USE OF INFORMATICS IN ANALYTICAL QUALITY

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DR L H HIRANANDANI HOSPITAL, MUMBAI

DR L H HIRANANDANI HOSPITAL

246-bed quaternary care hospital catering to multispecialities; 1st hospital from India to win the International Asia-Pacific Quality Award; NABH accredited institute since 2007; NABL (ISO 15189) accredited laboratory since 2008; NABH accredited Blood Bank Dept…

STRUCTURE OF PRESENTATION

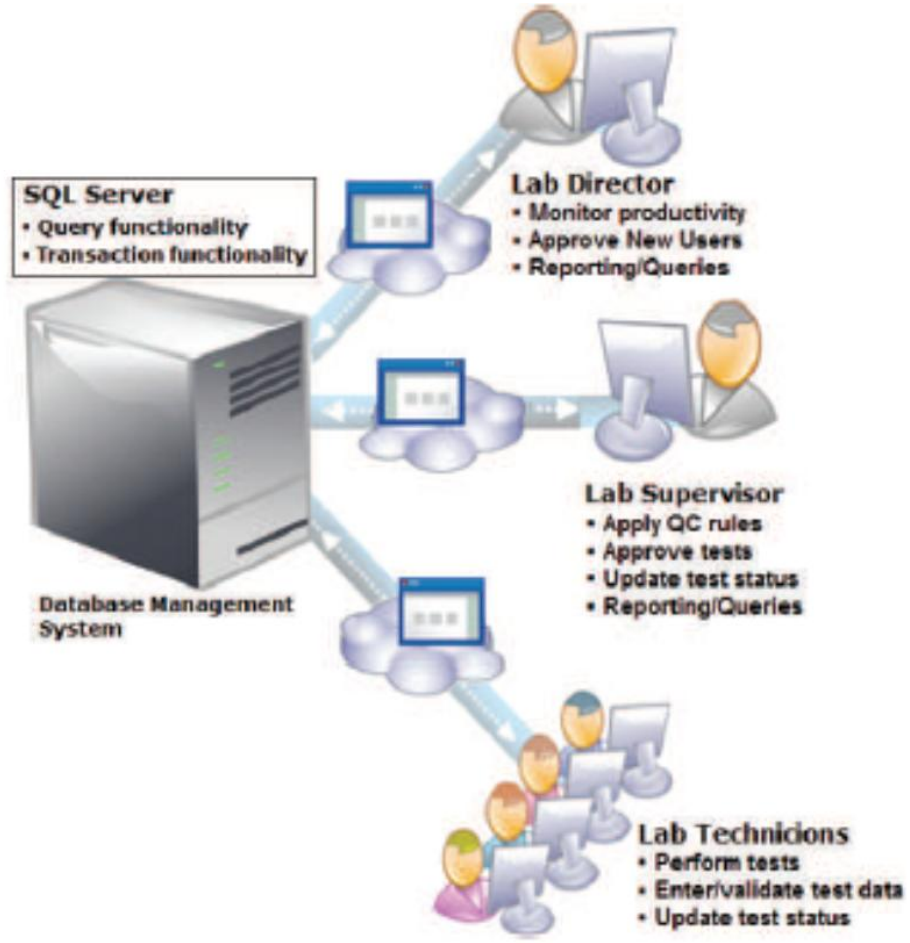
- Introduction
  - Need for informatics in lab
  - Disincentives of not having informatics
  - Applications of QC informatics
  - Advantages of QC informatics
- Applications and ISO 15189:2012
  - Review of results at regular intervals (5.6.2.3)
  - Prevent release of results in case of QC failure (5.6.2.3)
  - Inter-laboratory comparison (5.6.3.1) and Means to compare procedures and methods (5.6.4)
  - Quality indicators to monitor performance (4.14.7)
  - Determine measurement of uncertainty for each measurement procedure (5.5.1.4)
  - Clinically significant errors (5.6.2.3)
  - Records maintained towards performance of examinations (5.3.2.7)
  - Identification and control of non-conformities (4.9, 4.10, 4.13)
  - Design IQC procedure that verify attaining of intended quality of results (5.6.2.1)

NEED FOR INFORMATICS IN LAB

- Clinical labs are **data-mines of information** in the form of lab results (numbers, graphs, text etc) along with interpretative data to assist healthcare providers in delivering optimal patient care… need to properly package for its optimal use
- Informatics are aimed at improving the quality and cost-efficiency of patient care by **optimizing the operation** of clinical labs and most importantly the **interface** between healthcare providers and the clinical labs
- Interaction with informatics through user-friendly interfaces designed with a lean approach to optimize **efficiency** and maximize **productivity**
- However in general healthcare systems can be characterized as conservative and resistant to change…

LIMS – FUNCTIONALITY

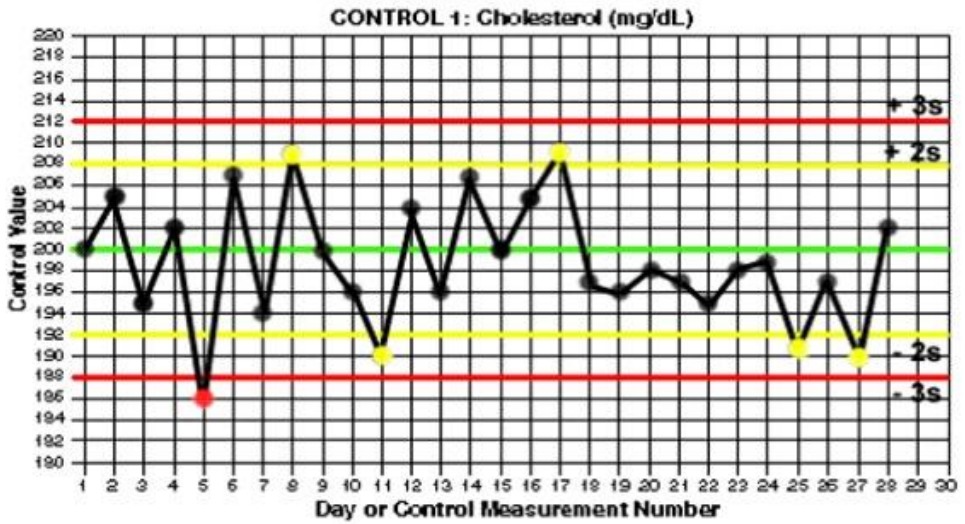
- Sample tracking
- Data entry
- Sample scheduling
- Quality assurance / QC module
- Electronic data transfer
- Reagent inventory
- Personnel and equipment management
- Maintenance



Client-server architecture

EXAMPLES OF MANUAL QC PLOTTING…

LJ CHART PLOTTED : AN EXAMPLE



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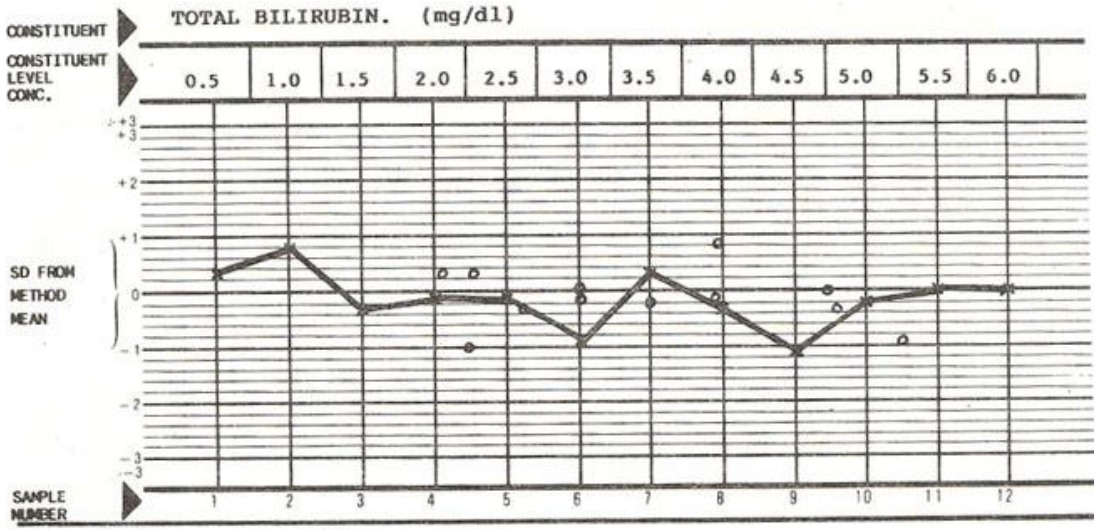


Figure 1. Serum Bilirubin – No bias for over reporting.

ESTIMATED PROCESSING TIME

Comparison	Web-based System	Paper-based System
Place test	<2 min	5 min
Approve test	<1 min	15 min – 1 hour
Apply Westgard rules	<1 min	15 min – 1 hour
View work productivity	<2 min	14 min – 1 hour
Prepare annual test report	<5 min	1 – 2 days

DISINCENTIVES OF NOT HAVING INFORMATICS

- Manual paper-based quality monitoring systems have a long lag time between tests and application of QC procedures
- Absence of a reporting system of the different system variables hinders the long-term planning and expansion of QC system
- Reduced reliability and productivity as these labs have been manually applying and assessing QC rules

APPLICATIONS OF QC INFORMATICS

1. Upload QC data points from a LIS, middleware or instrument, eliminating manual keying of QC data… saving precious man-hours
2. Basic QC rules, charts and reports… comprehensive QC data
3. Real-time bench connection and supervisor QC data review… improving alerts
4. Run validation with comprehensive audit trails… traceability
5. Westgard Advisor – automatic QC rules selection engine… advanced analysis
   - Recommend and automatically apply best QC rules
   - Reduce false rejections and desensitization to false error flags
   - Advanced charts and reports for data analysis

ADVANTAGES OF QC INFORMATICS

- Identify trends, instrument errors, reagent issues as soon as they arise, thus assuring validity and increasing confidence in result accuracy
- Optimize error detection, minimize costly repeat tests and reduce false rejections through use of multi-rule QC procedures
- Improving TAT and improve overall data quality
- Complete chain of custody and a full audit trail
- Improve PT performance by eliminating any undetected bias
- Ensure confidence in assigned target values
- Facilitate regulatory requirements (ISO 15189)

