## TRAINING UPDATE

Lab Location: Department: GEC, SGMC & WAH 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 SOPSection 4: add Z-scoreSection 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.

#### Non-Technical SOP

## Approved draft for training (version 1)

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 = Observed Result - 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.



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

Rejected Rule			Acti	on Log				
		• 😐						$\sim$
435 4/4/2015 5:49 PM			4.95	Y 🖵	0.10	IM I	<i>A</i> .	C
436 4/5/2015 1:56 AM	▼ 0.94	× ·	0.33			IM T	A	C
437 4/5/2015 9:57 AM	<ul> <li>1.17</li> </ul>	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	A.	C
439 4/5/2015 12:36 PM	▼ 0.92	¥ 🖵	0.11 5.07	¥ -	0.94	IM I	A.	C
440 4/E/201E E-E1 DM			E 16	~ -	1 50	The W	375	~

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

Action Log Lab: 544188 SCAH Vista 1 S.N. 330564 Lob: 16750 Unassayed Chemistry	<u>×</u>	
Field unit datify a service a ser	Code	List of Actions
AC. Repeat control with freshly poured QC accepted.	34	
AC. Control repeat failed. Troubleshooting - Patient testing suspended.     AC. Control repeat with fresh OC failed. Troubleshooting - Patient testing suspended.	80	
AC. Control repeat with fresh reagent failed. Troubleshooting - Patient testing suspendeus.	82	
✓ AC. Control: repeated level 2 - Accepted.	51	
✓ AC. Control: repeated level 1 - Accepted.	50	
AC. Control: repeated level 3 - Accepted.	52 💌	
The red check indicates that an action has been used and cannot be deleted or updated. Existing action: AC. Test/assay repeated QC in range. (ZS - 4/5/2015 10:19:33 AM)		Apply
Apply Close		_

- 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.

	Set Date Group								I	= Test In	ion	A	= Actio	'n	
				Lev	el 1				Lev	el 2					
	Date &	Time	Value	Y/N	Rules	z	Value	Y	/N	Rules	z	OP			
423	4/1/2015 6:01	PM 👻					5.06	Y	-		0.87	IM	II.	A	
424	4/2/2015 1:52	M 🖵	0.94	Y -		0.33						IM	II.	A	
425	4/2/2015 9:53	AM 🔽	0.92	Y -		0.11	5.00	Y	-		0.50	IM	II.	A	
426	4/2/2015 12:47	PM 🚽	0.93	Y -		0.22	5.01	Y	-		0.56	IM	II.	A	
427	4/2/2015 5:54	PM 🔽					5.05	Y	-		0.81	IM	I.		
428	4/3/2015 1:51	AM	0.92	Y -		0.11						IM	II.	A	
429	4/3/2015 9:54	AM 🗣	0.95	Y -		0.44	5.07	Y	-		0.94	IM	II.	A.	
430	4/3/2015 12:41	PM 👻	0.95	Y -		0.44	5.08	Y	-		1.00	IM	I.		
431	4/3/2015 5:54	PM 👻					4.98	Y	-		0.38	IM	I		
432	4/4/2015 1:50	AM 👻	0.94	Y -		0.33						IM	I	A	
433	4/4/2015 10:00	AM 👻	0.94	Y 🖵		0.33	5.01	Y	-		0.56	IM	I.		
434	4/4/2015 12:42	PM 👻	0.92			0.11	5.00	Y	-		0.50	IM	I		
435	4/4/2015 5:49	PM 👻	]				4.95	Y	-		0.19	IM	I	A	
436	4/5/2015 1:56	AM 👻	0.94	Y 💽		0.33						IM	I.		
437	4/5/2015 9:57	AM 👻	1.17	N -	1 25	2.89	5.17	Y	-		1.56	IM	I	<u> 75</u> +	
438	4/5/2015 10-12	AM -	0.04	× -		0.33						TM	10	375	

