

This is
Bio-Rad.

Unity Real Time® Quality Control Data Management



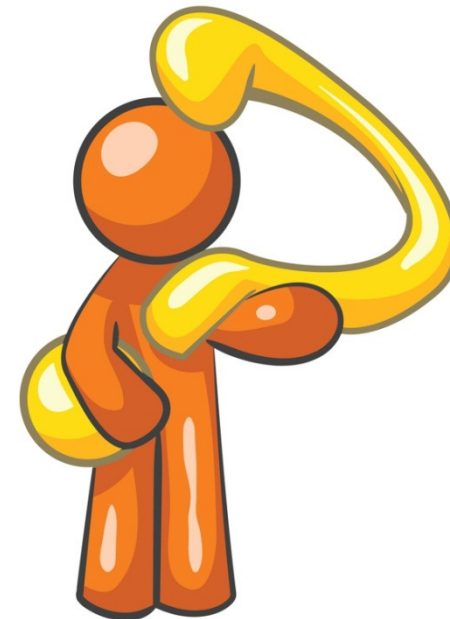
Mohamad Karim
Product Specialist – Informatics Solutions
Quality Systems Division

BIO-RAD

QC Data Management Software

Why to use a QC Data Management system?

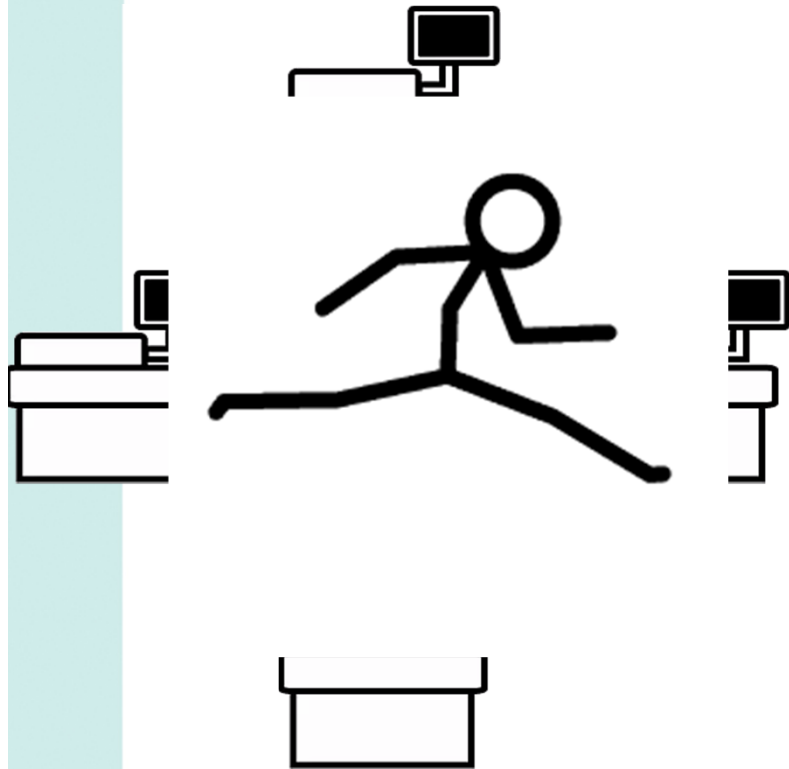
1- Help in Daily QC Routine



Evaluation of daily QC routine

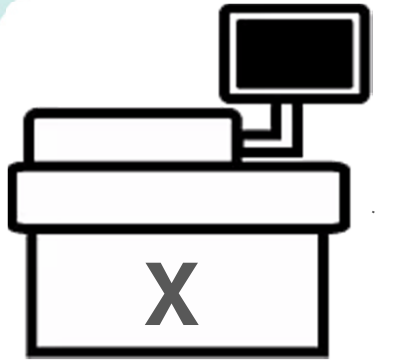
QC run

QC review

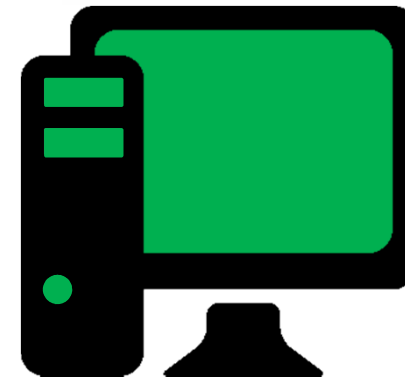


	Product	Analyte	Unit	Instrument	L1 Mean
+3SD	D-dimer	D-dimer	mg/L	Siemens ADVIA 1200	0,305
+2SD	Blood Gas	pCO2	mmHg	Roche cobas b 221 (Omni S)	7,69
+1SD	Blood Gas	pCO2	kPa	Siemens 248	7,85
mean	Blood Gas	pCO2	kPa	Siemens 248	7,6
	Blood Gas	pCO2	kPa	Siemens RAPIDPoint 400/405	8,01
-1SD	Blood Gas	pH	No Units	Roche cobas b 221 (Omni S)	7,285
-2SD	Blood Gas	pH	No Units	Siemens 248	7,235
-3SD	Blood Gas	pH	No Units	Siemens RAPIDPoint 400/405	7,205
	Blood Gas	pH	No Units	Siemens 248	7,227
	Blood Gas	pO2	mmHg	Roche cobas b 221 (Omni S)	7,62
	Blood Gas	pO2	kPa	Siemens 248	0
	Blood Gas	pO2	kPa	Siemens 248	6,69
	Blood Gas	pO2	kPa	Siemens RAPIDPoint 400/405	8,38
	Cardiac Marke	CK-MB Mas	ng/mL	Siemens ADVIA Centaur XP	3,7
	Cardiac Marke	CK-MB Mas	µg/L	Roche cobas e 411	2,76
	Cardiac Marke	CRP (C-Re)	mg/L	Roche cobas 6000	1,23
	Cardiac Marke	CRP, High	mg/L	Roche cobas 6000	0
	Cardiac Marke	Homocyste	µmol/L	Siemens ADVIA Centaur XP	4,21
	Cardiac Marke	Myoglobin	µg/L	Siemens ADVIA Centaur XP	51,11
	Cardiac Marke	Myoglobin	µg/L	Siemens ADVIA Centaur XP	56,66
	Cardiac Marke	Myoglobin	µg/L	Roche cobas e 411	39,67
	Cardiac Marke	Myoglobin	µg/L	Roche cobas 6000	34,69
	Cardiac Marke	NT-proBNP	pg/mL	Mitsubishi PATHFAST	307,5
	Cardiac Marke	NT-proBNP	pmol/L	Roche cobas 6000	138,1
	Cardiac Marke	Troponin-I	µg/L	Siemens ADVIA Centaur XP	0,08

QC Data Management Consolidation



Unity



Unity™ QC Data Management Software

The screenshot displays the Unity QC Data Management Software interface. On the left, a sidebar contains filters for Lab, Panel, Instrument, and Reviewed. The main area shows a table of QC data with columns for Reviewed, Lab Number, and Action. An 'Action Log' dialog box is open, showing details for Lab: 999988, Lot: 57410, and Test: PTH, Intact, Electrochemiluminescence (ECL). The dialog lists several actions with red checkmarks, indicating they have been used. A table within the dialog lists these actions and their codes. Below the list, a note explains that the red check indicates an action has been used and cannot be deleted or updated. An 'Existing action' field shows a selected entry: 'Control: repeated level 1 (sa - 09/11/2015 8:55:48 AM)'. Buttons for 'Apply' and 'Close' are at the bottom of the dialog.