EXAMPLES OF QC SOFTWARE

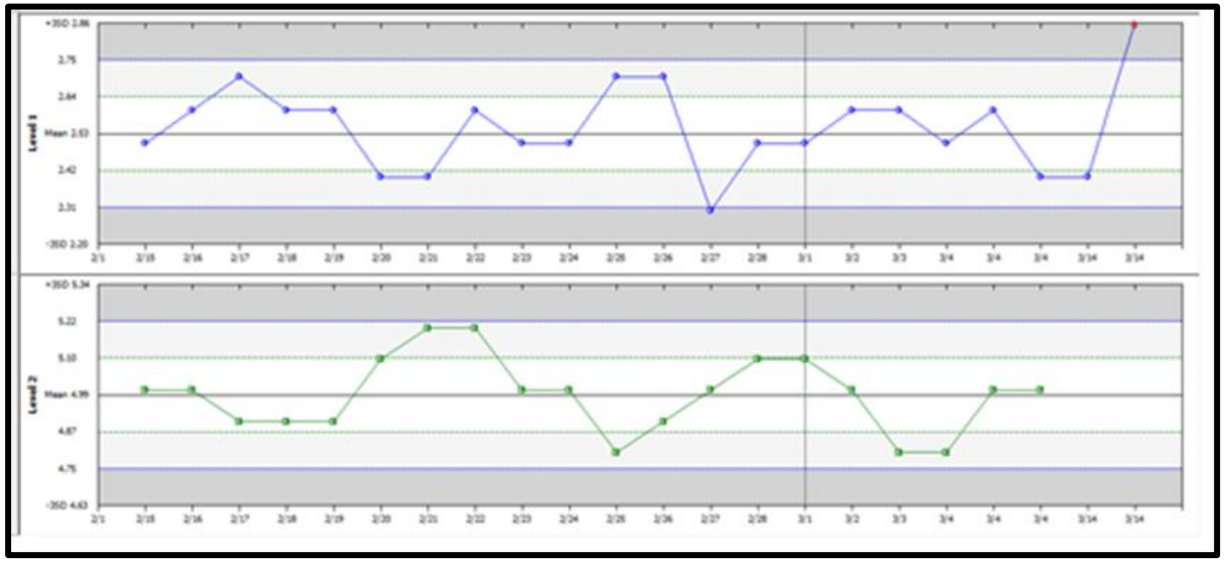
- Bio-Rad Unity (www.bio-rad.com)
- MAS/Dade LabLink (http://www.mas-inc.com)
- Hematronix Real-Time QC (http://www.hematronix.com) is primarily a "real-time“ peer-comparison service
- Sigma Diagnostics Computrol on Line (http://www.sigma-aldrich.com)
- Fisher Scientific ConCurTRAK (http://www.fishersci.com)
- Boston Biomedica AccuChart (http://www.bbii.com) is an internal QC program for specialized tests in infectious disease
- Blackhawk Biosystems Virotrol QA (http://www.blackhawkbiosystems.com)
- Westgard EZ Runs™ (http://www.westgard.com)

APPLICATIONS AND ISO 15189:2012

REVIEW OF RESULTS

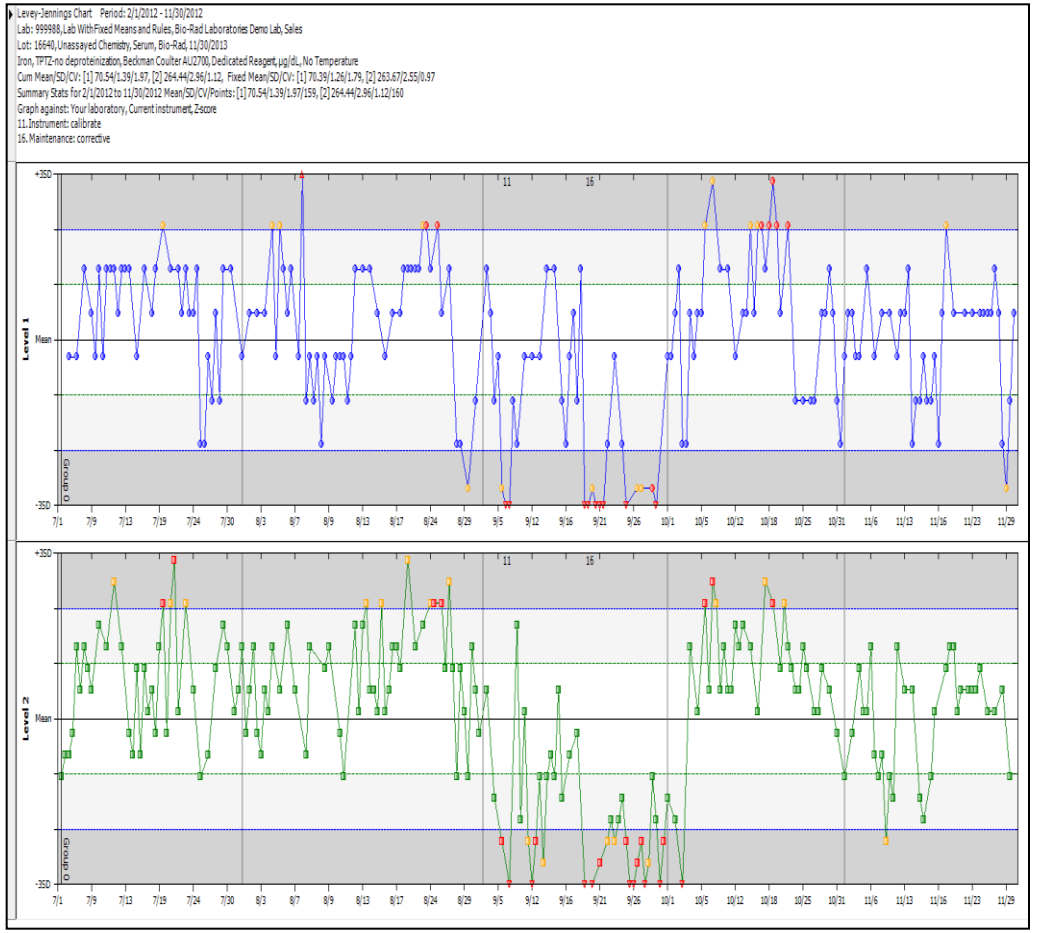
"Quality control data shall be reviewed at regular intervals to detect trends in examination performance" – ISO 15189:2012(E), Subclause 5.6.2.3

- Unity Real Time®2 provides a variety of charts for review of QC results:
  - ✓ Level-Jennings Chart
  - ✓ Multi Levey-Jennings Chart
  - ✓ Bar Chart
  - ✓ Youden Chart
  - ✓ Yundt Chart
  - ✓ Qualitative Bar Chart

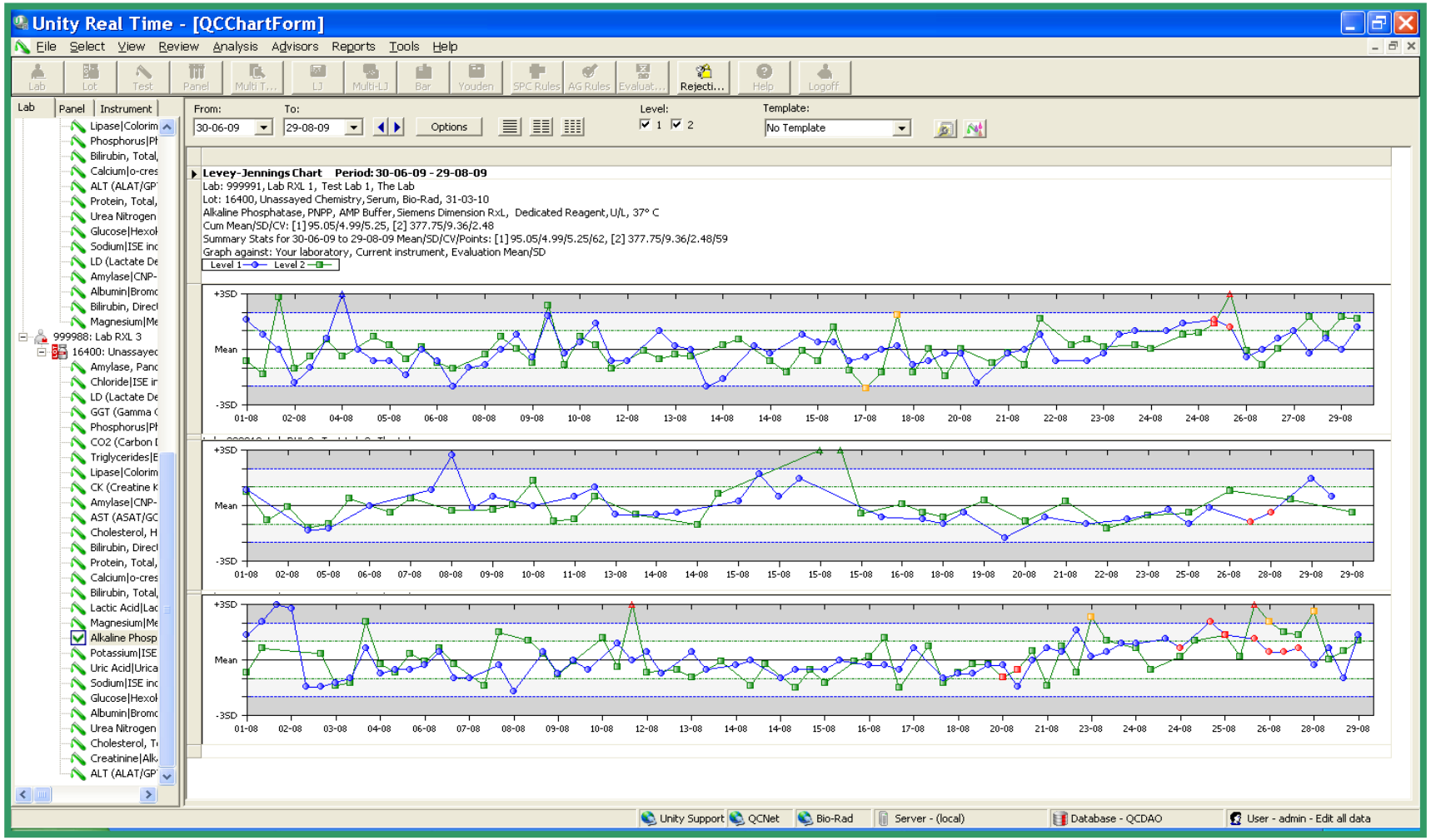


REVIEW OF RESULTS, LJ CHART

- View actions and add comments for the data on the chart
- Custom configuration of colors and ranges and chart header
- View by:
  - Day-to-day values and trends
  - Outliers and any actions
  - Consensus groups (peer, method, all labs)
  - 1 month, 6 months, or cumulative

