

Unity Interlaboratory Program

Optimize your laboratory performance as a member
of the world's largest community of QC users





Table of Contents

Unity Interlaboratory Program

An Effective Tool for Evaluating Analytical Performance	2
The Advantages of Participation	3
What are the Basic Comparison Statistics in an Interlaboratory Program and What Do They Indicate About Laboratory Performance?	4

Reports Reference Guide

Monthly Evaluation Report	5
Laboratory Performance Overview Report	6
Laboratory Comparison Report	7
Laboratory Histogram	8
Bias and Imprecision Histogram	9
Worldwide Report	10
Statistical Profile Report	11-13

Affiliated Reports

Overview	14
Laboratory Comparison Report: Abbreviated Summary	15
Laboratory Comparison Report	16
Laboratory Data Exception Report	17

Additional Reports

Qualitative Reports	18-19
Qualitative Worldwide Report	19
Qualitative Blood Bank Reports	20
InstantQC Reports	21

Additional Information

Glossary of Terms	22
Unity QC Data Management Solutions	23-25



Unity Interlaboratory Program: A Powerful Tool for Evaluating Analytical Performance

Join over 29,000 of your peers contributing data for over 52,000 instruments in the most robust program for clinical labs.

Quality Control practices have evolved to address patient safety concerns and other laboratory issues—including improvements in the use of statistical analysis for assessment of system performance. An effective interlaboratory program is only as reliable as the data it incorporates, giving laboratories the opportunity to measure and improve their analytical performance. Unity Reports are designed with these concerns in mind because so much depends on a lab's performance.

In addition to daily QC, ISO (International Organization for Standardization), CLSI (Clinical and Laboratory Standards Institute) and other regulatory and accreditation organizations highly recommend participation in an interlaboratory program. Unity data comparison provides the context and perspective of performance to your peers allowing for immediate action when potential problems are spotted.



"To compare our data with a substantial peer group ensures that we are turning out reliable patient data."

— **Laboratory Supervisor, School of Medicine**

"The reports are clean and easy to read and understand. For each test, Unity Reports for our lab show a summary of our data, our instrument group, and our method group—reports are simple."

— **Clinical Chemist, Hospital Laboratory**

"The documentation of Bio-Rad Controls using the Unity QC Program has been well accepted by CAP inspectors. Worry free QC."

— **Laboratory Director, Health Center**

"The laboratory shall participate in interlaboratory comparison programme(s) . . ."

— **ISO 15189:2012(E), Subclause 5.6.3.1.**

"The laboratory shall design internal quality control systems that verify the attainment of the internal quality of results. "

— **ISO 15189:2012(E), Subclause 5.6.2.1.**



Advantages of participating in an interlaboratory QC program:

"Verifying that a laboratory is producing QC results that are consistent with other laboratories using the same measurement procedure, and thus demonstrating that the laboratory is using the measurement procedure correctly.

Bias can be caused by events such as reagent or calibrator lot changes or reformulations, changes in calibration traceability to reference systems, or instrument software changes. Comparison of an individual laboratory's QC result to a peer group mean value can identify a trend or shift, or ascertain if other laboratories are experiencing the same changes.

PT/EQA programs verify performance at a point in time. Acceptable performance on the day of PT/EQA testing does not guarantee testing reliability every day because errors in a measurement procedure can occur at any time. In addition, the interlaboratory QC data can be used to investigate a failed or questionable PT/EQA result."

— CLSI, C24-A4, Vol. 36, No 12.



Using Interlaboratory Quality Control to Assess a Quality Control Program

Is your laboratory a statistical island?

An interlaboratory QC program is a means for statistically evaluating the performance of a measurement procedure by comparing results for QC materials to the results for the same (ie, identical lot numbers) QC materials measured by like (or substantially like) measurement procedures in other laboratories.

Receive reliable information from a trusted source

- Largest peer groups available in the clinical diagnostics industry.
- Provides a high degree of confidence in the statistical comparisons offered with more than 50,000 instruments participating from over 92 countries.
- Over 30 years of experience in managing peer programs.

Detect and identify potential analytical errors of importance

- Detect changes caused by reagent or calibrator reformulations, standardization adjustments or instrument software changes.
- Identify unrecognized trends or shifts that may occur between proficiency tests.
- Unity offers values to guide you on NEW control lot performance.
- Improve the reliability of test results for quality patient care.

Get a trusted, unbiased perspective

- Bio-Rad controls and software are not optimized for a specific test system.
- Obtain information from the largest peer group of data users.
- Receive values for both assayed and unassayed control materials.

Supplement Proficiency Testing (PT) Programs

- Complement your PT programs and verify performance on a daily basis by data comparison to your peer groups.
- Increase confidence that your PT outcomes will compare well to those of other laboratories.
- Unity may give meaningful comparisons for parameters not available in a PT program.

Meet accreditation and regulatory requirements

- Demonstrates commitment to procedural quality and can help you meet ISO 15189 and accreditation requirements.
- May be used to implement or maintain various LEAN and/or Six Sigma practices.

Access peer data on demand

- Real time data submission allows you to receive on-demand interlaboratory comparison reports with InstantQC.
- Critical for assessing performance while troubleshooting.



What are the Basic Comparison Statistics in an Interlaboratory Program and What Do They Indicate About Laboratory Performance?

Two of the most important metrics of an interlaboratory program are the coefficient of variation ratio (CVR) and standard deviation index (SDI), which are consensus-based metrics of imprecision and bias, respectively.

Coefficient of Variation (CVR)

The CVR allows you to evaluate your imprecision relative to your consensus group. The CVR is expressed mathematically by the formula:

$$\text{CVR} = \frac{\text{Your CV}}{\text{Consensus Group CV}}$$

If your test imprecision is equal to the imprecision of your consensus group, your CVR will be 1.0. The following guidelines are suggested for interpreting this statistic:

CVR < 1

Acceptable performance

1 < CVR < 1.5

Acceptable to marginal performance; may need to investigate test system imprecision

CVR > 1.5

Marginal performance; may need to perform corrective action

Standard Deviation Index (SDI)

The SDI is a useful parameter for evaluating your bias relative to your consensus group. The SDI is expressed mathematically by the formula:

$$\text{SDI} = \frac{\text{Your Mean} - \text{Consensus Group Mean}}{\text{Consensus Group SD}}$$

The target SDI is 0.0, which indicates that your mean is identical to the consensus group mean. A positive or negative deviation from this target statistic may indicate a bias compared to the consensus group mean. The following guidelines are suggested for interpreting this statistic:

-1 < SDI < 1

Acceptable performance

1 < SDI < 1.5 or -1 > SDI > -1.5

Acceptable to marginal performance; may need to investigate test system bias

SDI > 1.5 or SDI < -1.5

Marginal performance; may need to perform corrective action



Unity Interlaboratory Program

Optimize Laboratory Performance: Become a Member of the World's Largest Community of QC Users

Monthly Evaluation Report

Warns your lab of potential issues that require further investigation.

Unity

Monthly Evaluation

Immunoassay Plus • Lot 12345 • Exp 01-Dec-2022

Please review your QC reports for January 2020.

! The tests listed below may require investigation or review !

Gentamicin Immunoturbidimetric ug/mL

Level	Lab	Peer	Method
Siemens Dimension RXL			
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
Peer CVR 0.9	Mean 2	5.54	5.98
Method CVR 0.4	SD 2	0.171	0.209
Peer SDI -2.1	CV 2	3.1	3.5
Method SDI -1.6	# Points 32	6588	19764
	# Labs	220	659
Peer CVR 0.8	Mean 3	7.94	7.87
Method CVR 0.4	SD 3	0.215	0.273
Peer SDI 0.25	CV 3	2.7	3.5
Method SDI -0.33	# Points 33	6797	20391
	# Labs	223	670

January 2020 • Lab 12345

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

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.

Warning: Acceptable values are above -2.0, below 2.0

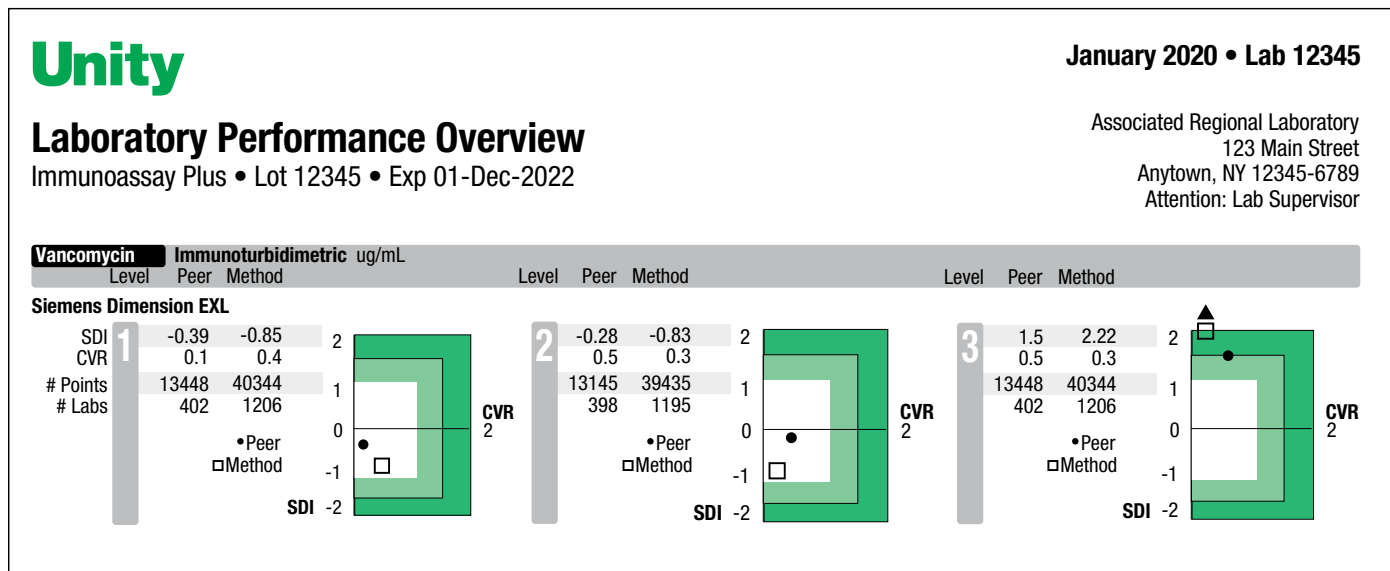
This level is within established parameters

Alerts you to submission issues, warnings, and data exclusions at a glance.

- Warns you when your SDI or CVR exceed a threshold of 2.0. These limits can be customized upon request.
- Alerts you to any data exclusions.
- Notifies you if your data was not received on time.