Action Log

Lab: 999988 Lab With Fixed Means and Rules
Lot: 57410 Specialty Immunoassay
Test: PTH, Intact, Electrochemiluminescence (ECL), , Intraoperative/STAT PTH, pg/mL, No Temperature

Action(s)	Code
✓ Calibrator: changed	1
✓ Calibrator: new lot	2
✓ Control: reconstituted new	3
✓ Control: repeated level 1	4
✓ Control: repeated level 2	5
✓ Control: repeated level 3	6
Control: repeated level 4	7

✓ The red check indicates that an action has been used and cannot be deleted or updated.

Existing action:
Control: repeated level 1 (sa - 09/11/2015 8:55:48 AM)

Buttons: Apply, Close

Annotations on the right side of the screenshot:

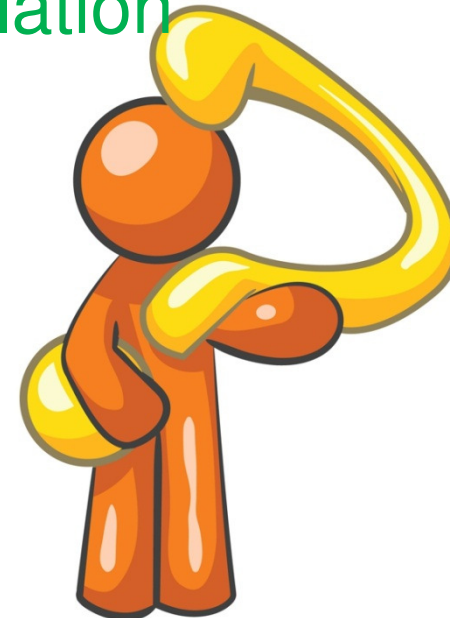
- QC warning (yellow arrow pointing to a yellow row)
- Normal QC data (white arrow pointing to a white row)
- QC rejection (pink arrow pointing to a pink row)
- Normal QC data (white arrow pointing to a white row)

Why to use a QC Data Management Software

Why to use a QC Data Management system?

1- Help in Daily QC Routine

2- QC Data Analysis and Correlation



QC Data Analysis and Correlation

LJ Chart Graphed Against Evaluation Mean (Fixed Mean)



Levey-Jennings Chart Period: 01/08/2014 - 31/08/2014

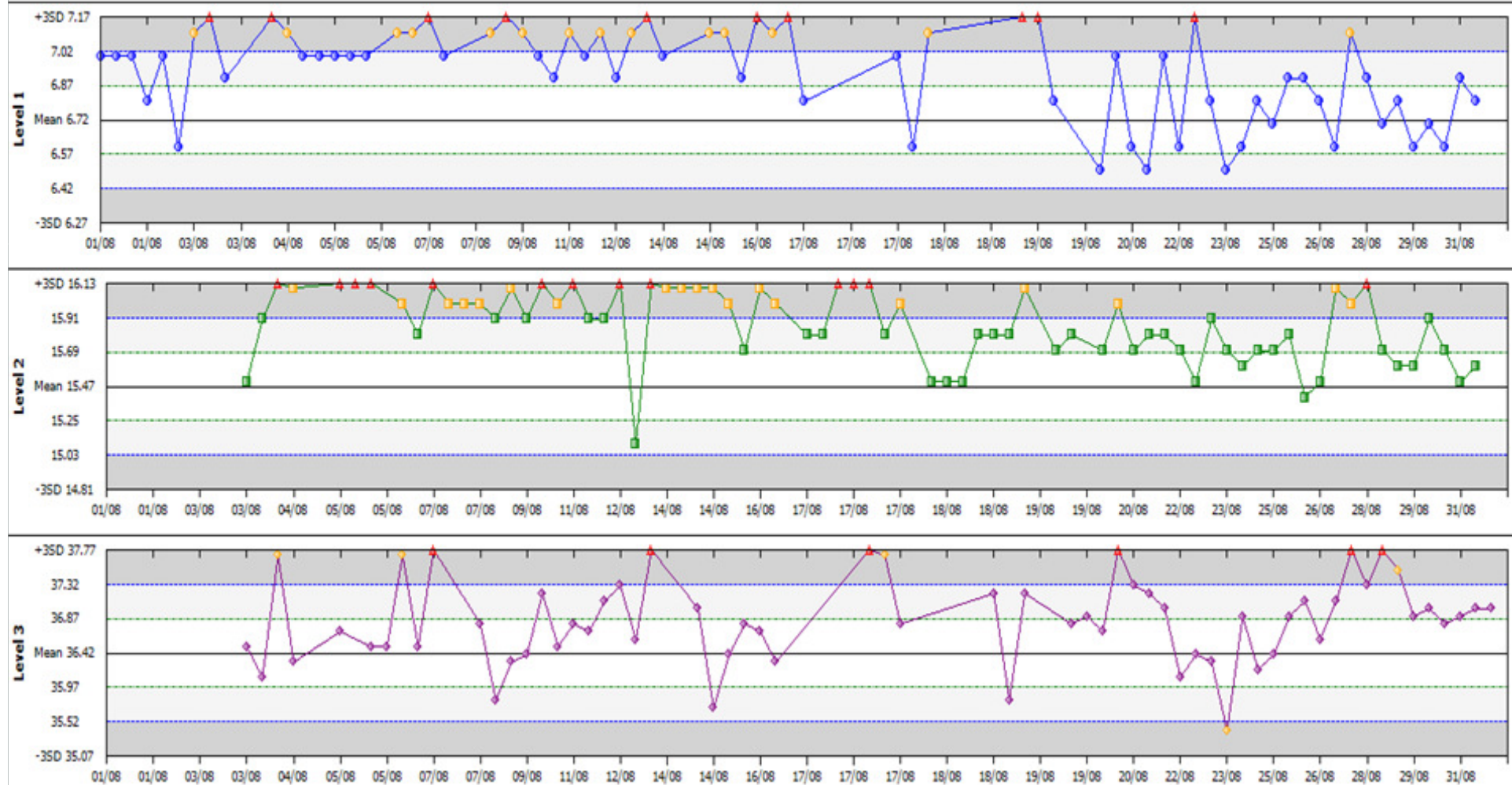
Lot: 40840, Immunoassay Plus, Bio-Rad

Salicylate, Enzymatic, Dedicated Reagent, mg/dL, No Temperature

Cum Mean/SD/CV: [1] 6.82/0.19/2.80, [2] 15.72/0.25/1.56, [3] 36.73/0.51/1.40, Fixed Mean/SD/CV: [1] 6.72/0.15/--, [2] 15.47/0.22/--, [3] 36.42/0.45/--