## 2. Adding a comment

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

 1211 1/2/2010 1002 000						4111		-	$\sim$
425 4/2/2015 9:53 AM	▼ 0.92	Y - 0.11	5.00	Υ 🖵	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	-		05	¥ 🖵	0.81	IM	I	A	C
428 4/3/2015 1:51 AM	0.02							1000	-
	· 0.52	L Omment				1000			
429 4/3/2015 9:54 AM	• 0.95	Comment	07	Y 💌	0.94	IM	I	A	C
429 4/3/2015 9:54 AM 430 4/3/2015 12:41 PM	<ul> <li>▼ 0.92</li> <li>▼ 0.95</li> <li>▼ 0.95</li> </ul>	Comment	07 08	Y - Y -	0.94	IM IM	I	A A	000

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

Comment		X
Lab: 544188 SGAH Vista 1 S.N. 3: Lot: 16750 Unassayed Chemistry Test: Albumin, Bromcresol Purple (t	30564 3CP), Siemens Dimension Vista, Dedicate	d Reagent, g/dL, No Temperature
Existing comment:		
	Comment	E E
New comment:		
1	+	<u>–</u>
OK	OK Canc	el

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

		Save Set I			Save Set Date Group						I = Test Information					严 = Action				
Т		F1						Lev	el 1			Level 2								
			D	ate & Tim	e	Value	Y	/N	Rules	z	Value	<b>Y</b>	/N	Rules	z	OP				
	423	4	/1/201	5 6:01 PM	-						5.06	Y	-		0.87	IM	I	A	C	
	424	4	/2/201	5 1:52 AM	-	0.94	Y	-		0.33						IM	II.	A	C	
	425	4	/2/201	5 9:53 AM	-	0.92	Y	-		0.11	5.00	Y	-		0.50	IM	II.	A	C	
	426	4	/2/201	5 12:47 PM	-	0.93	Y	-		0.22	5.01	Y	-		0.56	IM	I	A	C	
	407	-	(2/201	5 5:54 PM	-						5.05	Y	-		0.81	IM	II.	A	C	
	6			5 1:51 AM	-	0.92	Y	-		0.11						IM	II.	A	C	
		a	ve	5 9:54 AM	-	0.95	Y	-		0.44	5.07	Y	-		0.94	IM	I	A	C	
	~			5 12:41 PM	-	0.95	Y	-		0.44	5.08	Y	-		1.00	IM	I	A.	C	
	431	4	/3/201	5 5:54 PM	-						4.98	Y	-		0.38	IM	II.	A	C	
	432	4	/4/201	5 1:50 AM	-	0.94	Y	-		0.33						IM	I	A	C	
	433	4	/4/201	5 10:00 AM	-	0.94	Y	-		0.33	5.01	Y	-		0.56	IM	I	A.	C	
1	434	4	/4/201	5 12:42 PM	-	0.92	Y	-		0.11	5.00	Y	-		0.50	IM	I	AL.	C	
	435	4	/4/201	5 5:49 PM	-						4.95	Y	-		0.19	IM	I	<u>75.</u>	C	
	436	4	/5/201	5 1:56 AM	-	0.94	Y	-		0.33						IM	II.	<u>75.</u>	C	
	437	4	/5/201	5 9:57 AM	-	1.17	N	-	1-25	2.89	5.17	Y	-		1.56	IM	I	<b>A</b> +	C	
	420	-	10.000	5 10-10 AM		0.04	20			0.00						75.4	100	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
- 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.