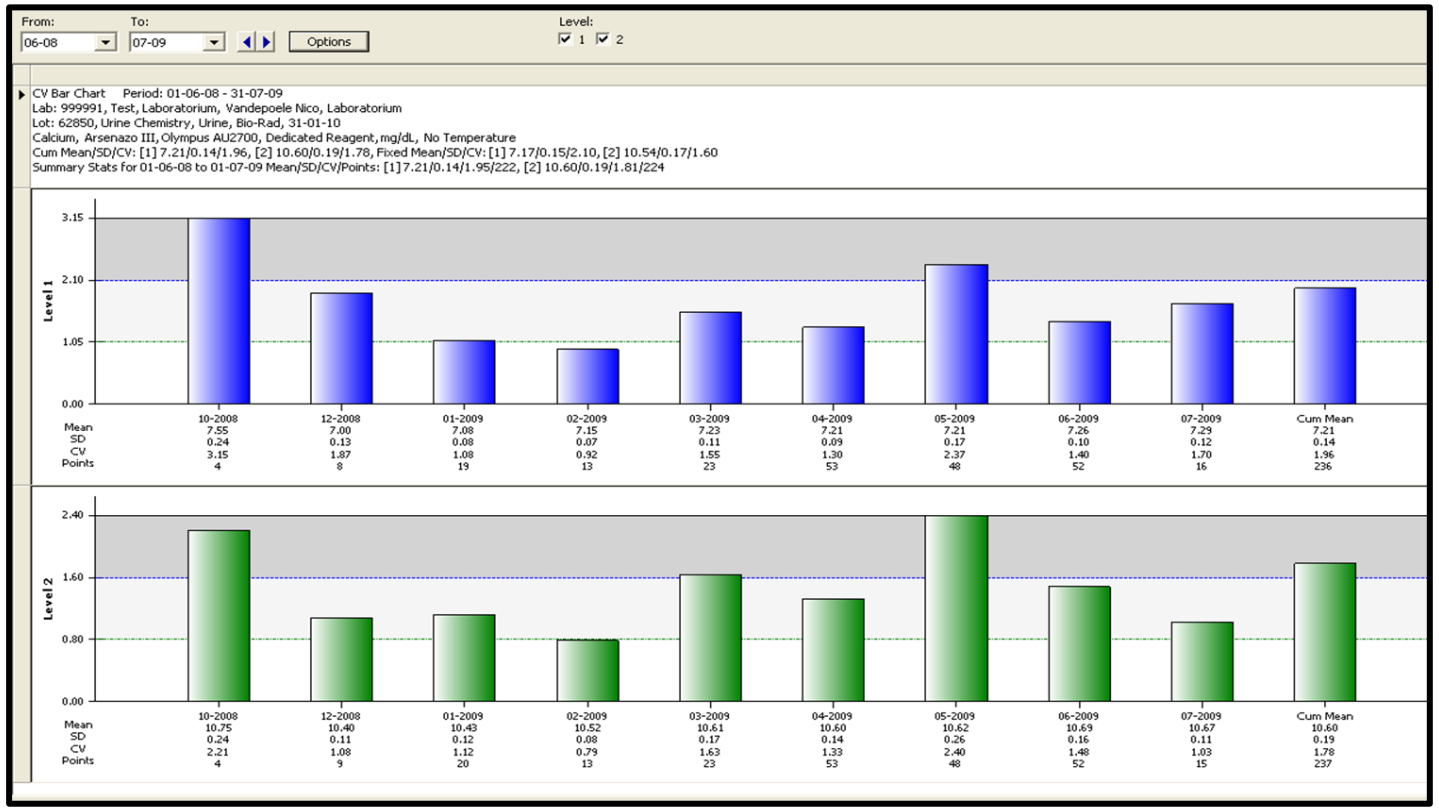


REVIEW, MULTI LEVEY-JENNINGS CHART



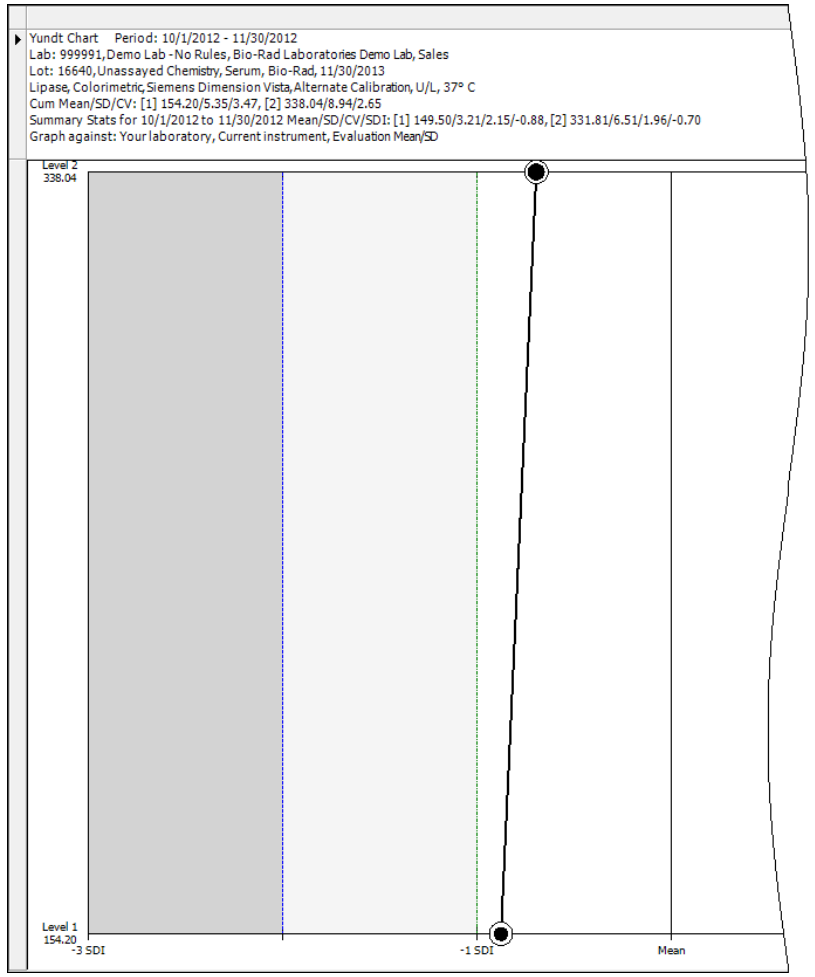
REVIEW OF RESULTS, BAR CHARTS

- Plots the monthly means or CV's
- Helps visualize long-term shifts and trends



REVIEW OF RESULTS, YUNDT CHART

- Each circle provides information about the SDI and CV for a test
- Allows comparison of the bias and imprecision of a selected data set

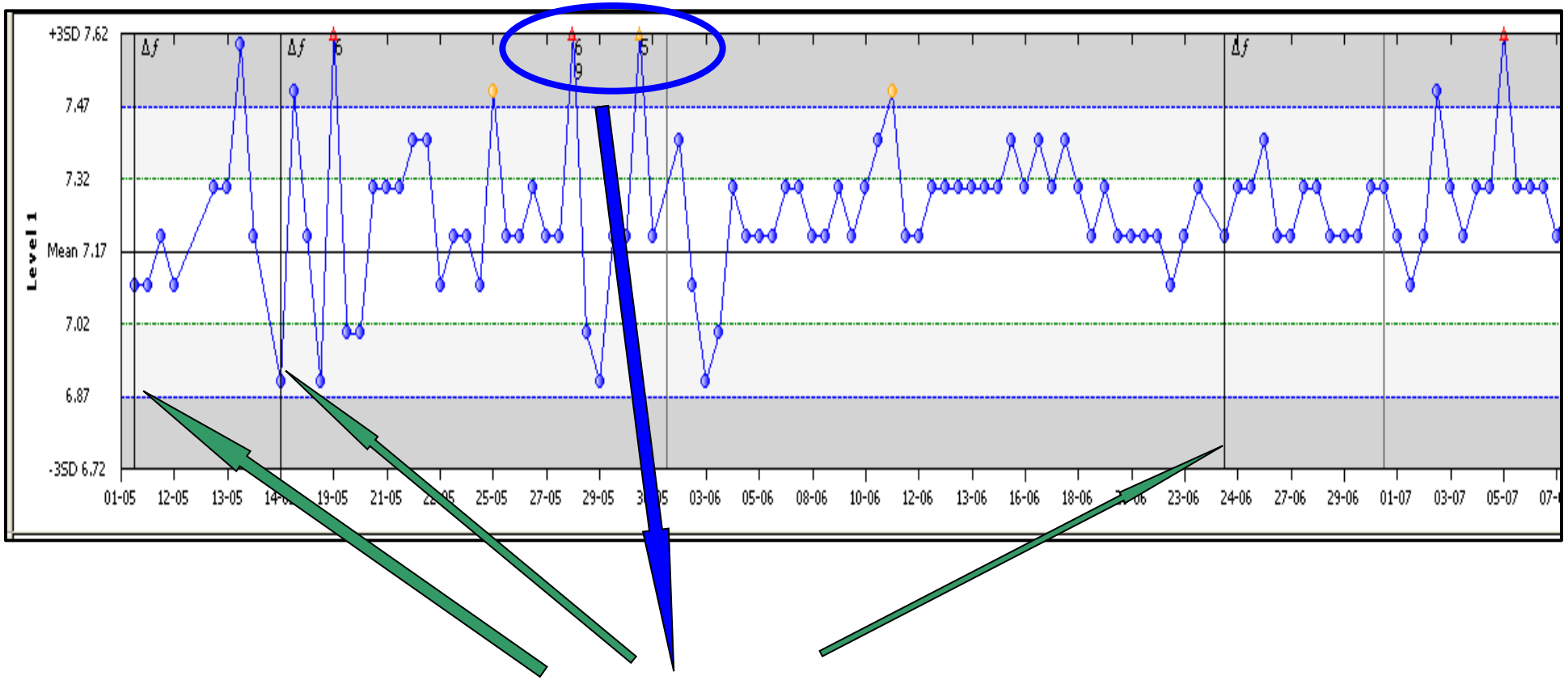


QUALITY CONTROL DATA

"The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure" – ISO 15189:2012(E), Subclause 5.6.2.3

- QC data should be reviewed at real-time and actions taken immediately
- System should be equipped with alert mechanism

LEVEY-JENNINGS CHART



- Delta f indicates changed fixed mean or SD
- And codified actions are displayed on demand

BENCH REVIEW

- Allows the bench technologist and supervisor to validate QC results
- Analysis of QC results is performed in real-time and in a standardized manner by all staff
- Allows the technologist to review data using the SPC rules established by the supervisor
- Use of Westgard rules to maintain the level of performance set by the laboratory supervisor or director
- Supervisor review is provided only for authorized users who can review results and filter any violations

SUPERVISOR'S REPORT

Unity Real Time

Supervisor's Report

BIO-RAD

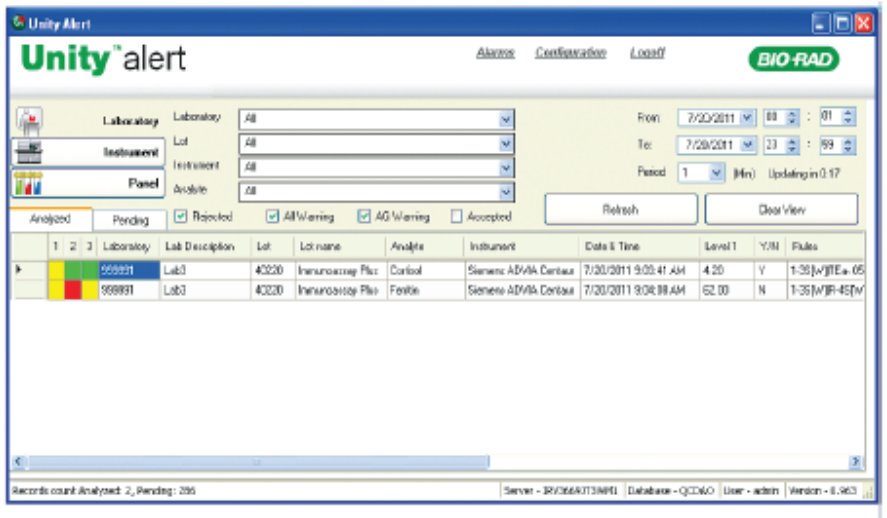
Data for 10/1/10 **through** 10/31/10 **Printed** 11/17/10 **Page** 1

Lab number:	922456	**Description:**	Demo
Lab name:	Demo	**Department:**	Biochemistry
Contact:		**Address:**	Biochemistry
City:	Gurgaon		
State:		**Postal/ZIP code:**	
Lot number:	14180	**Control name:**	Assayed Chemistry
Matrix:	Serum	**Manufacturer:**	Bio-Rad Laboratories
Expires:	9/30/11		

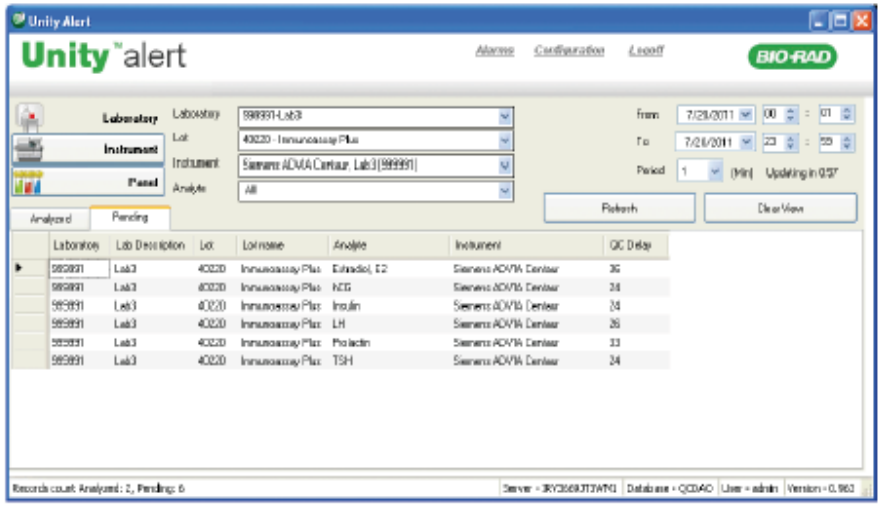
Date		Op	Level	Value		
Albumin, Bromcresol purple, Siemens Dimension RxL, Dedicated Reagent, g/dL, No Temperature						
10/21/10	12:00:00AM	sa	1	5.10	Rejected	1-3S
Action(s)	Test/assay repeated (sa - 11/17/10 01:05:13 PM)					
10/21/10	12:00:00AM	sa	2	5.20	Rejected	2-2S 1-3S
Action(s)	Test/assay repeated (sa - 11/17/10 01:05:13 PM)					

QC DATA – UNITY ALERT

- Notifications of missing QC runs (by level)
- Notifications of new violations
- Notifications sent by email or displayed in local application with toolbar indicator



Unity™ Alert provides a color-coded display for QC failures, helping draw attention to the most urgent issues.



