

Bio-Rad Unity Real Time (URT)

Clément Arès Bio-Rad Laboratories (Canada) Ltd Senior Product Manager





What is Unity Real Time?



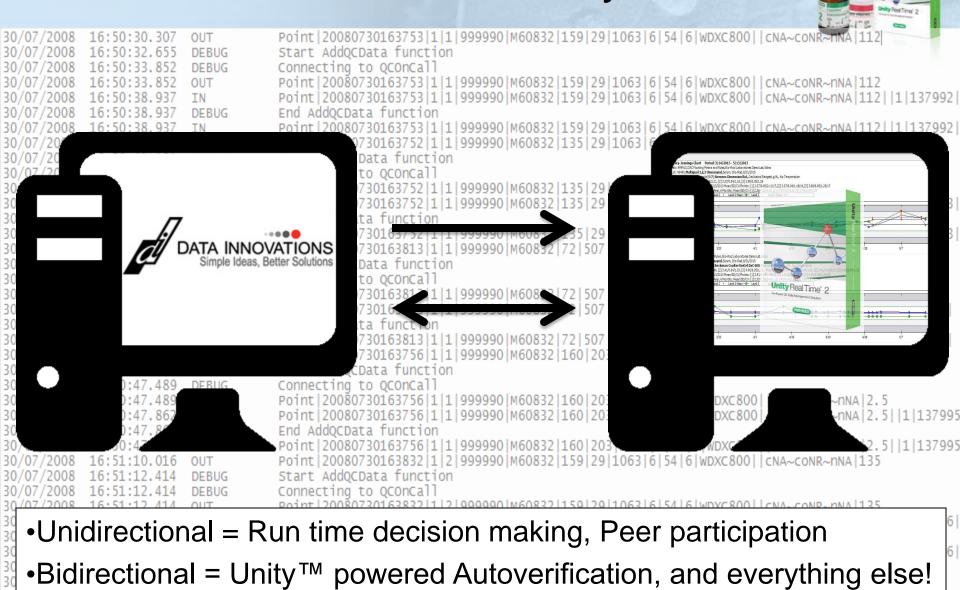


Don't Get Caught Standing Alone

- Unity Real Time . . .
 - QC data management program that provides statistical review, documentation and analysis across all controls used in the laboratory
 - Is a networkable QC program to cover every area in the lab
 - Analyzes all quality control data to assist the laboratory staff in completing their QC tasks per lab policy and regulations
 - Allows for external peer group analysis so you are not caught standing alone



Data Innovations Connectivity



707/2008 16:51:15.027 DEBOG COMMECTING to QCOMCATT
0/07/2008 16:51:15.027 OUT Point|20080730163832|1|2|999990|M60832|135|29|1063|6|54|6|WDXC800||cNA~coNR~nNA|5.0
0/07/2008 16:51:15.384 IN Point|20080730163832|1|2|999990|M60832|135|29|1063|6|54|6|WDXC800||cNA~coNR~nNA|5.0||1|137997|
0/07/2008 16:51:15.384 DEBUG End AddQCData function



Different connectivity options



	Data Innovations	LIS	Analyzer	Other Middleware
Additional Hardware	No	No	Yes	Yes/No
Real Time	Yes	No	Yes	Yes
Integrate w/ AutoVerification	Yes	No	No	No
Partnership with Bio-Rad	Yes	No	Siemens	No

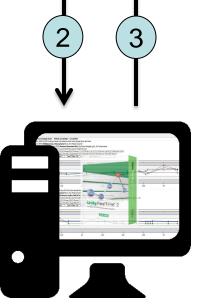


Auto-verification Workflow





- 1) QC Sent by Instrument
- 2) DI sends QC to URT
- 3) URT validates result & returns Pass/Fail and rules if failed



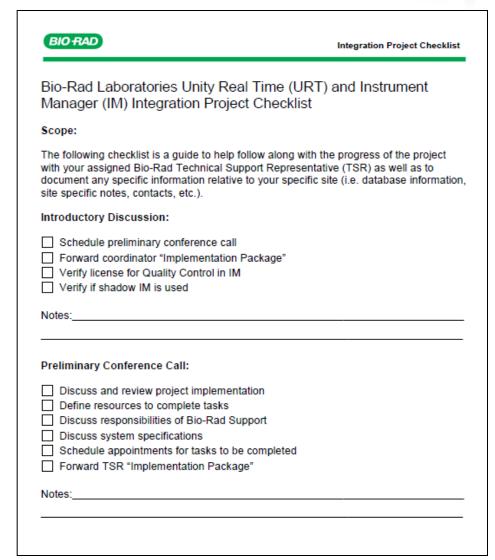
- a) If Pass: DI "automatically verifies" and releases result to LIS
- b) If Fail: DI holds results until manually released by Technician (after troubleshooting)



How is this implemented?



- You drive the schedule
- 100% Remote
- Introduction Conference Call
- 2. IT focused Conference Call
- 3. Unity Real Time installation
- 4. Connectivity Configuration
- Unity™ Training
- 6. Follow up Training



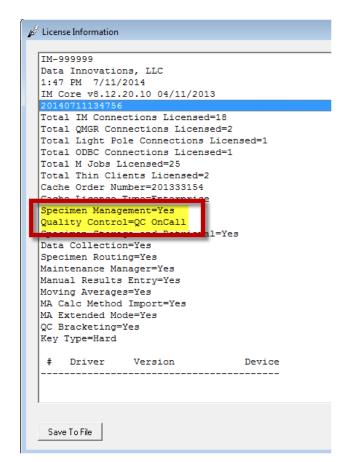


What do I need for Instrument Manager?



- For Instrument Manager:
 - ✓ Bi-directional QC Integration license *
 - √ Specimen Management license *
 - ✓ Unity Real Time "client" installed

- To determine if licensed
 - ✓ From the Instrument Manager menu,
 Reports → License Information

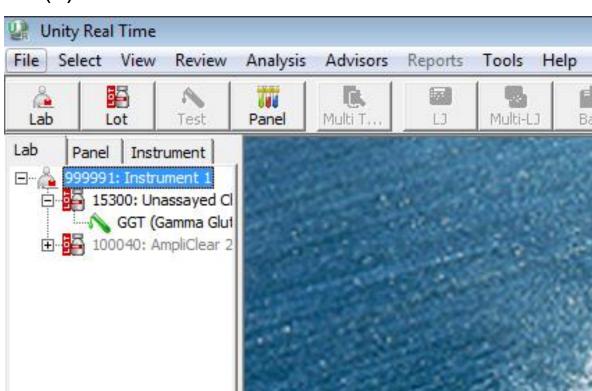




What do you need to have in URT?