Options	×
General Levey-Jennings Header Lines Graph Against Your laboratory Current strument Content struments	Consensus group
Your Laboratory	© 1 Month © 6 Months © Cumulative Date
C Evaluation Mean/SD Completive Date range From: 2/17/2006 To: 2/17/2006 C C 2/5core	
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

	1	🚇 Unity	y Real Tim	e						
Review		<u>Eile Se</u> l	ect View	Review	<u>A</u> nalysis	A <u>d</u> visors	Reports	Tools	<u>H</u> elp	Bench
		🔔 Lab	Lot	Bend Super	n Review <	Cular: ew F2		₩ 1.1	wi Multi-LJ	Review
			Panel In: 544188: SGA 544191: SGA 544208: SGA	strument AH Vista 1 AH Vista 2 AH Vista 3 AH Contau	s s			1111		

- 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**.

	ata Re	eview														٦				
	<u></u>		Lab	<u>A</u> ll data						1	.a <u>b</u> nu	mber: (A	<sup>II)</sup>		6			•		
	-	-		• Include rule	violations or da	ta with Actio	on or Com	ments			Lo <u>t</u> nu	mber: 🚺	II)		0			-		
	i i i		Panel								Instru	ment:						-		
1		Ter et		🗴 Include only	rule violations						-		K					_		
		Inst	ruipent	Include on a	AG violations										7				11	)
															'				14	-
	Rev	lewed		Refresh eve	ery 10 🚊 se	icunds								L		-				_
	Τ.									D 1 /2		Loc 1	le to a			1	0.1			
H	R	eviewed	Lab Numbe	er Lot Tumber	Control 1 ame	Instrument	Analyte	Method	Reagent	Date/Time	Level	Value	Evaluation Mea	an Evoluatio	0	uies	Status	By Action	Comment Rev	newed By Date
H			544235	101054	ACT 10, ADm	Beckman C	Placelet	Other	Dedicate	2/21/2015	1	92.00	79.00	2.75	ð		Accept	BV AC. CO	AC AC	4/8/2
		1	544225	101054	Blood Gas Lev	Abothist	pC02	Other	Dedicate	2/21/2015	1	22.60	22.70	2.15			Accept	sc	lot o lot c AC	4/9/2
			544235	101054	Blund Gas Lev	Abbott ST	peo2	Other	Dedicate	3/31/2015	1	7.02	7.03	0.03	-0.0		Accept	sc	let to lot c AC	4/8/2
H	- '	N.	544235	21054	Bloop Gas Lev	Abbott i-S	DH	Other	D. dicate	3/31/2015	1	7.77	7.76	0.03	0.24		Accept	GC	ot to lot c AC	4/8/2
		7	544235	1 1054	Blood G is Lev	Abbott i-ST	0.02	Other	Dedicite	3/31/2015	1	84.00	87.00	7.50	-0.4		Accept	GC .	lot to lot c AC	4/8/2
		7	544235	12.054	Blood Gas ev	Abbott i-ST	pO2	Other	Dedicate	/31/2015	1	151.00	148.00	11.25	0.27		<ul> <li>Accept</li> </ul>	GC	lot to lot c AC	4/8/2
		1 7	235	00000	ACT 10 AL	n C	MOV	Other	Dedicate	A(E) 01E 1	1	82.00	76.30	2.00	2.85	1-25	Reject	BV AC. Co	ENTERIN AC	4/8/2
		10	235	4	ACT :	in C	0		Dedica	1 5		76.00	76.30	2.00	-0.1		<ul> <li>Accept</li> </ul>	BV AC. Pa	AC	4/8/2
		13	235	4	BNPI 🕽	i-ST	9		Dedica	15		97.00	108.00	23.50	-0.4		Accept	JI	SAME LOT AC	4/8/2
			235		BNP I	i-ST			Dedica			2384.00	2697.00	480.00	-0.6		<ul> <li>Accept</li> </ul>	JI	SAME LOT AC	4/8/2
			544191	16750	Unassayed Ch	Siemens Di	ALT (AL	UV with	Dedicate	4/8/2015 1	2	108.30	101.00	3.50	2.09	1-25	Reject	IM AC. Te	AC	4/8/2