Unity™ Alert can identify missing QC runs and indicate the delay since the test was last run, helping to ensure proper monitoring of instrument performance.

INTERLABORATORY COMPARISONS

"The laboratory shall participate in an interlaboratory comparison programme(s)..." – ISO 15189:2012(E), Subclause 5.6.3.1

Note: Lab should participate in ILC programmes that substantially fulfill the relevant requirements of ISO/IEC 17043

"Whenever an interlaboratory comparison is not available, the laboratory shall develop other approaches and provide objective evidence for determining the acceptability of examination results" – ISO 15189:2012(E), subclause 5.6.3.2

Note: Whenever possible, this mechanism shall utilize appropriate materials (example: control materials that are tested daily in ILC programmes)

COMPARABILITY OF EXAMINATION RESULTS

"The laboratory shall establish quality indicators to monitor and evaluate performance" – ISO 15189:2012(E), Subclause 4.14.7

"There shall be a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals" – ISO 15189:2012(E), Subclause 5.6.4

- Reports which can all be exported to pdf or excel files
- Data analysis grid can compare one to up to 250 different instruments
- Provides evaluation tools to quickly evaluate and document comparability

COMPARABILITY OF EXAMINATION

RESULTS

Level 1 | Level 2 | All Levels

Data Set	Analyte	Instrument	Unit	Mean	SD	CV	Pts	Labs	SDI	CVR	Bias%	TE p<0.05	TEB%	Sigma	TEa	TEa Selection
A	Chloride	Siemens Dimension Vista[99...	mEq/L	84.58	0.64	0.76	148	1							5.00	CLIA
B1				87.47	1.42	1.62	92702	151	-2.04	0.47	-3.31	4.55	91.08	2.24		
B2				86.04	2.33	2.71	878523	1100	-0.62	0.28	-1.69	2.94	58.73	4.38		
B3				86.29	2.37	2.75	980036	1359	-0.72	0.27	-1.97	3.22	64.43	4.00		
B4				86.04	2.33	2.71	878523	1100	-0.62	0.28	-1.69	2.94	58.73	4.38		
A	Calcium	Siemens Dimension Vista[99...	mg/dL	8.41	0.12	1.41	178	1							12.27	CLIA
B1				8.16	0.20	2.49	80411	149	1.24	0.57	3.08	5.40	44.06	6.52		
B2				8.36	0.28	3.30	353482	649	0.19	0.43	0.61	2.94	23.96	8.27		
B3				8.40	0.53	6.26	805108	1943	0.02	0.23	0.16	2.48	20.21	8.60		
B4				8.36	0.28	3.30	353482	649	0.19	0.43	0.61	2.94	23.96	8.27		

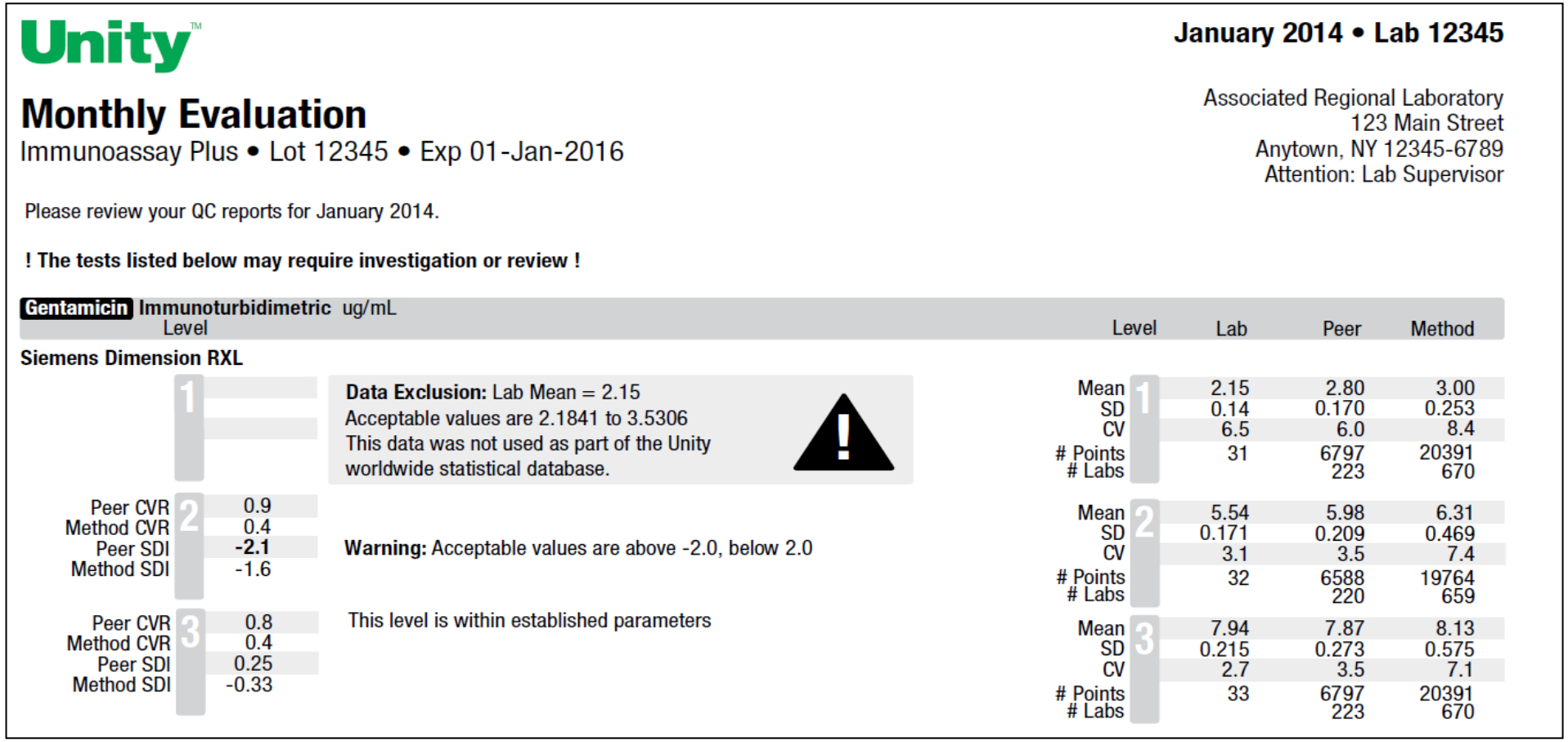
- Sigma = (TEa – Bias) / CVa
- TE = Bias + 1.65 CVa
- TEB% = (TE / TEa) x 100
- RCV (Reference Change Value)

- CVR = CVa / CVb
- SDI = (Mean a – Mean b) / SD b
- %Bias = [(Mean a – Mean b)/Mean b] x 100

Data Analysis Grid can be used for:

- Compare different instruments
- Compare to peer or method groups
- Follow up on historical performance
- Create quality indicator reports, for example **follow up monthly CV's** and set individual **alerts** to indicate poor performance

MONTHLY INTERLAB COMPARISON



Unity™

January 2014 • Lab 12345

Monthly Evaluation

Immunoassay Plus • Lot 12345 • Exp 01-Jan-2016

Associated Regional Laboratory
123 Main Street
Anytown, NY 12345-6789
Attention: Lab Supervisor

Please review your QC reports for January 2014.

! The tests listed below may require investigation or review !

Gentamicin **Immunoturbidimetric** ug/mL

Siemens Dimension RXL

Level		Lab	Peer	Method
Mean	1	2.15	2.80	3.00
SD		0.14	0.170	0.253
CV		6.5	6.0	8.4
# Points		31	6797	20391
# Labs			223	670

Data Exclusion: Lab Mean = 2.15
Acceptable values are 2.1841 to 3.5306
This data was not used as part of the Unity worldwide statistical database.

	Level	
Peer CVR	2	0.9
Method CVR		0.4
Peer SDI		**-2.1**
Method SDI		-1.6

Warning: Acceptable values are above -2.0, below 2.0

Level		Lab	Peer	Method
Mean	2	5.54	5.98	6.31
SD		0.171	0.209	0.469
CV		3.1	3.5	7.4
# Points		32	6588	19764
# Labs			220	659

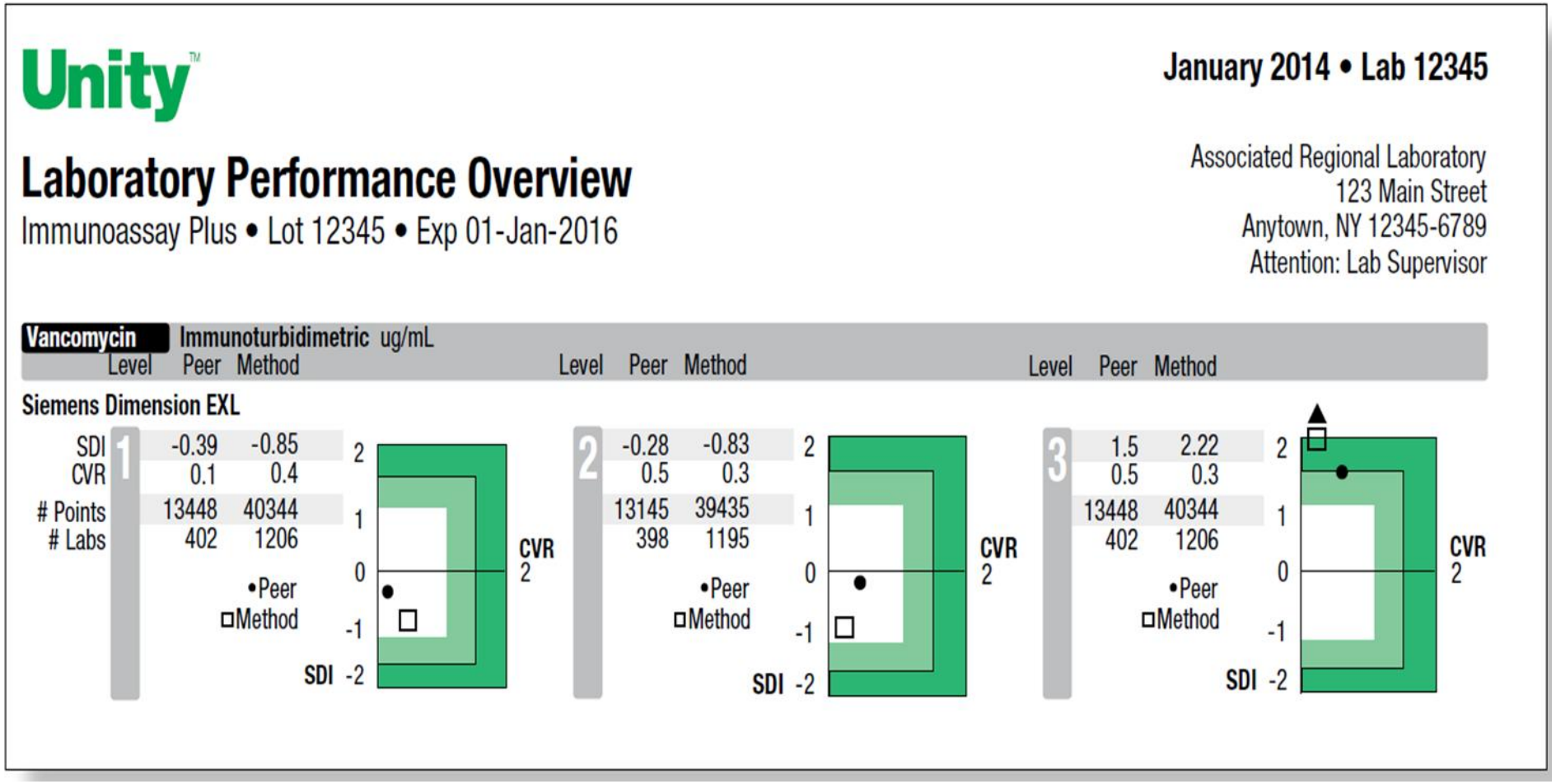
	Level	
Peer CVR	3	0.8
Method CVR		0.4
Peer SDI		0.25
Method SDI		-0.33