Laboratory Performance Overview Report

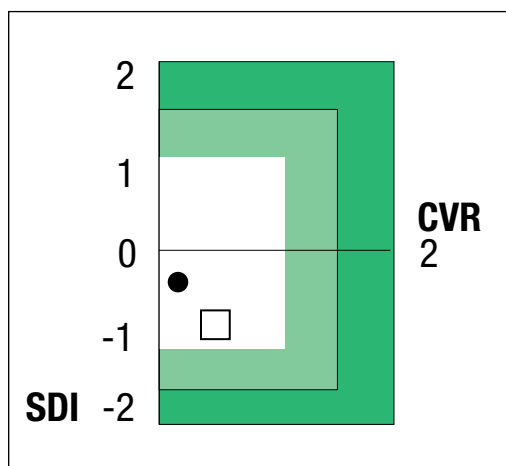
Bias (SDI) and imprecision (CVR) data in a modified Youden chart visually indicate your laboratory performance.



Performance versus peer (●) and method (□) consensus groups are plotted on a graph for fast comparison to your consensus group statistics.

- SDI (positive or negative) displays on the y-axis, and your CVR on the x-axis in a modified Youden chart.
- Print in either color or black and white.
- Data displays – up to 3 levels per row – for easy review.
- Arrows outside the chart margins indicate the presence of off the chart values.

- No Shading**
Acceptable performance
- Light Shading**
Acceptable to marginal performance.
May need to investigate test system performance.
- Dark Shading**
Marginal performance.
May need to perform corrective action.
- Outside of Graph**
Unacceptable performance.
Requires corrective action.



Laboratory Comparison Report

A comprehensive overview of your monthly and cumulative QC performance compared to peer and method consensus groups.



January 2020 • Lab 12345

Laboratory Comparison Report

Immunoassay Plus • Lot 12345 • Exp 01-Dec-2022

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

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

Vital statistics are displayed in an easy-to-read format comparing your results to those of consensus groups.

- Includes the SDI vs. CVR (from individual Laboratory Performance report) in a modified Youden chart.
- Provides key statistical measures, your monthly and cumulative Peer and Method CVRs and SDIs.
- Control data: Mean, SD, CV, the total number of Labs and Points broken down by your Lab, and Peer, and Method groups information is condensed by level into rows on a single page.

Statistics for Each Test

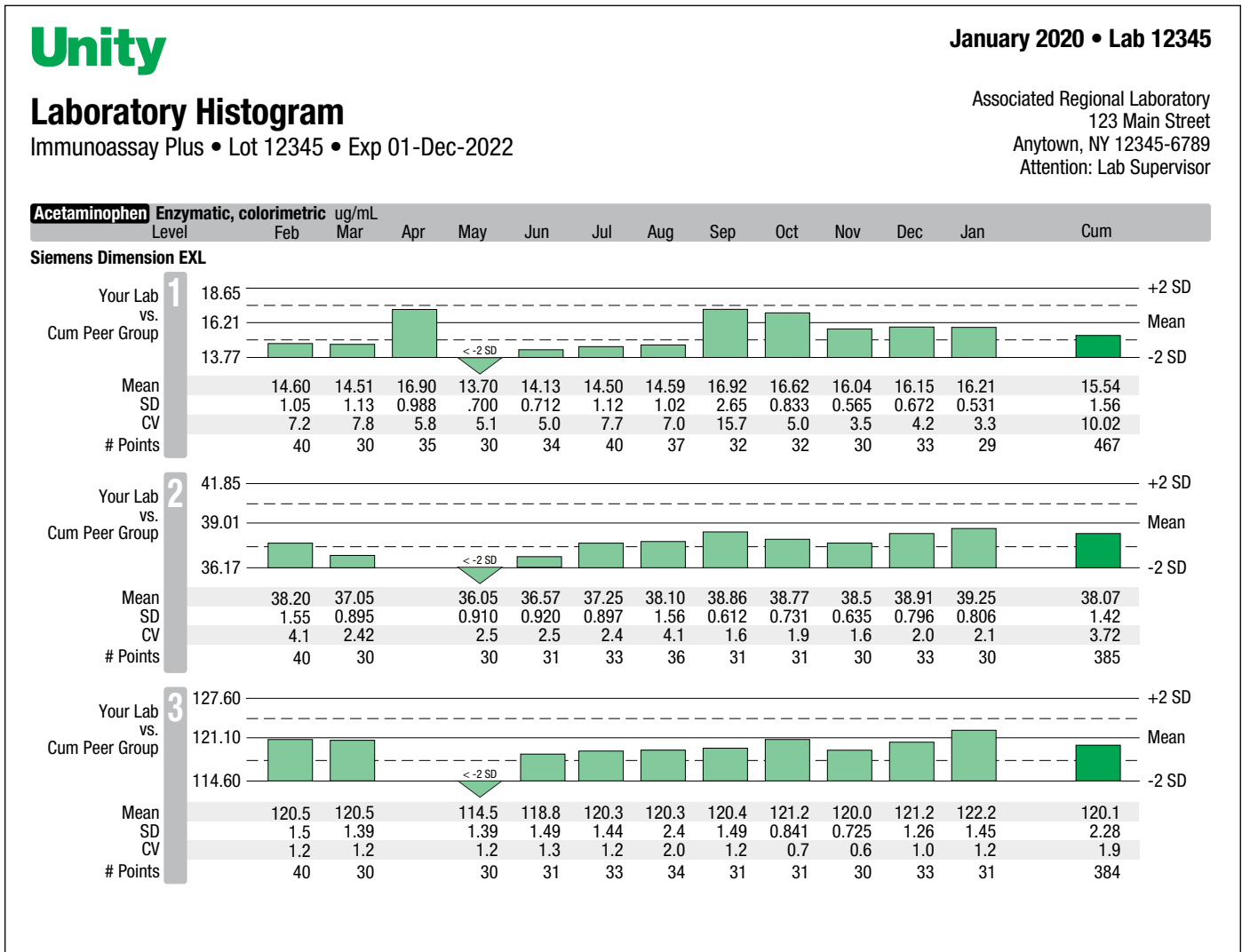
		Your Lab	
		Mon	Cum
Mean	1	2.99	2.99
SD		0.170	0.372
CV		5.7	12.5
# Points		33	316
# Labs			

Peer and Method Group Statistics

		Peer Group		Method Group	
		Mon	Cum	Mon	Cum
		Siemens Dimension Series		Immunoturbidimetric	
		2.97	3.01	2.90	2.90
		0.196	0.209	0.201	0.219
		6.6	7.0	6.9	7.6
		6794	53336	20382	160K
		226	308	677	925

Laboratory Histogram

Highlights your laboratory's trending data over the past 12 months against the cumulative peer group range, allowing you to see your lab's analyte data versus that of your current cumulative peer group.



An excellent tool to meet regulatory and accreditation requirements that oblige laboratories to monitor trends in bias and imprecision over time.

- Bar graph (a bar for each calendar month plus a cumulative bar) exhibits your mean versus your peer group mean.
- Data included for each bar: Mean, SD, CV and number of points represented.
- Labels and arrows clearly indicate values that fall outside of (above or below) the 2 SD range.
- Displaying < or > 2SD, this report is useful for identifying both shifts and trends in monthly analyte results.

Bias & Imprecision Histogram

Indicates performance changes in bias or imprecision over previous 12 months for detection of trends.

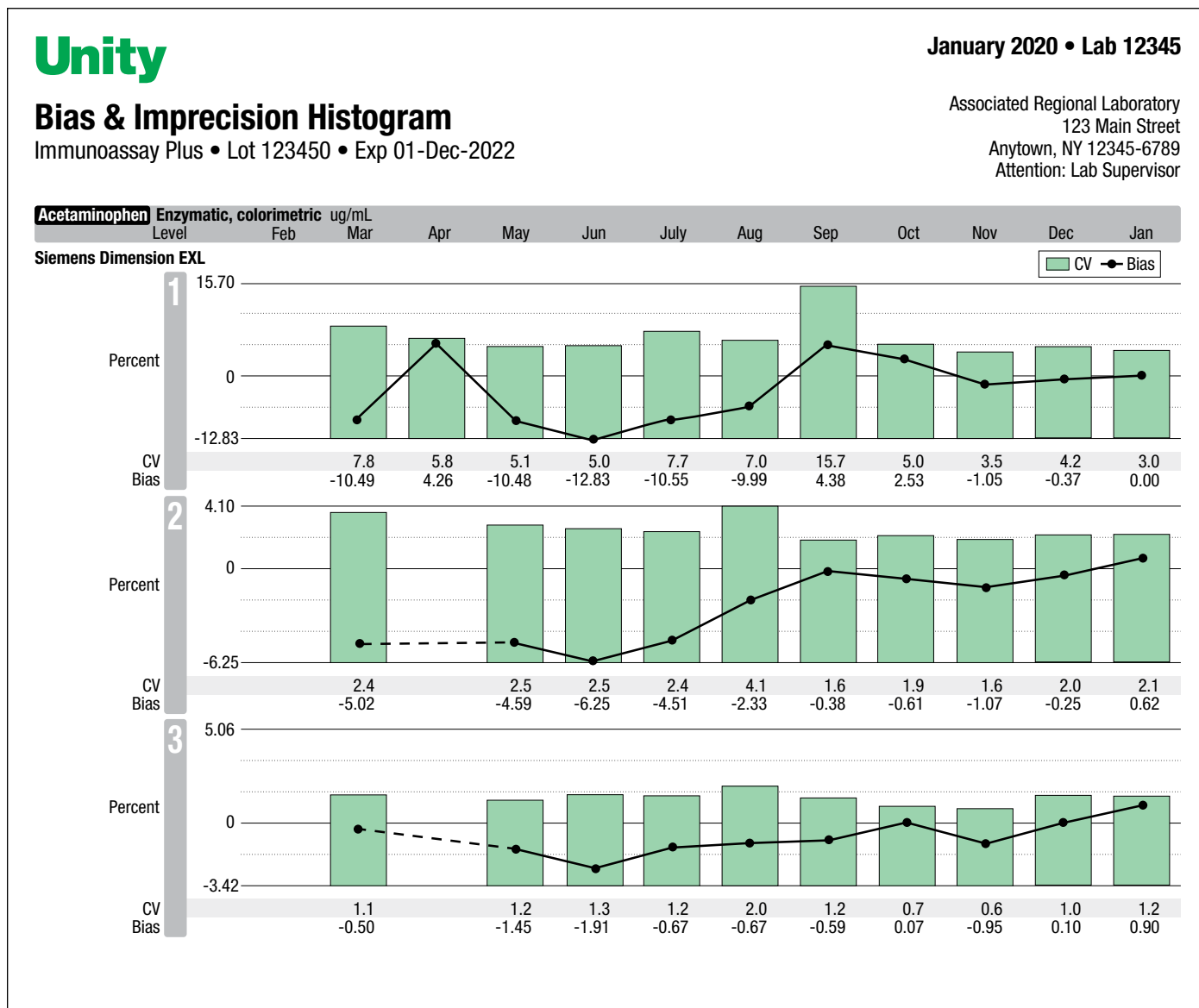


Chart represents your monthly CV as a bar and your bias as a connected line of dots.