			544191	16750	Unassayed Ch	Siemens Di	CK (Cre	NAC Act	Dedicate	4/8/2015 1	2	500.10	477.00	10.00	2.31	1-25	Reject	IM AC. Te	AC	4/8/2
			544188	40870	Immunoassay	Siemens Di	Gentam	Immun	Dedicate	4/8/2015 1	3	9.23	8.20	0.43	2.40	1-25	Reject	IM AC. Te	AC	4/8/2
H			544208	16750	Unassayed Ch	Siemens Di	ALT (AL	UV with	Dedicate	4/8/2015 4	1	28.40	32.00	1./5	-2.0	1-25	Reject	IM AC. Te	AC	4/8/2
			544226	16750	Unassayed Ch	Siemens Di	Chloride	TCE indi	Dedicate	4/9/2015 4	1	93.70	96.00	1.25	-1.5	1.201	Reject	M AC D	AC	4/0/2
			544235	16750	Unassayed Ch	Siemene Di	Chloride	ISE indi	Dedicate	4/8/2015 9	2	104.23	107.00	1.50	-3.2	1-001	Pajact		AC	4/8/2
E		<b>V</b>	544235	16750	Unassaved Ch	Siemens Di	Potassi	ISE indi	Dedicate	4/8/2015 9	1	3.71	3.97	0.06	-4.3	1-35	Reject	IM AC. Re	AC	4/8/2
		7	544235	16750	Unassaved Ch	Siemens Di	Potassi	ISE indi	Dedicate	4/8/2015 9	2	6.52	6.45	0.10	0.70		Reject	IM AC. Re	AC	4/8/2
		•	544235	16750	Unassayed Ch	Siemen		indi	Dedicate	4/8/2015 9	1	116.41	123.00	1.45	-4.5	1-35	Reject	M AC. Re	AC AC	4/8/2
		•	544235	16750	Unassayed Ch	Siemen	11	indi	Dedicate	4/8/2015 9	2	149.71	153.00	1.60	-2.0	2-25	Reject	IM AC. Re	AC	4/8/2
		~	544235	40870	Immunoassay	Siemen	11		Dedicate	4/8/2015 9	1	0.61	0.65	0.07	-0.5		Reject	IM AC. Re	AC AC	4/8/2
		~	544235	40870	Immunoassay	Siemens DI	-	EIA	Dedicate	4/8/2015 9	2	4.58	5.25	0.42	-1.6		Reject	IM AC. Re	AC AC	4/8/2
			544235	40870	Immunoassay	Sieme to Di	TSH	EIA	Dedicate	4/8/2015 9	3	24.20	29.50	2.10	-2.5	1-25	Reject	IM AC. Re	AC AC	4/8/2
		<b>v</b>	544235	51960	Ethanol/Amm	Siemens Di	Ethanol	E. tyma	Dedicate	4/8/2015 9	1	36.24	39.70	3.10	-1.1		Reject	IM AC. Re	AC AC	4/8/2
			544235	51960	Ethanon/Amm	Siemens Di	Ethanol	Enzyn a	Dedicate	4/8/2015 9	2	88.14	97.00	6.50	-1.3		Reje	M AC D	AC	4/8/2
			544235	51960	Ethanol/Amm	Siemens Di	Ethanol	Enzyma	Pedicate	4/8/2015 9	3	231.40	260.00	13.00	-2.2	1-25	Reje	11	AC	4/8/2
			544188	400.0	Immunoassay	Siemens Di	T4, Fre	Chemilu	Deu cate	4/8/2015 9	1	0.99	1.05	0.05	-1.2		Reje	14	AC	4/8/2
			544188	40870	Immunoassay	Siemens Di	14, Fre	Enzyme	Ciamora	4/8/2015 9	3	5.20	5.60	6.15	-2.0	1-25	Reje	M C C	AC	4/8/2
H			544188	51940	Ethanol/Amm	Siemens Di	Ammoni	Enzyma	Siemens	4/8/ 015 1	3	313.00	310.00	13.00	4.08	1-001	Reject	IM AC CO	AC	4/8/2
	4		544235	40870	Immunoassav	Siemens Di	TSH	FIA	Dedicate	4/8/2015 1	3	24.84	29.50	2.10	-2.2	1-251	Reject	IM AC. R	AC 4C	4/8/2
Ĺ					2	a since of			_ concolle				23100				- majort	ALC: NO	AC	1,3/2
												69 10	cordo					T		
1												Job re	corus					L		
	Ma	anage Co	Jumns	Manage Ex	pected Tests								Go to Data Entry	1		art	1	Save	1	
_																_				