- Unity Real Time
 - URT database on SQL Server on same LAN
 - URT configuration:
 - Unity Lab Number(s)
 - Instrument(s)
 - Control(s)
 - o Test(s)

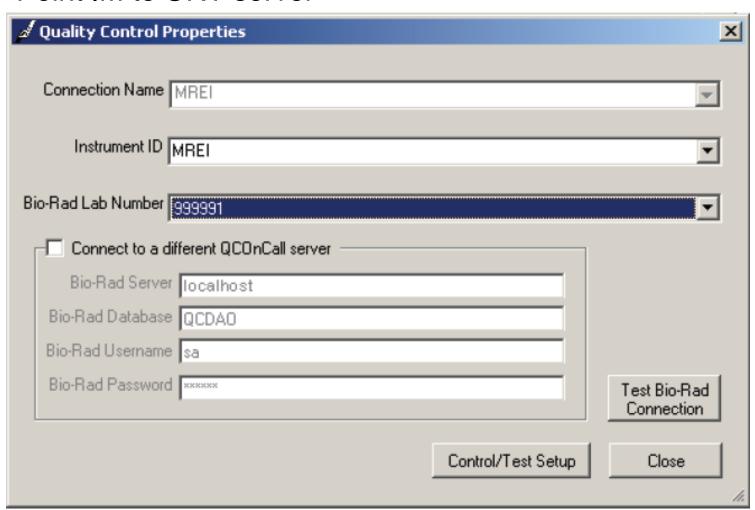




Instrument Manager Connection to URT



- Quality Control Setup
 - Point IM to URT server

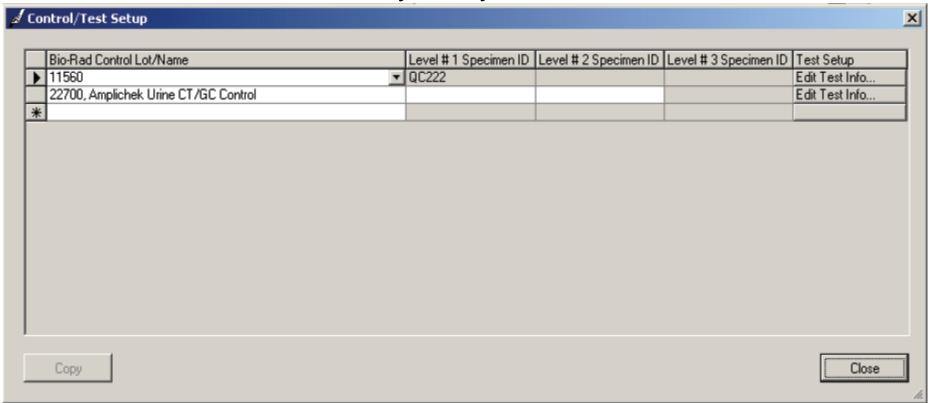




Instrument Manager Mapping



- Configure or "Map" codes
 - Instruments to Unity Lab Numbers
 - Specimen IDs to Unity Lot Numbers
 - Test Codes to Unity Analytes





So Many Regulations!













Ensure min of two levels of QC

Record of qualitative control results

Validity of QC ranges

QC Analysis occurring when scheduled

Statistical tools for analysis and display

Monitoring accuracy and precision

Monitoring Lab performance Proper patient processing when QC errors

Proper QC documentation



Correlations between instruments

Competency or Training

Retaining QC records

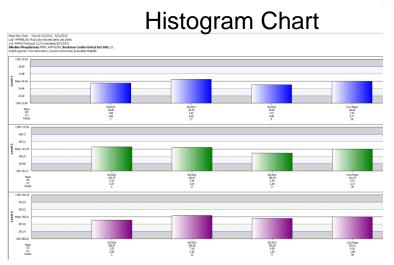


Unity Real Time and Regulations-Ensure Minimum of Two Levels of QC



- √ The Joint Commission
- **√**CAP
- **✓** COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Levey-Jennings Chart Period: 3/14/2013 - 5/13/2013 (Jule 1999)88,8-0-Red Laborateoe Dero Lib, Selec 1994 (Alborateoe Dero Lib, Selec 1994) (Alborateoe Dero Lib, Selec 1994) (Alborateoe Dero Lib, Selec 1994) (Alborateoe Coulter Naticel Dick 560, U/L. Graph against Your laboratory, Current Instrument, Evaluation Menylib (Alboratory, Current Instrument, Current Instrument, Current I