- Displays your lab's bias compared to the current cumulative peer group mean and your CV.
- Easy-to-read, color bars and clearly labeled control levels show changes over time.
- Helps identify whether any change is due to imprecision, bias or both.
- Can be used to detect aberrant bias or CVs.

Worldwide Report

Summarizing all the peer group data submitted to the Unity Interlaboratory Program, this report is available for each lot number of Bio-Rad controls on QCNet.com.



January 2020

Conventional Units

Worldwide Report

Multiquial 1, 2, 3 Unassayed • Lot 23456 • Exp 01-Dec-2022

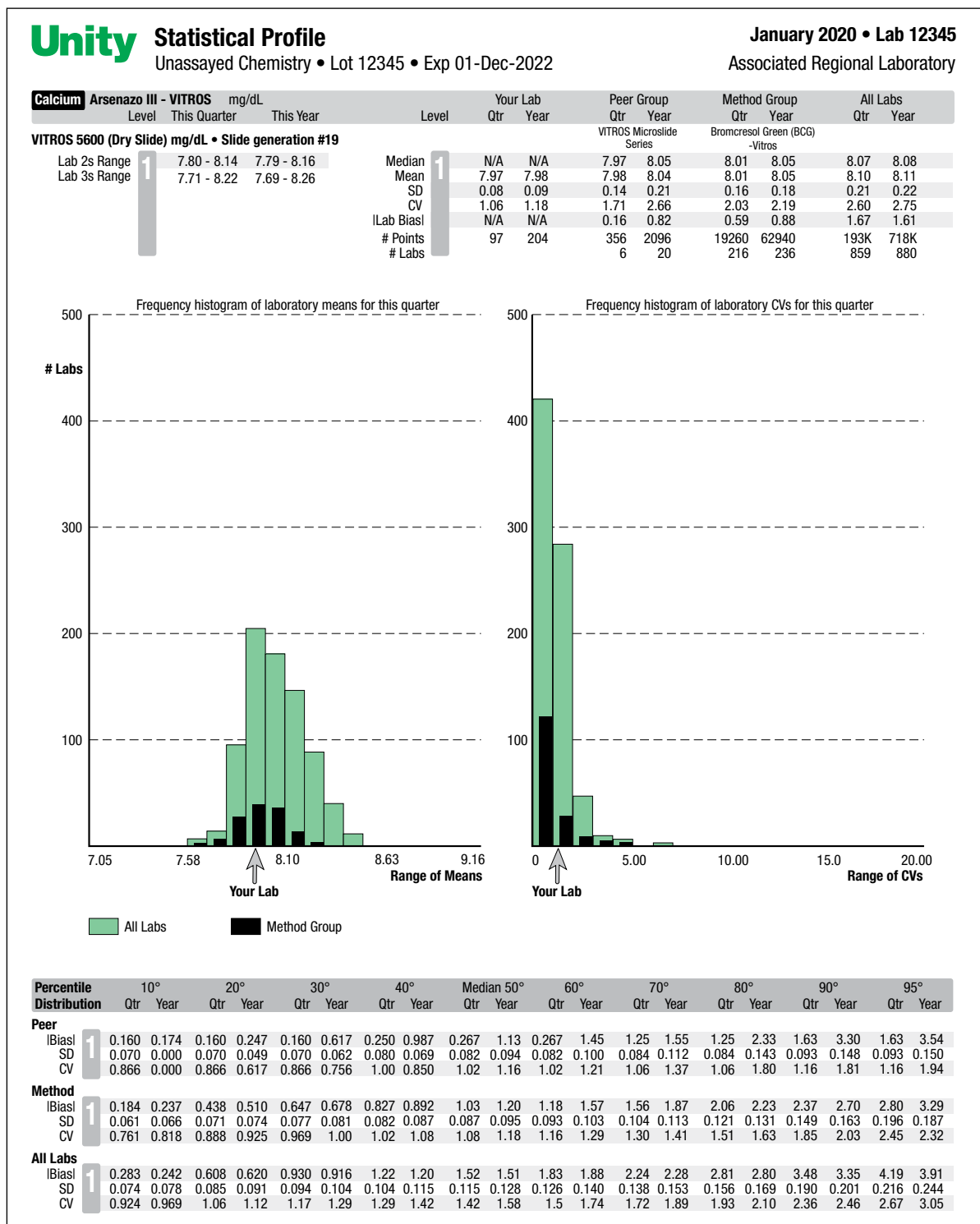
Albumin	Bromocresol Purple (BCP) g/dL								
Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Abbott AEROSET/ARCHITECT (c, i, ci models)									
Mean	1 2.40	2.40	2 3.39	3.33	3 3.93	3.88			
SD	0.032	0.050	0.026	0.057	0.169	0.086			
CV	1.3	2.1	0.8	1.7	4.3	2.2			
# Points	2346	48958	2270	44212	2346	48958			
# Labs	43	67	42	66	43	67			
Beckman Coulter CX Series									
Mean	1 2.44	2.44	2 -	-	3 4.06	4.04			
SD	0.051	0.056	-	-	0.062	0.094			
CV	2.1	2.3	-	-	1.5	2.3			
# Points	88	7108	-	-	112	7356			
# Labs	4	24	-	-	4	24			
Beckman Coulter LX20, LXi725, Chemistry Systems									
Mean	1 2.44	2.44	2 3.42	3.41	3 4.02	4.03			
SD	0.045	0.054	0.059	0.071	0.65	0.064			
CV	1.8	2.2	1.7	2.1	1.6	1.6			
# Points	436	16842	416	16540	436	16842			
# Labs	10	58	9	54	10	58			
Beckman Coulter UniCel DxC Series									
Mean	1 2.43	2.43	2 3.41	3.41	3 4.02	4.02			
SD	0.053	0.069	0.068	0.107	0.084	0.102			
CV	2.2	2.8	2.0	3.1	2.1	2.5			
# Points	12556	318K	12412	307K	12556	318K			
# Labs	225	390	222	373	225	390			
Siemens Dimension Series									
Mean	1 2.37	2.39	2 3.34	3.39	3 3.95	3.96			
SD	0.080	0.069	0.067	0.076	0.151	0.096			
CV	3.4	2.9	2.0	2.2	3.8	2.4			
# Points	12414	306K	12080	304K	12412	306K			
# Labs	276	552	272	546	276	552			

This report, inclusive of all consensus groups, can be useful for starting new control lots before you have submitted data.

- Supplies summary statistics: Means, SDs and CVs, for every peer and method group.
- Modified format also available – the Manufacturer’s Report – provides same statistical data but only for a particular manufacturer’s instruments.

Statistical Profile Report

Compare your laboratory's statistics to the peer, method, and all labs consensus groups using histograms that summarize where your values fall with respect to those of the indicated consensus groups.



One of the most sophisticated peer reports offered in the Unity Interlaboratory Program, the Statistical Profile Report contains information not offered elsewhere.

Statistical Profile Report: Section 1

Your lab's ranges for 2 and 3 SDs and summary statistics for quarter and year – Mean and median, CV, and Bias

- A table displays your lab's 2SD and 3SD range for the current quarter and year as well as summary statistics for your lab and consensus group.