## 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**.

Lab	Panel	Instrument	Lab	: 54418	88 SGAH Vista 1 S.N. 3	3056	4 Lot: 1	675	50 <b>r · ·</b>			Mati	rix:	erum					
	544188: S	GAH Vista 1 🔺	Tes	Test: Albumin, Bromcresol Purple (BCP), Siemens Dimer Expires: 4/30/2016 Rules: 1-26 1-36 2-26 Chore A								erature							
	16750	): Unassaye	Exp	ares: 4	730/2018 Rules: 1-2	\$ 1-5	5 2-25			Ster	04								
	- 🔨 Al	bumin Brom			Save	Set	Date						1	= Test I	nformati	ion	A	= Actio	n
	🔨 Al	kaline Phosp							_			_							
	- 🔨 AL	LT (ALAT/GP							Lev	el 1				evel 2					
	Ar	mylase CNP-			Date & Time		Value	Y	/N	Rules	z	Value	Y/	N Rules	z	OP			
	A 🔨	ST (ASAT/GC		434	4/3/2015 9:48 AM	-	2.77	Y	-		0.20	4.01	Y	-	-0.36	IM	I	A	C
	BI	lirubin, Direc		435	4/3/2015 12:28 PM	-	2.70	Y	-		-0.50	3.97	Y	-	-0.73	IM	I	A	C
	BI	iirubin, Totai		436	4/3/2015 5:43 PM	-	]					4.01	Y	-	-0.36	IM	I	A	C
		alcium jo-cre:		437	4/4/2015 1:48 AM	-	2.72	Y	-		-0.30					IM	I	A	C
		holesterol H		438	4/4/2015 9:52 AM	-	2.68	Y	-		-0.70	4.03	Y	-	-0.18	IM	I	A	C
	A d	holesterol, T		439	4/4/2015 12:28 PM	-	2.68	Y	-		-0.70	3.95	Y	-	-0.91	IM	I	A	C
	A G	K (Creatine )		440	4/4/2015 5:46 PM	-	]					3.98	Y	-	-0.64	IM	I	A	C
	CC	O2 (Carbon		441	4/4/2015 6:36 PM	-	2.79	Y	-		0.40	4.04	Y	-	-0.09	IM	I	A	C
	- A Cr	reatinine Alk		442	4/5/2015 1:47 AM	-	2.74	Y	-		-0.10					IM	I	A	C
	G	GT (Gamma		443	4/5/2015 9:49 AM	-	2.73	Y	-		-0.20	4.10	Y	-	0.45	IM	I	A	C
	GI	ucose Hexo		444	4/5/2015 12:31 PM	-	2.69	Y	-		-0.60	3.98	Y	-	-0.64	IM	I	A	C
	In In	on Ferene S		445	4/5/2015 5:42 PM	-	]					4.00	Y	-	-0.45	IM	I	A	C
	- 🔨 La	actic Acid La		446	4/6/2015 1:45 AM	-	2.71	Y	-		-0.40					IM	I	A	C
	🔨 LC	D (Lactate D		447	4/6/2015 9:49 AM	-	2.74	Y	-		-0.10	4.01	Y	-	-0.36	IM	I	A	C
	🚽 🔨 Lip	pase Colorin		448	4/6/2015 12:23 PM	-	]					4.02	Y	-	-0.27	IM	I	A	C
	- 🔨 Lit	thium Colorir		449	4/6/2015 12:54 PM	-	2.71	Y	-		-0.40					IM	I	A	C
	- 🔨 M	agnesium M		450	4/6/2015 5:44 PM	-	1					4.05	Y	-	0.00	IM	I	A	C
