
UnityWeb 2

Reference Guide for Easy QC Data Management

September 2017

Version 2.0



Contents

Getting Started	1
Welcome	1
Contact Bio-Rad	2
Organization of this Guide	2
Typographical Styles and Conventions	2
Software Items.....	2
Keyboard Keys	2
Notes, Tips, and Important Notes	3
Note	3
Tip	3
Important.....	3
Essential Startup Tasks for New Users.....	3
First Time Log In	3
QC Configuration	4
Program Hints	4
Tabs	4
Menu Items	5
Links	5
Buttons	5
Check Boxes	5
Options	5
Lists	6
Scroll Bars and Scroll Arrows	6
Unavailable Items	7
Introduction to Quality Control Statistics	8
What is Quality Control?	8
How are QC Results Used?.....	8
Normal and Abnormal Controls	9
Example Scenario.....	9
CLIA Requirements	10
Basic QC Statistics	11
Useful Statistics.....	12
Mean	12
Standard Deviation (SD)	12
Calculate a Control Mean and Range	13
Standard Deviation Index (SDI)	14
Interpreting the SDI.....	14
Bias.....	15
Coefficient of Variation (CV)	15
Example Scenario.....	15
Determining an Acceptable CV	16

Coefficient of Variation Ratio (CVR)	16
Total Error (TE) and Total Allowable Error (TE_a)	17
z-score.....	17
SPC Rules.....	18
1-2s	18
1-2.5s	19
1-3s	20
1-3.5s	20
1-4s	21
1-5s	21
2-2s	21
Across Run Violation.....	22
Within Run Violation.....	22
2 of 3-2s	23
R-4s.....	23
3-1s and 4-1s	24
3-1s Within a Control Level.....	24
4-1s Across Control Levels	24
7-T	25
N-x Rules	25
8-x Within a Control Level.....	26
9-x Across Control Levels	26

Choose and Troubleshoot a QC Procedure	27
Recommended Steps.....	27
Determine Quality Requirements for the Test.....	28
Identify Appropriate QC Materials.....	29
Evaluate Test Performance.....	29
Six Sigma.....	29
Use of Six Sigma.....	31
Qualitative Evaluation of a Test's Bias and Imprecision.....	31
Identify Possible QC Procedures.....	32
Predict the Performance of the QC Procedures	32
Choose Goals Based on Required Quality	33
Select a QC Procedure	33
Troubleshoot QC Results	33
Repeat the Control.....	33
Try a New Control.....	34
Recalibrate.....	34
Good Laboratory Habits	34
Determine the Type of Error	34
Relate the Error to Possible Causes	35
Consider Common Factors on Multi Test Systems	35
Relate the Problem to Recent Changes.....	36
Systematic Error	36

Random Error	36
Verify and Document.....	36
Keys to a Productive Review of the Laboratory Quality System.....	37
Issues to Consider	37
Program and Database Basics	39
First Time Log In.....	39
Regular Log On and Log Off Process.....	40
Log On to the Software	40
Log Off the Software	40
Current Lab, Panel, Lot, and Test.....	41
Example Lists.....	41
Understand the Navigation Tree.....	42
Example of the Navigation Tree	42
UnityWeb Tabs and Functions.....	43
Functions and Where to Find Them	46
Download Adobe Reader.....	51
System Requirements.....	51
Update the License.....	51
Update the License via the Internet	51
Update the License via an XML File	52
Upgrade to UnityWeb	53
Configure UnityWeb.....	53
Configure UnityWeb	53
Data Entry Configuration	54
Actions and Comments.....	54
View Database Information.....	55
Notifications.....	55
Transmission.....	55
Configure Unity Interlaboratory Report Frequency	56
Database Basics.....	56
Export Data.....	56
Condense Data	58
Reconcile Data.....	59
Delete a Range of Data	59
User Profiles and Security.....	61
Define, Modify, and Delete Users	61
Add a User.....	62
Modify a User.....	62
Delete a User	63
Passwords.....	63
Password Requirements	63
Group Login ID and Password	64

Password Expiration.....	64
Set a Password Expiration.....	64
Change a Password.....	65
User Permissions.....	65
Administration/Setup Permissions	66
Manage Users	66
Edit Action Log	66
Edit Setup Options	66
Operator Setup.....	66
Data Review Permissions	66
Database Permissions.....	66
Condense Data.....	66
Reconcile Data	66
Rules and Settings Permissions	67
Labs, Lots, Tests, and Panels Permissions	67
Manage Labs/Lots/Tests.....	67
Manage Panels.....	67
Data Handling Permissions.....	67
Communicate with Unity Interlab.....	67
Export Data	68
Data Permissions	68
Edit All Data.....	68
Edit Last Line.....	68
Enter New Data Only	68
View Data Only	68
Set Up User Permissions.....	68
Labs and Lots	69
Labs	69
Types of Lab Numbers	69
Primary Lab Number	69
Additional Lab Numbers.....	69
Affiliated Lab Numbers	70
Add and Update Lab Numbers.....	70
Add a Lab Number.....	70
Update Lab Number Information	70
Duplicate a Lab Number	71
Open and Close Lab Numbers	71
Close a Lab Number	72
Open a Lab Number	72
Delete Lab Numbers.....	72
Lots	73
Add a Bio-Rad Lot	73
Add Non-Bio-Rad Lots.....	73
Duplicate Lots	74

Items Automatically Duplicated.....	74
Optional Items When Duplicating.....	74
Duplicate a Bio-Rad Lot Number.....	75
Duplicate a Non-Bio-Rad Lot Number.....	75
Edit Lot Numbers	76
Edit a Bio-Rad Lot Number.....	76
Edit a Non-Bio-Rad Lot Number and Expiration Date.....	76
Close and Open Lots.....	77
Close a Lot.....	77
Open a Closed Lot.....	77
Arrange and Sort Lots.....	77
Delete Lot Numbers.....	78
Lot Expiration Notifications	78
Tests.....	79
Overview	79
Add Tests	81
Direct Methods of Adding Tests.....	81
Indirect Methods of Adding Tests	81
Add Tests Manually	81
Add Tests with Instrument Setup.....	82
Limitations of Instrument Setup	83
Add Tests Using Instrument Setup	83
Add Tests with a Code of “Other”	84
Test Rules and Settings	84
Select SPC Rules	84
Select Test Settings.....	85
Use a Fixed Mean and SD.....	85
Specify a Fixed Mean and SD.....	85
Duplicate Tests	86
Update Tests	86
Update a Test.....	86
Close and Open Tests.....	87
Close a Test	87
Open a Test.....	87
Sort Tests	88
Sort Tests for a Lab Number	88
Sort Tests in a Panel.....	88
Delete Tests.....	89
Delete a Test	89
VITROS Slide Generation Numbers.....	90
Change the VITROS Slide Generation Number	90
Update the VITROS Slide Generation Number.....	91

Panels and Data Groups	92
Panels	92
Create a Panel and Add Tests	92
Sort Tests in a Panel.....	93
Remove Tests from a Panel	93
Rename a Panel.....	93
Sort Panel Names	94
Delete a Panel.....	94
Data Groups	94
Overview of Groups.....	95
Change the Current Data Option	95
Define or Edit a Group	96
Apply QC Rules	97
Overview of Rule Evaluation.....	97
Notes About Rule Evaluation	97
Rule Status	98
SPC Rules Precedence When Showing Rule Violations	98
Set SPC Rules.....	99
Set SPC Rules at the Test Level	99
Set SPC Rules at the Lot Level.....	100
Use a Fixed Mean and Fixed SD with SPC Rules	101
Useful Facts about Fixed Mean and Fixed SD	102
Set a Fixed Mean and/or Fixed SD	102
Set Floating Statistics as a Fixed Mean and/or Fixed SD	103
SPC Rules: Tabular Summary	103
Enter Data	106
Overview	106
Overview of the Single Test Data Entry Dialog Boxes	107
Lab, Panel, Lot, and Test Information	107
Command Buttons and Options.....	108
Data Entry Grid	109
Paging Arrows.....	110
Summary Statistics	110
Example of Summary Statistics.....	110
Group Statistics	111
Example of Group Statistics.....	111
Fixed Mean and SD.....	111
Data Entry Features	111
Use the Set Date Feature	111
Change the Date and Time for a Row of Data	112
View a Levey-Jennings Chart	112
View Rules and Settings.....	113

Navigate the Single Test Data Entry Dialog Boxes.....	113
Single Test Point Data Entry.....	114
Single Test Point Data Entry Grid.....	114
Fixed Statistics	115
Important Facts	115
Floating Mean/Floating SD.....	116
Floating Mean/Fixed SD.....	116
Fixed Mean/Fixed SD.....	116
Fixed Mean/Floating SD.....	117
Enter Single Test Point Data	117
Single Test Summary Data Entry	118
Summary Data Entry Grid.....	118
Enter Single Test Summary Data	119
Qualitative Data Entry.....	119
Enter Qualitative Data.....	120
Send Qualitative Data to the Unity Interlaboratory Program.....	121
Multi Test Data Entry	121
Multi Test Data Entry Information	121
Multi Test Data Entry Grid.....	123
Enter Multi Test Data	124
Manage Data	125
Overview	125
Change Data.....	125
Data Entry Permissions	125
Edit Data, Date, and Time.....	126
Edit Data	126
Edit the Date and Time.....	127
Change a Data Point's Accepted/Rejected Status	128
Change the Accepted/Rejected Status.....	128
Insert Data.....	129
Insert a Data Row	129
Delete Data.....	130
Delete a Row of Data from the Data Entry Dialog Box	130
Delete a Range of Data	130
Operator Setup	131
Operator Setup Shifts.....	132
Review and Annotate Data.....	134
Overview	134
Bench Review.....	134
Perform Bench Review.....	135
Select a Data Set.....	135
Review Data	136

