.11/2.72	

H. Printing Reports:

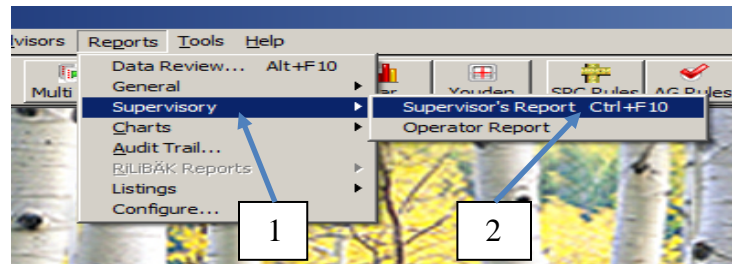
This software provides the following reports:

- **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.

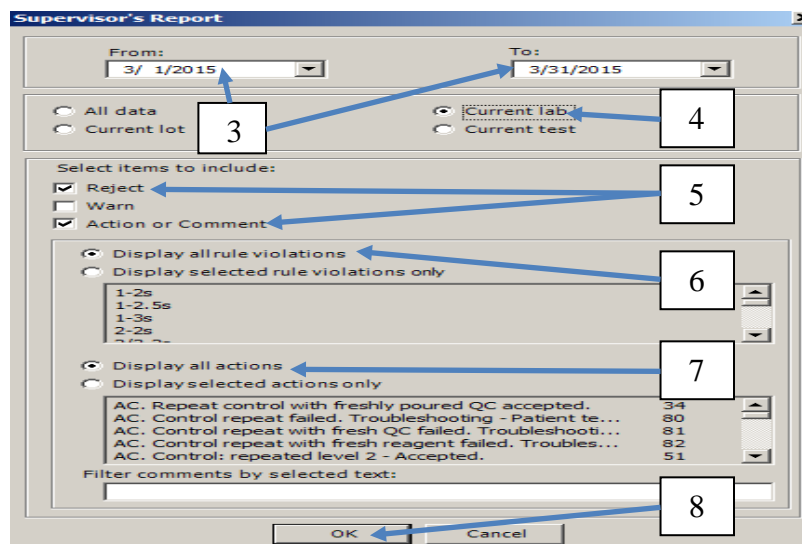
1. **To print any report**, first the “Reports” tab needs to be activated.
 - a. Go to desired lab number
 - b. Select desired or a random lot number
 - c. High light desired or a random test



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



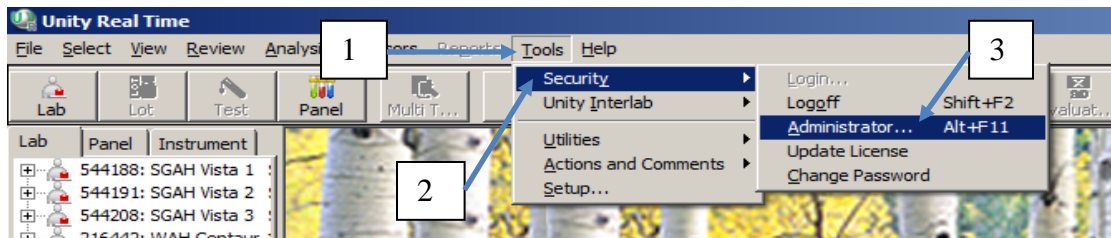
- c. Select the desired date
- d. Always select **Current Lab**
- e. Check both **Reject** and **Action or Comment**
- f. Select **Display all rule violations**
- g. Select **Display all actions**
- h. Select **OK**