	- <b>^ o</b>	smolality Fre		451	4/7/2015 1:45 AM	-	2.75	Y	-		0.00					IM	I	A	C
	Pł	nosphorus P		452	4/7/2015 9:49 AM	-	2.74	Y	-		-0.10	4.09	Y	-	0.36	IM	I	A	C
	PC No	otassium ISE		453	4/7/2015 12:30 PM	-	2.71	Y	-		-0.40	4.01	Y	-	-0.36	IM	I	A	C
	Pr	otein, Total		454	4/7/2015 5:45 PM	-	i					4.02	Y	-	-0.27	IM	I	A	C
	Sc Sc	odium ISE ini		455	4/8/2015 1:42 AM	-	2.73	Y	-		-0.20			_		IM	Ī	A	č
		BC (Total Ire		456	4/8/2015 9:50 AM	-	2.74	Y	-		-0.10	4.08	Y	-	0.27	IM	Ī	A	Č
	Tr North	riglycerides [t		457	4/8/2015 12:25 PM	-	2.75	Ŷ	-		0.00	4.05	Ŷ	- -	0.00	IM	Ť	A	č
		rea Nitrogen		458	4/8/2015 5:39 PM	-	1					4.09	Y	-	0.36	IM	T	A	č
	BE 10200	N Dediatric 3		459	4/9/2015 1:42 AM	-	2.75	Y	-		0.00			_		TM	Ť	-	č
	19390	Cardiac M		460	4/9/2015 9:50 AM		2.75	Ŷ			0.00	4.11	Y	-	0.55	TM	Ť	10	č
	40870	): Immunoac		461	4/9/2015 12:28 PM		2 77	Ŷ			0.20	4.08	Y	-	0.27	TM	Ť	25	č
	51940	: Ethanol/A		462	4/9/2015 5:44 PM		1		<u> </u>		0.20	3.99	×	-	-0.55	TM	Ť	25	č
L L	66300	): Immunolor		463	4/10/2015 1:44 AM	-	2 74	~			-0.10	5.55		-	0.55	TM	- Ť	25	č
E E	55590	): Spinal Elui		464	4/10/2015 8·28 AM	-		1			0.10					A1-1	÷	25	č
-	55620	): Spinal Flui	<u> </u>		11201201200120701			·				-	_		_	_			
÷.	64380	: Urine Chei	Poi	nt Data	Summary Data							7							
÷.	71830	): Urine Toxi																	
÷.	72500	): Urine Toxi	Sta	tistics	Chart														
	40850	): Immunoas				1							1		1				
÷	52480	): Immunolog	Su Su	ımmar	y Statistics		Month		C	umulati		Month		Cumulat	ive				
🖻 " 🚵	544191: S	GGAH Vista 2	4/	10/20	15 8:28:13 AM			-		_		_							
🖻 🖓 🦾	- 544208: SGAH Vista 3 Mean		2.	72		2.74	+ 0				.04								
P 🖗	216442: V	WAH Centau	SI SI			0.	03		0.04	+ S	tep	2	(	.06					
P 🖗	275159: 0	SEC Xpand 2	<u></u>	·		1.	28		1.47	7	· · r		1.43						
12 🔶	278307: N	vot in use (E	<u>P</u> o	oints		30			335		2.			37					
1200	13/244: S	GARI Cental																	
12.9	544211+ V	ALL Viete 1	Cu	rrent F	fixed Mean/SD/CV		2.75	<b>;/0</b> .	.10/	3.64		4.05	5/0.	1/2.72					