Manage Columns	136
Document the Review.....	136
All Data Option	136
Save and Transmit	137
InstantQC	137
Actions and Comments	137
Actions.....	138
View Actions.....	138
Configure Actions.....	138
Add a Custom Action	138
Edit an Action	139
Delete an Action	139
Add, Edit, and Delete Actions in the Data Entry Dialog Boxes.....	139
Add an Existing Action to a Row of Data.....	139
Add a New Action to a Row of Data	140
Edit the Action List from the Data Entry Dialog Box	140
Delete an Action from the Action List from the Data Entry Dialog Box ...	
141	
Automatic Action Logs	141
Set Up Automatic Action Logs.....	142
Turn Off Automatic Action Logs	142
Comments	142
View Comments	143
Add a Comment to a Row of Data.....	143
Actions and Comments by Instrument.....	143
Add an Action by Instrument.....	144
Add a Comment by Instrument.....	144
Add an Action and Comment by Instrument	145
Require Audit Trail Comments.....	145
Require Audit Trail Comments	146
Turn Off the Require Audit Trail Comments Feature.....	146
UnityWeb Charts.....	147
Overview	147
General Chart Options	147
Fill Background	148
Select Fill Background	148
Grid Lines and Color	148
Edit Grid Lines and Color.....	148
Chart Header Options	149
Example of a Chart Header.....	149
Select Chart Header Options	149
Save and Print Charts.....	150
Levey-Jennings Chart.....	151
How to Use the Levey-Jennings Chart	151

Select Levey-Jennings Chart Options.....	152
Levey-Jennings Chart Legend.....	153
Other Options.....	154
Create a Levey-Jennings Chart	154
Multi-LJ Chart.....	154
Select Multi-LJ Chart Options.....	154
Create a Multi-LJ Chart	155
Bar Chart.....	155
Select Bar Chart Options.....	156
Other Options.....	156
Create a Bar Chart	156
Youden Chart	157
How to Use the Youden Chart.....	157
Select Youden Chart Options	157
Other Options.....	158
Create a Youden Chart.....	158
UnityWeb Reports	159
Overview	159
Save and Print Reports.....	160
Save Reports	160
Print Reports.....	161
Document Report Reviews.....	162
Data Review Report.....	162
Create a Data Review Report	163
Point Data Report.....	163
Point Data Report Options	163
Create a Point Data Report	163
Summary Data Report	164
Summary Data Report Options	164
Create a Summary Data Report	164
Statistical Report	165
Statistical Report Options.....	165
Create a Statistical Report.....	165
Supervisor's Report	166
Supervisor's Report Options.....	166
Create a Supervisor's Report.....	166
Operator Report	167
Operator Report Options.....	167
Create an Operator Report.....	167
Audit Trail Report	168
Audit Trail Events.....	168
Create an Audit Trail Report.....	168
Listings Reports.....	169
Listings Report Options.....	169

Create a Listings Report.....	170
Send Data to the Unity Interlaboratory Program	171
Overview	171
Submit Data Monthly	171
Submit Data Manually	171
Activate Automatic Monthly Transmission.....	172
Submit Data from the Bench Review	172
Activate Transmission for InstantQC	172
Unity Interlaboratory Reports	174
Overview	174
Monthly Reports.....	175
Comprehensive Reports.....	175
Optional Reports	175
InstantQC Reports and Charts	175
Consensus Groups	176
View and Print Interlaboratory Reports.....	176
Monthly Reports	176
Monthly Evaluation Report.....	177
How to Use This Report.....	177
Example Monthly Evaluation Report.....	177
Data Rejection Report	178
How to Use This Report.....	178
Limits for the Mean	178
Limits for the CV	178
Example Data Rejection Report	179
Laboratory Performance Overview Report.....	179
How to Use This Report.....	179
Example Laboratory Performance Overview Report	180
Laboratory Comparison Report	180
How to Use This Report.....	180
Example Laboratory Comparison Report	181
Laboratory Histogram Report	182
How to Use This Report.....	182
Example Laboratory Histogram Report	183
Bias and Imprecision Histogram Report.....	183
How to Use This Report.....	183
Example Bias and Imprecision Report.....	184
Comprehensive Reports	184
Worldwide Report	184
How to Use This Report.....	185
Example Worldwide Report.....	185
Manufacturer Report	186

How to Use This Report.....	186
Example Manufacturer Report	186
Optional Reports.....	187
Statistical Profile Report	187
How to Use This Report.....	187
Laboratory 2SD and 3SD Ranges.....	187
Example Laboratory 2SD and 3SD Ranges.....	187
Summary Statistics.....	188
Example Summary Statistics.....	188
Frequency Histograms.....	188
Example Frequency Histogram	189
Percentile Distribution Table	189
How to Use This Report.....	189
Example Percentile Distribution Table.....	190
Affiliated Reports.....	190
Affiliated Laboratory Comparison Report	190
How to Use This Report.....	191
Example Affiliated Laboratory Comparison Report	192
Affiliated Laboratory Comparison Report: Abbreviated Summary.....	192
How to Use This Report.....	193
Example Affiliated Laboratory Comparison Report: Abbreviated Summary.....	193
Affiliated Data Exception Report	193
How to Use This Report.....	193
Example Affiliated Data Exception Report	194
Urinalysis Report.....	195
Chemistry Section.....	195
Microscopy Section.....	196
InstantQC Reports and Charts.....	197
InstantQC Reports	198
How to Use This Report.....	198
View InstantQC Reports.....	198
InstantQC Chart	199
How to Use This Report.....	199
View InstantQC Charts.....	200
Regulatory Requirements and Reports	201
Overview	201
CLIA Requirements.....	201
CAP Accreditation Requirements	208
ISO 15189 Requirements.....	220
Westgard Advisor online	222
Overview	222

View Existing QC Rules	223
View Lab Data and Group Statistics	223
Configure Westgard Advisor online	223
Total Allowable Error (TE _a) Options.....	224
View TE _a Details.....	224
Configure the TE _a for an Analyte.....	225
Configure the TE _a for All Analytes	225
Return TE _a Selections to the Default	226
Data Requirements	226
Specify Data Requirements.....	226
Grid Display Options	227
Select Grid Display Options	227
Generate Rules with Westgard Advisor online	227
Consensus Groups	228
Use the Westgard Advisor online Wizard	228
Use the Advanced Option	230
Use the Westgard Advisor online Defaults	231
Apply Rules with Westgard Advisor online.....	231
Apply Rules.....	232
Westgard Advisor online Report.....	232
Print the Westgard Advisor online Report	233
Delete Historical Suggestions.....	234
OPSpecs Chart	234
OPSpecs Chart Components.....	235
How to Interpret an OPSpecs Chart	237
When Westgard Advisor online Recommends a Maximum QC Procedure...	
238	
 Supplemental Information.....	 239
Action Log Messages	239
Audit Trail Events	240
Rejection Log Messages.....	241
 References.....	 244
QC References	244
Articles	244
Books	244
Guidelines	245
 Glossary	 246
 License Agreement.....	 259
License Agreement.....	259

Warranty Information.....	259
Trademark Notices.....	260

Getting Started

In This Chapter

Welcome	1
Essential Startup Tasks for New Users.....	3
Program Hints	4

Welcome

Welcome to UnityWeb, Bio-Rad's expert quality control (QC) data management software. New users will find this powerful and user-friendly software provides access to advanced tools and functions designed to meet or exceed clinical laboratory quality requirements. UnityWeb provides data access, analysis, review, management, storage, and reporting.

One of the most powerful utilities of UnityWeb is the ability to connect a laboratory to the worldwide clinical laboratory community. Bio-Rad's Unity Interlaboratory Program collects data from thousands of laboratories worldwide and combines the data to create consensus groups for data comparison.

Existing users of other Bio-Rad software will find UnityWeb provides familiar functionality plus several new features. New features include:

- **Westgard Advisor online** (page 222)

This optional feature recommends statistical process control (SPC) rules based on a total allowable error plus historical data and Bio-Rad consensus group information.

- **New charts and chart options** (page 147)

- **Bench review** (page 134)

Provides documentation of QC data review and helps improve laboratory QC workflow.

- **Qualitative Data Entry** (page 119)

Enter qualitative and semi-quantitative data and send to Bio-Rad's Unity Interlaboratory Program for comparison.

- **Automatic Monthly Transmission** (page 172)

Ensures data always arrives at Bio-Rad on time.

- **Audit Trails** (page 168)

Comprehensively tracks events which could affect decisions determined from QC data.

Contact Bio-Rad

Every attempt has been made to ensure this guide is accurate and complete. However, if you need to contact Bio-Rad for assistance, you can:

- Search the Bio-Rad knowledge base at: <http://support.QCNet.com>.
- Send an e-mail to: unity_support@bio-rad.com.
- In the United States, phone a Bio-Rad Software Support Representative at 1-800-854-6737. Software Support Representatives are available Monday through Friday, 5 am to 5 pm (Pacific Standard Time).



Important: If phoning Bio-Rad outside of normal working hours, leave a message and a Software Support Representative will return the call, typically within 24 hours.

- Outside the United States, contact your local Bio-Rad QC Program Representative.

Organization of this Guide

This guide is organized with more frequently used information at the beginning of the guide and the less frequently used information at the end of the guide.

The major function of UnityWeb is to oversee QC data. Therefore, QC information appears first in this guide, the specifics of using the software appear next, and set up instructions appear last.

Typographical Styles and Conventions

This guide uses consistent styles and conventions to assist with readability. The following information describes the styles and conventions.

Software Items

Software Item	Example
Tab	Click the Reports tab.
Menu item	Click Security .
Dialog box	Comments that are added in the Data Entry dialog box do not appear on the Audit Trail Report.
Button	Click Save .
Option	Select the Lab or Panel option.
Check box	Select the Overlay check box.

Keyboard Keys

Names of keys on the keyboard appear in all capital letters. For example, press the TAB key on the keyboard.

Notes, Tips, and Important Notes

This guide uses *notes*, *tips*, and *important* notes to call attention to additional information or information of special importance.

Note

A *note* indicates information supplementing the main text. A note supplies information that may only apply in special cases and is separated from the surrounding text by a box. For example:



Note: A comment is automatically added when you insert a row of data.

Tip

A *tip* provides useful extra information and suggestions for implementation. A tip is not essential to the basic understanding of the text and is separated from the surrounding text by a box. For example:



Tip: For convenience, you can rearrange the order of tests in the **Open tests** list to match your instrument or LIS printout.

Important

An *important* note provides information essential to the completion of a task. Do not disregard information in an important note. An important note is separated from the surrounding text by a box. For example:



Important: Make sure to select **Dedicated reagent or kit** as the **Reagent Type** if using a VITROS instrument.