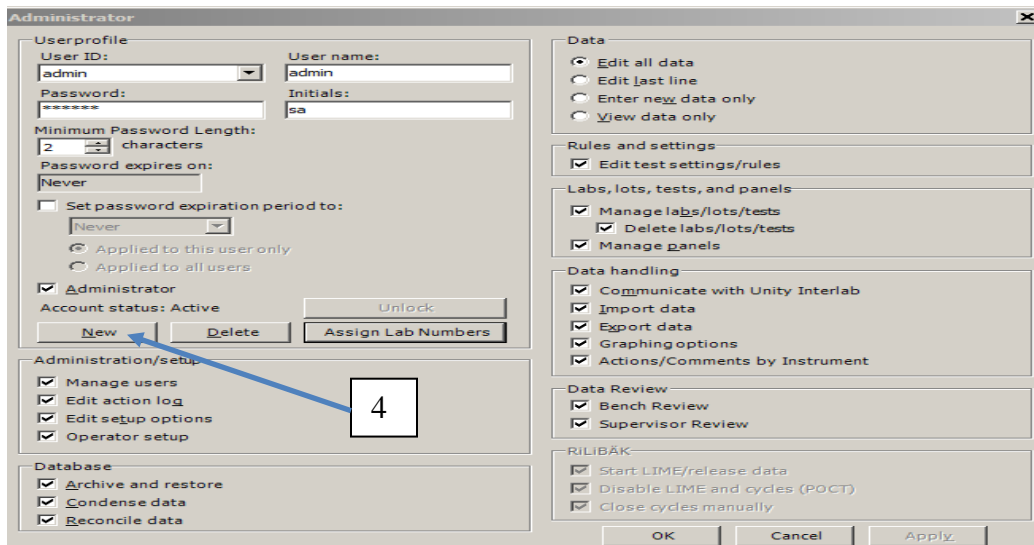
I. To add or edit employee information: (Supervisors Only)

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):

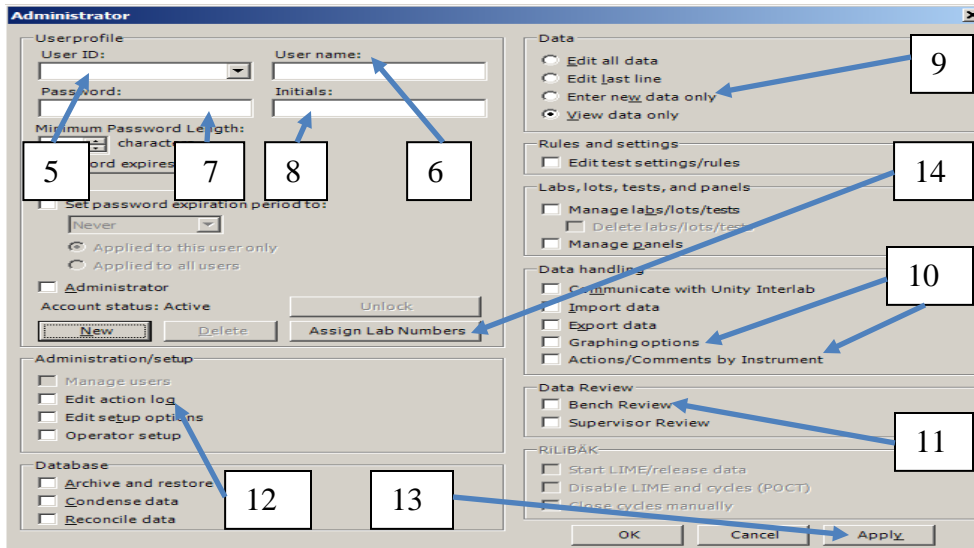
1. Select **Tools** tab
2. Select **Security**
3. Select **Administrator**



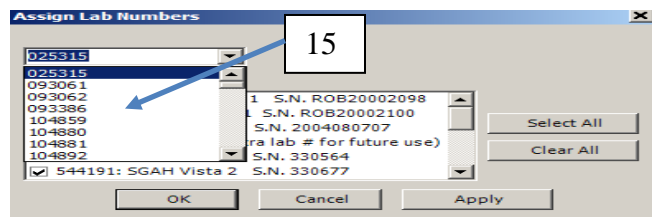
4. To add a new employee information select **New**



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**



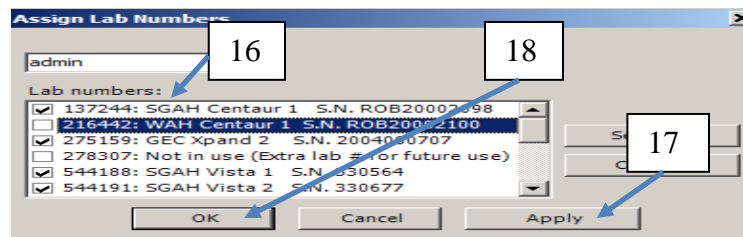
15. Select the employee number of the individual to be edited