Unity Statistical Profile

Unassayed Chemistry • Lot 12345 • Exp 01-Dec-2022

January 2020 • Lab 12345

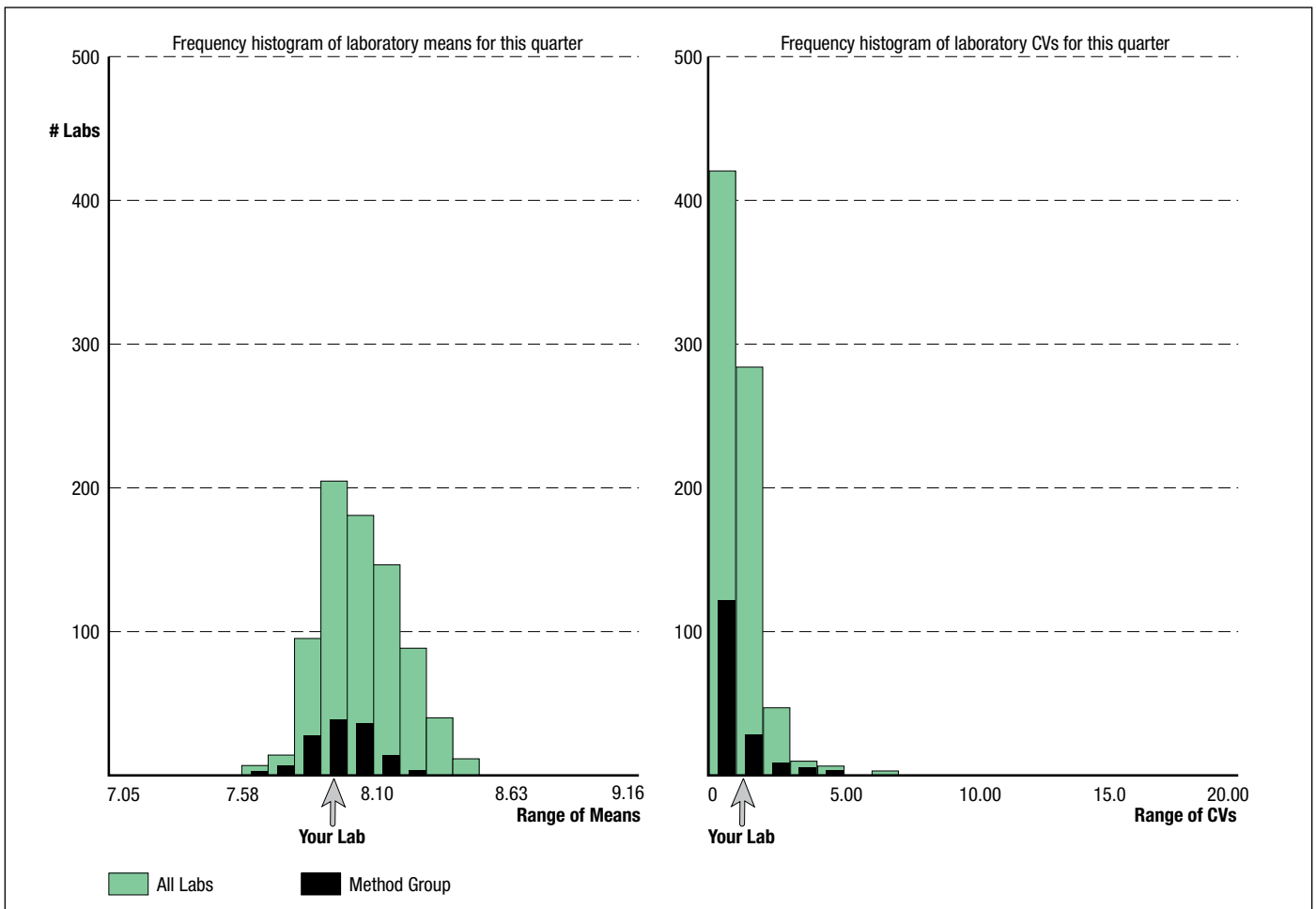
Associated Regional Laboratory

Calcium	Arsenazo III - VITROS	mg/dL		Level	Your Lab	Peer Group		Method Group		All Labs			
	Level	This Quarter	This Year		Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	
VITROS 5600 (Dry Slide) mg/dL • Slide generation #19													
Lab 2s Range	1	7.80 - 8.14	7.79 - 8.16	Median	1	N/A	N/A	7.97	8.05	8.01	8.05	8.07	8.08
Lab 3s Range		7.71 - 8.22	7.69 - 8.26	Mean		7.97	7.98	7.98	8.04	8.01	8.05	8.10	8.11
				SD		0.08	0.09	0.14	0.21	0.16	0.18	0.21	0.22
				CV		1.06	1.18	1.71	2.66	2.03	2.19	2.60	2.75
				Lab Bias		N/A	N/A	0.16	0.82	0.59	0.88	1.67	1.61
				# Points		97	204	356	2096	19260	62940	193K	718K
				# Labs				6	20	216	236	859	880

Statistical Profile Report: Section 2

Frequency histogram of Means and CVs

- Two histograms show: (1) the location of your lab's mean and (2) your lab's CV plotted on the range of means / CVs for all labs in the consensus group.



Statistical Profile Report: Section 3

Percentile distributions: Organized by percentile, then by quarter and by year

- A table includes the consensus group (peer, method and all labs) distributions for absolute bias, SD and CV by quarter and year.

Percentile Distribution	10°		20°		30°		40°		Median 50°		60°		70°		80°		90°		95°		
	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	
Peer																					
Bias	1	0.160	0.174	0.160	0.247	0.160	0.617	0.250	0.987	0.267	1.13	0.267	1.45	1.25	1.55	1.25	2.33	1.63	3.30	1.63	3.54
SD		0.070	0.000	0.070	0.049	0.070	0.062	0.080	0.069	0.082	0.094	0.082	0.100	0.084	0.112	0.084	0.143	0.093	0.148	0.093	0.150
CV		0.866	0.000	0.866	0.617	0.866	0.756	1.00	0.850	1.02	1.16	1.02	1.21	1.06	1.37	1.06	1.80	1.16	1.81	1.16	1.94
Method																					
Bias	1	0.184	0.237	0.438	0.510	0.647	0.678	0.827	0.892	1.03	1.20	1.18	1.57	1.56	1.87	2.06	2.23	2.37	2.70	2.80	3.29
SD		0.061	0.066	0.071	0.074	0.077	0.081	0.082	0.087	0.087	0.095	0.093	0.103	0.104	0.113	0.121	0.131	0.149	0.163	0.196	0.187
CV		0.761	0.818	0.888	0.925	0.969	1.00	1.02	1.08	1.08	1.18	1.16	1.29	1.30	1.41	1.51	1.63	1.85	2.03	2.45	2.32
All Labs																					
Bias	1	0.283	0.242	0.608	0.620	0.930	0.916	1.22	1.20	1.52	1.51	1.83	1.88	2.24	2.28	2.81	2.80	3.48	3.35	4.19	3.91
SD		0.074	0.078	0.085	0.091	0.094	0.104	0.104	0.115	0.115	0.128	0.126	0.140	0.138	0.153	0.156	0.169	0.190	0.201	0.216	0.244
CV		0.924	0.969	1.06	1.12	1.17	1.29	1.29	1.42	1.42	1.58	1.5	1.74	1.72	1.89	1.93	2.10	2.36	2.46	2.67	3.05

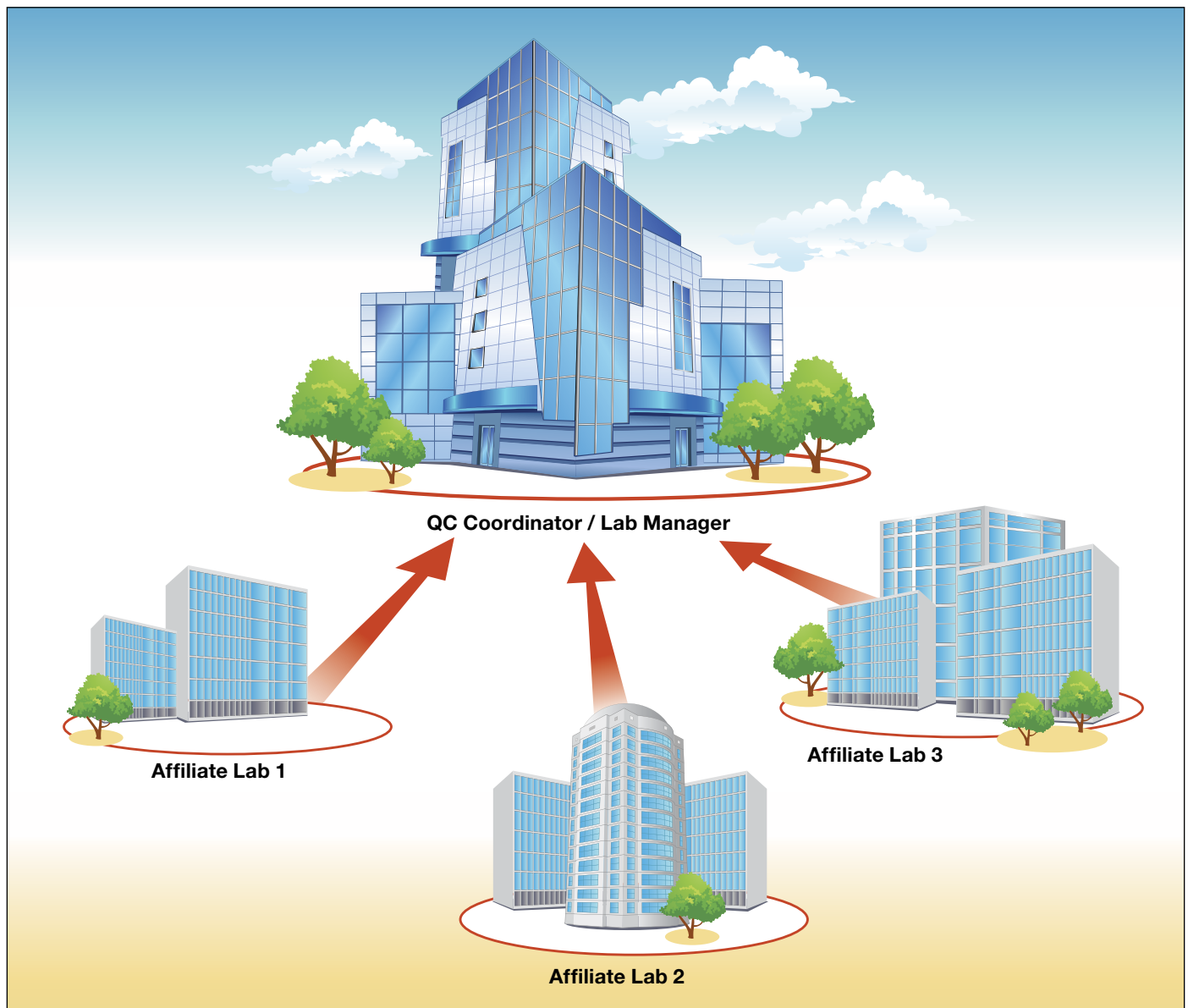
Affiliated Reports

The Affiliated Reports allow a group of labs to obtain a simplified, yet detailed, view of their performance and see data warnings and rejections for all affiliate labs. These reports allow a group of labs to become their own consensus group.

Ideal reports for Laboratory Managers or Quality Control Coordinators responsible for multiple sites or multiple instruments of a common make and model.

Types of Affiliated Reports Available:

- Affiliated Laboratory Comparisons Report: Abbreviated Summary
- Affiliated Laboratory Comparisons Report
- Affiliated Data Exception Report



Contact your Bio-Rad QC Program Representative to request any of the available Affiliated Reports

Additional charges may apply to configure and maintain Affiliated Reports.

Affiliated Laboratory Comparison Report: Abbreviated Summary

This popular summary report provides a simplified view of performance for all your affiliated labs.



January 2020

Affiliated Laboratory Comparison Report: Abbreviated Summary

Unassayed Chemistry • Lot 12345 • Exp 01-Dec-2022

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

123456 Reference Laboratory	234567 Western Laboratory	456789 Eastern Laboratory
135789* R&D Laboratory	345678 Central Laboratory	999999* Southern Laboratory

* Lab data was not available for processing for the date listed. Consequently no reports were generated for this lab during the reporting cycle.