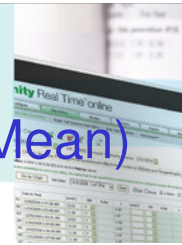
Summary Stats for 01/08/2014 to 31/08/2014 Mean/SD/CV/Points: [1] 6.87/0.20/2.88/50, [2] 15.79/0.21/1.35/53, [3] 36.69/0.50/1.36/45

Graph against: Your laboratory, Current instrument, Evaluation Mean/SD, Mean/SD/CV: [1] 6.72/0.15/2.23, [2] 15.47/0.22/1.42, [3] 36.42/0.45/1.24



QC Data Analysis and Correlation

LJ Chart Graphed Against Cumulative Mean (Floating / Running Mean)



Levey-Jennings Chart Period: 01/08/2014 - 31/08/2014

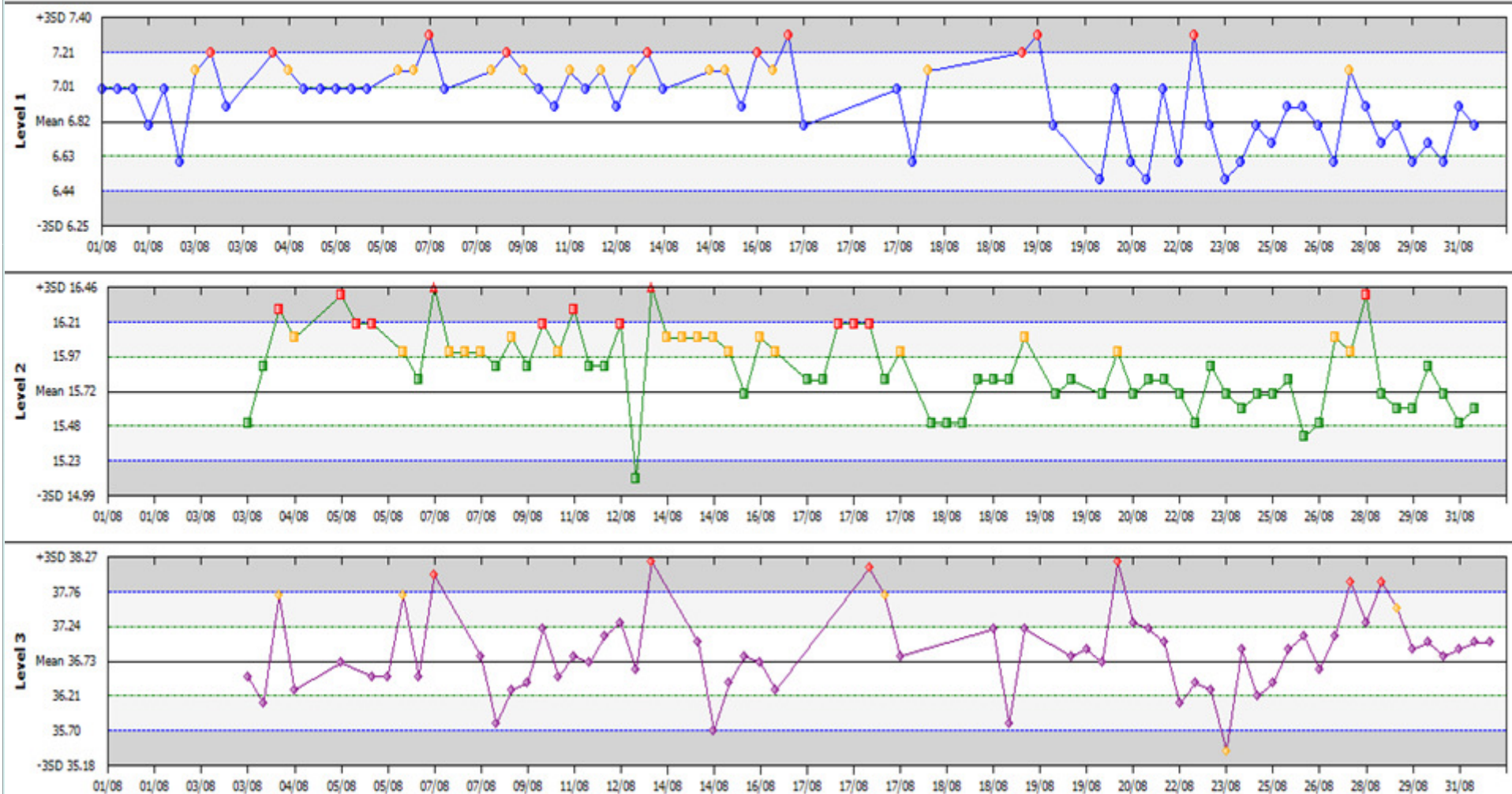
Lot: 40840, Immunoassay Plus, Bio-Rad

Salicylate, Enzymatic, Dedicated Reagent, mg/dL, No Temperature

Cum Mean/SD/CV: [1] 6.82/0.19/2.80, [2] 15.72/0.25/1.56, [3] 36.73/0.51/1.40, Fixed Mean/SD/CV: [1] 6.72/0.15/--, [2] 15.47/0.22/--, [3] 36.42/0.45/--

Summary Stats for 01/08/2014 to 31/08/2014 Mean/SD/CV/Points: [1] 6.87/0.20/2.88/50, [2] 15.79/0.21/1.35/53, [3] 36.69/0.50/1.36/45