Essential Startup Tasks for New Users



Important: Make sure to disable any pop-up blockers or allow pop-ups for the UnityWeb site.

Bio-Rad provides your laboratory with an administrator ID and password for UnityWeb. This default administrator login allows new users first time access to the software. For ultimate security of UnityWeb, delete the default administrator login after another administrator login has been setup.

First Time Log In

- 1 Start an Internet browser window and navigate to www.QCNet.com.
- 2 to **Unity Interlab** and then click **UnityWeb 2.0**.

The **Server Login** dialog box appears.

- 3 Type the server name provided by Bio-Rad in the **Server** field or click  (ellipsis button) located to the right of the **Server** field and select the server from the list.
 - 4 Select the **SQL Server authentication** option.
 - 5 Type the server user name in the **User** field. This is the server user name provided by Bio-Rad.
 - 6 Type the server password in the **Password** field. This is the server password provided by Bio-Rad.
 - 7 Type the database name provided by Bio-Rad in the **Database** field or click  (ellipsis button) located to the right of the **Database** field and select the database from the list.
 - 8 Click **OK**.
- The **Login** dialog box appears.
- 9 Type the group login ID provided by Bio-Rad in the **User** field.
 - 10 Type the password in the **Password** field.
 - 11 Click **Login**.



Note: See Chapter 5, “User Profiles and Security” for more information about adding additional users and security basics.

QC Configuration

Perform the following tasks before manually entering data:

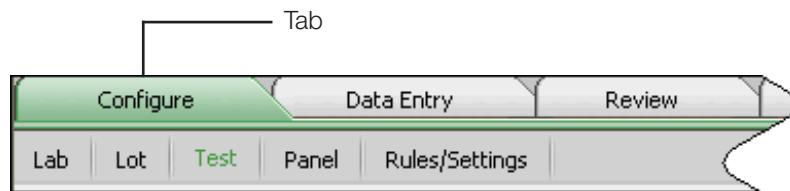
- Add a lab number—see Chapter 6, “Labs and Lots”
- Add a lot number—see Chapter 6, “Labs and Lots”
- Add tests—see Chapter 7, “Tests”

Program Hints

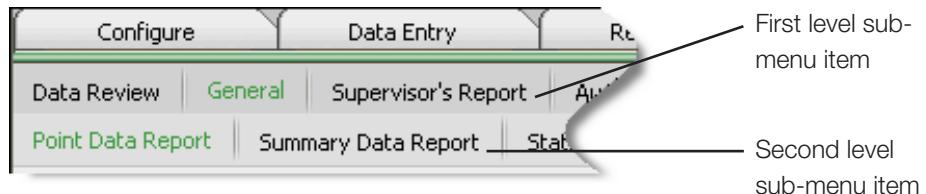
UnityWeb contains common software elements you have probably used with other Internet-based software. Each element provides a specific function for performing different actions.

Tabs

Software functions in UnityWeb are organized by different tabs. Click each tab to access different functionality of the software.



Menu Items



Links

Click a link to go to or open another window in the software. Links are underlined in blue.

[Generate Rule Suggestions](#)



Buttons

Click a button to initiate an action.

Check Boxes

A square box selected or cleared to turn on or off an option. More than one check box can be selected.

Level: 1 2 3

Options

A round button used to select one of a group of options. Unlike check boxes, only one option can be selected.

Lab Panel

Lists

A list has a down-pointing arrow next to it. Click the arrow to open the list and make a selection.

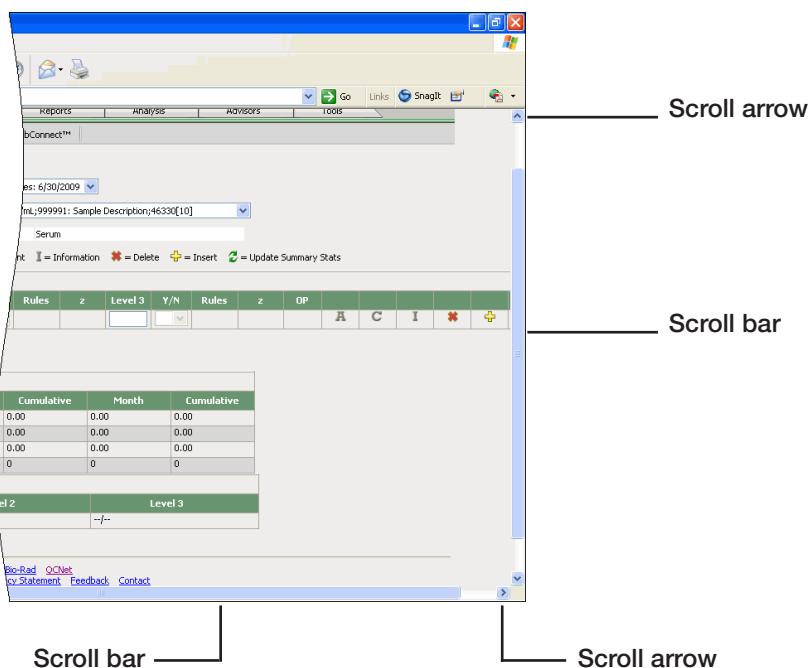
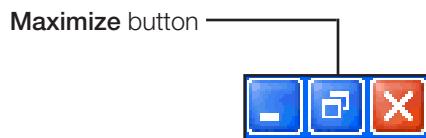
Lot number:



Scroll Bars and Scroll Arrows

Depending on the size of your monitor, it may be necessary to use the scroll bars and scroll arrows to view the entire contents on the screen.

Click the **Maximize** button to enlarge the screen to its largest size and to minimize scrolling.



Unavailable Items

Items in the software appear dimmed if not available. Items that may appear dimmed include buttons, options, check boxes, and icons. Items may be dimmed if a user does not have the required permission to perform a task or if another action is required before the item is available.

A button appears dimmed if it is unavailable.

 Delete

Introduction to Quality Control Statistics

In This Chapter

What is Quality Control?	8
Basic QC Statistics.....	11
SPC Rules.....	18

What is Quality Control?

Quality control in the medical laboratory is a statistical process used to monitor and evaluate the analytical process producing patient results. The statistical process requires:

- **Regular testing of quality control products along with patient samples.**

Good laboratory practice requires testing normal and abnormal controls at least once a day when patient testing is performed. If the test is stable for less than 24 hours or some change has occurred that could potentially affect the test stability, controls should be tested more frequently. All laboratories in the United States must comply with CLIA Requirements (see “CLIA Requirements” on page 10 for more information).

- **Generation of QC results for evaluation.**

When performing a diagnostic test in the medical laboratory, the outcome of the test is a *result*. The result may be a patient result or a quality control (QC) result. The result may be quantitative (a number), qualitative (positive or negative), or semi-quantitative (limited to a few different values).



Note: UnityWeb currently provides QC rule evaluation only for quantitative tests. You may enter data from qualitative and semi-quantitative tests; however, the data is not evaluated against any rules.

How are QC Results Used?

Use QC results to validate patient results. After the validation of QC results, use patient results for diagnosis, prognosis, or treatment planning. For example, when testing a patient’s serum for potassium, the test result shows how much potassium (what concentration) is present in the blood. The physician uses this result to determine whether the patient has a low, normal, or high potassium level.

For example, if the measured value of potassium in a patient’s serum is 2.8 mmol/L (a unit of measure, millimoles per liter), this result is abnormally low and indicates an inappropriate loss of potassium.

What indicates this test is truly reliable? Perhaps the instrument is out of calibration and the patient’s true

potassium value is 4.2 mmol/L, which is a normal result.

Resolve the question of reliability for most testing by regular testing of quality control materials and the application of statistical process control values.

Test QC materials and develop a database of values to calculate a mean and range (for example, the mean $\pm 3SD$). Compare the QC results to the range using statistical process control (SPC) rules and make decisions to accept or reject patient results based on the outcome of the rule evaluation.

Normal and Abnormal Controls

A normal control product contains normal levels for the analyte. An abnormal control product contains the analyte at a concentration above or below the normal range for the analyte. For example, the normal range for a potassium level is approximately 3.5–5.0 mmol/L. A normal control contains potassium at a level within this range. An abnormal control contains potassium at a level below 3.5 mmol/L or above 5.0 mmol/L.

Example Scenario

The following example QC log shows normal and abnormal control results as well as patient results for a seven-day period.

Analyte: Potassium

Instrument: Instrument Number 1

Unit of measure: mmol/L

		Level 1 (Normal Control)	Level 2 (Abnormal Control)	Patient Results
Range:		3.7 – 4.3 mmol/L	6.7 – 7.3 mmol/L	
Date:	Dec-01	4.0	7.0	4.2, 4.0, 3.8, 5.0, 5.8, 4.2
	Dec-02	4.1	7.0	3.8, 4.4, 4.6, 3.9, 4.6, 4.4, 3.9
	Dec-03	4.0	6.9	4.4, 3.9, 3.7, 4.7
	Dec-04	4.2	7.1	4.7, 5.6, 4.2, 3.7, 4.3
	Dec-05	4.1	7.0	4.3, 4.3, 4.1, 4.3
	Dec-06	4.1	7.0	4.6, 4.4, 5.5, 3.8, 3.2
	Dec-07	4.2	8.0	2.8, 4.6, 4.2, 3.2, 3.9, 4.1, 6.0, 4.3

The acceptable range for Level 1 (normal control) is 3.7–4.3 mmol/L. The acceptable range for Level 2 (abnormal control) is 6.7–7.3 mmol/L. When comparing the daily QC result obtained for the normal control to the range calculated for the normal control, each result is within the expected range. This indicates the analytical process is “in control” at the normal level on the day of testing.

When comparing the daily QC result for Level 2 (abnormal control) to the defined range for the abnormal control, the analytical process is “in control” for each day of testing except for the last day (Dec-07 in the example above). On December 1 through December 6, both levels were “in control,” and the laboratory could

report patient values reliably.

However, the laboratory was “out of control” for abnormal high potassium on December 7 because the value obtained for the QC material (8.0 mmol/L) was outside the acceptable range (6.7–7.3 mmol/L). This result indicates some type of error occurred which may have produced unreliable patient results which are abnormally high. In this scenario, the laboratory should not report any patient samples with an abnormally high potassium until resolving the error and re-testing the abnormally high sample.