Albumin Bromocresol Green (BCG) g/dL	Level	Mean	SD	CV	# Points	Affiliated CVR	Affiliated SDI	Peer CVR	Peer SDI	Method CVR	Method SDI
Roche MODULAR (ISE, D, P, E170)											
Affiliated Group	1	2.88	0.085	3.0	1324 (4 Labs)			1.11	-0.91	0.9	-0.42
Peer Group		2.95	0.078	2.7	6698 (45 Labs)						
Method Group		2.93	0.102	3.5	33164 (435 Labs)						
123456 Reference Laboratory • Roche MODULAR		2.90	0.072	2.5	358	0.8	0.22	0.9	-0.67	0.7	-0.24
234567 Western • Roche MODULAR		2.88	0.065	2.3	358	0.8	0.00	0.9	-0.90	0.7	-0.42
345678 Central • Roche MODULAR		2.88	0.120	4.2	311	1.4	-0.06	1.6	-0.97	1.2	-0.47
456789 Eastern • Roche MODULAR		2.89	0.072	2.5	297	0.9	-0.21	1.0	-1.13	0.7	-0.60
Affiliated Group	2	4.58	0.084	1.8	1327 (4 Labs)			1.0	-0.69	0.7	-0.28
Peer Group		4.64	0.083	1.8	6686 (45 Labs)						
Method Group		4.62	0.122	2.6	32710 (429 Labs)						
123456 Reference Laboratory • Roche MODULAR		4.60	0.064	1.4	358	0.8	0.22	0.8	-0.47	0.5	-0.13
234567 Western • Roche MODULAR		4.59	0.056	1.2	357	0.7	0.07	0.7	-0.62	0.5	-0.23
345678 Central • Roche MODULAR		4.57	0.119	2.6	312	1.4	-0.18	1.5	-0.88	1.0	-0.41
456789 Eastern • Roche MODULAR		4.57	0.086	1.9	300	1.0	-0.16	1.1	-0.85	0.7	-0.39
Roche cobas 6000/8000 Series											
Affiliated Group	1	2.86	0.121	4.2	561 (2 Labs)			1.08	-0.78	1.23	-0.70
Peer Group		2.95	0.115	3.9	9376 (150 Labs)						
Method Group		2.93	0.102	3.5	33164 (435 Labs)						
123456 Reference Laboratory • Roche cobas 6000		2.86	0.113	4.0	280	0.9	-0.05	1.0	-0.78	1.2	-0.70
123456 Reference Laboratory • Roche cobas 6000		2.87	0.128	4.4	281	1.1	0.05	1.1	-0.67	1.3	-0.57
Affiliated Group	2	4.66	0.112	2.4	557 (2 Labs)			0.96	-0.17	0.92	0.41
Peer Group		4.68	0.118	2.5	9406 (151 Labs)						
Method Group		4.61	0.122	2.6	32710 (429 Labs)						
123456 Reference Laboratory • Roche cobas 6000		4.65	0.102	2.2	278	0.9	-0.07	0.9	-0.25	0.8	0.32
123456 Reference Laboratory • Roche cobas 6000		4.67	0.121	2.6	279	1.1	0.7	1.0	-0.12	1.0	0.44

A quick review allows you to focus on key statistics to allow comparison between multiple instruments of a common make and model for statistical comparison of each lab's results.

- Provides the CVR and SDI for the peer, method, and affiliated groups to allow statistical comparison of each lab's results.
- You can request this report to appear in either SI or Conventional units, rather than both.

Standard for Each Test

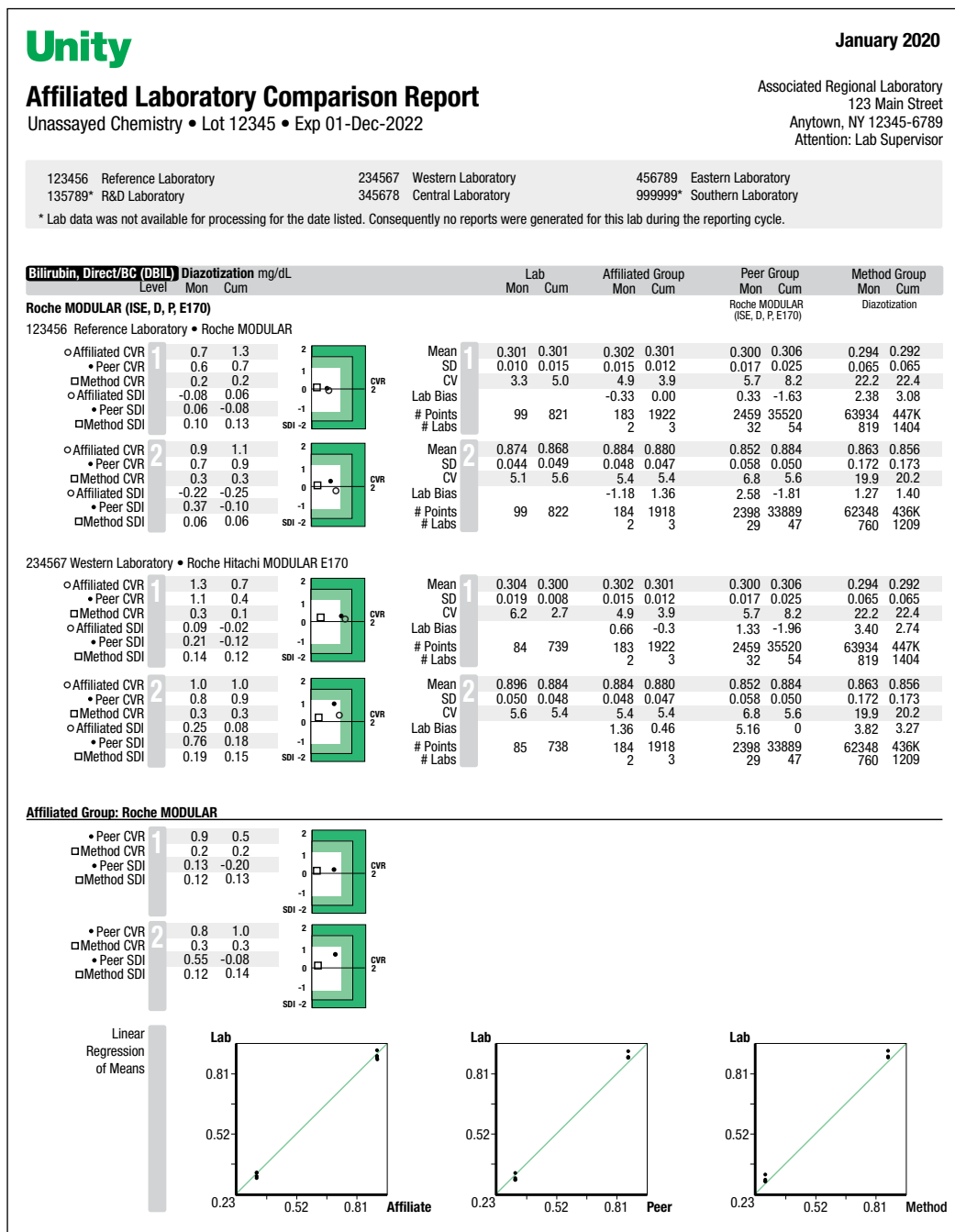
- Lab Mean
- Lab SD
- Lab CV
- Number of data points reported
- CVR compared to the Peer Method and Affiliated groups
- SDI compared to Peer Method and Affiliated groups

Additional for Peer, Method & Affiliated Groups

- Mean
- SD
- CV
- Number of data points reported
- Number of labs reporting

Affiliated Laboratory Comparison Report

Summarizing the performance of each participating affiliated laboratory – provides a detailed look at each lab's performance.



Useful in comparing multiple instruments made by the same manufacturer located within or across sites.

- Designed for managers responsible for overseeing multiple sites / multiple instruments.
- Statistics provided for each affiliated laboratory include Mean, SD, CV and number of points.
- Condensed format provides comprehensive performance comparisons of each lab versus Affiliated, Peer and Method for the month and cumulative.
- Modified Youden graphs display linear regression plots of means for multiple instrument comparisons.
- You can request this report to appear in either SI or Conventional units.

Affiliated Data Exception Report

Indicates data warnings and rejections for affiliate labs and provides an overview of exceptions for all labs in the affiliated group.

Unity

Affiliated Data Exception Report

Unassayed Chemistry • Lot 12345 • Exp 01-Jan-2022

January 2020

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

123456 Reference Laboratory	234567 Western Laboratory	456789 Eastern Laboratory
135789* R&D Laboratory	345678 Central Laboratory	999999* Southern Laboratory

* Lab data was not available for processing for the date listed. Consequently no reports were generated for this lab during the reporting cycle.

Lipase Colorimetric (Siemens calibrated) U/L 37°C

Level	Level	Lab	Affiliated	Peer	Method
-------	-------	-----	------------	------	--------

Siemens Dimension Series

123456 City Regional Hospital • Siemens Dimension EXL

Affiliated CVR	0.9				
Peer CVR	1.0				
Method CVR	0.9				
Affiliated SDI	1.71				
Peer SDI	2.30	Warning:	Acceptable values are above -2 and below 2		
Method SDI	2.24	Warning:	Acceptable values are above -2 and below 2		

Affiliated CVR	0.7				
Peer CVR	0.8				
Method CVR	0.6				
Affiliated SDI	1.82				
Peer SDI	2.37	Warning:	Acceptable values are above -2 and below 2		
Method SDI	1.89				

	Mean	165.7	151.9	148.1	147.8
	SD	8.31	8.09	7.66	8.01
	CV	5.0	5.3	5.2	5.4
	# Points	33	564	5872	10482
	# Labs		3	158	261

	Mean	353.4	325.6	325.6	320.4
	SD	11.99	15.25	15.25	17.48
	CV	3.4	4.7	4.7	5.5
	# Points	34	571	5872	10482
	# Labs		3	158	261

3456789 Reference Lab • Siemens Dimension EXL

2

Data Exclusion: Lab Mean = 28.21
Acceptable values are 282.35 - 361.85
This data was not used as part of the Unity worldwide statistical database

	Mean	28.21	325.6	322.1	320.4
	SD	1.10	15.25	13.25	17.48
	CV	3.9	4.7	4.1	5.5
	# Points	34	571	5872	10482
	# Labs		3	158	261

Coding Rejections

The following data was not used as part of the Unity worldwide statistical database due to a suspected test configuration error. Please review the "Submitted Test Configuration" and "Suggested Test Configuration" columns below.

In your Bio-Rad software, please correct the test configuration that corresponds with the highlighted area(s) in the "Suggested Test Configuration" column. Upon correction, reports will be generated at your request.

For additional assistance or if you feel your current test configuration is correct, please contact Bio-Rad's Quality Control Program directly or your local Bio-Rad Office.

Submitted Test Configuration	Suggested Test Configuration
123456 City Regional Hospital	
Data for Analyte	01-2013, 12-2012
Method	Amylase
Instrument	Maltotetraose
Reagent	Siemens Dimension EXL
Units	Dedicated Reagent
Temp	U/L
	37° C
	CNP-triose/CNP G3

Includes SDI/CVR warnings, data exclusions, coding rejections.

For all laboratories within the affiliated lab group, this report lists any analyte that:

- Exceeds specified SDI or CVR warning limits compared to the consensus group.
- Is rejected by a Unity Interlaboratory Program data filter.
- Contains a suspected coding error (data rejected due to possible test configuration errors and suggests potential corrections).