Graph against: Your laboratory, Current instrument, Cumulative



QC Data Analysis and Correlation

LJ Chart Graphed Against Peer Mean



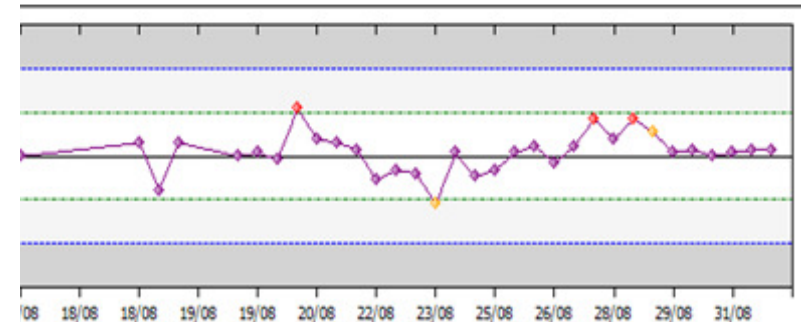
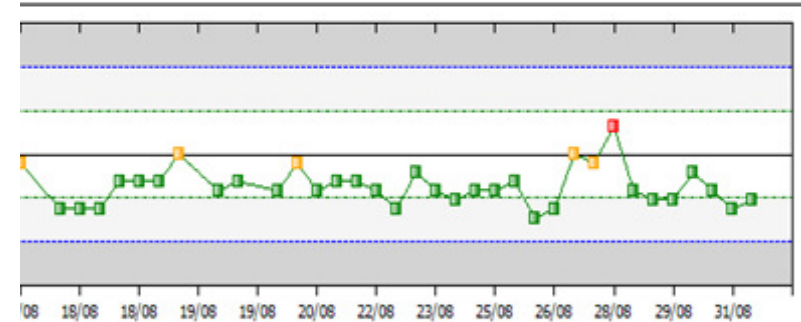
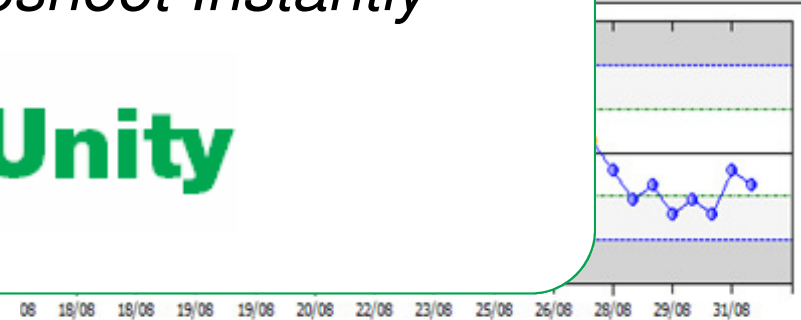
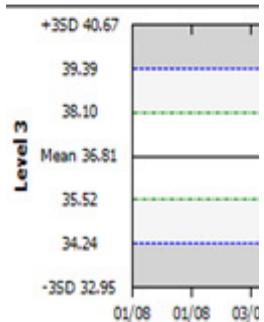
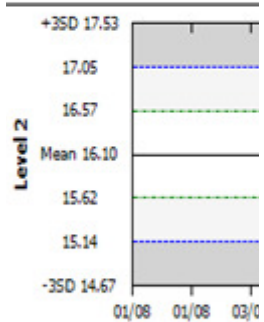
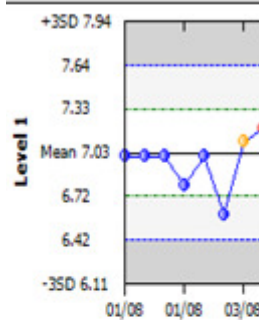
Levey-Jennings Chart Period: 01/08/2014 - 31/08/2014
 Lot: 40840, Immunoassay Plus, Bio-Rad
 Salicylate, Enzymatic,
 Cum Mean/SD/CV: [1] 6.82/0.19/2
 Summary Stats for 01/08/2014 to :
 Graph against: Consensus group,

Captain QC



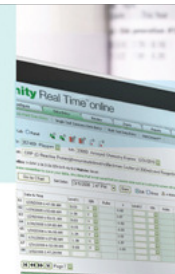
Troubleshoot Instantly

With **Unity**



QC Data Analysis and Correlation

Multi LJ Chart 2 Instruments Data Correlation



Levey-Jennings Chart Period: 15/08/2014 - 15/09/2014

Lot: 40840, Immunoassay Plus, Bio-Rad

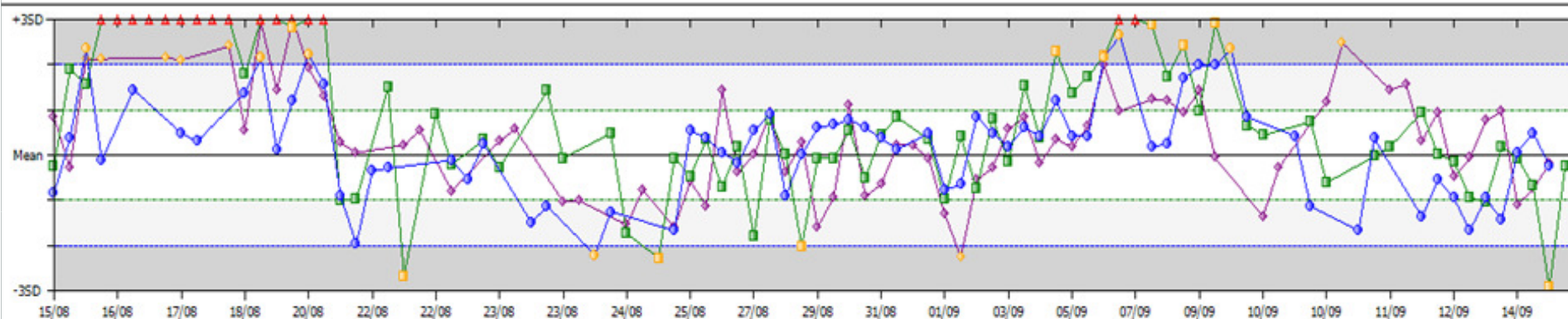
Valproic Acid (Depakene), KIMS, Dedicated Reagent, µg/mL, No Temperature

Cum Mean/SD/CV: [1] 33.41/1.79/5.36, [2] 77.42/3.52/4.54, [3] 114.09/4.42/3.88, Fixed Mean/SD/CV: [1] 33.19/1.67/--, [2] 76.38/2.76/--, [3] 113.77/4.25/--

Summary Stats for 15/08/2014 to 15/09/2014 Mean/SD/CV/Points: [1] 33.26/1.79/5.38/62, [2] 76.99/3.44/4.46/65, [3] 114.18/4.25/3.72/63

Graph against: Your laboratory, Current instrument, Evaluation Mean/SD, Mean/SD/CV: [1] 33.19/1.67/5.03, [2] 76.38/2.76/3.61, [3] 113.77/4.25/3.74