16. Assign desired **Lab numbers**

17. Select **Apply**

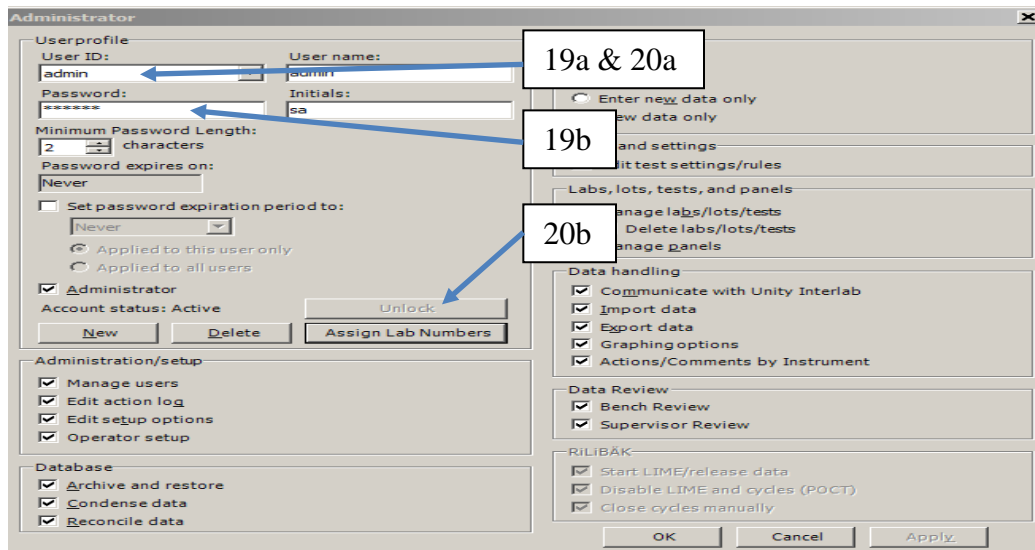
18. Select **OK**



19. If an employee forgets his/her password and cannot log into Unity Real Time:

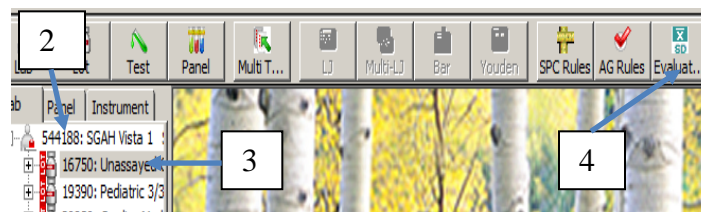
- a. Repeat steps 1-3 and select the correct employee
- b. Provide a temporary password to the employee
- c. Select OK (When the employee logs back in the Unity Real Time, it will ask them to reset their password)

20. 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:
- Repeat steps 1-3 and select the correct employee
 - 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.