From this example, it is apparent the range defined for each level of control is fundamental to the quality control system. The section “Basic QC Statistics” on page 11 describes the calculations required to develop an acceptable control range.

CLIA Requirements

In the United States, the Clinical Laboratory Improvement Amendments (CLIA) of 1988, as modified by the final CLIA Rule, requires the testing of two levels of control (one normal and one abnormal) each day the test is performed. This requirement applies to all non-waived tests, unless the Centers for Medicare and Medicaid Services (CMS) approves an equivalent quality testing procedure as specified in Appendix C of the State Operations Manual.

In other words, if testing patient samples for potassium on Wednesday, the laboratory must test at least one normal and one abnormal potassium control product on Wednesday, unless CMS has approved an equivalent QC procedure. Blood gas testing is slightly different.

For instruments verifying calibration internally, a laboratory in the United States must run one control every eight hours and use a combination of materials including low and high values on each day of testing.

If the instrument does not verify calibration internally, a laboratory must test these same controls with each patient sample.

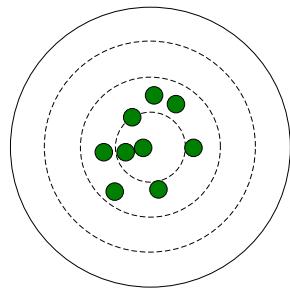


Note: As with any government regulation, these requirements can change.

Basic QC Statistics

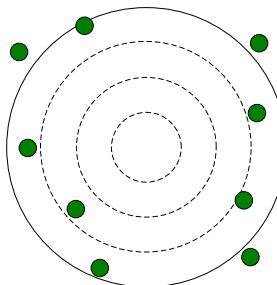
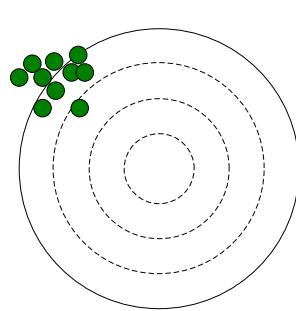
A total QC system must control both trueness and precision. The goal is for a test to have both low bias and low imprecision. Problems with imprecision are less likely to cause analytical failure in the modern laboratory due to computerization and mechanization of the analytical process. Therefore, bias is brought to the forefront.

The following illustration represents low bias and low imprecision as a target, where the center of the target represents the target value.



The illustrations below show two other possibilities.

- The illustration on the left represents a situation where the standard deviation (SD) for a test is small (good precision) but is shifted away from the target value (high bias).
- The illustration on the right represents poor precision but surprisingly, low bias because the average of the results is close to the target. Of course, individually none of the points are close, and their individual z-scores would reflect this.



Note: Bias and imprecision are most important at the clinical decision levels. For example, β -hCG clinical decision levels are at low concentrations (corresponding to early pregnancy in the female and early testicular cancer in the male) or at moderate concentrations (to diagnose the progression of pregnancy).

Useful Statistics

Evaluation of a test's bias and imprecision uses several calculations. Although UnityWeb performs these calculations, it is useful to understand the calculations, which include:

- Mean (page 12)
- Standard Deviation (page 12)
- Standard Deviation Index (page 14)
- Bias (page 15)
- Coefficient of Variation (page 15)
- Coefficient of Variation Ratio (page 16)

Mean

The mean for a group of data points is simply the calculated average. The mean provides a laboratory's best estimate of the analyte's "true" value for a specific level of control. The mean \pm a predetermined number of standard deviations represents the error expected in a test when the analytical system is stable. Use the following formula to calculate the mean:

$$\text{Mean} = \sum \frac{x_n}{n}$$

Where: Σ = sum

x_n = each value in the data set

n = the number of values in the data set

Standard Deviation (SD)



Note: Standard deviation is often abbreviated as SD or s.

The standard deviation measures a test's precision; that is, how close individual measurements are to each other. (The standard deviation does not measure bias, which requires the comparison of your results to a target value such as your peer group.) The standard deviation provides an estimate of how repeatable a test is at specific concentrations. Test repeatability can be consistent (low standard deviation, low imprecision) or inconsistent (high standard deviation, high imprecision).

It is optimum to have repeated measurements of the same specimen in order to have results as close to each other as possible. Good precision is especially important for tests repeated regularly on the same patient in order to track treatment or disease progress. For example, a diabetic patient in a critical care situation may have glucose levels run every two to four hours. In this case, test precision is important since the lack of precision can cause loss of test reliability. If there is a lot of variability in the test performance (high imprecision,

high standard deviation), the glucose result at different times may not be true.

Use the following formula to calculate the standard deviation:

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

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 values in the data set

A high standard deviation can be attributed to:

- Inherent variability in the test which represents expected error.
- Analytical system malfunction which represents unexpected error the laboratory must investigate and correct.



Tip: Levey-Jennings Charts allow you to visually review data points plotted against a $\pm 3SD$ range.
See "Levey-Jennings Chart" on page 151 for more information.

Calculate a Control Mean and Range

- 1 Collect a minimum of twenty data points for each level of control.
 - Obtain data points from twenty separate analytical runs reflecting variables such as calibration frequency, change of reagent or reagent lot, operator technique, temperature and humidity of testing location, daily and weekly maintenance, and so on.

*Based on the Clinical and Laboratory Standard Institute (CLSI) recommendation for the minimum number of data points necessary to calculate a range.

 - Compare new control products to previously validated controls (parallel testing).
- 2 Calculate the mean and standard deviation from the data points collected.
 - Use a statistical test for outliers before eliminating any questionable data points.
 - Calculate the statistical control limit from the mean $\pm 2SD$ and the mean $\pm 3SD$.



Important: Use product insert ranges as guidelines only. Ranges are based on reagent lots and materials available at the time of value assignment. During the life of the control lot, manufacturers may reformulate tests or begin using a new source of raw materials for kit/reagent production. Published ranges cannot account for variables such as instrumentation software updates or performance differences over time.

Standard Deviation Index (SDI)

The standard deviation index is a measurement of bias (how close your value is to the target value). The Bio-Rad Unity Interlaboratory Program uses the consensus group value as the target value. Use the following formula to calculate the SDI:

$$\text{SDI} = \frac{\bar{x}_{\text{lab}} - \bar{x}_{\text{group}}}{s_{\text{group}}}$$

Where: \bar{x}_{lab} = laboratory mean
 \bar{x}_{group} = consensus group mean
 s_{group} = consensus group standard deviation

Interpreting the SDI

The target SDI is 0.0, which indicates there is not any difference between the laboratory mean and the consensus group mean. A SDI ± 1 indicates a possible problem with the test.

The SDI expresses bias as increments of the standard deviation. A SDI of -1.8 indicates a negative bias of 1.8 standard deviations from the consensus group mean. This is not favorable.

Bias increases or decreases the percentage of patients outside the defined reference limit. For example, a positive bias decreases the percentage of patients normally outside the lower limit and increases the percentage of patients normally outside the upper reference limit. This creates an increase in false positive test results. Negative bias has an opposite effect and decreases true positives and creates false negatives.

Use the following guidelines to interpret the SDI:

SDI value	Interpretation
0.0	Perfect comparison with consensus group.
≤ 1.25	Acceptable.
1.25–1.49	Acceptable to marginal performance. Some investigation of the test system may be required.
1.5–1.99	Marginal performance. Investigation of the test system is recommended.
≥ 2.0	Unacceptable performance. Remedial action usually required.

Bias

Bias measures how far your observed value is from a target value. Determine bias by a reference value or estimate from outside sources such as proficiency testing results or the Bio-Rad Unity Interlaboratory Program. Express bias as a percentage. Use the following formula to calculate bias:

$$\text{Laboratory bias\%} = \frac{\text{laboratory mean} - \text{concensus group mean}}{\text{concensus group mean}} \times 100$$

Coefficient of Variation (CV)

The coefficient of variation is the ratio of the standard deviation to the mean. Express CV as a percentage. Use the following formula to calculate the CV:

$$CV = (s \div \bar{x})$$

Where:
 s = standard deviation
 \bar{x} = mean

Using the CV makes it easier to compare the overall precision of two analytical systems. The CV is a more accurate comparison than the standard deviation as the standard deviation typically increases as the concentration of the analyte increases. Comparing precision for two different methods using only the standard deviation can be misleading.

Example Scenario

Compare a hexokinase method and glucose oxidase method for measuring glucose. The standard deviation for the hexokinase method is 4.8. The standard deviation for the glucose oxidase method is 4.0. Based on the standard deviation, you might conclude the glucose oxidase method is more precise than the hexokinase method.

However, in this example, a comparison of the CV shows the methods are equally precise. Assuming the mean for the hexokinase method is 120 and the mean for the glucose oxidase method is 100, the CV for both methods is 4%.

Example of coefficient of variation (CV) versus standard deviation (SD)

Analyte: Glucose
Method: Hexokinase
Standard deviation: = 4.8
Mean = 120



Analyte: Glucose
Method: Glucose oxidase
Standard deviation: = 4.0
Mean = 100

Which is more precise?

Calculate the CV to find out:

$$\text{CV (\%)} = \frac{\text{standard deviation}}{\text{mean}} \times 100$$

$$\frac{4.8 \text{ (SD)}}{120 \text{ (mean)}} \times 100 = 0.04\% \text{ CV} \quad \frac{4.0 \text{ (SD)}}{100 \text{ (mean)}} \times 100 = 0.04\% \text{ CV}$$

In the above example, the CV proves both methods are equally precise.

Determining an Acceptable CV

When determining an acceptable CV, several sources provide expected levels of precision, including:

- Precision information provided in the product insert or instrument manual.
- Interlaboratory comparison programs.
- Proficiency surveys.
- Evaluations of instruments and methods published in professional journals.

These sources are useful for evaluating the CV for a test or when comparing two test systems.

Coefficient of Variation Ratio (CVR)

The coefficient of variation ratio compares your laboratory precision for a specific test to the CV of other laboratories performing the same test. Use the following formula to calculate the CVR:

$$\text{CVR} = \frac{\text{within laboratory CV}}{\text{concensus group CV}}$$

In UnityWeb, the CVR appears on the following Unity Interlaboratory Reports:

- Laboratory Comparison Reports
- Monthly Evaluation Reports
- Affiliated Laboratory Comparison Report: Abbreviated Summary

This report includes the CVR based on your affiliated group as well as the CVR for the Peer and Method consensus groups.