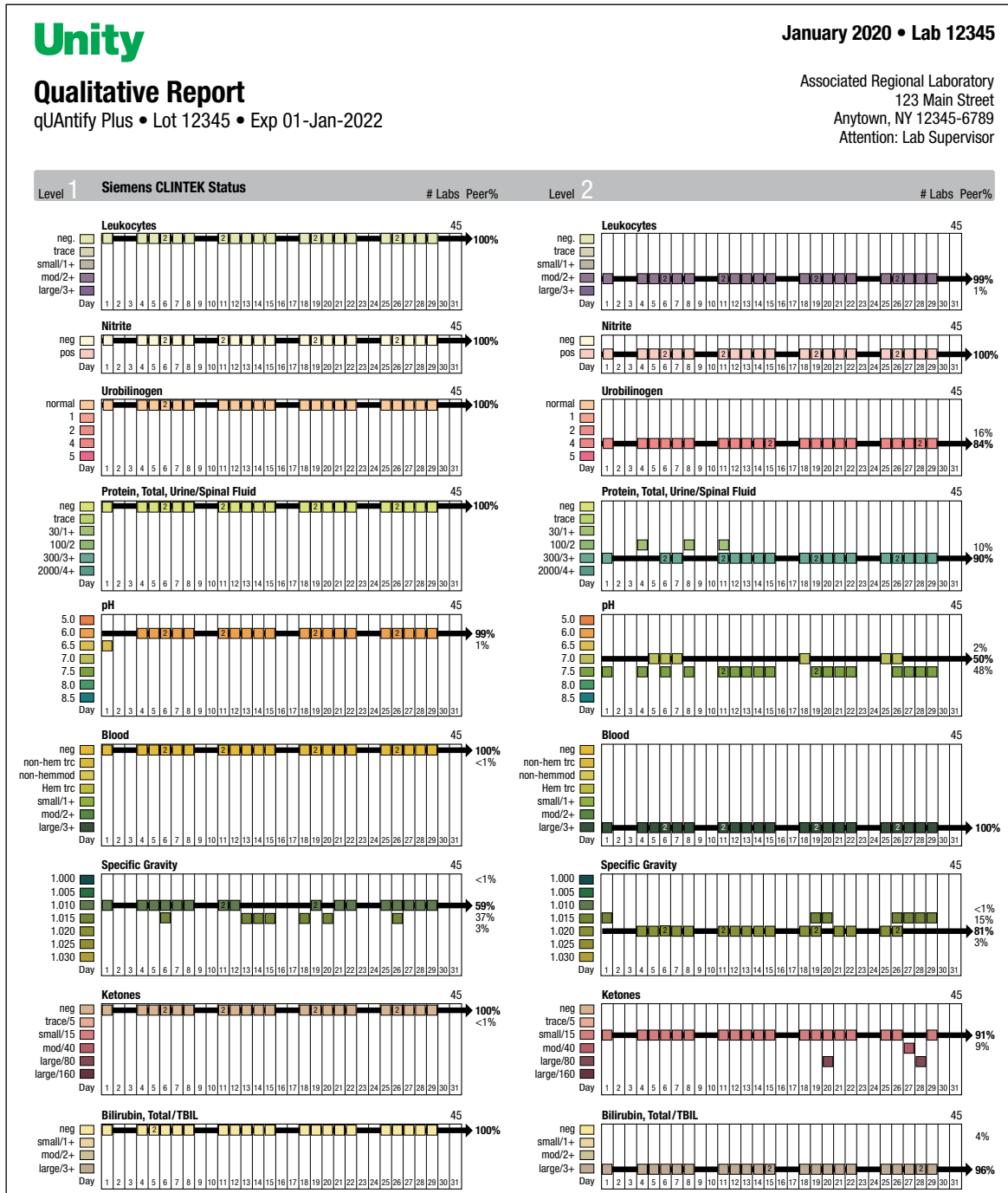
Qualitative Reports

Data submitted for Liquichek Urinalysis, qUAntify and qUAntify Plus Controls generates a qualitative report consisting of Chemistry and Microscopic Reports for each method submitted (when appropriate) with a cover page.

Urine Chemistry Report

Provides a simulation of your laboratory responses versus a representation of group responses using the visual color changes to reagent strips.

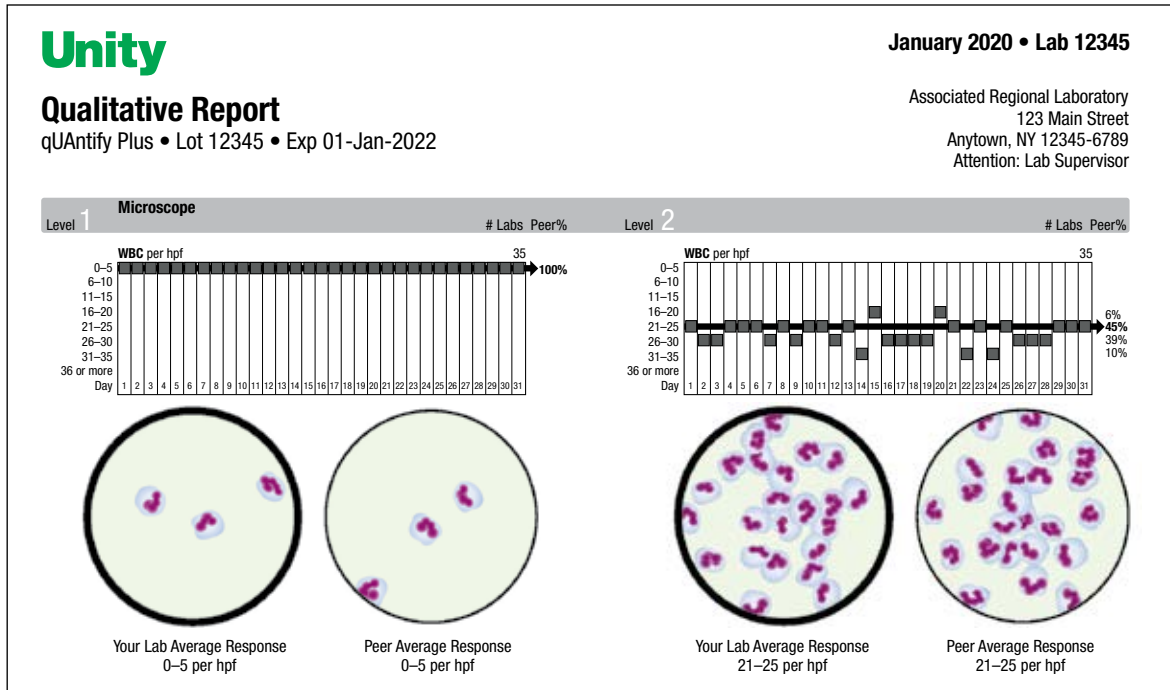
- Arrows identify the majority group response.
- Displays multiple responses per day.



Microscopic Report

Graphics simulate your average response and the group's average response.

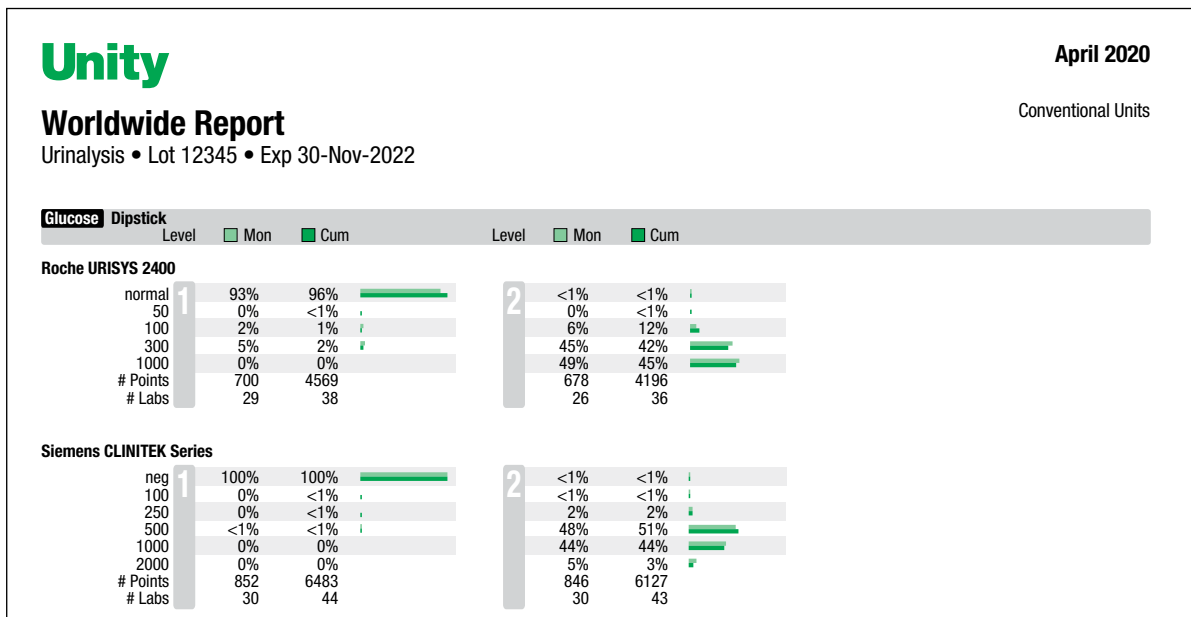
- Your lab's daily responses appear above the graphics; an arrow indicates the majority group response.



Qualitative Worldwide Report

Summarizing all the peer group data submitted to the Unity Interlaboratory Program, this report is available for each lot number of Bio-Rad controls on QCNet.com.