Level 1—●— Level 2—■— Level 3—◆—



Lot: 40840, Immunoassay Plus, Bio-Rad

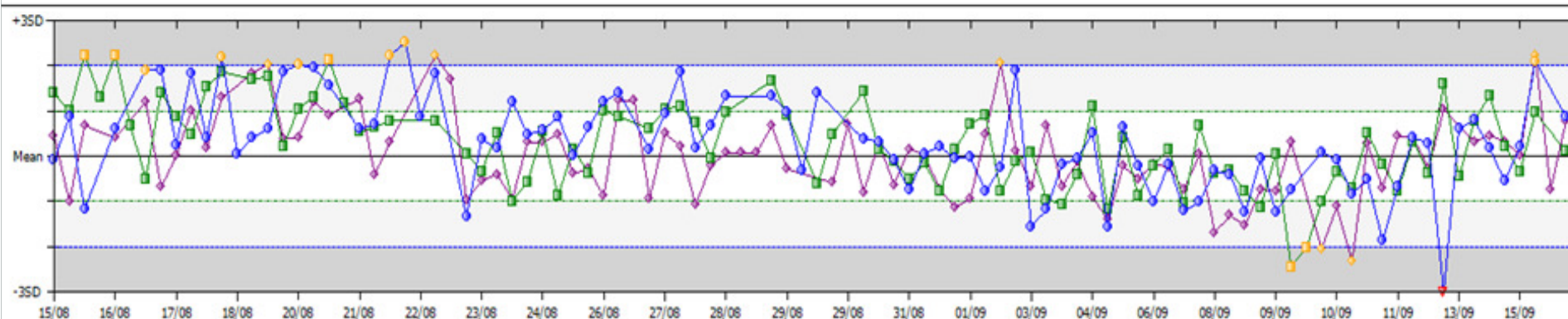
Valproic Acid (Depakene), KIMS, Dedicated Reagent, µg/mL, No Temperature

Cum Mean/SD/CV: [1] 35.14/2.60/7.39, [2] 79.81/4.83/6.05, [3] 120.08/6.99/5.82

Summary Stats for 15/08/2014 to 15/09/2014 Mean/SD/CV/Points: [1] 36.06/2.63/7.29/88, [2] 81.12/4.56/5.62/89, [3] 120.10/6.53/5.44/89

Graph against: Your laboratory, Current instrument, Evaluation Mean/SD, Mean/SD/CV: [1] 35.14/2.60/7.39, [2] 79.81/4.83/6.05, [3] 120.08/6.99/5.82

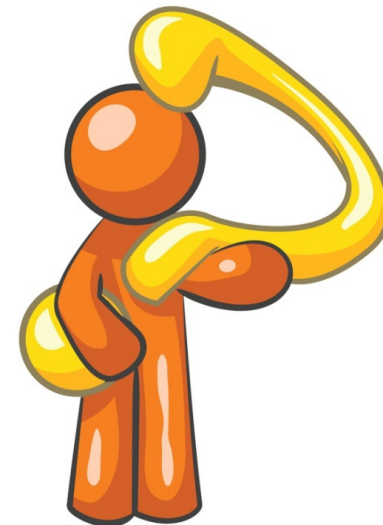
Level 1—●— Level 2—■— Level 3—◆—



Why to use a QC Data Management Software

Why to use a QC Data Management system?

- 1- Help in Daily QC Routine
- 2- QC Data Analysis and Correlation
- 3- Participate in the largest Interlaboratory Program Worldwide



Unity™ Interlaboratory Program

Unity Interlaboratory Program Connects Your Laboratory to Worldwide Laboratory Community

- Get compared with more than 25,000 Labs worldwide.
- Largest most comprehensive peer group comparison world wide for internal QC with more then 46,000 instruments in 92 countries.
- Receive monthly reports for routine QC data review.
- Receive On Demand Daily Peer Group Report



Unity™ Interlaboratory Program

Internal QC

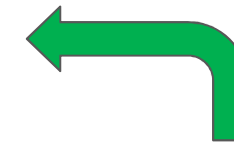
Data entry
(Manually or via Connectivity)



**QC Data
Management
Solution =
Unity Real Time**

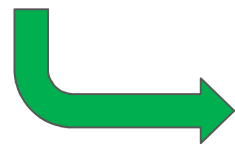


Monthly
Unity Reports



QCNet™

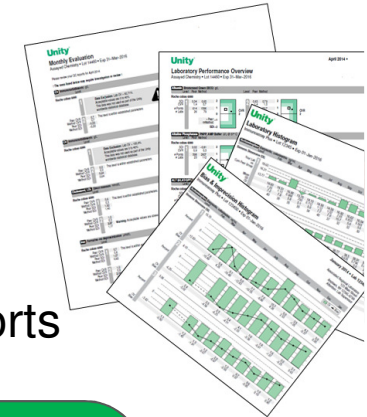
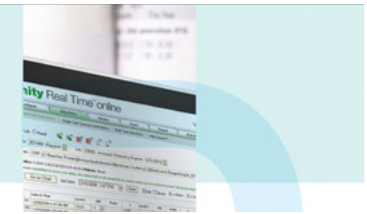
Data
Transmission