Total Error (TE) and Total Allowable Error (TE_a)

Total error and total allowable error are useful when choosing the SPC rule(s) to apply to a test. For example, SPC rules can identify a test exceeding a quality specification (TE_a). Total error for a test includes both bias and imprecision. Use the following formula to calculate the TE:

$$\text{Laboratory TE} = [\text{laboratory bias\%}] + z\text{-factor} \times (\text{laboratory imprecision \%})$$

TE_a specifications are available from several sources as described in “Determine Quality Requirements for the Test” on page 28. After choosing a TE_a , calculate the TE budget. Use the following formula to calculate the TE budget:

$$\text{TE budget \%} = \frac{\text{laboratory TE}}{TE_a}$$

With the optional Westgard Advisor online, choose a TE_a and the program suggests SPC rules based on test data and Unity Interlaboratory Program information.

Z-score

The z-score is the number of standard deviations a control result is from the expected mean. Use the following formula to calculate the z-score:

$$z\text{-score} = \frac{\text{observed result} - \text{expected mean}}{\text{expected standard deviation}}$$

A z-score of 2.3 indicates the observed value is 2.3SD away from the expected mean. A data point with this z-score would violate the 1-2s rule, but not the 1-3s rule. The z-score appears on the **Single Test Point Data Entry** dialog box.

SPC Rules

In 1981 Dr. James Westgard of the University of Wisconsin published an article on laboratory quality control setting the basis for evaluating analytical run quality for medical laboratories. The Westgard system is based on the principles of statistical process control used in manufacturing nationwide since the 1950s. There are six basic rules in the Westgard scheme: 1-3s, 2-2s, R-4s, 1-2s, 4-1s, and 10-x. Use these rules individually or in combination (multi-rule) to evaluate the quality of analytical runs.

The rationale for applying these rules is:

- Reduce false rejections made when applying just the 1-2s rule for run rejection.
- Increase error detection more than provided when applying just the 1-3s rule for run rejection.
- Include rules to detect and distinguish random and systematic error (1-3s and R-4s to detect random error and 2-2s, 4-1s, and 10-x to detect systematic error).

Westgard devised a shorthand notation for expressing quality control rules. Most quality control rules can be expressed as NL, where N represents the number of control observations to be evaluated and L represents the statistical limit for evaluating the control observations. Therefore, 1-3s represents a control rule violation when one control observation exceeds the $\pm 3SD$ control limit.

1-2s

The 1-2s rule is usually a warning rule violated when a single control observation is outside the $\pm 2SD$ limit.

Some laboratories consider any quality control value outside its $\pm 2SD$ limit to be out of control, and therefore incorrectly decide the patient specimens and QC values are invalid.

An analytical run usually should not be rejected if a single quality control value is outside the $\pm 2SD$ QC limit but within the $\pm 3SD$ QC limit. Approximately 4.5% of all valid QC values will fall somewhere between $\pm 2SD$ and $\pm 3SD$ limit.

Laboratories universally rejecting values outside the $\pm 2SD$ limit end up rejecting good runs too frequently.

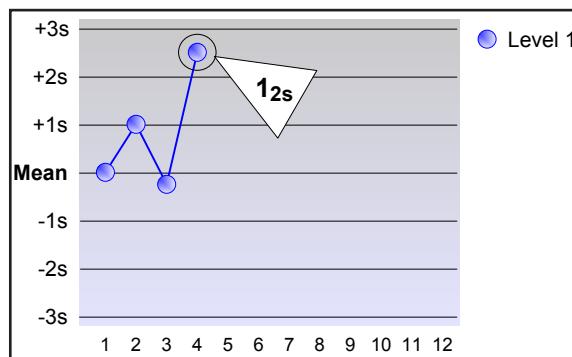
The 1-2s rule was originally designed as a warning rule for manual application of the Westgard rules. If one control measurement within a run exceeds the mean $\pm 2SD$ in a manual application of Westgard rules, evaluate other controls in the run (within the run) and in previous runs (across runs) before accepting the run and reporting the results. With computer-based applications of Westgard rules, the 1-2s rule is usually not necessary.

Using the 1-2s rule alone in performing quality control tests causes frequent rejection of valid runs. According to Dr. Westgard, failure to allow for valid points between 2SD and 3SD may result in falsely rejecting:

- 5% of all analytical runs when using one level of control.
- 10% of all analytical runs when using two levels of control.
- 14% of all analytical runs when using three levels of control.

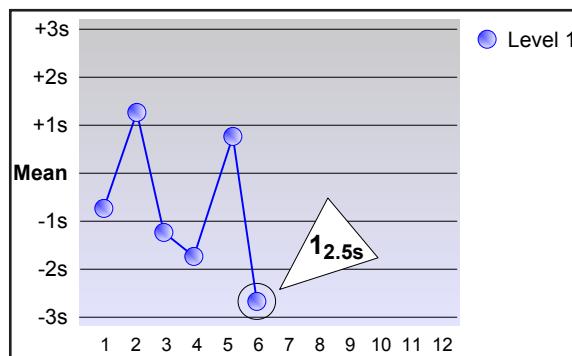
These false rejections result in the unnecessary repeat of patient samples, the waste of labor and materials, and the unnecessary delay of patient results.

The following figure shows a Levey-Jennings Chart with a data point between +2SD and +3SD.



1-2.5s

The 1-2.5s rule indicates random error and may also point to systematic error. This rule is applied within the run only. The following figure shows a Levey-Jennings Chart with a data point outside the $\pm 2.5SD$ limit.

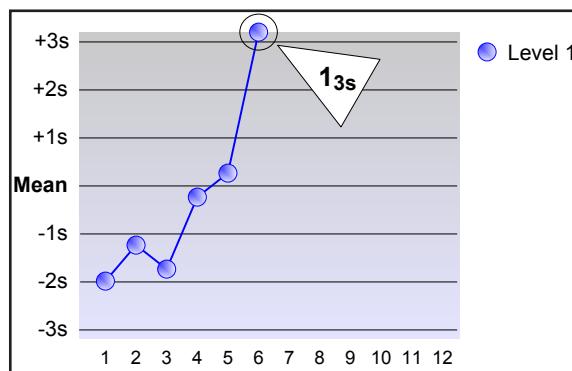


1-3s

The 1-3s rule identifies unacceptable random error or possibly the beginning of a large systematic error. Any QC result outside $\pm 3SD$ violates this rule. Since only 0.3% or 3 out of 1000 points will fall outside the $\pm 3SD$ limit, any value outside of $\pm 3SD$ is usually considered to be associated with a significant error condition.

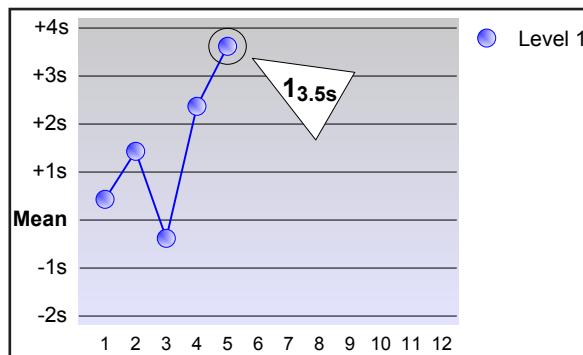
While a value outside $\pm 3SD$ may be statistically significant, it may not be biologically or medically relevant due to the fact that modern laboratory instruments are often more precise than what is needed medically.

The following figure shows a Levey-Jennings Chart with a data point outside the $\pm 3SD$ limit.



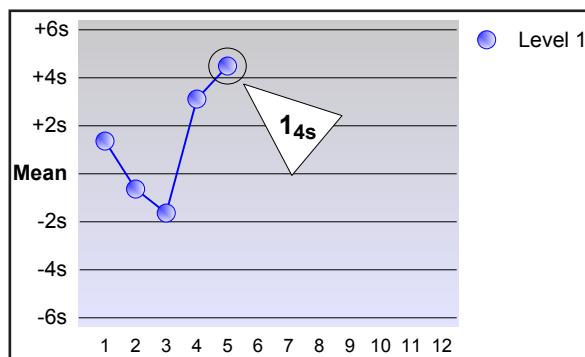
1-3.5s

The 1-3.5s rule indicates random error and may also indicate systematic error. The run is considered out of control when one control value exceeds the mean $\pm 3.5SD$. This rule is applied within the run only. The following figure shows a Levey-Jennings Chart with a data point outside the $\pm 3.5SD$ limit.



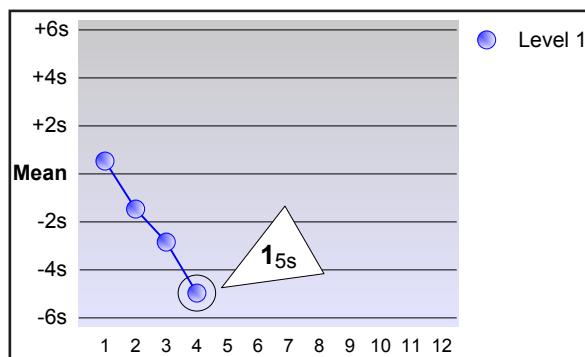
1-4s

Violation of the 1-4s rule indicates random error and may also point to systematic error. The run is considered out of control when one control value exceeds the mean $\pm 4SD$. This rule is applied within the run only. The following figure shows a Levey-Jennings Chart with a data point outside the $\pm 4SD$ limit.



1-5s

Violation of this rule indicates random error and may also point to systematic error. The run is considered out of control when one control value exceeds the mean $\pm 5SD$. This rule is applied within the run only. The following figure shows a Levey-Jennings Chart with a data point outside the $\pm 5SD$ limit.



2-2s

The 2-2s rule detects systematic error only. The 2-2s rule is violated when two consecutive QC results are:

- Greater than 2SD.
- On the same side of the mean.