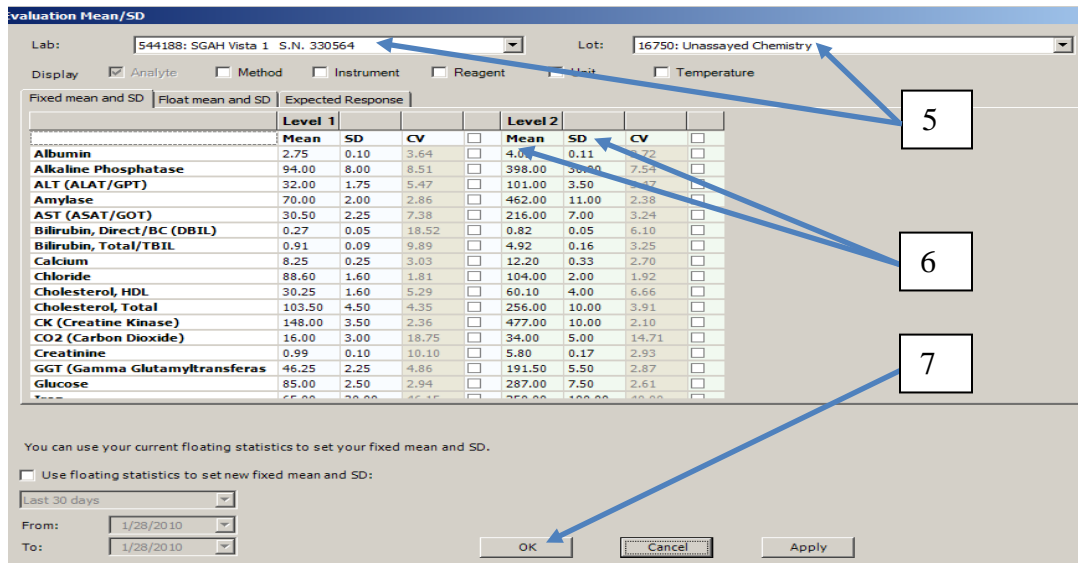


J. Adjusting QC ranges:

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



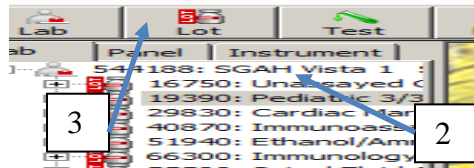
- Double check the **Lab** and **Lot** number
- Adjust the QC ranges by simply typing the new **Mean** and **SD**
- Select **OK**



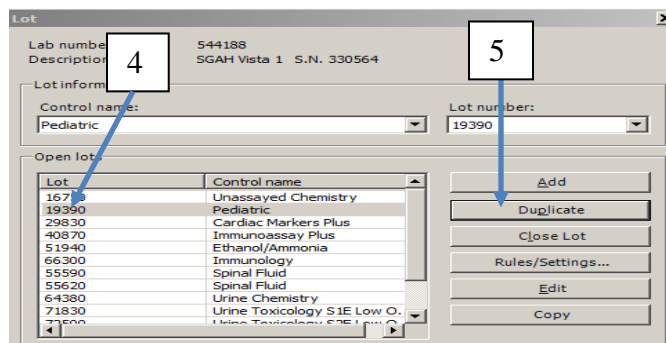
K. Managing (adding and closing) lot numbers

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.**

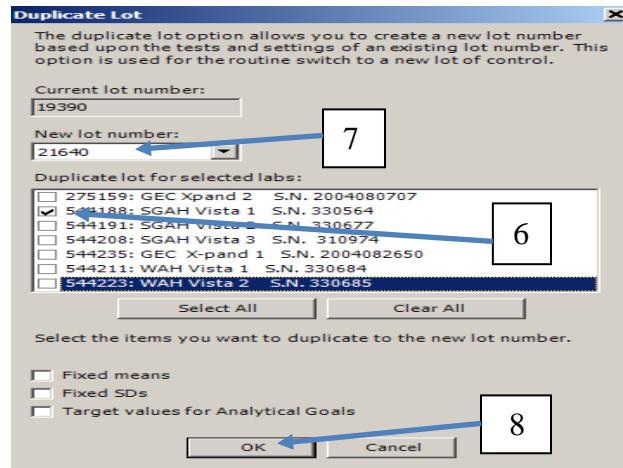
1. Go to main page (refer to section 5.2.A)
2. Select the desired lab
3. Select **Lot** tab



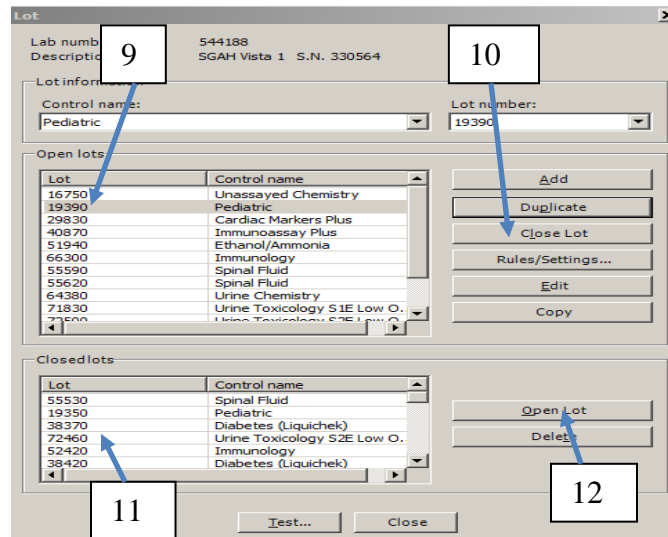
4. To open a new lot, select the current lot of QC in use
5. Select Duplicate