Unity™



BIO-RAD



Unity™ Interlaboratory Program

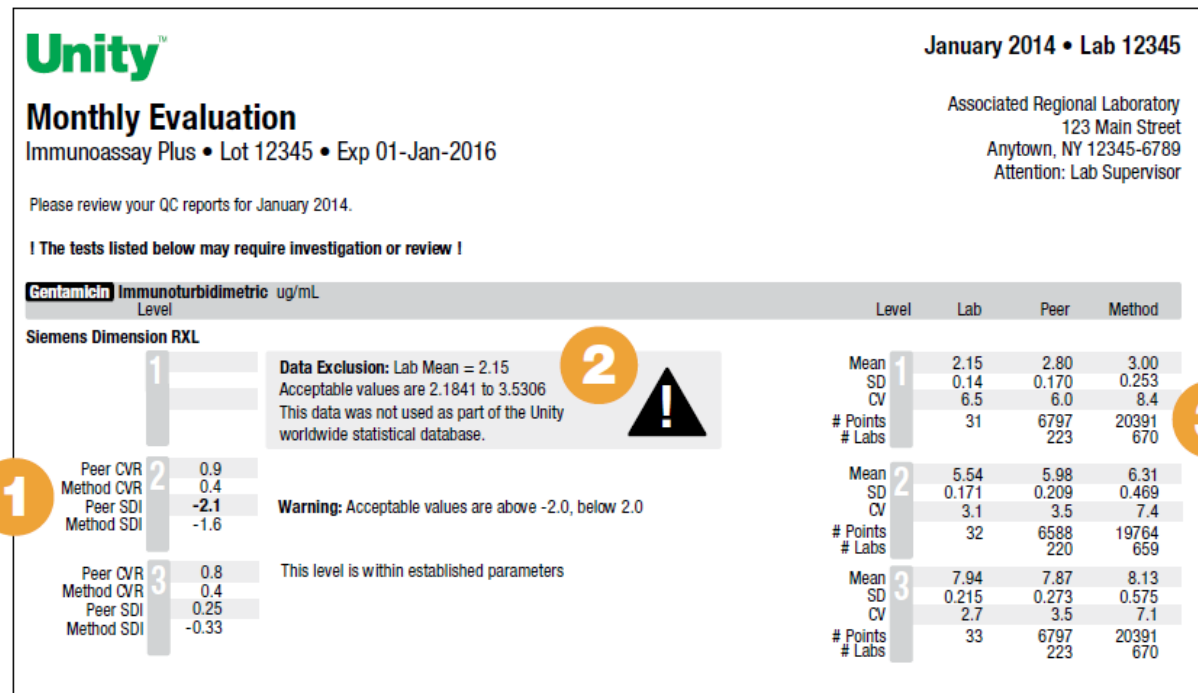
Monthly Evaluation Report

Provides a quick overview of laboratory performance for the month

1. Key statistical measures for Peer and Method CVRs and SDIs.

2. Notifies the laboratory if data has been rejected and therefore not compared to the peer group.

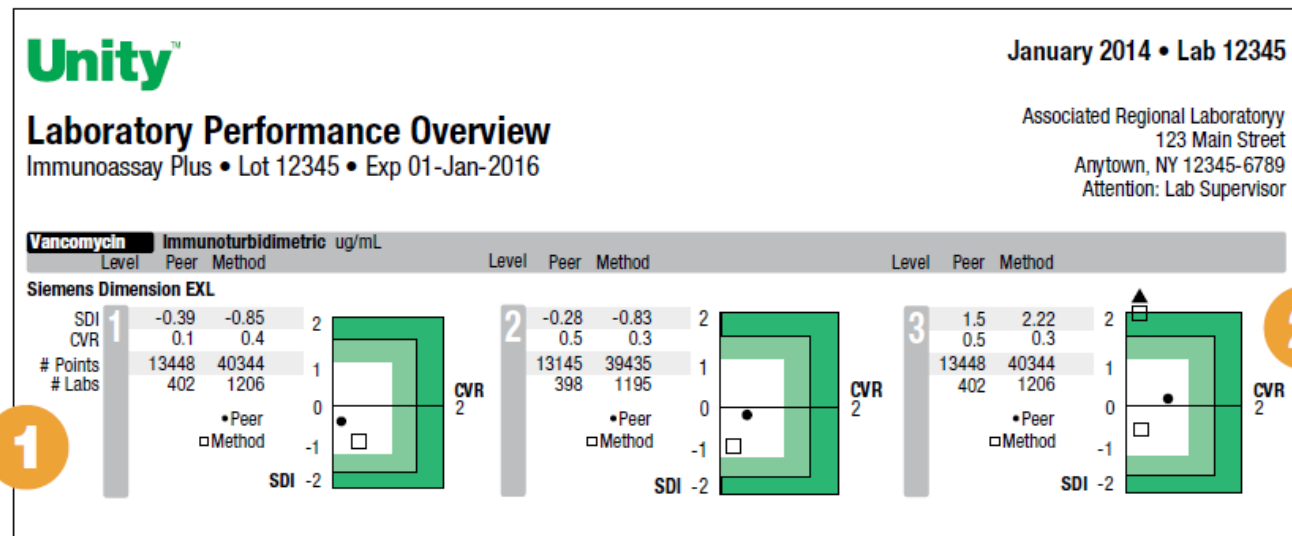
3. Detail: Mean, SD, CV and total number of Labs and Points – arranged by your Lab, Peer, and Method groups.



Unity™ Interlaboratory Program

Laboratory Performance Overview Report

Providing a visual indication of your laboratory performance in terms of bias (SDI) and imprecision (CVR), in a modified Youden chart.



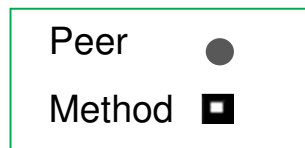
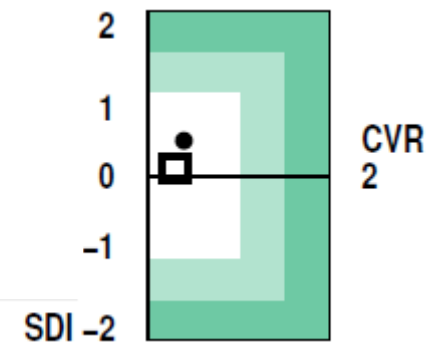
1. Data displays in rows with up to 3 levels per row;
2. Arrows outside the chart margins indicate the presence of off the chart values.

Unity™ Interlaboratory Program

Laboratory Performance Overview Report (continued)

Allows visual evaluation of bias (SDI) and imprecision (CVR) for each test compared to the peer and method consensus group.

<input type="checkbox"/>	No Shading Acceptable performance.
<input type="checkbox"/>	Light Shading Acceptable to marginal performance. May need to investigate test system performance.
<input type="checkbox"/>	Dark Shading Marginal performance. May need to perform corrective action.
<input type="checkbox"/>	Outside of Graph Unacceptable performance. Requires corrective action.