This level is within established parameters

Level		Lab	Peer	Method
Mean	3	7.94	7.87	8.13
SD		0.215	0.273	0.575
CV		2.7	3.5	7.1
# Points		33	6797	20391
# Labs			223	670

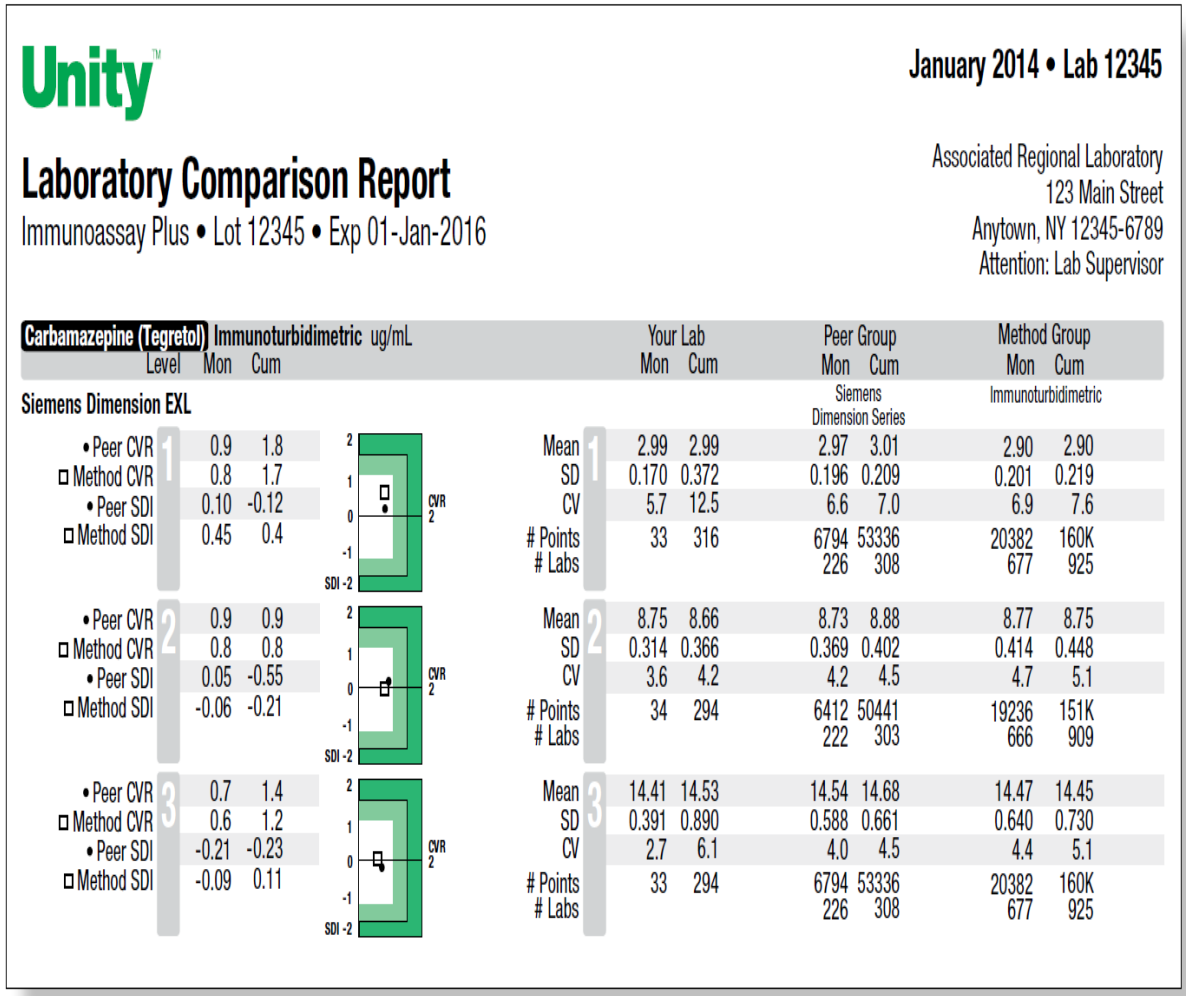
- Combined with Data Rejection Report for ease of use
- Provides quick overview of possible issues
- Includes submission status, warnings, and data rejections in one location

LAB PERFORMANCE OVERVIEW



- Provides visual indication of performance in terms of bias (SDI) and imprecision (CVR)
- New report includes arrow for values that are off the chart

LAB COMPARISON REPORT



Unity™

January 2014 • Lab 12345

Laboratory Comparison Report

Immunoassay Plus • Lot 12345 • Exp 01-Jan-2016

Associated Regional Laboratory
123 Main Street
Anytown, NY 12345-6789
Attention: Lab Supervisor

Carbamazepine (Tegretol) Immunoturbidimetric ug/mL

Level		Your Lab Mon	Your Lab Cum	Peer Group Mon	Peer Group Cum	Method Group Mon	Method Group Cum
Siemens Dimension EXL				Siemens Dimension Series		Immunoturbidimetric	
1	• Peer CVR	0.9	1.8				
	□ Method CVR	0.8	1.7				
	• Peer SDI	0.10	-0.12				
	□ Method SDI	0.45	0.4				
	Mean	2.99	2.99	2.97	3.01	2.90	2.90
	SD	0.170	0.372	0.196	0.209	0.201	0.219
	CV	5.7	12.5	6.6	7.0	6.9	7.6
	# Points	33	316	6794	53336	20382	160K
	# Labs			226	308	677	925
2	• Peer CVR	0.9	0.9				
	□ Method CVR	0.8	0.8				
	• Peer SDI	0.05	-0.55				
	□ Method SDI	-0.06	-0.21				
	Mean	8.75	8.66	8.73	8.88	8.77	8.75
	SD	0.314	0.366	0.369	0.402	0.414	0.448
	CV	3.6	4.2	4.2	4.5	4.7	5.1
	# Points	34	294	6412	50441	19236	151K
	# Labs			222	303	666	909
3	• Peer CVR	0.7	1.4				
	□ Method CVR	0.6	1.2				
	• Peer SDI	-0.21	-0.23				
	□ Method SDI	-0.09	0.11				
	Mean	14.41	14.53	14.54	14.68	14.47	14.45
	SD	0.391	0.890	0.588	0.661	0.640	0.730
	CV	2.7	6.1	4.0	4.5	4.4	5.1
	# Points	33	294	6794	53336	20382	160K
	# Labs			226	308	677	925

- Comprehensive overview of monthly and cumulative performance
- New report includes graphical display

MEASUREMENT UNCERTAINTY

Extract CV's and bias for measurement uncertainty calculations

"The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase used to report quantity values on patients' samples" – ISO 15189:2012(E), subclause 5.5.1.4

SUMMARY DATA REPORT

Unity Real Time
Summary Data Report

BIO-RAD

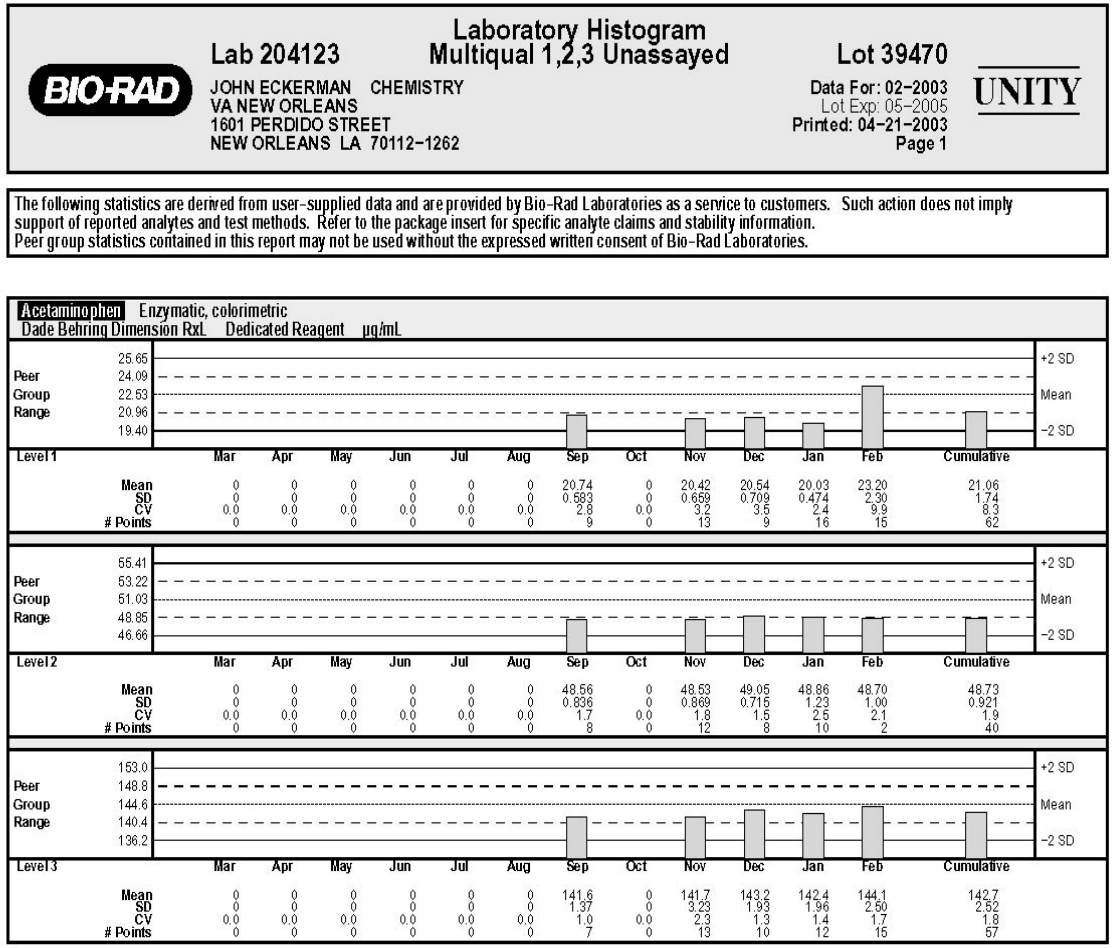
Printed	11/17/10	Range	Oct 2010	through	Nov 2010	Page	1