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



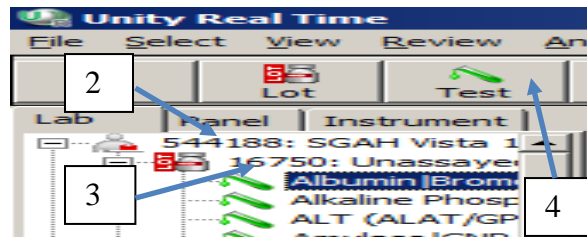
9. To close a lot, select the desired lot
10. Select **Close Lot**
11. To reopen a closed lot, select the desired lot
12. Select **Open Lot**



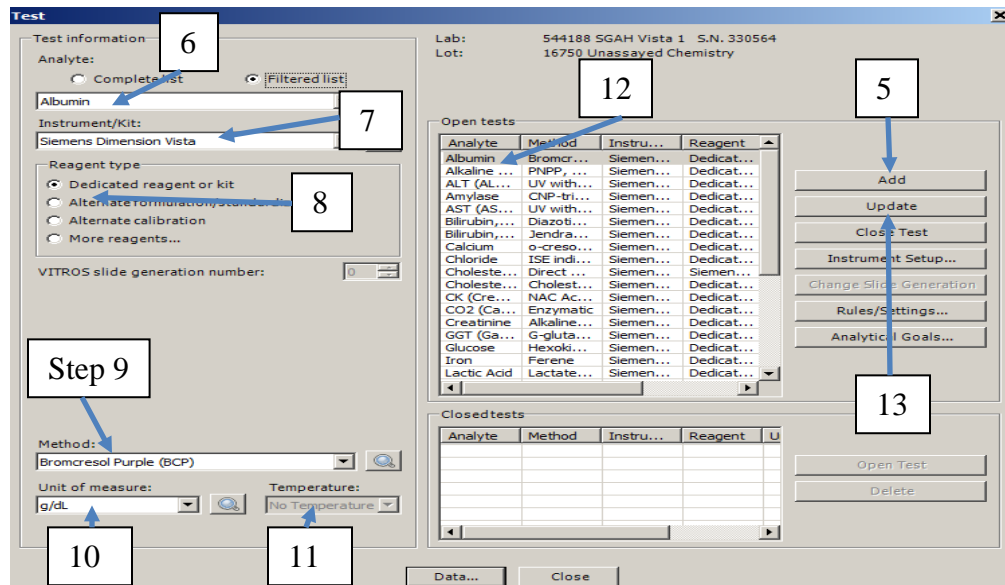
L. Managing Tests

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



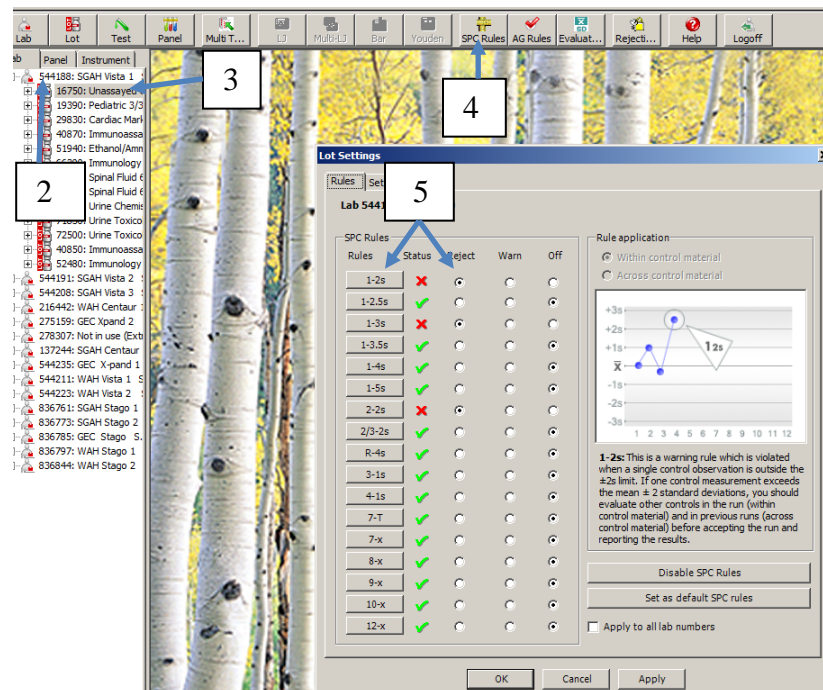
5. To add a new test, Select Add
6. Select desired Test
7. Select desired Instrument
8. Select desired Reagent
9. Select desired Method
10. Select desired Units of Measure
11. Select desired Temperature
12. To update a current test, highlight the desired Test
13. Select Update and repeat steps 7 through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