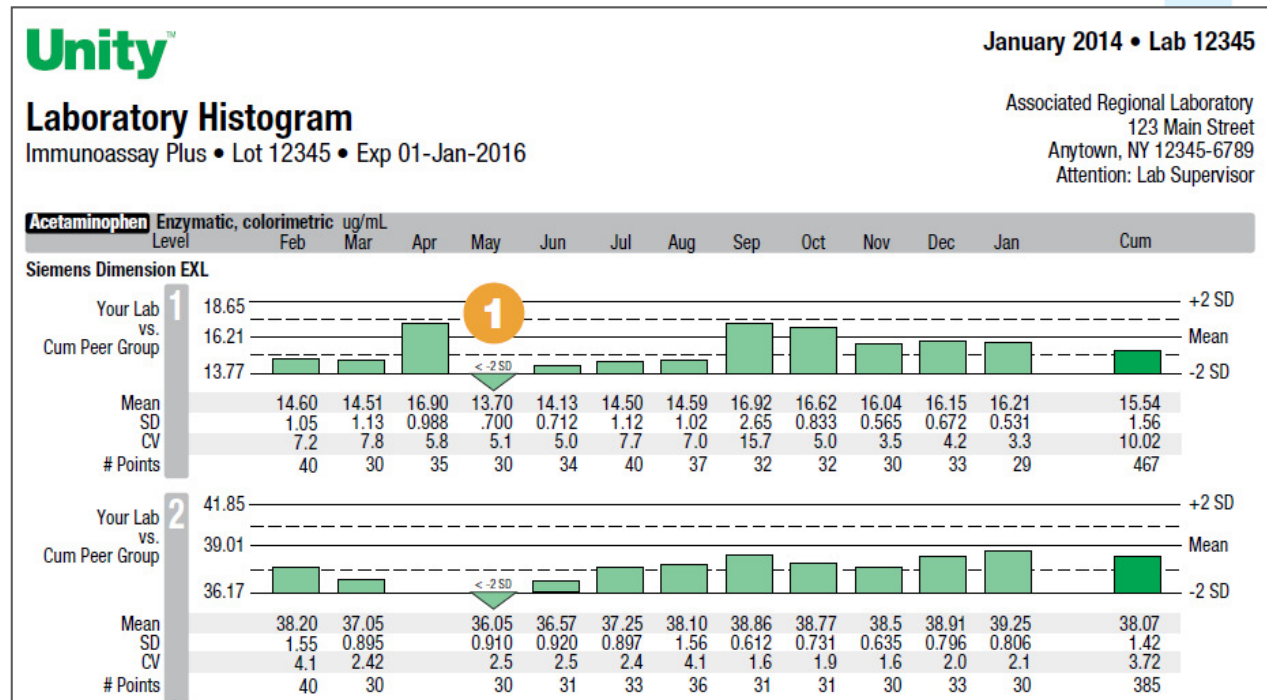
Unity™ Interlaboratory Program

Laboratory Histogram Report

- Allows visual comparison of a laboratory's performance to the peer group over a 12-month period.
- Helps identify shifts (abrupt changes in values) and trends (gradual changes in values) in monthly results.



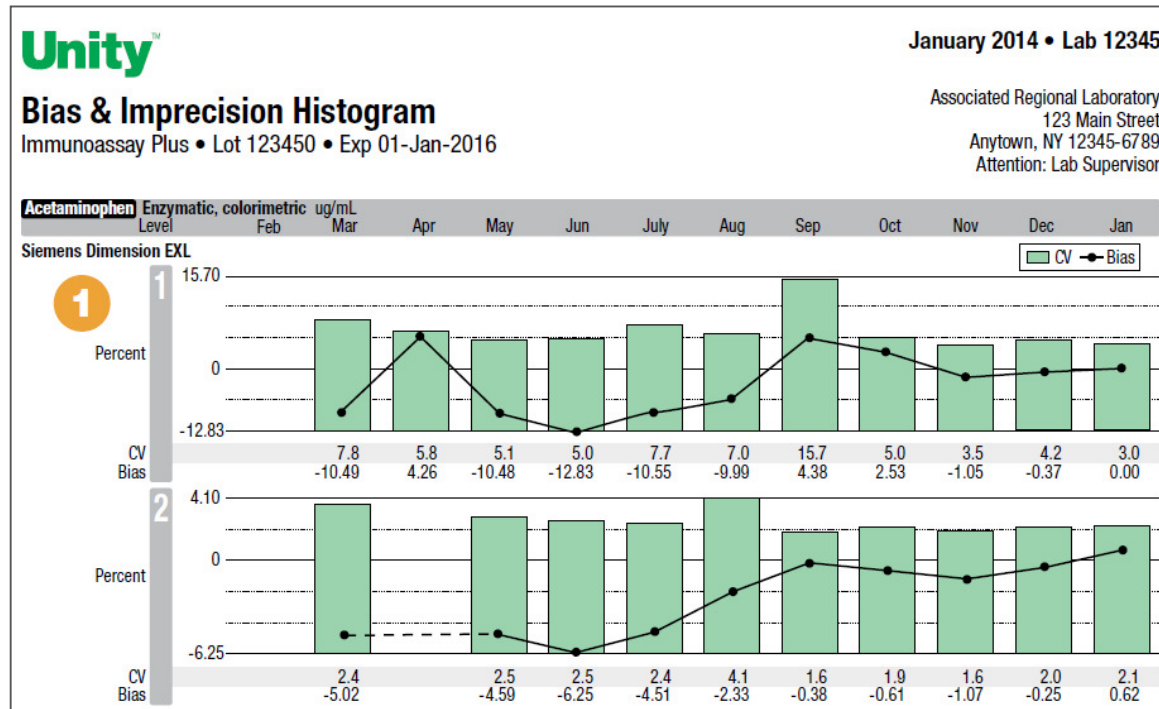
1. labeling and arrows clearly indicate values that fall outside of (either above or below) the 2 SD range.