Lab number:	922456	**Description:**	Demo
Lab name:	Demo	**Contact:**	
Department:	Biochemistry	**Address:**	Biochemistry
City:	Gurgaon		
State:		**Postal/ZIP code:**	
Lot number:	14180	**Control name:**	Assayed Chemistry
Manufacturer:	Bio-Rad Laboratories	**Matrix:**	Serum
Expires:	9/30/11		

		Month				Cumulative			
	Level	**Mean**	**SD**	**CV**	**# Points**	**Mean**	**SD**	**CV**	**# Points**
Albumin, Bromcresol purple, Siemens Dimension RxL, Dedicated Reagent, g/dL, No Temperature									
2010/10	1	4.13	0.10	2.39	19	4.13	0.10	2.39	19
2010/10	2	2.46	0.31	12.69	19	2.46	0.31	12.69	19

Summary Statistics		**Mean**	**SD**	**CV**	**# Points**	**Fixed Mean**	**Fixed SD**	**Fixed CV**
10/1/10	- 11/17/10							
Level	1	4.13	0.10	2.39	19			
Level	2	2.46	0.31	12.69	19			

LAB HISTOGRAM



Laboratory Histogram
Multiqual 1,2,3 Unassayed

BIO-RAD

Lab 204123
JOHN ECKERMAN CHEMISTRY
VA NEW ORLEANS
1601 PERDIDO STREET
NEW ORLEANS LA 70112-1262

Lot 39470
Data For: 02-2003
Lot Exp: 05-2005
Printed: 04-21-2003
Page 1

UNITY

The following statistics are derived from user-supplied data and are provided by Bio-Rad Laboratories as a service to customers. Such action does not imply support of reported analytes and test methods. Refer to the package insert for specific analyte claims and stability information.
Peer group statistics contained in this report may not be used without the expressed written consent of Bio-Rad Laboratories.

Acetaminophen Enzymatic, colorimetric
Dade Behring Dimension RxL Dedicated Reagent µg/mL

Peer Group Range: 25.65 / 24.09 / 22.53 / 20.96 / 19.40 — +2 SD / Mean / -2 SD

Level 1

	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Cumulative
Mean	0	0	0	0	0	0	20.74	0	20.42	20.54	20.03	23.20	21.06
SD	0	0	0	0	0	0	0.583	0	0.659	0.709	0.474	2.30	1.74
CV	0.0	0.0	0.0	0.0	0.0	0.0	2.8	0.0	3.2	3.5	2.4	9.9	8.3
# Points	0	0	0	0	0	0	9	0	13	9	16	15	62

Peer Group Range: 55.41 / 53.22 / 51.03 / 48.85 / 46.66 — +2 SD / Mean / -2 SD

Level 2

	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Cumulative
Mean	0	0	0	0	0	0	48.56	0	48.53	49.05	48.86	48.70	48.73
SD	0	0	0	0	0	0	0.836	0	0.869	0.715	1.23	1.00	0.921
CV	0.0	0.0	0.0	0.0	0.0	0.0	1.7	0.0	1.8	1.5	2.5	2.1	1.9
# Points	0	0	0	0	0	0	8	0	12	8	10	2	40

Peer Group Range: 153.0 / 148.8 / 144.6 / 140.4 / 136.2 — +2 SD / Mean / -2 SD

Level 3

	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Cumulative
Mean	0	0	0	0	0	0	141.6	0	141.7	143.2	142.4	144.1	142.7
SD	0	0	0	0	0	0	1.37	0	3.23	1.93	1.96	2.50	2.52
CV	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.3	1.3	1.4	1.7	1.8
# Points	0	0	0	0	0	0	7	0	13	10	12	15	57

- Provides a bar graph of monthly means, SD and %CV for last 12 months
- Overlaid onto the current cumulative peer group for quick comparison
- Easy to identify shifts, trends, missing data

QC DATA – ANALYTICAL GOALS

"When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re- examined after the error condition has been corrected" – ISO 15189:2012(E), Subclause 5.6.2.3

- Unity Real Time provides analytical goals to evaluate the clinical relevance of the error condition
- Westgard Advisor will use Sigma Metrics to design the best statistical process control to ensure detection of clinical relevant errors and prevent unnecessary false rejections

QC DATA – ANALYTICAL GOALS

Prioritization for analytical goals was established in 1999 at the Stockholm Conference, International Conference (IFCC, IUPAC, WHO) Consensus for determining the quality specifications in the medical laboratory

Recommendations for choosing analytical goals:

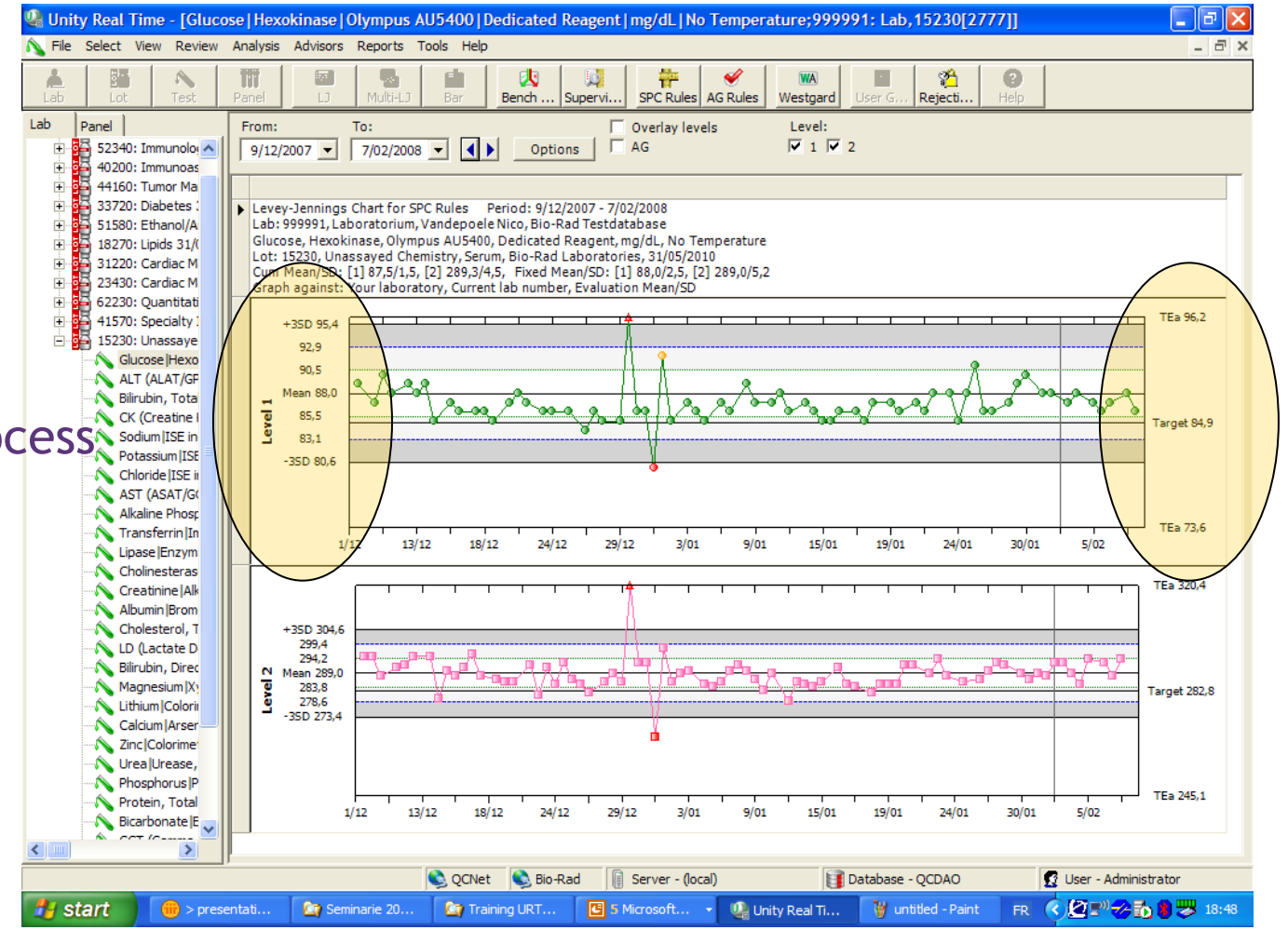
1. Quality specifications in specific clinical situations
2. Biological Variation or medical opinions
3. Professional / Regulatory recommendations
4. State-of-Art

QC DATA – ANALYTICAL GOALS

- Unity Real Time®2 is regularly updated with these values necessary for calculating analytical goals
- Specifications currently provided in Unity Real Time®2:
  - ✓ Biological Variation (Dr Ricos & Fraser)
  - ✓ CLIA (Clinical Laboratory Improvement Amendments)
  - ✓ RCPA (Royal College of Pathologist of Australasia)
  - ✓ Rilibak (German Guidelines)
  - ✓ IPH Belgium (Institute for Public Health Belgium)
  - ✓ QMP-LS (Quality Management Program – Laboratory Services Ontario Canada)
  - ✓ Qualab (Committee for quality assurance – Switzerland)
- User definable specifications available

QC DATA – ANALYTICAL GOALS

Analytical Process

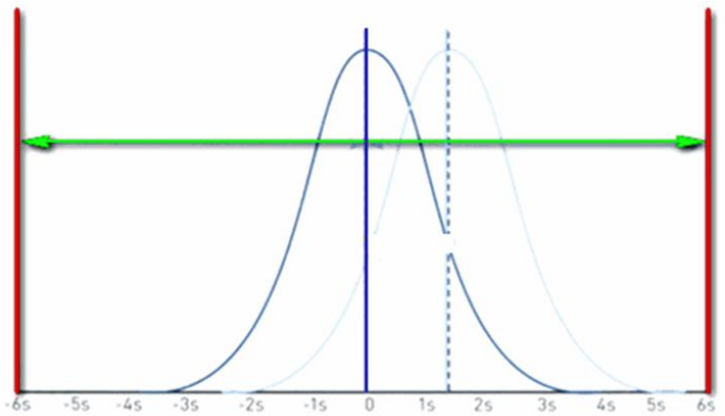


Analytical Goal

QC DATA – WESTGARD ADVISOR

- Maximize the effectiveness of processes; it is a comprehensive approach to quality improvement
- The capability of an analytical system is a measurement of the ratio between the actual performance and the performance required