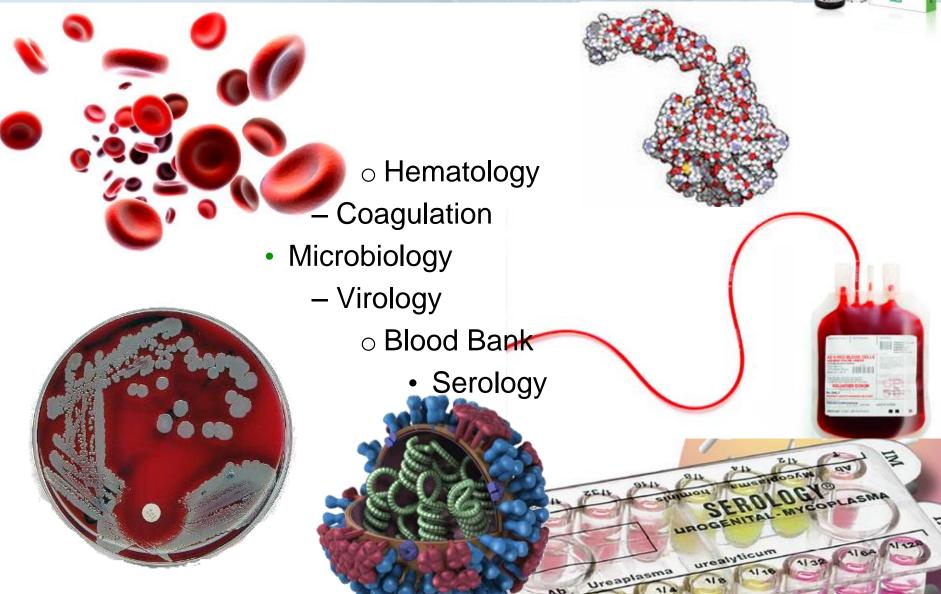
Data Set Analysis Grid

Data Set	Analyte	Instrument	Unit	Mean	SD	CV	Pts	Labs	SDI	CVR	Blas%	TE p<0.05	TEB%	Sigma	TEa	TEa Selection
A	Albunin	Bedonan Coulte	g/dL	2,41	0.04	1.46	22	1							10.00	CLIA
B1				2,31	0.89	38,40	1228	28	0.12	0.04	4,62	7.03	70.26	3.69		
A	Alkaline Phosph	Bedonan Coulte	U/L	26.36	1.52	5.77	28	1							30.00	CLIA
B1				27.07	1.37	5.05	1105	26	-0.52	1.14	-2.64	12.16	40.52	4.74		
A	ALT (ALAT/GPT)	Bedonan Coulte	U/L	28.92	1.30	4,49	37	1							20.00	CLIA
B1				29,14	1.07	3.66	1100	24	-0.21	1.23	-0.76	8.17	40.85	4.28		
A	Arrylase	Bedonan Coulte	U/L	47.11	1.10	2,34	19	1							30.00	CLIA
B1				46.93	1.31	2.78	701	22	0.13	0.84	0.37	4.23	14.09	12.68		
A	Arrylase, Panor	Bedonan Coulte	UL	23,15	1.28	5.53	13	1							26,50	BV Min blas/ Min
B1				0.00	0.00	0.00										
A	AST (ASAT/GOT)	Bedonan Coulte	U/L	40.32	0.95	2,34	25	1							20.00	CLIA
B1				40.18	1.05	2.61	1099	24	0.13	0.90	0.34	4.21	21.06	8.38		
A	Bilirubin, Direct/	Bedonan Coulte	ng/dL	0.20	0.02	12.59	36	1							66.80	BV Min blas/ Min
B1				0.21	0.03	13.53	1147	28	-0.36	0.93	-4.89	25.67	38.42	4.92		
A	Bilirubin, Total/T	Bedonan Coulte	ng/dL	0.64	0.13	19,88	44	1							57,90	CLIA
B1				0.69	0.11	15,48	1197	28	-0.48	1.28	-7.90	40.29	69.60	2.54		
A	Calcium	Bedonan Coulte	ng/dL	5.73	0.09	1.56	26	1							15.14	CLIA
B1				6.61	2,18	32.93	1566	29	-0.40	0.05	-13,20	15.77	104.18	1,24		
A	Chloride	Bedonan Coulte	nEq/L	78.18	0.83	1.06	47	1							5.00	CLIA
B1				82.73	13.01	15.73	1569	29	-0.35	0.07	-5.90	7.25	145.02	-0.47		
A	Cholesterol, HDL	Bedonan Coulte	no/dL	30.58	0.58	1.90	58	1							30.00	CLIA



It's not only about Chemistry!





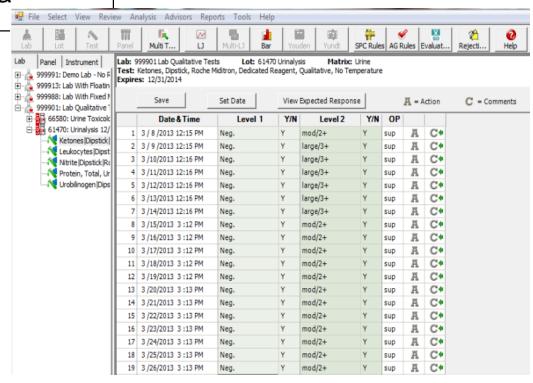


Regulations - Record of Qualitative Control Events



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Qualitative data input screen





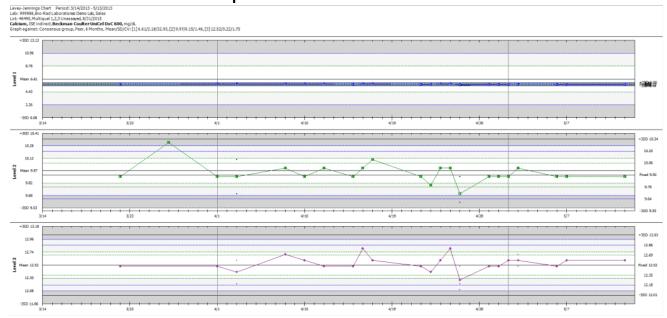
Regulations - Validity of QC Ranges



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

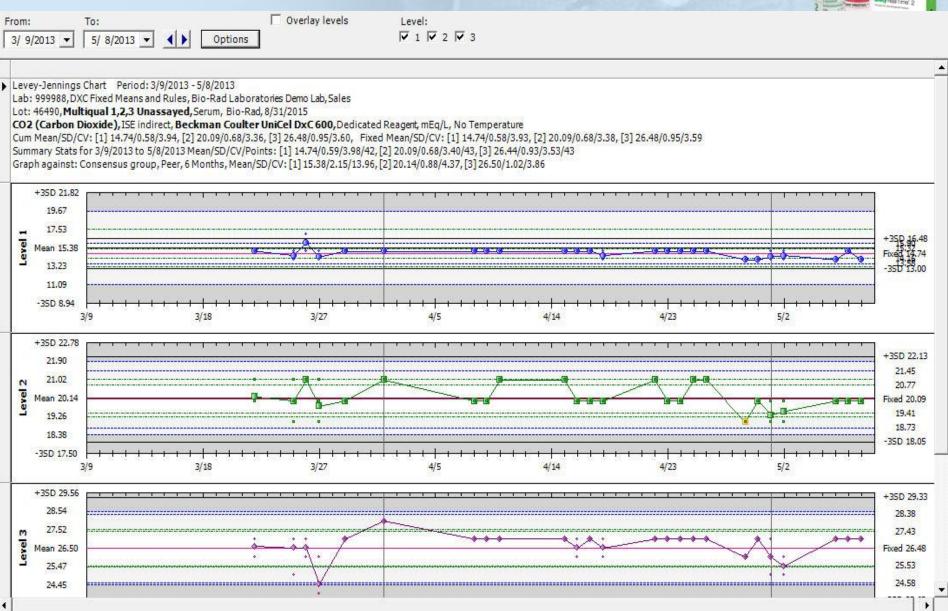
Levey Jennings Graphed against peer data