## **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

visors	Reports Tools	<u>H</u> elp						
5	Data Review	Alt+F10		🖢   🕀   🏪   🛩				
Multi	General		•	ar Vouden SDC Dules AC Dujes				
100	Supervisory		•	Supervisor's Report_Ctrl+F10				
Care -	Charts	<b>t</b>	►	Operator Report				
-	<u>A</u> udit Trail		-	NOR ALL REAL PROPERTY OF THE				
	<u>R</u> iLiBÄK Report	5	⊧	7.9 8 8 4 1 1				
and the second	Listings		►					
100	Configure							
	Contraction of the local distribution of the		1.1					
1	100 March 100 Ma	>1	3					

- 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

From: 3/ 1/2015	To: 3/31/2015	
C All data C Current lot 3	Current lab Current test	
Select items to include: Reject Warn Action or Comment	5	
Display all rule violations     Display selected rule violations     1-2s     1-2.5s     1-3s     2-2s     2/2.2s		
O isplay all actions     Display selected actions only     AC. Repeat control with freshly p     AC. Control repeat failed. Trouble     AC. Control repeat with fresh QC	7 Dured QC accepted. 34 shooting - Patient te 80 failed. Troubleshooti 81	3
AC. Control repeat with fresh rea AC. Control: repeated level 2 - Ac Filter comments by selected text:	gent failed. Troubles 82 scepted. 51	

- 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

🚇 Unity Real Time		
<u>File Select View Review Analysi</u>	Tools Help	3
	Security >	Login
Lab Lot Test Panel	Multi T	Logoff Shift+F2 valuat
Lab Panel Instrument	Utilities 🕨	Administrator Alt+F11
F	Actions and Comments 🕨	Change Dagsword
544191: SGAH Vista 2	2 2 <u>S</u> etup	
🗄 🚡 544208: SGAH Vista 3 🕴		
亩為 216442• W∆H Centaur 1	RO RO	

4. To add a new employee information select New

Administrator	×
User profile User name: admin Password: Initials: sa	Data Edit all data Edit last line Enter new data only View data only
Minimum Password Length: 2	Rules and settings         Image: Edit test settings/rules         Labs, lots, tests, and panels         Image: Index labs/lots/tests         Image: Delete labs/lots/tests </td
Account status: Active Unlock           New         Delete         Assign Lab Numbers           Administration/setup         Administration/setup         Administration/setup	Import data     Export data     Graphing options     Actions/Comments by Instrument
Image users       Image users <t< td=""><td>Data Review           Ø Bench Review           Ø Supervisor Review           BILBAK</td></t<>	Data Review           Ø Bench Review           Ø Supervisor Review           BILBAK
Database          Image: Condense data         Image: Condense data         Image: Condense data         Image: Condense data	Image: Start LIME/release data         Image: Disable LIME and cycles (POCT)         Image: Close cycles manually         OK       Cancel

- 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:
  - 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.

Administrator	×
User profile User name: admin	19a & 20a
Password:     Initials:       Password:     sa       Minimum Password Length:     sa       2     characters       Password expires on:     Never       Set password expiration period to:     Never       Set password expiration period to:     Never       © Applied to this user only     Applied to all users       Ø Administrator     Account status: Active       New     Delete	C Enter new data only         ew data only         and settings         it test settings/rules         Labs, lots, tests, and panels         20b         Delete labs/lots/tests         nage panels         Data handling         ✓ Communicate with Unity Interlab         ✓ Import data         ✓ Export data
Administration/setup  Manage users  Edit action log  Edit setup options  Operator setup  Database  Archive and restore  Condense data  Reconcile data	Image: Construction of the second

## 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

adation mean/30										
Lab: 544188: SGAH Vista 1	S.N. 3305	i64 🗲			-	Lot:	16750	Unassa	ayed Chemistry	-
Display 🖾 Analyte 🗖 Metho	d 🗖 I	nstrument		Reage	nt i	11-11		Temper	ature	
Fixed mean and SD Float mean and SD	Expected	d Response	:)							
	Level 1				Level 2				5	
	Mean	SD	cv		Mean	SD 🚽	cv		C	
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		6	
Chloride	88.60	1.60	1.81		104.00	2.00	1.92		Ŭ	
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		7	
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			
*	CE 00	20.00	AC AC	-	252.00	100.00	40.00	-		
You can use your current floating statist	ics to set d mean an	your fixed d SD:	mean an	d SD.						
Last 30 days 💌										
From: 1/28/2010 -										
T-1 (20 (20 10 )						1		-	Analy.	
1/28/2010					OK		Cano	ei	Apply	