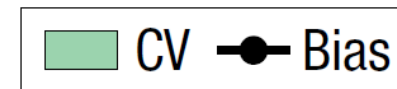
Unity™ Interlaboratory Program

Bias and Imprecision Histogram Report

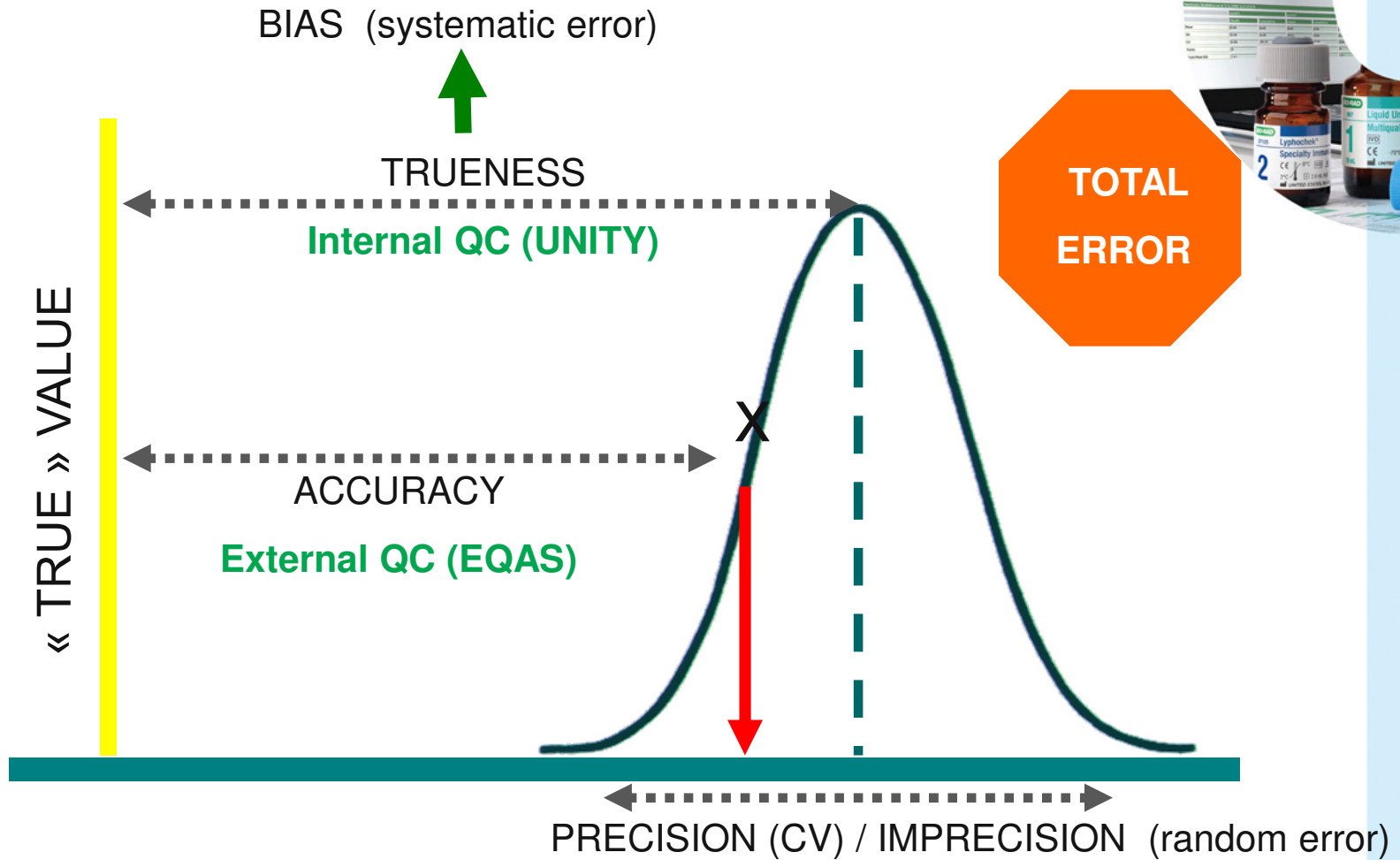
- Identifies whether performance changes are due to imprecision, bias, or both.
- Helps detect change in performance over time



Provides a graphical representation of the laboratory's CV and bias compared to the current cumulative peer group mean.



Traditional Error Model



EQAS VS Unity Interlaboratory Program

EQAS and UNITY
Fully Complementary

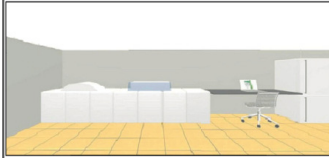


 **EQAS** →
performance T

 **UNITY** →
ongoing
performance



Biochemistry



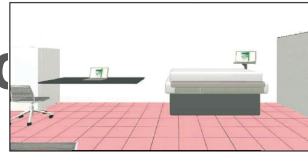
Control Portfolio

- Multiqual
- Immunology
- Urine Chemistry
- Immunoassay Plus Control
- Diabetes
- Cardiac Marker
- Specialty
- Tumor Marker
- EQAS Chemistry, IA, Cardiac, Serum Prot, Lipid, Diabetes, Blood Gas, Ethanol /Ammonia

Additional Controls

- (Un)Assayed Chemistry
- Quantitative Urine
- Elevated CRP
- Maternal Serum
- Ethanol Ammonia

Virology



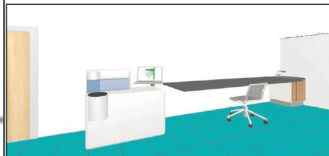
Control Portfolio

- Virotrol I
- Virotrol II
- Virotrol III
- Viroclear
- Virotrol HIV-2
- Virotrol HIV-1 Ag
- EQAS HIV/Hepatitis
- EQAS Syphilis

Additional Controls

- Virotrol HAV IgM,
- Virotrol HBC IgM, Virotrol Hbe Ag
- Virotrol Syphilis LRA and B,
- Virotrol RPR
- Virotrol Lyme, Virotrol Chagas
- Virotrol WNV
- Pneumotrol , PyloriTrol

Toxicology



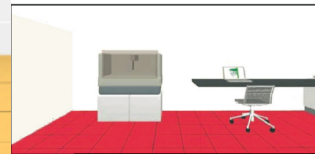
Control Portfolio

- TDM
- Urine Toxicology
- Whole Blood control
- EQAS TDM

Additional Controls

- Qualitative Urine Toxicology
- Serum Volatiles
- Whole Blood Metals
- Whole Blood Immunosup

Serology



Control Portfolio

- Virotrol ToRCH-M
- Viroclear ToRCH
- Liq ToRCH Plus
- EQAS ToRCH EBV MumZ

Additional Controls

- ToRCH Plus
- ToRCH Plus IgM
- Virotrol EBV
- Virotrol ToRCH

Hematology



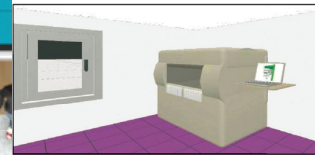
Control Portfolio

- Hematology (A, C, S ou X)
- Sedimentation Rate
- EQAS HEMATO

Additional Controls

- Reticulocyte (A, C, S ou X)

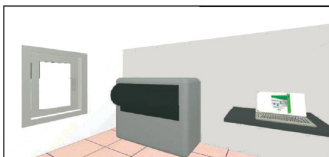
Immunohematology



Control Portfolio

- EQAS Blood Typing

Hemostasis



Control Portfolio

- Coagulation
- D-Dimer
- EQAS Coag

Additional Controls

- Hemostasis

Bacteriology



Control Portfolio

- Urinalysis
- EQAS Urinalysis

Additional Controls

- Quantify Plus Control
- Quantify Control

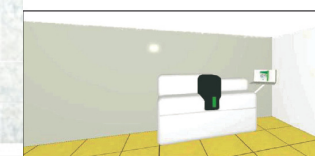
Allergy



Control Portfolio

- Allergen IgE Control

Autoimmunity



Control Portfolio

- ANA Controls Set Positive
- ANA Controls Homogenous
- ANA Controls Speckled
- Autoimmune Negative Control

Additional Controls

- ANA Control Nucleolar
- ANA Control Centromere
- ANA Control Mitotic Spindle
- Anti-Mitochondrial Control
- Anti-Smooth Muscle Control



Thanks for your attention
Any questions ?

**Visit Bio-Rad at
Saudi Health
2016
Booth #735-1**





*Thank
You*