Full line of Unity Reports









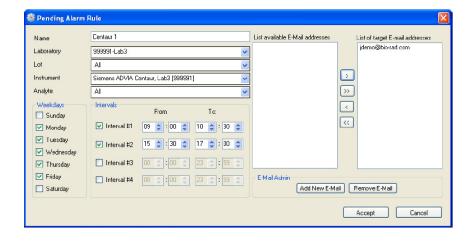


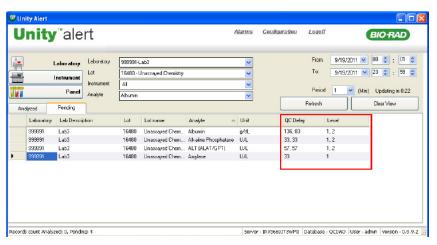
Regulations-QC analysis occurring when scheduled



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Unity Alert





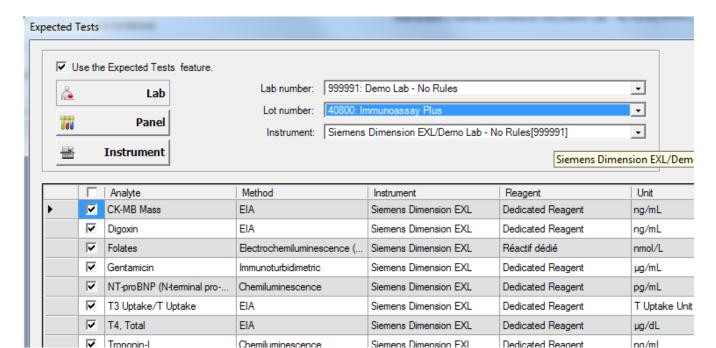


Regulations-QC analysis occurring when scheduled



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Manage Expected QC Results



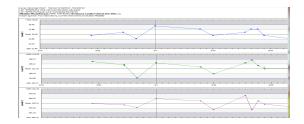


Regulations-Statistical tools for analysis and display

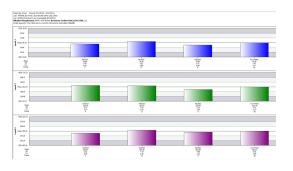


- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

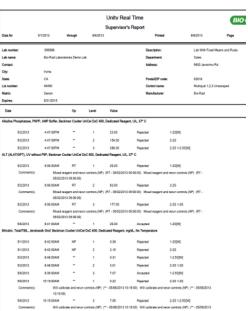
Levey-Jennings



Histogram Chart



Supervisor Report



Data Set Analysis Grid

Data Set	Analyte	Instrument	Unit	Mean	SD	CV	Pts	Labs	SOI	CVR	Blas%	TE p<0.05	TEB%	Sigma	TEa	TEa Selection
A	Abunin	Bedonan Coulte	9/1	2.41	0.04	1/6	22	1							10.00	CLIA
81				2.31	0.89	33.4)	1228	28	0.12	0.04	4,62	7.03	70.26	3.69		
A	Aliaine Phosph	Bedonan Coulte	U,L	26.36	1.52	5.77	28	1							30.00	CLIA
81				27.07	1.37	5.05	1105	26	-0.52	1.14	-2.64	12.16	40.52	474		
A	ALT (ALAT/GPT)	Bedonan Coulte	U,L	28.92	1.30	4.49	37	1							20.00	CLIA
81				29.14	1.07	3.66	1100	24	-0.21	1.23	-0.76	8.17	40.85	4.28		
A	Arrylase	Bedonan Coulte	U,L	47.11	1.10	2.34	19	i							30.00	CLIA
B1				46.93	1.31	2.78	701	22	0.13	0.84	0.37	4.23	14.09	12.68		
A	Arrylase, Pancr	Bedonan Coulte	U,L	23.15	1.28	5.53	13	i							26.50	8/ Min blas/ Min
81				0.00	0.00	0.00										
A	AST (ASAT/GOT)	Bedonan Coulte	U,L	40.32	0.95	2.34	25	1							20.00	CLIA
81				40.18	1.05	2.61	1099	24	0.13	0.90	0.34	421	21.06	8.38		
A	Bilirubin, Direct/	Bedonan Coulte	ng/d.	0.20	0.02	12.59	36	i							66.80	8/ Min blas/ Min
B1				0.21	0.03	13.53	1147	28	-0.36	0.93	4.89	25.67	38.42	492		
A	Bilirubin, Total/T	Bedonan Coulte	ng/d.	0.64	0.13	19.88	44	1							57.90	CLIA
81				0.69	0.11	15,48	1197	28	-0.48	1.28	-7.90	40.29	69.60	2.54		
A	Calcium	Bedonan Coulte	ng/d.	5.73	0.09	1.56	26	1							15.14	CLIA
81				6.61	2.18	32.93	1566	29	-0.40	0.05	-13.20	15.77	104.18	1.24		
A	Chloride	Bedonan Coulte	rEqL	78.18	0.83	1.05	47	1							5.00	CLIA
81				82.73	13.01	15.73	1999	29	-0.35	0.07	-5.90	7.25	145.02	-0.47		
Δ	Orolesterol, HDL	Bedonan Coulte	rold.	30.59	0.58	1.90	58	- 1							30.00	OIA