The rule is applied both within a run and across runs:

- Within run violation

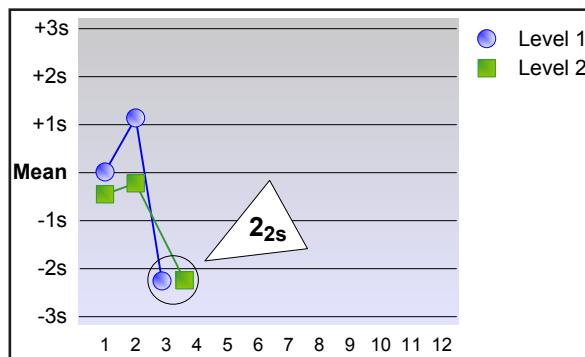
Two control values in the same run are $>2SD$ on the same side of the mean. Violation of the within run application indicates systematic error is present and potentially affecting the entire analytical curve.

- Across run violation

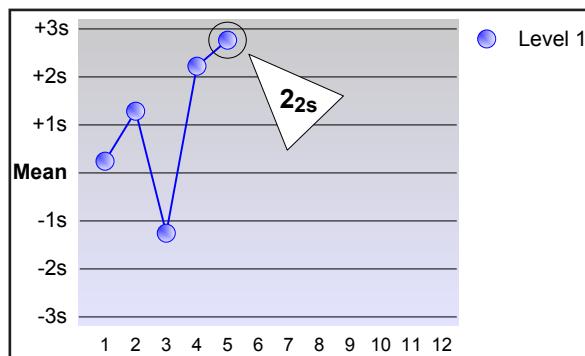
In one run a single level of control is $>2SD$ from the mean. In the next run, the same level of control is $>2SD$ on the same side of the mean. Violation of the across run application indicates systematic error is present but affects only a single portion of the analytical curve.

The following figures show a Levey-Jennings Chart with a data point violating the 2-2s rule within and across a run.

Across Run Violation

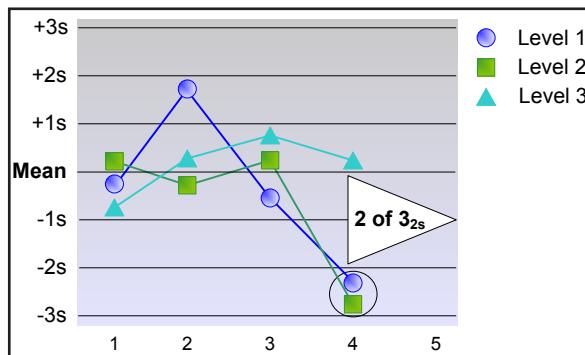


Within Run Violation



2 of 3-2s

This is a variation of the 2-2s rule and detects systematic errors. It is triggered when any two of all three levels of control in a run exceed 2SD on the same side of the mean. The following figure shows a Levey-Jennings Chart with two points violating the 2 of 3-2s rule.

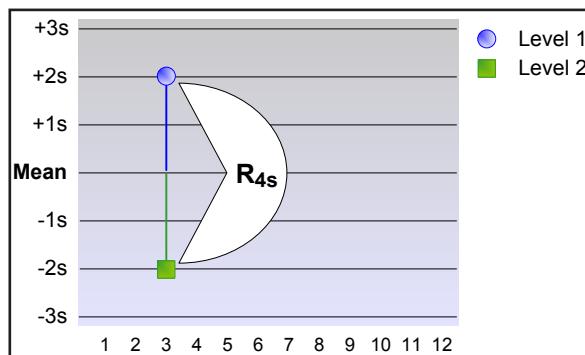


R-4s

The R-4s rule identifies random error. It is applied only within the current run. This rule is violated when there is at least a 4SD difference between control values within a single run.

For example, assume both Level 1 and Level 2 have been tested within the current run. Level 1 is +2.8SD above the mean and Level 2 is -1.3SD below the mean. The total difference between the two control levels is greater than 4SD ($+2.8\text{SD} - (-1.3\text{SD}) = 4.1\text{SD}$).

The following figure shows a Levey-Jennings Chart with two points violating the R-4s rule.



3-1s and 4-1s

These rules are violated when three or four consecutive results are:

- Greater than 1SD.
- On the same side of the mean.

The 3-1s and 4-1s rules have two applications:

- Within a control level (for example, all Level 1 control results).

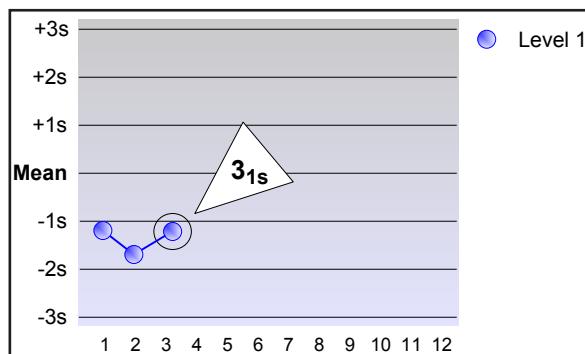
Violations within a control level indicate systematic bias in a single area of the method curve.

- Across control levels (for example, Level 1, 2, and 3 control results in combination).

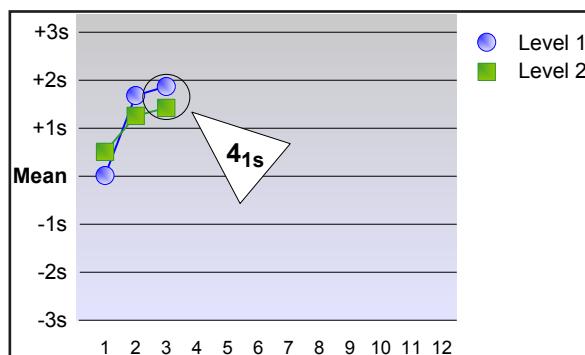
Violations across control levels indicate systematic error over a broader range of concentrations.

The following figures show a Levey-Jennings Chart with a data point violating the 3-1s rule within a run and a 4_{1s} rule across a run.

3-1s Within a Control Level



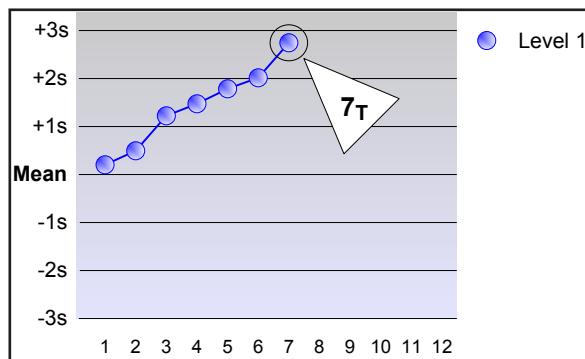
4-1s Across Control Levels



7-T

The 7-T rule is violated when a group of seven consecutive data points for a single level of control show either a “strict” increasing or decreasing pattern. A “strict” increasing pattern is defined as a series of points increasing incrementally from the previous point (each point greater than the last) without a break in the pattern. A “strict” decreasing pattern is the same pattern in the opposite direction.

The following figure shows a Levey-Jennings Chart with points violating the 7-T rule.



N-x Rules

N-x rules are violated when there are 7, 8, 9, 10, or 12 control results on the same side of the mean.

Each of these rules has two applications:

- Within a control level (for example, all Level 1 control results).

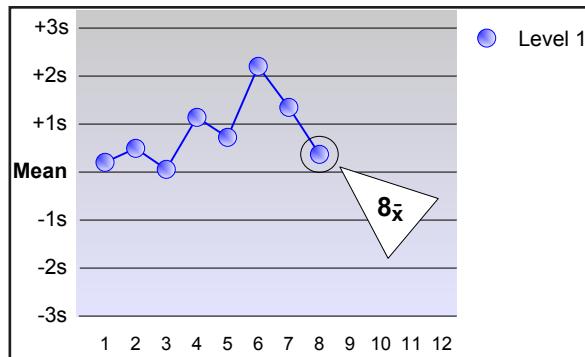
Violations within a control level indicate systematic bias in a single area of the method curve.
- Across control levels (for example, Level 1, 2, and 3 control results in combination).

Violations across control levels indicate systematic error over a broader range of concentrations.

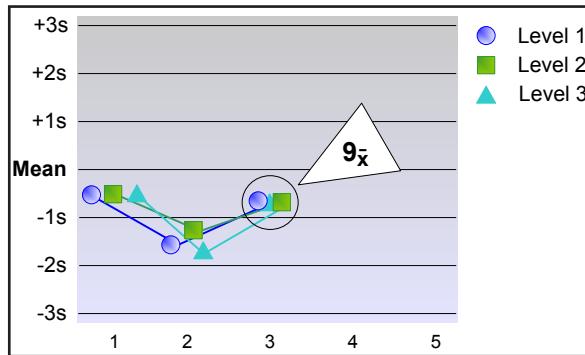
The 7-x control rule is far more sensitive to analytical bias than the 12-x rule. The chance of finding seven consecutive control observations on one side of the mean is much higher than finding twelve.

The following figures show a Levey-Jennings Chart with data points violating the 8-x rule within a run and the 9-x rule across a run.

8-x Within a Control Level



9-x Across Control Levels



Choose and Troubleshoot a QC Procedure

In This Chapter

Recommended Steps.....	27
Determine Quality Requirements for the Test.....	28
Identify Appropriate QC Materials	29
Evaluate Test Performance	29
Identify Possible QC Procedures.....	32
Predict the Performance of the QC Procedures	32
Choose Goals Based on Required Quality	33
Select a QC Procedure.....	33
Troubleshoot QC Results.....	33
Good Laboratory Habits	34
Keys to a Productive Review of the Laboratory Quality System.....	37

Recommended Steps

When setting up a QC system, it is important to make sure you choose statistical process control (SPC) rules to maximize error detection while minimizing false rejections.

Clinical and Laboratory Standards Institute (CLSI-C24-A3, section 6) recommends using the following steps when setting up a QC system:

- 1 Determine the quality requirements for the test.
- 2 Identify appropriate control materials to use.
- 3 Evaluate test performance.
- 4 Identify possible QC procedures.
- 5 Predict the performance of the identified QC procedures.
- 6 Choose goals based on the required quality.
- 7 Select a QC procedure.

Obviously, this is not a simple process which may explain why many laboratories fall back on the 1-2s rule. Although the 1-2s rule produces too many false alarms, it feels safe.