- Supplies monthly and cumulative response distributions
- Modified format also available – The Manufacturer’s Report – provides the same response distribution for a single manufacturer’s instruments

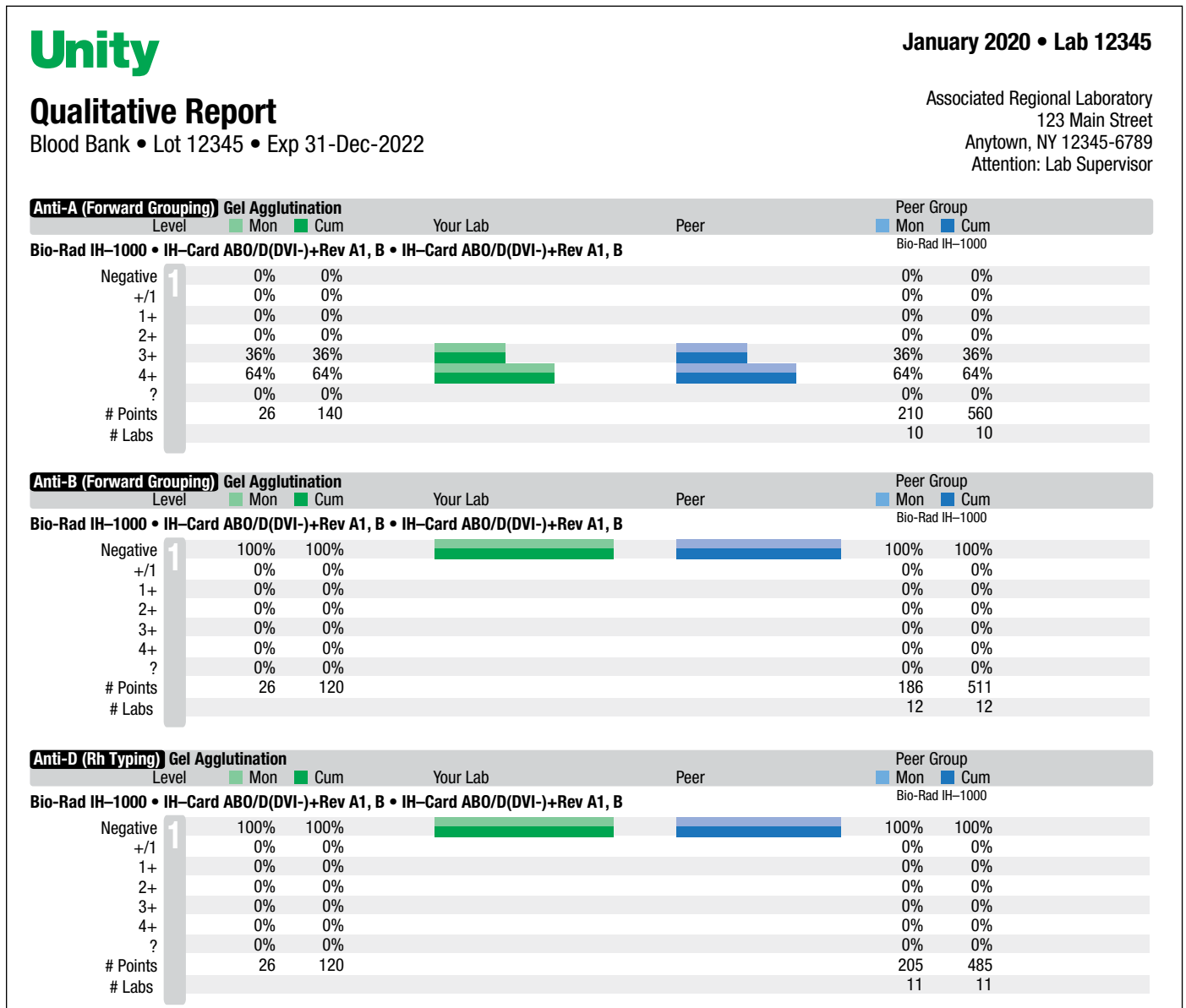


Qualitative Reports

Blood Typing/Serum Indices Reports

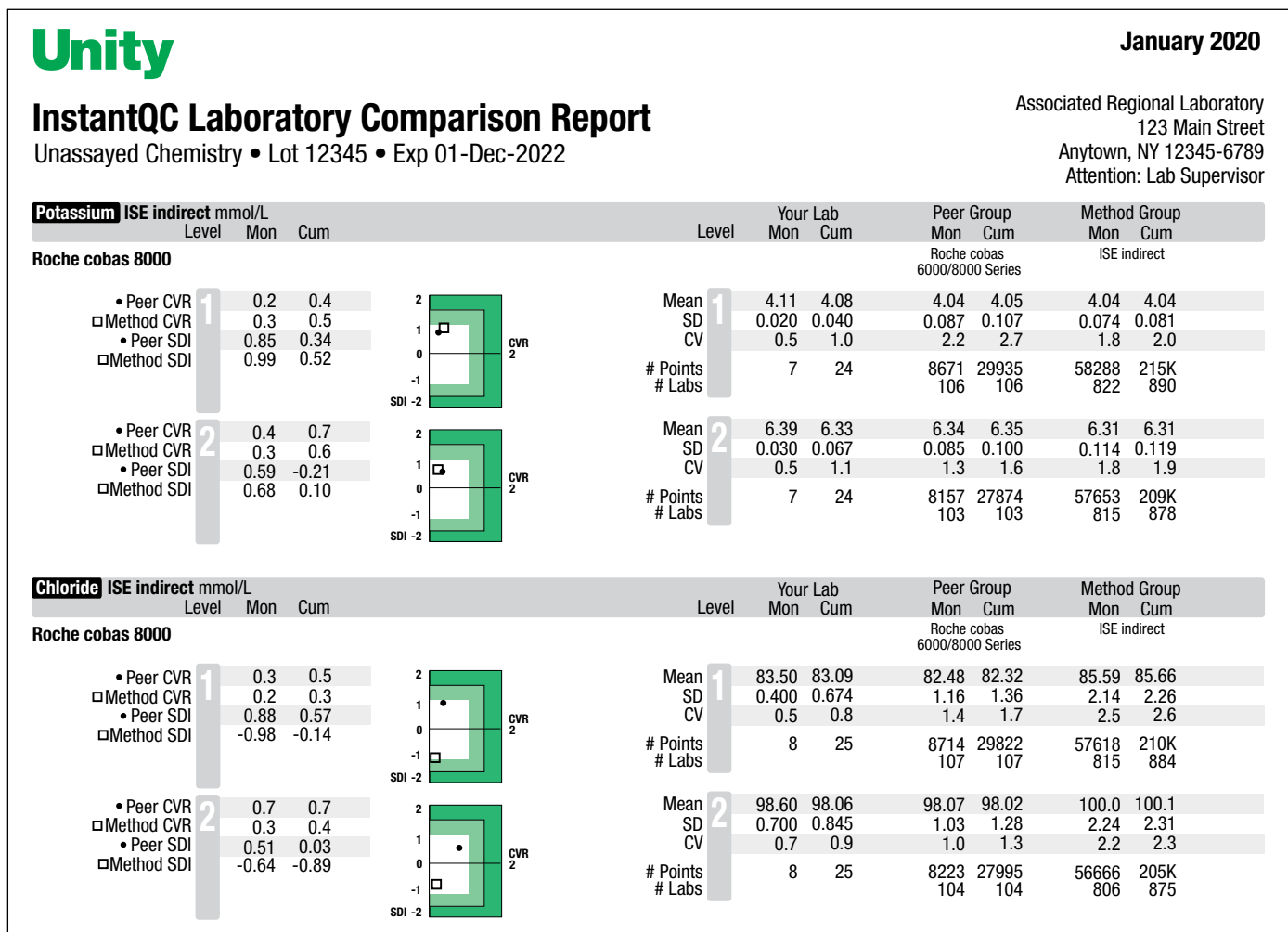
Displays your laboratory data compared to your peer group data

- Supplies monthly and cumulative response distributions
- Compares your laboratory response distribution to the peer group distribution
- Displays visual histogram



InstantQC Reports

The Unity Interlaboratory Program offers all program participants the ability to receive on-demand InstantQC Reports.



With up-to-the-minute peer group performance data, these immediate reports are particularly useful for troubleshooting issues with test system performance.

- InstantQC Reports are available to all Unity participants with access to the QCNet website (www.qcnet.com).
- Reports are generated with all the peer group data available at the moment the report is requested—whether you have submitted your data for the selected month or not.
- All Unity report participants can generate InstantQC Reports for open tests at any time.
- InstantQC Reports are generated in the same language you request for your monthly Unity Interlaboratory Reports.
- InstantQC Reports are available as Adobe Acrobat® PDF files.

The InstantQC Reports are intended primarily for troubleshooting test system performance when a malfunction is suspected. For the reason, the reports are only provided for time periods up to the release of the standard monthly Unity Interlaboratory Program Reports. You should always refer to your standard monthly reports as they become available. The monthly reports are more comprehensive and the application of a deadline ensures that peer group sizes are maximized for regular, documented review of your test systems.

Glossary of Terms

Affiliated Group

A group of labs that the Unity Interlaboratory Program groups together to form an ad hoc consensus group and for which it generates specific Affiliated Reports. You must contact your Bio-Rad Software Support Representative to request inclusion in an affiliated group.

All Labs Group

The Unity Interlaboratory Program consensus group that encompasses all labs reporting values for an analyte/matrix combination irrespective of the methodology, instrument or reagents. Of peer, method and all labs, this is the least specific consensus group.

Bias

The difference between the expected test results and an accepted reference value. In Unity, the consensus groups are used for the comparator.

$$\text{Bias\%} = \left(\frac{\text{Your Mean} - \text{Consensus Group Mean}}{\text{Consensus Group Mean}} \right) \cdot 100$$

NOTE: Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value. [ISO 3534-1]

Coefficient of Variation (CV)

The relative standard deviation (i.e., the standard deviation expressed as a percentage of the mean). The CV is useful because it is concentration independent.

$$\text{CV} = \left(\frac{\text{Standard Deviation}}{\text{Mean}} \right) \cdot 100$$

CVR

Coefficient of variation ratio — a statistic that compares your lab's precision to that of other labs in a consensus group.

$$\text{CVR} = \frac{\text{Your CV}}{\text{Consensus Group CV}}$$

Imprecision

Imprecision is a term to describe the dispersion or spread of a set of values about the mean value of a normal or gaussian distribution. It is usually expressed as a standard deviation (SD) or coefficient of variation (CV).

Mean

The arithmetic average of a set of data points.

Method Group

The Unity Interlaboratory consensus group that encompasses all labs reporting an analyte using the same methodology code (e.g., all customers reporting glucose by hexokinase).

Peer Group

The "ideal" consensus group that encompasses all labs using the exact same methodology, instrument and reagents.

Standard Deviation (SD)

Abbreviated as SD or s. The SD quantifies the degree of dispersion of data points around the mean and is defined by the formula:

$$\text{SD} = \sqrt{\frac{\sum (x_n - \bar{x})^2}{n - 1}}$$

Where:

- SD = standard deviation
- \bar{x} = mean (average) of the QC values
- $\sum (x_n - \bar{x})^2$ = the sum of the squares of differences between individual QC values and the mean
- n = the number of QC values in the data set

Standard Deviation Index (SDI)

A statistic that measures your lab's bias relative to your consensus group.

$$\text{SDI} = \frac{\text{Your Mean} - \text{Consensus Group Mean}}{\text{Consensus Group SD}}$$



Choose From Four Unity Solutions

Bio-Rad Laboratories offers several options for participation in the Unity Interlaboratory Program. Refer to the product comparison grid below to help determine which solution is the most appropriate for your laboratory.

Internet-based solutions such as UnityWeb and Unity Real Time online eliminate the need to install and update software locally in your laboratory, and reduce the amount of support necessary from on-site IT staff.

Desktop software solutions, like Unity Real Time, are appropriate if your internet connection is not sufficient, or if you prefer maintaining local software.