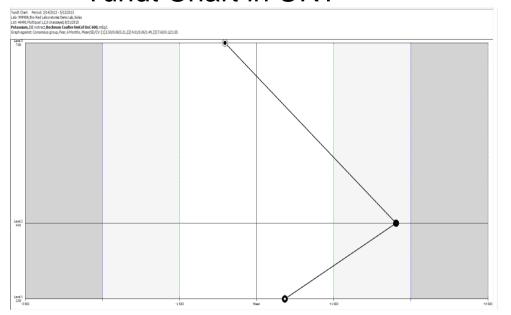


Regulations-Monitoring Accuracy and Precision

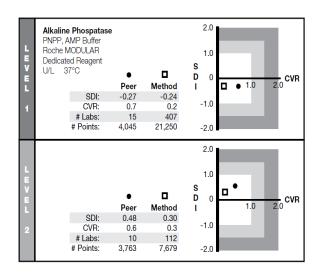


- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Yundt Chart in URT



And Unity Reports-Performance Overview





Regulation - Monitoring Lab Performance



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Unity Real Time offers Six Sigma and Total Allowable Error in the data set analysis grid and SDI and CVR with the peer group



Unity peer group Reports offers SDI and CVR

BIO RAD

Data Analysis Grid



'															8
Ten	nplate		Lab	b: 999988 L	.ot: 4649	90 Multiqu	ual 1,2,3	Unassay	red M	latrix: S	Serum				
Bed	kman DXC 600		▼ D	Data Set Configu	uration	Config	igure TEa	Co	onfigure Ale	ert	Export	Print	Close		
	1))	ا برامانی													
Leve.		Level 3 All Levels													
	Data Set	Analyte	Instrument		SD	CV	Pts	Labs	SDI	CVR	Bias%	Sigma	TEa	TEa Selection	RCV
I — I	A		Beckman Coulte.	e 24.38	1.02	4.17	1661	11						BV Des bias/ De	
	01	reference set: Data S Selection: Current Lo								1.33	-5.05	2.29			35.87
1-8	A Data	Set A: Consensus gro	roup: Peer, 6 mo										16.70	BV Des bias/ De	
	B1 Data	Set B1: Your laborate	tory, Current Inst	strument: Lab V	With Fixed	d Means a	and Rules	[999988],	Cumulativ	ve 0.73	1.00	6.70			34.71
	A Alert	t thresholds: SDI: ± 2.0	.00, CVR: 2.00, S	oigma: 4.00									44.50	BV Des bias/ De	
	B1		Beckman Coulte.	e 0.20	0.02	12,59	36	1	-0.29	0.86	-4.22	3.20			107.81
	Α	Bilirubin, Total/T	Beckman Coulte.	e 0.73	0.12	16.11	18873	51					31.10	BV Des bias/ De	
	B1		Beckman Coulte.	e 0.64	0.13	19.88	44	1	-0.75	1.23	-12.11	0.96			85.95
	Α	Calcium	Beckman Coulte.	e 5.78	0.12	2.08	17506	52					2.55	BV Des bias/ De	
	B1		Beckman Coulte.	e 5.73	0.09	1.56	26	1	-0.37	0.75	-0.76	1.15			7.24
	A	Chloride	Beckman Coulte.	e 78.12	1.31	1.68	17558	52					1.47	BV Des bias/ De	
	B1		Beckman Coulte.	e 78.18	0.83	1.06	47	1	0.04	0.63	0.07	1.32			4.44
	Α	Cholesterol, HDL	Beckman Coulte.	e 31.30	1.08	3.44	8404	40					11.60	BV Des bias/ De	
	B1		Beckman Coulte.	e 30.58	0.58	1.90	58	1	-0.67	0.55	-2.30	4.90			20.91
	A	Cholesterol, LDL	Beckman Coulte.	e 49.28	1.43	2.90	4341	28					11.90	BV Des bias/ De	
	B1	-	Beckman Coulte.		0.86	1.76	37		-0.16	0.61	-0.45	6.52			22.16
	A	Cholesterol, Total	Beckman Coulte.	e 98.83	1.86	1.88	17862	45					9.01	BV Des bias/ De	
I — II	B1	-	Beckman Coulte.		1.39	1.40	46			0.75	0.68	5.95			17.08
	A	CK (Creatine Kin			3.15	3.76	17104	_						BV Des bias/ De	
-	B1	-	Beckman Coulte.		1.87	2.14	43		1.27	0.57	4.76	11.96			63.47
	A		Beckman Coulte.		0.89	5.92	17560	52		7.37		11.55	17.77	3SD	337.17
	B1	-	Beckman Coulte.		0.59		43		-0.39	0.67	-2,30	3.92	27.77		



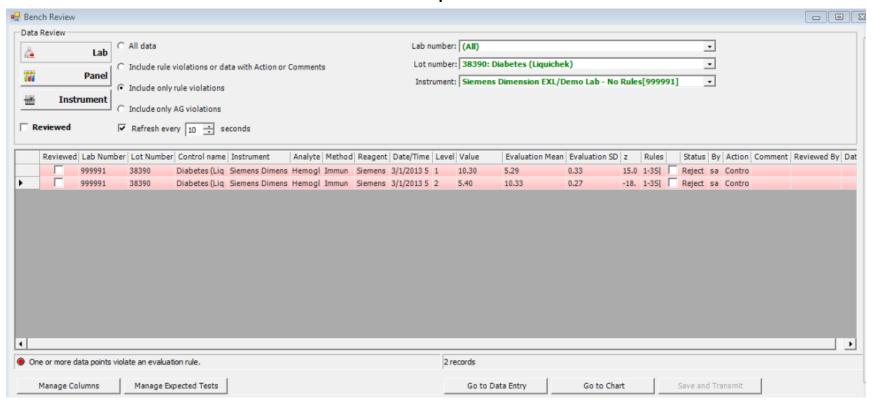
Regulation:

Proper handling of QC results if outside set limits



- √ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

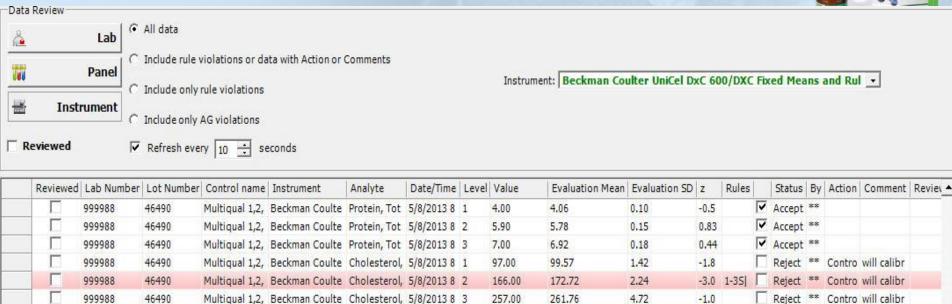
Bench and Supervisor Review





Bench Review





	999988	46490	Multiqual 1,2,	Beckman Coulte	Protein, Tot	5/8/2013 8	3	7.00	6.92	0.18	0.44		~	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	Cholesterol,	5/8/2013 8	1	97.00	99.57	1.42	-1.8		П	Reject **	Contro	will calibr	
	999988	46490	Multiqual 1,2,	Beckman Coulte	Cholesterol,	5/8/2013 8	2	166.00	172.72	2.24	-3.0	1-35	Г	Reject **	Contro	will calibr	
	999988	46490	Multiqual 1,2,	Beckman Coulte	Cholesterol,	5/8/2013 8	3	257.00	261.76	4.72	-1.0			Reject **	Contro	will calibr	
	999988	46490	Multiqual 1,2,	Beckman Coulte	LD (Lactate	5/8/2013 9	1	90.00	95.24	2.42	-2.1	1-25[✓	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	LD (Lactate	5/8/2013 9	2	142.00	137.58	4.34	1.02		굣	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	LD (Lactate	5/8/2013 9	3	332.00	328.36	7.94	0.46		굣	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	Triglycerides	5/9/2013 7	1	88.00	84.63	2.83	1.19		굣	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	Triglycerides	5/9/2013 7	2	129.00	124.76	2.05	2.07	1-25[✓	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	Triglycerides	5/9/2013 7	3	219.00	218.76	3.29	0.07		굣	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	CK (Creatine	5/9/2013 7	1	94.00	87.60	1.84	3.48	1-35	Г	Reject **	Contro		
	999988	46490	Multiqual 1,2,	Beckman Coulte	CK (Creatine	5/9/2013 7	2	279.00	274.22	3.91	1.22			Reject **	Contro		
	999988	46490	Multiqual 1,2,	Beckman Coulte	CK (Creatine	5/9/2013 7	3	659.00	662.98	6.86	-0.5		П	Reject **	Contro		
	999988	46490	Multiqual 1,2,	Beckman Coulte	Creatinine	5/9/2013 7	1	0.68	0.59	0.08	1.13		굣	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	Creatinine	5/9/2013 7	2	1.62	1.85	0.11	-2.1	1-25[V	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	Creatinine	5/9/2013 7	3	6.46	6.46	0.15	0.01		V	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	ALT (ALAT/	5/10/2013	1	29.00	28.89	1.32	0.09		哮	Accept **			
	999988	46490	Multiqual 1,2,	Beckman Coulte	ALT (ALAT/	5/10/2013	2	84.00	86.74	1.56	-1.7		V	Accept **		,	•
4)

One or more data points violate an evaluation rule.

3,499 records

Manage Columns Manage Expected Tests

Go to Data Entry

Go to Chart

Save and Transmit



Regulations:

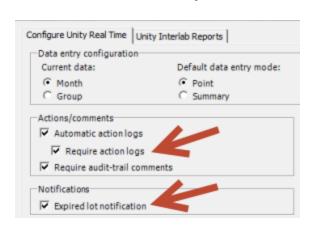
Proper QC documentation



- √ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Automatic documentation required on out of control events.

Audit trail keeps track of changes that can affect result interpretation



$\overline{}$														•
49 5/10/5019 0:01 HM	▼ 3.20	1 4		-0.30	10.50	I v		-0.23			1.0	n	UT	
50 2/11/2013 7:48 AM	→ 5.30	Υ		-0.26	10.30	Υ·		-0.23		88	I	A	C+	Action Log
51 2/12/2013 7:58 AM	▼ 5.20	Υ·		-0.55	10.30	Υ -] .	-0.23		88	I	Ā	C+	Action cog
52 2/13/2013 8:22 AM	▼ 5.00	Υ·		-1.13	10.00	Υ·		1.24		**	I	Ā	C+	Et annual at a st
53 2/14/2013 8:06 AM	₹ 5.20	Υ·		-0.52	10.30	Υ·		-0.20		**	I	Ā	C+	Lab: 99991 Demo Lab - No Rules Lot: 38390 Diabetes (Liquichek)
54 2/15/2013 7:51 AM	₹ 5.10	Υ·		-0.81	10.20	Υ·		-0.54		88	I	Ā	C+	Test: Hemoglobin A1c (NGSP), Immunoturbidimetric, Siemens Dimension EXL, Siemens Dimension HA1C, REF DF105, %, No
55 2/15/2013 10:38 AM	→ 5.10	Υ·		-0.79	10.40	Υ·		0.16		88	I	A	C+	Temperature
56 2/16/2013 8:04 AM	▼ 5.20	Υ·		-0.49	10.30	γ.		-0.19		**	I	Ā	C+	
57 2/17/2013 8:53 AM	₹ 5.10	Υ·		-0.78	10.10	Υ·		-0.89		**	I	Ā	C+	Action(s) Code
58 2/18/2013 8:41 AM	₹ 4.90	Υ·		-1.37	10.10	Υ·		-0.88		**	I	Ā	C+	
59 2/19/2013 8:01 AM	→ 4.80	Υ·		-1.63	10.30	Υ .	1	-0.16		**	I	Ā	C+	Calibrator: changed 1
60 2/19/2013 8:30 AM	→ 5.20	Y -		-0.41						**	I	Ā	C+	Calibrative now lot
61 2/20/2013 7:39 AM	₹ 5.20	Y -		-0.40	10.20	γ.		-0.51		**	I	A	C+	Control: reconstituted new 3
62 2/21/2013 7:30 AM	₹ 5.10	Υ·		-0.70	10.30	Y .		-0.15		**	I	Ā	C+	Control: repeated level 1 4
63 2/22/2013 7:27 AM	₹ 5.20	Υ·		-0.39	10.20	Υ·	1	-0.51		**	I	Ā	C+	Control: repeated level 2 5
64 2/23/2013 7:51 AM	→ 5.10	Υ·		-0.69	10.10	γ.	1	-0.86		88	I	A	C+	Control: repeated level 3 6
65 2/24/2013 7:43 AM	◆ 4.60	Υ·		-2.19	10.10	γ.		-0.85		**	I	A	C+	Control: repeated level 4
66 2/24/2013 8:16 AM	₹ 5.00	Y -		-0.92						**	I	Ā	C+	▼ The red check indicates that an action has been used and cannot be deleted or updated.
67 2/25/2013 7:44 AM	₹ 5.20	Υ·		-0.32	10.30	Υ·	1	-0.11		**	I	Ā	C+	
68 2/26/2013 7:52 AM	₹ 5.00	Υ·		-0.91	10.30	Υ·	1	-0.11		**	I	Ā	C+	Bristing action:
69 2/27/2013 7:26 AM	→ 5.20	γ .		-0.30	10.30	γ.	١.	-0.11		88	I	A	C+	
70 2/28/2013 7:39 AM	→ 4.80	Y -		-1.49	10.30	γ.		-0.11		**	I	A	C+	
71 2/28/2013 8:03 AM	₹ 5.30	Y -		0.02				/		**	I	A	C+	
72 2/28/2013 8:03 AM	₹ 5.30	Υ·		0.02						**	I	Ā	C+	
73 3/1/2013 5:51 PM	→ 10.3	N	1-35	15.04	5.4	N	1-35	18.59		sa	T	A	C	