Tip: The optional Westgard Advisor online makes the complex task of choosing the appropriate SPC rules easier. See Chapter 18, “Westgard Advisor online” for more information.

Determine Quality Requirements for the Test

How good does a test need to be? Answering this question will help determine the total allowable error (TE_a); the amount of error a test has and is still considered “in control.” The laboratory can use several models to determine quality requirements:

- 1 Medical usefulness requirements based on the effect of analytical performance on clinical decisions such as:
 - Biological variation information.
 - Clinicians’ opinions.
- 2 Published professional recommendations from:
 - National and international expert bodies and agencies.
 - Expert local groups or individuals.
- 3 Performance goals set by:
 - Regulatory bodies and agencies.
 - Organizers of External Quality Assessment (EQA) schemes.
- 4 Goals based on the current state of the art, which include:
 - Interlaboratory comparison programs such as the Unity Interlaboratory Program.
 - EQA or proficiency testing schemes.
 - Current published information on methodology.

The preceding hierarchy is based on the consensus agreement published in the *Scandinavian Journal of Clinical and Laboratory Investigation* 1999; 59: 585.



Note: When available and appropriate, models higher in the list are preferred to those lower in the list.

Based on requirements needed to maintain accreditation, proficiency testing requirements define the minimum standards for performance. While proficiency testing may be appropriate for some tests, medical usefulness requirements are usually more stringent and may be preferred.

Identify Appropriate QC Materials

CLSI (C24-A3, Section 6.2) suggests the following considerations when selecting control materials:

- The control material should share common characteristics with the intended patient sample types.
- To minimize the amount of testing required when a lot change occurs the laboratory should purchase a large enough volume of control materials. If practical, at least a one year supply is recommended.
- Upon opening, the control material should demonstrate stability over the claimed shelf life.
- The vial to vial variance should be much less than the expected variance of the procedure being tested.
- To verify proper performance over the measuring range, the control material should consist of a sufficient number of levels and concentrations.



Note: Local government regulations might specify a minimum number of control levels for particular testing protocols.

- The control material should contain the analyte to be tested in concentrations at the clinically relevant levels that might be seen in patient samples.

Evaluate Test Performance

After the quality requirement for a test is determined, evaluate the bias and imprecision for the test in order to quantify its total error (TE). UnityWeb uses the following formula to calculate the laboratory total error (TE) at a 99% ($p < 0.01$) confidence interval:

$$\text{Laboratory TE} = |\text{Laboratory Bias (\%)}| + 2.33 \text{ Laboratory CV}$$

This formula shows a test can have a higher bias as long as the CV (imprecision) is low, and vice versa. The objective is to limit the total error in patient test results.

You can evaluate the bias and imprecision of a test using the standard deviation index (SDI) and coefficient of variation ratio (CVR). Several Unity Interlaboratory Reports contain both.

As scientists, laboratorians should concern themselves with which component (bias or imprecision) is contributing to error, in what amount, and how the component's performance can be improved. However, as long as patient test results do not have more than the total allowable error (TE_a), laboratorians should not be concerned about the reliability of those results. When analytical error exists, the question becomes whether it is critical error; this depends on the quality requirements chosen for the test.

Six Sigma

Six sigma provides a convenient way to monitor the performance capability of a testing system. During the 1980s, Motorola set out to improve their manufacturing process so virtually no defective product would be produced. Motorola defined this as having six sigmas (standard deviations) of process variation fit within the product tolerances.

Assuming a normal (Gaussian) distribution, the following table shows the effect of product specifications (expressed as standard deviations) on the defect rate and defects per million.

SD range	Defect rate (%)	Defects per million
±2SD	4.5	45,400
±3SD	< 0.27	~2,700
±4SD	0.0063	63
±5SD	0.0057	0.57
±6SD	0.000002	0.002



Note: The advantage of controlling a process to six sigma is that the process can tolerate small shifts without significantly increasing the defect rate. In an ideal world, all processes would be six sigma and could be monitored with very simple QC.

Unfortunately, not all processes are six sigma and as process capability decreases, the choice of QC procedures becomes increasingly important in detecting significant errors. In fact, some processes may have such low process capacity (that is, a high total error), that they cannot be controlled to a defined level of quality. This condition would trigger a maximum QC condition in the optional Westgard Advisor online.

For clinical laboratory tests, the total error (TE) for a test provides an indication of the process capability of the test because the TE combines bias and imprecision. The following formula is used to calculate sigma:

$$\text{Sigma} = \frac{\text{Total Allowable Error} - \text{Bias}}{\text{Coefficient of Variation}}$$



Note: The optional Westgard Advisor online calculates and displays sigma based on the data for a test, the selected TE_a , and the consensus group.

It is possible to correlate sigma with the TE_a as shown in the following table. (The table assumes bias is zero.)

Process classification	Process capability criterion
4-sigma process	$TE_a > \text{bias} + 4 \text{ SD}$
3-sigma process	$TE_a > \text{bias} + 3 \text{ SD}$
2-sigma process	$TE_a > \text{bias} + 2 \text{ SD}$



Note: When the bias is not zero, the sigma classification of a process decreases as its bias increases.

The information in this chapter was abstracted from the *Six Sigma Quality Management and Desirable Laboratory Precision* lesson available on <http://www.westgard.com>. Dr. Westgard provides an interesting correlation between CLIA performance requirements and the performance requirements for a five or six sigma process. As Dr. Westgard concludes, "Six sigma quality management sets demanding standards of performance for laboratory testing processes."

Use of Six Sigma

The sigma value for a test is a good indication of its process capability because it considers both bias and imprecision. Unfortunately, most clinical laboratory tests are below six sigma processes.

So how is six sigma achieved? The obvious answer is to choose a test method with a six sigma process. Laboratories can take steps to control precision through proper training, instrument maintenance, and so on; however, to a large extent, method precision is a function of instrument methodology.

While method precision may not be controllable, a QC procedure can be chosen that detects small changes in the testing system so that reject runs having defects are identified and corrective action taken.



Note: The optional Westgard Advisor online calculates sigma values and displays them on the **Grid** and **Chart** options on the **Design QC Rules** dialog box. The sigma value also appears on the Westgard Advisor online Report.

Qualitative Evaluation of a Test's Bias and Imprecision

Laboratories can access information about imprecision using interlaboratory comparison reports supplied by the vendor of their control materials. While these reports can also be used to evaluate bias, some laboratories prefer proficiency report data for this purpose.

Participants in the Bio-Rad Unity Interlaboratory Program can use the Laboratory Comparison Report, the Laboratory Performance Overview Report, or the Statistical Profile Report. These reports contain two relevant statistics for qualitative assessment of laboratory bias and imprecision:

- CVR (coefficient of variation ratio)

CVR is a peer-based evaluation of imprecision. The ratio is calculated as the laboratory coefficient of variation (CV) for the test divided by the average CV reported for the consensus group.

- SDI (standard deviation index)

SDI is a relative peer-based estimate of bias.

SDI describes or quantifies bias (the difference between the laboratory's observed mean and the consensus group mean) in terms of standard deviation.

OPSpecs Charts and sigma values are available in the optional Westgard Advisor online and provide information about a test's maximum allowable bias (inaccuracy) and imprecision. See Chapter 18, "Westgard Advisor online" for more information.

Identify Possible QC Procedures

Consider and include the following components in any QC procedure design:

- The QC materials to use (see “Identify Appropriate QC Materials” on page 29).
- The number of control samples to analyze with each run.
- The distribution of the control samples within the run (for example, at the beginning, in the middle, at the end, or distributed throughout the run).
- The statistical process control (SPC) rules to apply to optimize the QC process while reducing false errors.

Consider the following when making decisions about how to apply these components to the QC procedure:

- The quality required for the testing procedure.
- The anticipated instability of the testing procedure (for example, the type, size and frequency of the errors).
- The practicality of the QC procedure working for the laboratory.

The optional Westgard Advisor online module is an excellent tool for assisting in the design of QC procedures. While considering the selected quality specifications, Westgard Advisor online makes recommendations as to the SPC rules to apply and the number of control samples to run. See Chapter 18, “Westgard Advisor online” for more information.

Predict the Performance of the QC Procedures

You can predict the performance of a QC procedure using probability calculations or computer simulation studies. It is important to know before selecting a QC procedure what the probability is that the procedure will detect a critical systemic error and the probability that the procedure will produce false rejections.

The optional Westgard Advisor online calculates the probability of error detection (P_{ed}) and the probability of false rejections (P_{fr}) for each recommended SPC rule and number of control samples combination. Each of these values is shown on the Westgard Advisor online Report with the P_{ed} corresponding to the detection level expressed as AQA (SE).



Note: AQA (SE) is the percent of analytical quality assurance (AQA) for systematic error (SE) and indicates the chance of detecting medically important systematic errors. Percent AQA (SE) is synonymous with probability of error detection (P_{ed}).

Choose Goals Based on Required Quality

The objective of any QC procedure is to optimize the chance of detecting out-of-control conditions while minimizing the amount of false error flags. Each laboratory must choose the desirable goals to use for achieving quality requirements, the acceptable level of P_{ed} (probability of error detection), and P_{fr} (probability of false rejections).

Select a QC Procedure

When selecting a QC procedure for implementation, select the procedure that best fits the following parameters:

- Optimizes error detection
- Minimizes false rejections
- Lowest cost (for example, the least number of control samples per run)
- Easiest to implement (for example, the simplest control rules)

Regardless of the procedure selected, it must meet or exceed the laboratory's established quality requirements.



Note: The optional Westgard Advisor online automatically recommends the best QC procedure.

Troubleshoot QC Results

Inevitably, a QC system will indicate an out-of-control situation. What does a laboratory do then? In a lesson titled "QC—The Out-of-Control Problem," Elsa F. Quam BS, MT (ASCP) describes two common bad habits and provides five good habits to use when troubleshooting QC results.

Repeat the Control

Laboratories often apply the 1-2s rule, which yields a false rejection rate of 5% for N=1, 9% for N=2, and 14% for N=3 (where N is the number of control materials tested in the run).

When using the 1-2s rule, some laboratories think it is reasonable to simply repeat the test for the control. However, with carefully chosen SPC rules, this approach is unnecessary. As an example, consider that the false rejection rate for a 1-3s rule is only 0.3%. It is also important to remember that even if the repeat value is within control limits and the run is accepted, it is possible that a problem is being ignored until a future run.