$$\text{Sigma} = \frac{(\text{TEa} - \text{bias})}{\text{SD}}$$

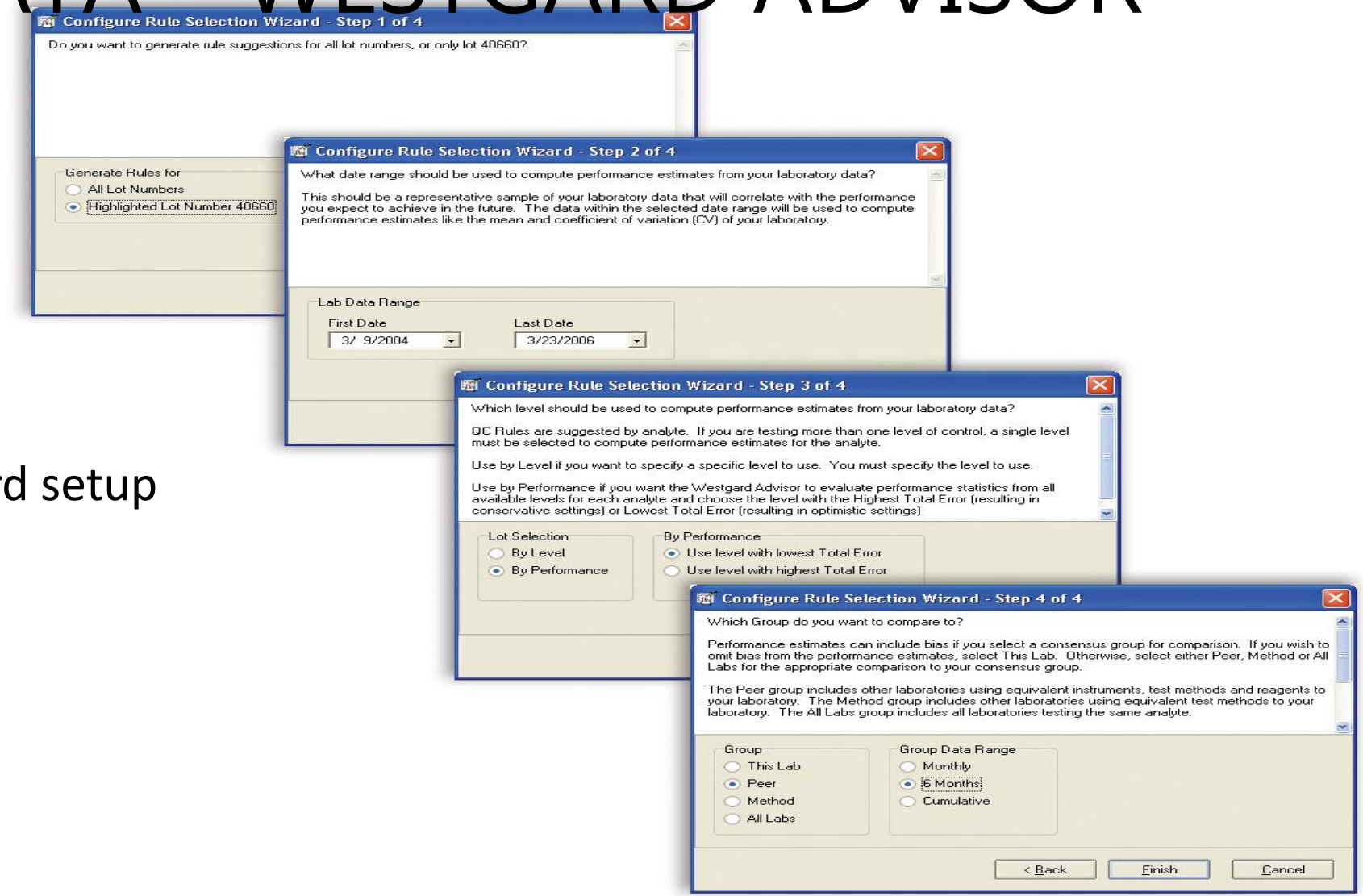


- A Six Sigma process is one in which 99.99966% of the products manufactured are statistically expected to be free of defects (3.4 defects per million)

QC DATA – WESTGARD ADVISOR

- Save time and money by **reducing unnecessary repeats** and troubleshooting
- Recommends and automatically **applies the best QC rules** with patented technology
- Easy step-by-step automatic **rule selection** capabilities
- Provides the highest possible **analytical quality assurance** (>90% AQA)
- Reduce **false rejections** and desensitization to false error flags

QC DATA – WESTGARD ADVISOR



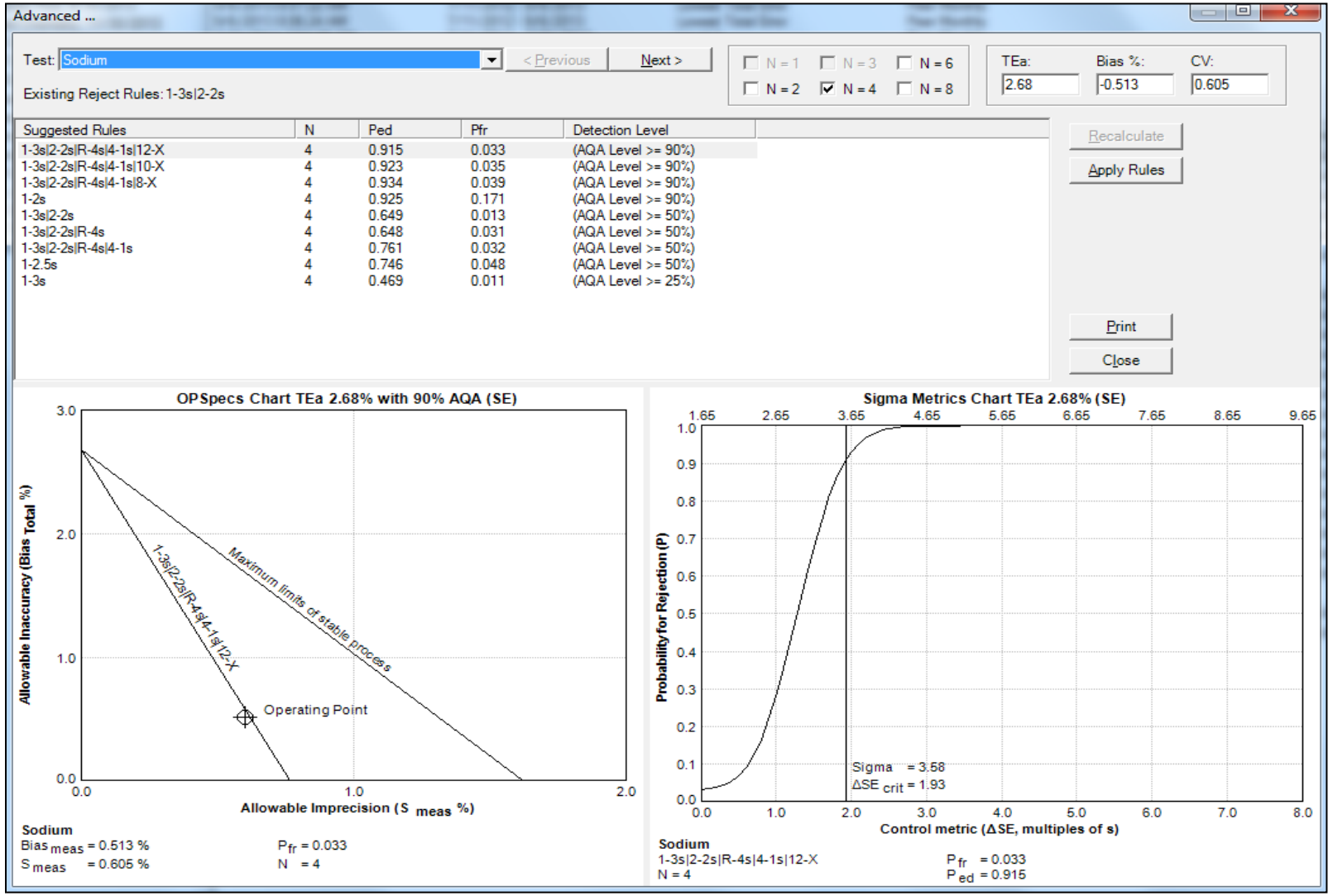
4-step wizard setup

QC DATA – WESTGARD ADVISOR

Data Grid | Data Charts

Selected	Analyte	Level	TEa Selecti	TEa	Bias %	CV	Sigma	Existing Reject Rules	Suggested Rules	N	Detection Level	False Reject
☑	Sodium	2	CLIA	2.68	-0.513	0.605	3.58	1-3s|2-2s	1-3s|2-2s|R-4s|4-1s|12-X	4	(AQA Level >= 90%)	3.33%
☑	Chloride	2	CLIA	5.00	-1.21	0.756	5.01	1-3s|2-2s	1-3s|2-2s	2	(AQA Level >= 90%)	0.65%
☑	Calcium	2	CLIA	8.38	2.70	1.40	4.05	1-3s|2-2s	1-3s|2-2s|R-4s|4-1s|10-X	2	(AQA Level >= 90%)	1.32%
☑	CO2 (Carbon Dioxide)	1	3SD	29.0	0.239	4.60	6.25	1-3s|2-2s	1-4s	2	(AQA Level >= 90%)	0.01%
☑	Albumin	1	CLIA	10.0	5.71	0.316	13.6	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Creatinine	2	CLIA	15.0	-0.682	2.39	6.00	1-3s|2-2s	1-3.5s	2	(AQA Level >= 90%)	0.08%
☐	Lipase		BV Min bias/					1-3s|2-2s	< 10 consensus group data points re			
☑	Magnesium	2	CLIA	25.0	10.7	1.40	10.2	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Urea Nitrogen	2	CLIA	9.00	-0.966	2.50	3.21	1-2s	1-3s|2-2s|R-4s|4-1s|10-X	2	(AQA Level >= 50%)	1.32%
☑	Glucose	2	CLIA	10.0	3.17	1.77	3.86	1-3s|2-2s	1-3s|2-2s|R-4s|4-1s|10-X	2	(AQA Level >= 90%)	1.32%
☑	Amylase	1	CLIA	30.0	-6.19	1.76	13.6	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Triglycerides	2	CLIA	25.0	0.155	1.82	13.6	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Uric Acid	2	CLIA	17.0	3.83	2.22	5.93	1-3s|2-2s	1-3.5s	2	(AQA Level >= 90%)	0.08%
☑	ALT (ALAT/GPT)	2	CLIA	20.0	-6.13	2.28	6.09	1-3s|2-2s	1-3.5s	2	(AQA Level >= 90%)	0.08%
☑	AST (ASAT/GOT)	2	CLIA	20.0	7.75	1.42	8.60	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Alkaline Phosphatase	2	CLIA	30.0	-8.91	3.23	6.53	1-3s|2-2s	1-4s	2	(AQA Level >= 90%)	0.01%
☑	Cholesterol, Total	2	CLIA	10.0	-3.98	1.89	3.19	1-3s|2-2s	1-3s|2-2s|R-4s|4-1s|10-X	2	(AQA Level >= 50%)	1.32%
☑	Phosphorus	2	BV Min bias/	15.3	3.20	1.54	7.87	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Protein, Total, Serum	1	CLIA	10.0	5.30	1.13	4.17	1-3s|2-2s	1-3s|2-2s|R-4s|4-1s|10-X	2	(AQA Level >= 90%)	1.32%
☑	Cholesterol, LDL	1	BV Min bias/	20.4	-7.47	2.10	6.17	1-3s|2-2s	1-4s	2	(AQA Level >= 90%)	0.01%
☑	Bilirubin, Direct/BC (DB	2	BV Min bias/	66.8	0.467	1.32	50.3	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Bilirubin, Total/TBIL	1	CLIA	35.9	-1.37	0.772	44.7	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☐	Cholesterol, HDL		CLIA					1-3s|2-2s	< 10 consensus group data points re			
☑	CK (Creatine Kinase)	2	CLIA	30.0	-1.15	1.12	25.7	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%
☑	Potassium	2	CLIA	7.83	-2.42	0.174	31.2	1-3s|2-2s	1-5s	2	(AQA Level >= 90%)	0.00%