	Basic User Options		Advanced User Options	
	UnityWeb	Unity Real Time LT	Unity Real Time online	Unity Real Time
Type of Solution				
Web Service (Web-based)	X		X	
Desktop Software		X		X
Unity Interlaboratory Reports				
Monthly Reports	X	X	X	X
InstantQC Reports	X	X	X	X
Basic Intralaboratory Charts & Reports				
Westgard Rules	X	X	X	X
Various Charts and Reports	X	X	X	X
Additional Features				
Westgard Advisor (Subscription sold separately)	X		X	X
Bench Review with Data Review Report	X	X	X	X
Supervisor Data Review with Data Review Report			X	X
Analytical Goals			X	X
Dynamic Data Set Comparisons			X	X
Database Platform				
Bio-Rad Hosted	X		X	
Installed on Local Laboratory PC		X		X
Connectivity (Sold separately)				
WebConnect	X		X	
UnityConnect	X	X	X	X



Basic



Advanced



Desktop based



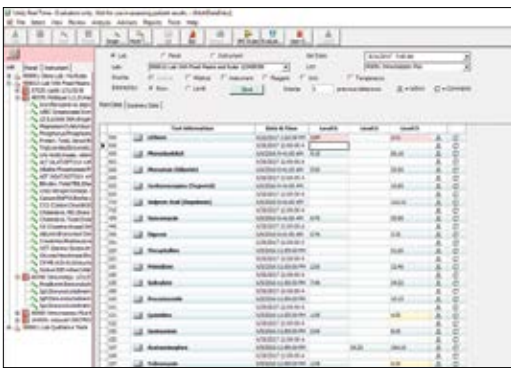
Web based



Mobile

Want to know more? Discover the power of Unity Solutions at www.bio-rad.com/qc-datamanagement

Basic User Options

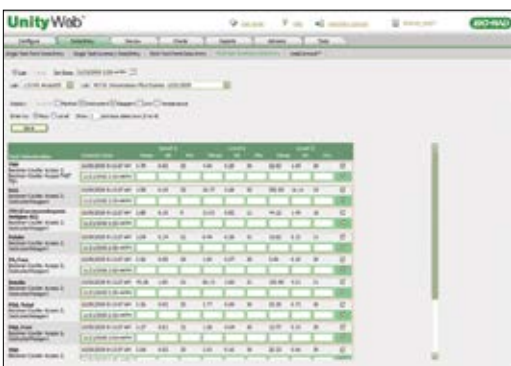


Unity Real Time LT



Entry-Level Desktop QC Data Management Solution

- Basic QC rules, charts and reports
- Configurable Levey-Jennings charts
- Upgrade easily to Unity Real Time for more advanced tools and features
- Upload QC data points from an LIS, middleware or instrument (optional)



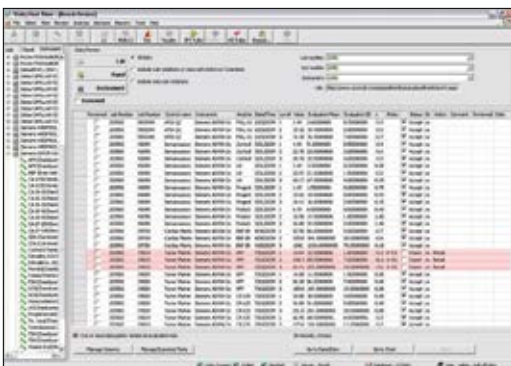
UnityWeb



Entry-Level Online QC Data Management Solution

- No software to install and maintain
- Use basic QC rules, charts and reports
- Upgrade easily to Unity Real Time online for more advanced tools and features
- Upload QC data points from an LIS, middleware or instrument (optional)

Advanced User Options



Unity Real Time



Expert QC Data Management Solution for Desktop Users

- Facilitate regulatory compliance under CLIA and ISO 15189
- Improve real-time bench and supervisor QC data review
- Implement best QC rules when used with Westgard Advisor
- Run validation with comprehensive audit trails
- Advanced charts and reports for data analysis
- Reduce non-essential retests with Analytical Goal options
- Upload QC data points from an LIS, middleware or instrument (optional)
- RiLiBÄK Advisor module available to comply with German regulations



Unity Real Time online



Expert QC Data Management Solution for Online Users

- Facilitate regulatory compliance under CLIA and ISO 15189
- Improve real-time bench and supervisor QC data review
- Implement best QC rules when used with Westgard Advisor
- Run validation with comprehensive audit trails
- Advanced charts and reports for data analysis
- Reduce non-essential retests with Analytical Goal options
- Upload QC data points from an LIS, middleware or instrument (optional)

Bio-Rad Mission: Control



Take the guesswork out of your QC strategy

Employing a robust quality control system is an essential step for any laboratory hoping to provide reliable results for appropriate patient care. Unfortunately for clinical laboratories, selecting the right QC rules and frequency can be challenging, and questions often arise.

- How often should controls be run for specific assays— is there an optimal frequency?
- How can QC be managed to minimize the risk of releasing incorrect patient results?

Bio-Rad Mission: Control is the first objective risk management solution for quality control in laboratories. The intuitive interface allows users to focus on patient safety by assessing the risk of reporting incorrect patient results in their laboratory.

Bio-Rad Mission: Control allows you to:

- Determine your laboratory's Risk Management Index (RMI)
- Evaluate your test method performance based on your QC results
- Quantify the likelihood and severity of reporting incorrect patient results
- Assess how much you can lower your risk, based on instrument performance

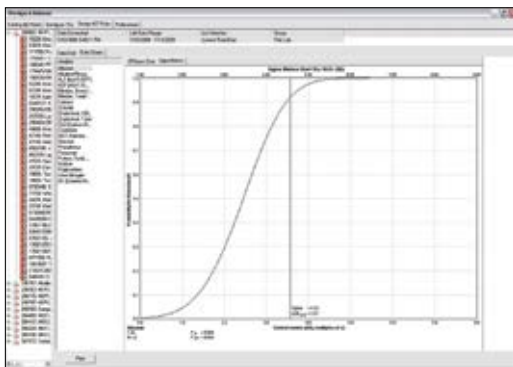


- Create a QC Plan by confidently selecting rules and frequency that fit your risk tolerance

Minimize your risk of reporting unreliable patient results

A patient risk approach to Quality Control is a progressive step toward improving quality assurance and patient care. Bio-Rad can help you understand what this means for your laboratory and how to take steps to implement an effective approach for Quality Control within your analytical test phase.

For more information, visit www.qcnet.com/missioncontrol



Westgard Advisor



Automatic QC Rules Selection Engine

- Recommend and automatically apply best QC rules with patented technology
- Easy step-by-step automatic rule selection capabilities
- Reduce false rejections and desensitization to false error flags
- Save time and money by reducing unnecessary repeats and troubleshooting
- Improve laboratory test quality with optimally selected QC rules
- Available as an optional module with Unity QC data management solutions

Unity Alert



Continuously Monitor QC Status

- Notifications of missing QC runs can help to ensure proper monitoring of instrument performance
- Notifications of new violations can be useful for troubleshooting and monitoring problem analytes
- Alert rules are easy to set up and customize for specific instruments or tests
- Receive emails remotely to stay informed of QC issues in your laboratory
- Color-coded displays help draw attention to the most urgent QC issues
- Notifications are provided even when Unity Real Time is not in use
- Available as an optional module with Unity Real Time

Connectivity



Basic

WebConnect



Automated Uploads to Unity Software

A web-based connectivity solution that allows laboratories to easily upload QC data from LIS systems, middleware and/or instruments directly into Unity Real Time online or UnityWeb

- Eliminate manual keying of data
- Standard LIS QC reports can be used
- No software to install

Advanced

UnityConnect



A connectivity solution that allows QC data from LIS systems, middleware and/or instruments to be quickly and easily imported into Unity software and web services

- Eliminate manual keying of QC data
- Standard LIS QC reports can be used
- Automatic data import and real-time connection
- Transparent to the flow of data to the LIS
- Capture and analyze QC data economically from laboratory instruments not connected to the LIS
- Easy-to-install optional interface hardware
- Choose from soft, serial and ethernet connections

Ordering Information

Cat # Description

Unity Real Time LT

804	Installation Package	Single use
805-1	Unity Real Time LT	Annual subscription
825i	Unity Remote Installation & Training	Single use

UnityWeb

870-1	UnityWeb	Annual subscription
-------	--------------------	---------------------

Unity Real Time

804	Installation Package	Single use
804-1	Unity Real Time.	Annual subscription
825i	Unity Remote Installation & Training	Single use

Unity Real Time online

804-W1	Unity Real Time online	Annual subscription
--------	----------------------------------	---------------------

Bio-Rad Mission: Control

1100002	Mission: Control	Annual Subscription
1100005	Mission: Control	Subscription and Service Bundle

Cat # Description

Westgard Advisor

811-1	Westgard Advisor	Annual subscription
-------	----------------------------	---------------------

Unity Alert

806-1	Unity Alert.	Annual subscription
825i	Unity Remote Installation & Training	Single use

WebConnect

870-W1	WebConnect 2.0.	Annual subscription
825i	Unity Remote Installation & Training	Single use

UnityConnect

820-1	UnityConnect Software.	Annual subscription
825i	Unity Remote Installation & Training	Single use

Contact your Bio-Rad sales representative for region-specific information. Hardware solutions available for serial and network devices. Contact your Bio-Rad sales representative for recommendation.



Bio-Rad Laboratories, Inc.

For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com/qc-datamanagement

Clinical Diagnostics Group

Website www.bio-rad.com/diagnostics Australia +61 (2) 9914 2800 Austria +43 (0) 1 877 89 01 9 Belgium +32 (0) 3 710 53 00 Brazil +55 11 3065 7550 Canada +1 514 334 4372 China +86 21 6169 8500 Czech Republic +420 241 431 660 Denmark +45 44 52 10 00 Finland +358 9 804 22 00 France +33 (0)1 47 95 60 00 Germany +49 (0) 89 31884 393 Greece +30 210 7774396 Hong Kong +85 2 2789 3300 Hungary +36 1 459 6190 India +91 124 4029300 Israel +972 03 963 6025 Italy +39 024 94 86 600 Japan +81 3 6361 7070 Korea +82 080 007 7373 Mexico +52 (55) 5488 7670 The Netherlands +31 (0)318 540 666 New Zealand +64 (9)415 2280 Norway +47 23 38 41 30 Poland +48 22 331 99 99 Portugal +351 21 47 27 700 Russia +7 495 721 1404 Singapore +65 6415 3170 South Africa +27 11 442 8508 Spain +34 91 490 6580 Sweden +46 844 98053 Switzerland +41 (0) 61 717 9555 Taiwan +886 (2) 2578-7189 Thailand (662) 651 8311 United Kingdom +44 (0)1923 471301