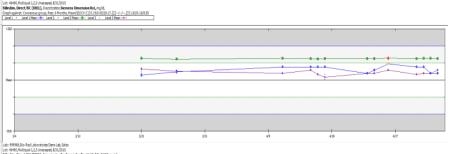


Regulations - Instrument Correlations



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Multi Levey-Jennings



Data Set Analysis Grid Will also help

Unity Affiliate Report

Graph a Level 1	paneConsesso group, Pass (Anthron, Mean SSCCE)[12.210.1321.33,]]1.120.140.135, []1.146(1.140.25) · Lord 1 Mean — Lord 2 · Lord 2 Mean — Lord 3 - Lord 3 Mean —
+350-	
Hean -	
-350 ·	4 20 22 25 49 49 40

Bilirubin, Direct/BC (DBIL) mg/dL cont.				Lev	el 1							Lev	el 2			
Lab Instrument	Mean SD	CV # Points	CVR (Feet)	CVR (Method)	CV R (ATTRate)	SDI (Foor)	SDI (Method)	SDI Affiliato	Moan SD	CV # Points	CVR (Peer)	CVR (Mathod)	CVR (Affiliata)	SDI (Peer)	SDI (Method)	SDI Affiliato
1702/8 Associated Regional Lab 1 Roche Hitachi Systems (USA)	0.30/	0.00	0.00	0.00	0.00	0.14	-0.40	0.50	1.17 0.04	3.42	0.45	0.15	0.68	-0.33	-0.63	0.34
170293 Associated Regional Lab 5 Roche Hitachi Systems (USA)	030/	0.00/	0.00	0.00	0.00	0.14	-0.40	-0.50	120/	0.00/	0.00	0.00	0.00	0.00	-0.54	0.86
194633 Associated Regional Lab 8 Roche Hitachi Systems (USA)	0.26/	7.59/	0.53	0.32	1.01	-0.79	-0.90	-1.32	0.08	7.02/	0.92	0.30	1.40	-0.66	-0.73	-0.17
227703 Associated Regional Lab 2 Roche Hitachi Systems (USA)	0.30	333/	0.23	0.14	0.43	0.14	-0.40	0.50	1.12 0.04	357/ 23	0.47	0.16	0.72	-0.88	-0.79	-0.52
Diazotization Dedicated Reagent Peer Method Affiliate	Mea 0.29 0.33 0.28	4 0.0		CV 14.63 24.10 7.61	# Poi 169 121	90 21	# Lab 25 317 4	S	Mea 1.2 1.3 1.1	0 0.	5 D 091 317 058	7.58 23.14 5.04	# Poi 161 116	19 76	# Lab 24 303 4	5



Multi Levey-Jennings Chart



Levey-Jennings Chart Period: 3/14/2013 - 5/13/2013

Lab: 999913, DXC Floating Means and Rules, Bio-Rad Laboratories Demo Lab, Sales

Lot: 46490, Multiqual 1,2,3 Unassayed, Serum, Bio-Rad, 8/31/2015

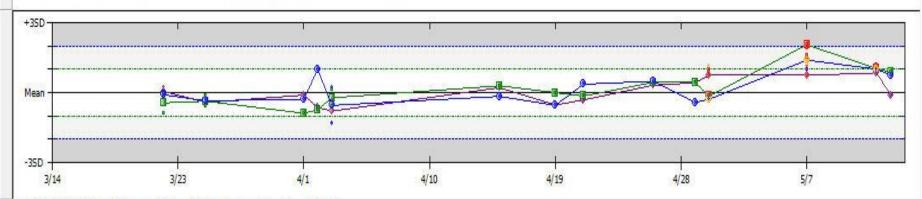
Albumin, Bromcresol Purple (BCP), Siemens Dimension RxL, Dedicated Reagent, g/dL, No Temperature

Cum Mean/SD/CV: [1] 2.37/0.05/2.11, [2] 3.37/0.04/1.18, [3] 3.98/0.05/1.26

Summary Stats for 3/14/2013 to 5/13/2013 Mean/SD/CV/Points: [1] 2.37/0.05/2.11/17, [2] 3.37/0.04/1.18/16, [3] 3.98/0.05/1.26/17

Graph against: Consensus group, Peer, 6 Months, Mean/SD/CV: [1] 2.36/0.08/3.28, [2] 3.37/0.07/2.02, [3] 3.99/0.09/2.37

Level 1 · Level 1 Mean → Level 2 · Level 2 Mean → Level 3 · Level 3 Mean →



Lab: 999988, DXC Fixed Means and Rules, Bio-Rad Laboratories Demo Lab, Sales

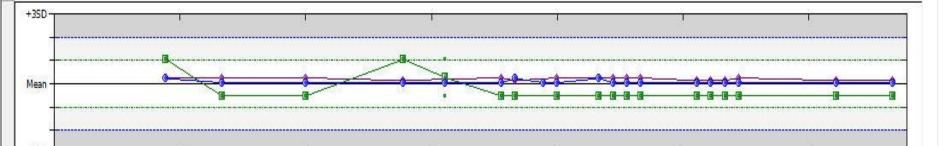
Lot: 46490, Multiqual 1,2,3 Unassayed, Serum, Bio-Rad, 8/31/2015