QC DATA – WESTGARD ADVISOR

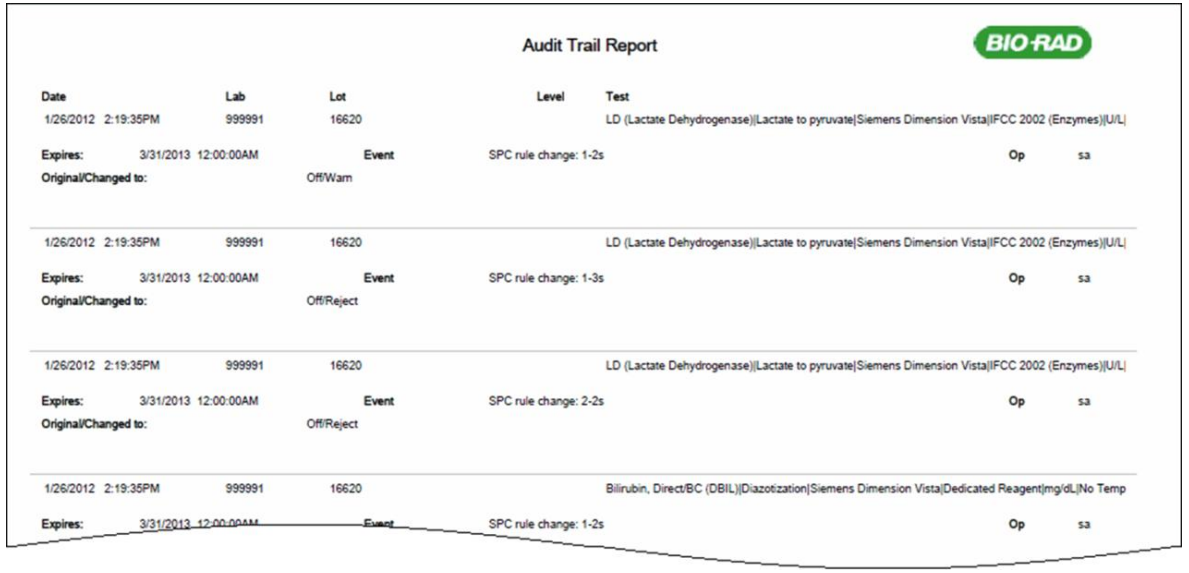


TRACEABILITY

"Records shall be maintained for each reagent and consumable that contributes to the performance of examinations" – ISO 15189:2012(E), Subclause 5.3.2.7

- Audit Trail Report: Lab must be able to justify the quality of its results at any time
  - This report shows the full traceability
  - All phases of the QC data are shown
  - The date and time the QC data was validated

    by the Bench Technologist and Supervisor
  - Any corrective actions implemented



Audit Trail Report

BIO-RAD

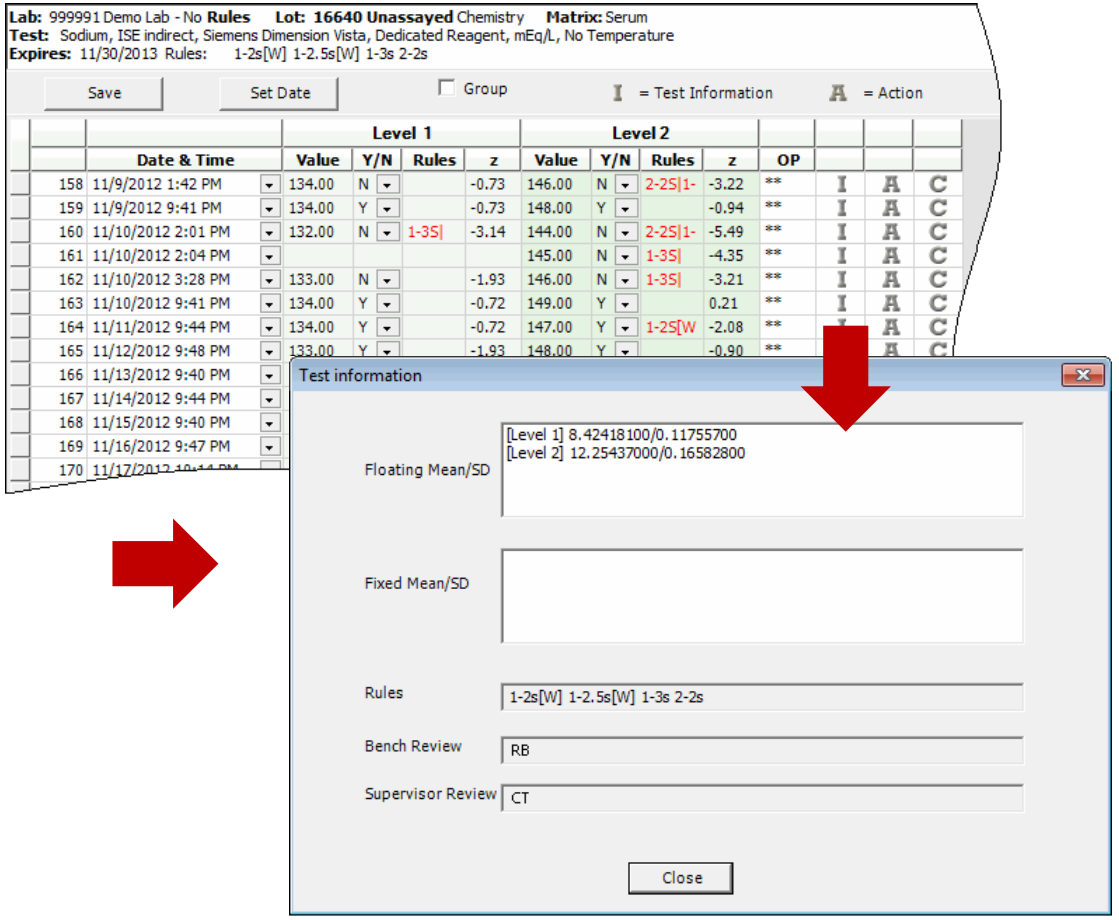
Date	Lab	Lot	Level	Test
1/26/2012 2:19:35PM	999991	16620		LD (Lactate Dehydrogenase)|Lactate to pyruvate|Siemens Dimension Vista|IFCC 2002 (Enzymes)|U/L|
Expires: 3/31/2013 12:00:00AM		Event	SPC rule change: 1-2s	Op sa
Original/Changed to:		Off/Warn		
1/26/2012 2:19:35PM	999991	16620		LD (Lactate Dehydrogenase)|Lactate to pyruvate|Siemens Dimension Vista|IFCC 2002 (Enzymes)|U/L|
Expires: 3/31/2013 12:00:00AM		Event	SPC rule change: 1-3s	Op sa
Original/Changed to:		Off/Reject		
1/26/2012 2:19:35PM	999991	16620		LD (Lactate Dehydrogenase)|Lactate to pyruvate|Siemens Dimension Vista|IFCC 2002 (Enzymes)|U/L|
Expires: 3/31/2013 12:00:00AM		Event	SPC rule change: 2-2s	Op sa
Original/Changed to:		Off/Reject		
1/26/2012 2:19:35PM	999991	16620		Bilirubin, Direct/BC (DBIL)|Diazotization|Siemens Dimension Vista|Dedicated Reagent|mg/dL|No Temp
Expires: 3/31/2013 12:00:00AM		Event	SPC rule change: 1-2s	Op sa

TRACEABILITY – STATISTICS AND RULES

Test Information:

Click I on the data entry screen to view information about a test:

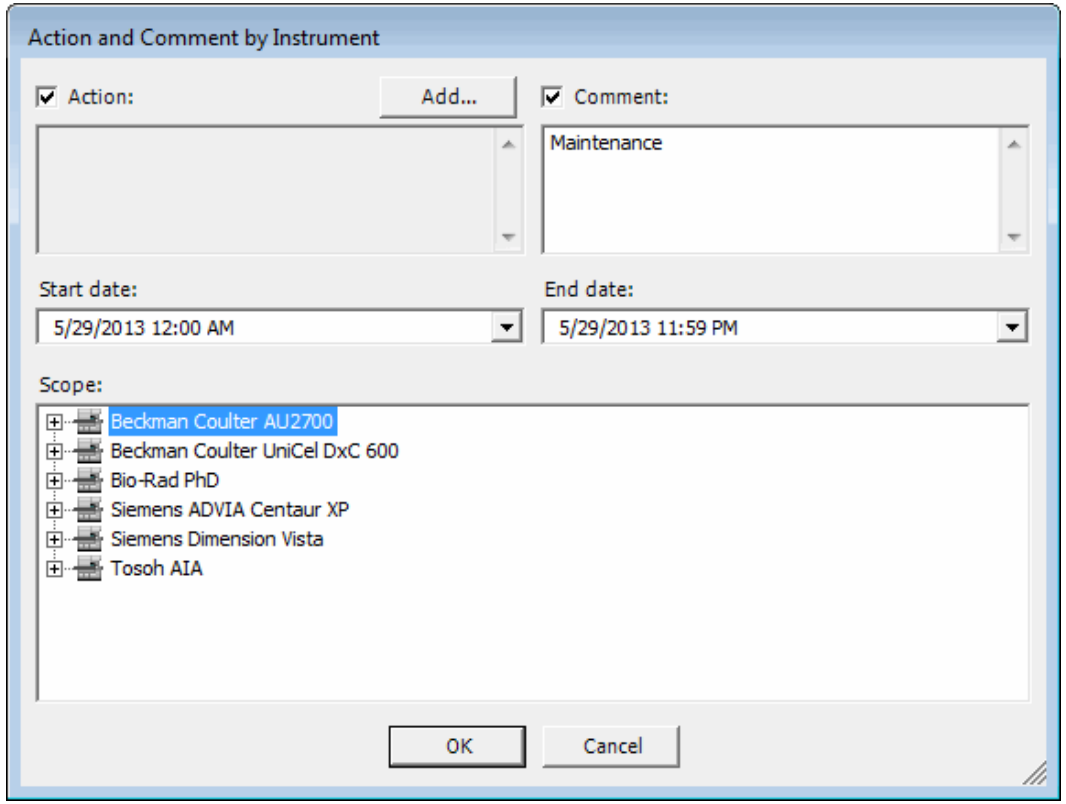
- Floating Mean/SD
- Fixed Mean/SD
- Active SPC Rules
- Bench Reviewer initials
- Supervisor Reviewer initials



TRACEABILITY – DOCUMENT CORRECTIVE ACTIONS

Actions and Comments by Instrument:

- Simplifies the documentation procedure
- Add an action or comment one time and apply it to all
- Save time documenting instrument maintenance



IDENTIFICATION AND CONTROL OF NON-CONFORMITIES

- This traceability also applies to the following requirements

"The laboratory shall have a documented procedure to identify and manage nonconformities in any aspect of the quality management system" – ISO 15189:2012(E), Subclause 4.9

"The laboratory shall take corrective action to eliminate the cause of nonconformities" – ISO 15189:2012(E), Subclause 4.10

"Records shall be created concurrently with performance of each activity that affects the quality of the examination" – ISO 15189:2012(E), Subclause 4.13

ENSURING QUALITY OF EXAMINATION RESULTS

"The laboratory shall design internal quality control procedures that verify the attainment of the intended quality of results" – ISO 15189:2012(E), subclause 5.6.2.1

- General requirement applies to the next quality control material requirement and the quality control data requirement

SUMMARISE…

- Without effective management of QC results, labs are **at risk** of producing erroneous patient results
- Examining results manually or using spreadsheet is a **time-consuming** process and can prove costly to the labs
  - Deciding whether a results is acceptable or not
  - Re-running controls that didn't need to be re-run
- Modern QC program must aim at improving accuracy and reliability of lab results by maximizing **error detection** and minimizing **false rejections** of test runs
- Quality management module should support **accreditation** requirements (CAP, CLIA, ISO 15189 standards)

REFERENCES

- Sepulveda JL, Young DS. The ideal laboratory information system. Arch Pathol Lab Med. 2013;137:1129 – 1140
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- Paszko C, Pugsley C. Considerations in selecting a laboratory information management system (LIMS). Sept 2000

thank you...