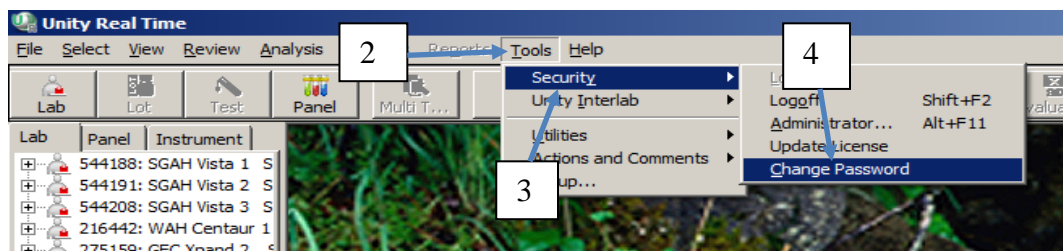
1. Go to main page (refer to section 5.2.A)
2. Open the desired **Lab**
3. High light the desired **Lot**
4. Select **SPC Rule** tab
5. Select the desire rules



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.

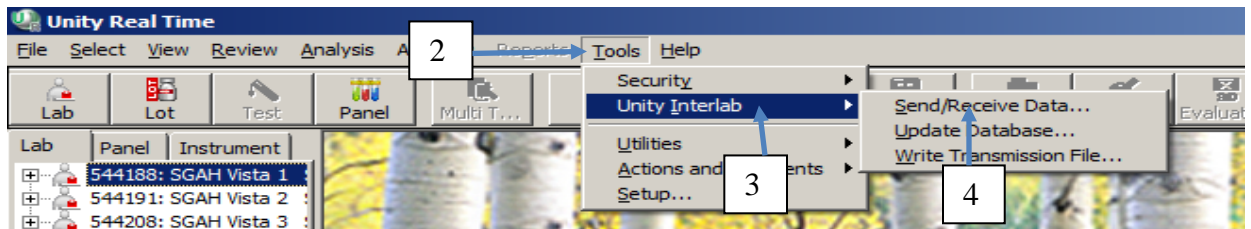
1. Go to main page (refer to section 5.2.1)
2. Select **Tools**
3. Select **Security**
4. Select **Change Password**



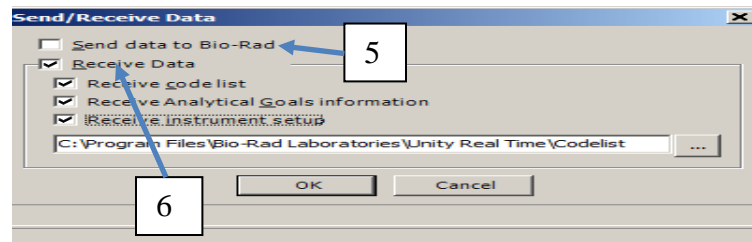
5.3 Communication with Bio-Rad:

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**



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 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_YYMMDDHHMMSS.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

9. ADDENDA AND APPENDICES

N/A