Albumin, Bromcresol Purple (BCP), Beckman Coulter UniCel DxC 600, Dedicated Reagent, g/dL, No Temperature

Cum Mean/SD/CV: [1] 2.41/0.04/1.46, [2] 3.41/0.04/1.03, [3] 4.06/0.05/1.24, Fixed Mean/SD/CV: [1] 2.41/0.04/1.66, [2] 3.41/0.04/1.17, [3] 4.06/0.05/1.23

Summary Stats for 3/14/2013 to 5/13/2013 Mean/SD/CV/Points: [1] 2.41/0.04/1.46/22, [2] 3.41/0.04/1.03/22, [3] 4.06/0.05/1.24/22

Graph against: Consensus group, Peer, 6 Months, Mean/SD/CV: [1] 2.37/0.58/24.41, [2] 3.43/0.06/1.86, [3] 3.88/0.87/22.49



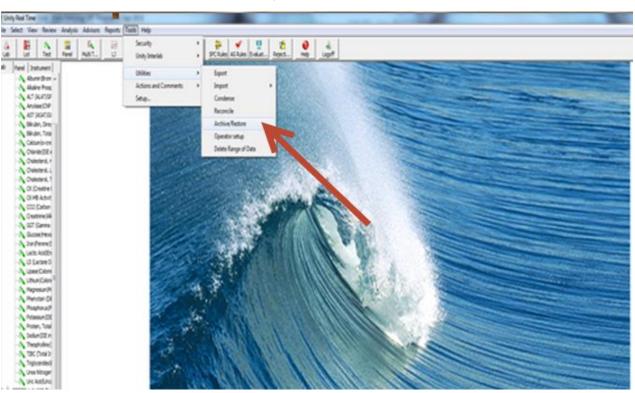


Regulations - Retaining QC Records



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada

Archive QC data

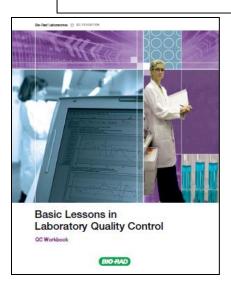


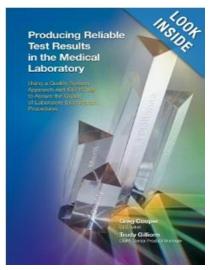


Regulations - QC Competency or Training



- ✓ The Joint Commission
- ✓ CAP
- ✓ COLA
- ✓ QMP-LS/OLA
- ✓ Accreditation Canada







General Quality Control



Unity Real Time



UnityWeb



Unity Real Time Online



Unity Real Time LT



Unity Alert



Other Unity Software

Unity Training Notes, Quick Guides & Data Files

For step-by-step directions and instructions use these links:

Data File Directions - Creating files for instruments and Laboratory Information Systems (LIS).

Training Notes - Commonly used software functions.

Quick Reference Documents - Review fundamental QC procedures.

Software User & Reference Guides - Detailed instruction manuals for Data Management products.

Unity Software Review - Web based seminars: refreshers to previous training.

Webex - Pre-Scheduled sessions with trainer.

QCNet University provides online, self-paced education on Bio-Rad Software and laboratory QC.

PACE CEUs available for most courses.

Certificates of Completion available for all.

A few current offerings:

Bio-Rad Software Demos:

- UnityWeb® 2.0
- UnityWeb® 1.0
- Unity Real Time®2.0

Laboratory QC Education:

- Basic Lessons in Laboratory Quality Control
- Controlling Error Using Biological Variation
- ISO 15189

QCNet University »



A Experiencing Intermittent outage

Favorite educational brochures. books and articles.

- QC Workbook Basic Lessons in Quality Control »
- Using Quality Control »
- Discover the Importance of Third Party Quality Control »
- Seeking laboratory accreditation under ISO 15189 »
- Maximum Day to Day Imprecision and ISO 15189 »

Over 100 videos related to QC and Quality in the Lab.

Interested in a quick video on Youden Plots? Have 22 minutes for Uncertainty & Traceability? Find both and more on the premier online source for clinical laboratory education videos.

Visit our YouTube Channel and subscribe to receive notifications when new videos are added

Topics Include:

- Levey-Jennings Charts »
- Introduction To
- Quality Control Playlist » Basic QC Calculations »
- Biological Variation »

BIORADQC »

Regulatory Websites

Website links for more Quality Control, EQA / PT, and quality

- Quality Specification »
- US Regulations »
- International Regulations »
- Australia / New Zealand »
- Organizations »
- Laboratory Practices & Guidelines »





Integrating Bio-Rad Unity Real Time® Rule Examples for Instrument Manager



IM Use Case Examples



QC Failure Notification *

IF:	({Specimen Type} = "Q") {AND} ({QC Rule Violated} {On Any Test} {Contains} {Value List:QCFlag})								
THEN:	{Trigger Notifier Event} "QC Failure" {AND} {Add} {Notifier Event Text of} "QC Failure" = "Any text you want to include in message"								
Value List:	Row Enabled QCFlag ★								

Notifier Function in Instrument Manager

- ✓ Event time and day of week determines whom to notify
- ✓ Notices sent via email, text, network notice, and/or light pole



IM Use Case Examples



QC Rule Violation (Autoverification) *

IF: {({Specimen Type} = "Q") {AND} ({QC Rule Violated} {On Any

Test} {Contains} {Value List:QCFlag})

THEN: {Trigger Notifier Event} "QC Failure" {AND} {Add} {Notifier Event

Text of "QC Failure" = "Any text you want to include in message"

{AND} {Start Holding That Test with That Instrument ID for

Verification}

Value List:

	Row Enabled	QCFlag
*		
Þ	•	1-3S
	~	2-2s
	~	R4s

^{*} Note: Instrument Manager rules provided as an example. Customer is responsible for testing and validation of any rules in their system.





Thank you for your time!

Sale	es	
	Data Innovations	802.658. 2850 northamerica-sales@datainnovations.com
	Bio-Rad	1.800.854.6737 – US 1.800.361.1808 – Canada
Sup	port	
	Data Innovations	802.658.1955 northamerica-support@datainnovations.com
	Bio-Rad	1.800.854.6737 - US 1.800.361.1808 option 1 - Canada