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

ab numbe escription	544188 SGAH Vista 1 S.N. 330564	5
4		
.ot inform		
Control name:		Lot nur ber:
Pediatric		19390
2		
penious		
Lot	Control name	
Lot 167	Control name Unassayed Chemistry	<u>A</u> dd
Lot 167.0 19390	Control name Unassayed Chemistry Pediatric	Add Duglicate
Lot 167 9 19390 29830	Control name Unassayed Chemistry Pediatric Cardiac Markers Plus	Add Du <u>p</u> licate
Lot 167 9 19390 29830 40870	Control name Unassayed Chemistry Pediatric Cardiac Markers Plus Immunoassay Plus	Add Duglicate Close Lot
Lot 16710 19390 29830 40870 51940	Control name Unassayed Chemistry Pediatric Cardiac Markers Plus Immunoassay Plus Ethanol/Ammonia	Add Duglicate Close Lot
Lot 167 19390 29830 40870 51940 66300	Control name Unassayed Chemistry Pediatric Cardiac Markers Plus Immunoassay Plus Ethanol/Ammonia Immunology	Add Duglicate Close Lot Bules/Settings
Lot 167 19390 29830 40870 51940 66300 55590	Control name Unassayed Chemistry Pediatric Cardiac Markers Plus Immunoassay Plus Ethanol/Ammonia Immunology Soinal Fluid	Add Duglicate Close Lot Rules/Settings
Lot 167 0 19390 29830 40870 51940 66300 55590 55590 55520	Control name  Unassayed Chemistry Pediatric Cardiac Markers Plus Immunoassay Plus Ethanol/Ammonia Immunology Spinal Fluid Spinal Fluid	Add Duglicate Close Lot Rules/Settings
Lot 16755 19390 29830 40870 51940 66300 55590 55620 64380	Control name Unassayed Chemistry Pediatric Cardiac Markers Plus Ethanol/Ammonia Immunology Spinal Fluid Urine Chemistry	Add Duplicate Close Lot Rules/Settings Edit

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

Duplicate Lot
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
Duplicate lot for selected labs:
□ 275159: GEC Xpand 2       S.N. 2004080707         ♥ 541188: SGAH Vista 1       S.N. 330564         544191: SGAH Vista 2       S.N. 330677         □ 544208: SGAH Vista 3       S.N. 310974         6       544225: GEC X-pand 1         544221: 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

🍓 Unity Real Time		
<u>File Select View Review Analysis</u>	2 Reports Tools Help	4
Lab Panel Instrument	Security       Model T       Up by Interlab       Validities	Logoff Shift+F2 Administrator Alt+F11
	Actions and Comments	Update license Change Password
	AREA STORE	A

## 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 I	Real Tim	e				
<u>File</u> <u>S</u> elec	t <u>V</u> iew	<u>R</u> eview <u>A</u>	nalysis A	2	Tools Help	
8	55		777		Security	
Lab	Lot	Test	Panel	Multi T	Unity <u>I</u> nterlab	Send/Receive Data
Lab Pi	anel   Ins	strument	1			Update Database      Write Transmission File
🕀 🖓 🕀 🕂	4188: SGA	H Vista 1		and a little	Actions and 3 en	nts
🗄 🐴 54	4191: SGA	H Vista 2 🕴	643	ALC: NOT	Setup	
🗼 🚔 54	4208: SGA	AH Vista 3 🚦	10 m		a set and the set of the	

- 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.

Send/Receive Data
Send data to Bio-Rad 5 ✓ Receive Data ✓ Receive gode list ✓ Receive Analytical Goals information ✓ Receive Analytical Goals information ✓ Receive Instrument setup C: Vrograf Files Bio-Rad Laboratories Unity Real Time (Codelist)

## 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	<b>Reason for Revision</b>	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