Try a New Control

Another bad habit is to test a different vial of control and repeat the testing until it falls within an acceptable range. Although a bad vial of control material is unlikely, it can occur. For example, controls are not properly reconstituted, are stored improperly, are used beyond their expiration date, and so on. Training can address these issues. Cost is another issue. A new vial of control material is usually much less expensive than repeating a patient run.

As Ms. Quam concludes, “Automatically repeating controls or blaming the control itself are often attempts to resolve the problem without the hassle and time delay necessary in finding and eliminating the true cause of the QC failure. These practices have become habit because they are easy and we often do not have or do not teach the skills necessary to resolve the problem using a more systematic approach.”

Recalibrate

Although not mentioned in Ms. Quam’s lesson, another bad habit is frequent recalibration. It is important to be concerned about the number of times a test is recalibrated as each calibration or recalibration potentially introduces new or additional systematic errors. Frequent recalibration can indicate a defective SPC protocol (rules applied, mean, and range in use), instrument malfunction, sub-optimal reagent quality, or failure to follow the manufacturer’s instructions and schedule for maintenance.

Good Laboratory Habits

If bad habits are eliminated, what are they replaced with? Ms. Quam lists five good habits in her lesson:

- 1 Inspect the control charts or rules violated to determine type of error.
- 2 Relate the type of error to possible causes.
- 3 Consider factors in common on multi test systems.
- 4 Relate the problem to recent changes.
- 5 Verify the solution and document the remedy.

Although not mentioned by Ms. Quam, a sixth good habit is to perform a regular review of the quality system to assess its effectiveness. See “Keys to a Productive Review of the Laboratory Quality System” on page 37 for more information.

Determine the Type of Error

Determining the type of error, random or systematic, is a good first step when investigating QC results. Different rules are sensitive to different types of errors. For example:

- The 1-3s and the R-4s rules usually indicate increased random error because they test the tails or width of a distribution.
- The 2-2s, 4-1s, and 10-x rules usually indicate systematic error because they examine consecutive QC

results that exceed the same limit.

Levey-Jennings Charts also indicate the type of error.



Tip: When possible, always identify the type of error before trying to identify the cause of the problem. Further classification of systematic error as a shift or trend is also useful.

✓ Relate the Error to Possible Causes

Random errors (imprecision) and systematic errors (bias) have different causes. Systematic errors are more common and usually easier to investigate.

- Systematic error is evidenced by a change in the mean of the control values. The change in the mean may be gradual and demonstrated as a trend or it may be abrupt and demonstrated as a shift. Causes of systematic error include change in reagent lot, change in calibrator lot, wrong calibrator values, improperly prepared reagents, deterioration of reagents, deterioration of calibrator, inadequate storage of reagents or calibrators, change in sample or reagent volumes due to pipettor misadjustments or misalignment, change in temperature of incubators and reaction blocks, deterioration of a photometric light source, and change in procedure from one operator to another.
- Random error is any deviation away from an expected result. For QC results, any positive or negative deviation away from the calculated mean is defined as random error. Random error can be acceptable (or expected) as defined by the laboratories acceptable range or unacceptable (unexpected), which is any data point outside the expected population of data (for example, a data point outside the $\pm 3SD$ limit). Random errors can be caused by bubbles in reagents and reagent lines, inadequately mixed reagents, unstable temperature and incubation, unstable electrical supply, and individual operator variation in pipetting, timing, and so on.

Erratic performance due to occasional air bubbles in sample cups or syringes or defective unit-test devices are a different kind of random error, often called “flyers.” Flyers are not actually caused by a change in the imprecision of the method, but rather represent an occasional disaster. It is very difficult to catch flyers using quality control. Patient replicate determinations are a better way of detecting these types of events.

✓ Consider Common Factors on Multi Test Systems

If a multi test system is in use, there may be a problem with a single test or with several tests.

- One test involved
Apply the first two steps (for example, determine the type of error and relate it to possible causes).
- Several tests involved

Consider what, if anything, the tests have in common. Ask the following questions:

- Do all the tests have small or large sample sizes?
- Do all the tests use the same filter?
- Do all the tests with the problem use the same lamp and tests without the problem use a different lamp?

- Do all the tests use the same mode of detection (for example, endpoint versus rate, MEIA versus FPIA)?
- Do all the tests have certain mechanical components in common or certain optical components in common?

✓ Relate the Problem to Recent Changes

“What changed?” is a good question to ask when QC problems arise. The error has already been classified as random or systematic which gives clues about what to investigate first.



Tip: When performing troubleshooting, use a systematic and logical approach in isolating the cause. Make only one change at a time and document each action taken.

Systematic Error

If a sudden shift is observed, inspect the reagent, calibration, and maintenance records, and note any recent actions. For example, if the shift occurred immediately following a reagent replacement, verify the lot number is correct, that it has been checked out or calibrated, that the reagent has been properly prepared, and the reagent is indeed the correct reagent.

If a systematic trend is observed, review the QC records, including documentation of function checks prior to taking actions to resolve the cause. Trends can be caused by a slowly deteriorating reagent, a calibration shift, a change in instrument temperature, or a deteriorating filter or lamp. Unfortunately, systematic trends can be more difficult to resolve than shifts because they occur over a longer time period.

Random Error

The causes of increased random error are generally more difficult to determine because of their random nature. Random errors are more likely due to bubbles in the reagent, reagent lines, sampling or reagent syringes, an improperly mixed or dissolved reagent, pipette tips not fitting properly, a clog in the pipettor, imprecise pipettor, the power supply, and even power fluctuations.

Many of these problems can be detected by inspecting the machine during operation. If a careful inspection provides no clues, consult the manufacturer’s troubleshooting guides and recommendations.

If a run is repeated and the controls are acceptable but concern remains that a problem still exists, perform a precision run using ten back-to-back determinations on the same patient sample. This precision run may help identify further imprecision problems. Duplicate analysis of patient specimens is also recommended when monitoring random error problems.

✓ Verify and Document

After identifying and correcting a problem, verify the correction by retesting the controls. Generally, the controls are run at the beginning of a run. If the new QC values are in control, repeat patient samples from the out-of-control run as necessary. Finally, document the out-of-control event along with the corrective action.



Note: UnityWeb provides reports and charts that are useful for problem solving, especially for unusual problems.

Problems may be correlated with UnityWeb intralaboratory reports and charts, Unity Interlaboratory Reports, and InstantQC reports and charts.

Keys to a Productive Review of the Laboratory Quality System

A laboratory quality system should include regular reviews of the QC results. CAP-accredited laboratories must review and document QC performance at least once a week. These reviews, which are often done retrospectively, offer an excellent opportunity to critically assess the SPC rules applied to a test.

Issues to Consider

- Statistical out-of-control events.
- Frequency of outliers (QC values outside the established total allowable error limits) during the period or across periods.
- The amount of bias present, if any.

Assessing these issues is key to a productive review and can be facilitated by asking the following questions:

- Are the statistical process control (SPC) rules in effect for the test too restrictive when the capability of the methodology or technology and TE_a are considered jointly?
- Should another more stringent single rule or more complex multi-rule be applied to improve error detection?
- Should the mean for the test be adjusted?
- How much imprecision is present and is it a significant contributor to total error? Should the laboratory focus its efforts on improving precision?
- How much comparative bias is present and is it a significant contributor to total error? Should efforts be focused on removing or reducing analytical bias?
- Is the appropriate consensus group (Peer, Method, All Labs) being used to estimate the laboratory's comparative bias for the test?
- Are the performance goals for test imprecision and bias (which also affect TE_a), set appropriately?
- How frequently do SPC errors occur for the test during the review period? Are the errors across review periods? Are frequent errors due to inappropriate selection of SPC rules, larger than expected imprecision, or the presence of bias? Does the mean and range need adjustment?
- How frequently is the test being recalibrated? Does calibration exceed the frequency recommended by the manufacturer?

There is probably not enough time to ask all of these questions during each review cycle. However, each of these questions represents an opportunity to measure and appraise the effectiveness of the process control in effect for a specific test.

Program and Database Basics

In This Chapter

First Time Log In.....	39
Regular Log On and Log Off Process	40
Current Lab, Panel, Lot, and Test	41
Understand the Navigation Tree.....	42
UnityWeb Tabs and Functions	43
Functions and Where to Find Them	46
Download Adobe Reader	51
System Requirements	51
Update the License	51
Upgrade to UnityWeb	53
Configure UnityWeb.....	53
Database Basics	56

First Time Log In

- 1 Start an Internet browser window and navigate to www.QCNet.com.
- 2 Point to **Unity Interlab** and then click **UnityWeb 2.0**.

The **Server Login** dialog box appears.

- 3 Type the server name provided by Bio-Rad in the **Server** field or click  (ellipsis button) located to the right of the **Server** field and select the server from the list.
 - 4 Select the **SQL Server authentication** option.
 - 5 Type the server user name in the **User** field. This is the server user name provided by Bio-Rad.
 - 6 Type the server password in the **Password** field. This is the server password provided by Bio-Rad.
 - 7 Type the database name provided by Bio-Rad in the **Database** field or click  (ellipsis button) located to the right of the **Database** field and select the database from the list.
 - 8 Click **OK**.
- The **Login** dialog box appears.
- 9 Type the group login ID provided by Bio-Rad in the **User** field.

10 Type the password in the **Password** field.

11 Click **Login**.



Note: See Chapter 5, “User Profiles and Security” for more information on adding additional users and security basics.

Regular Log On and Log Off Process

Log On to the Software

- 1 Start an Internet browser window and navigate to www.QCNet.com.
- 2 Point to **Unity Interlab** and then click **UnityWeb 2.0**.
- 3 Type your user ID in the **User** field.
- 4 Type your user password in the **Password** field.
- 5 Click **Login**.



Note: See “User Permissions” on page 65 for more information about users and security.

Log Off the Software



Important: Save all data before logging off the software. Make sure to use the **Log out** link to exit the software. Otherwise, access to the software can be temporarily restricted due to concurrent user licensing.

When ready to log off the software, click  [admin, Log out](#) located at the top of the screen.



Note: “Admin” will be replaced with your user ID.

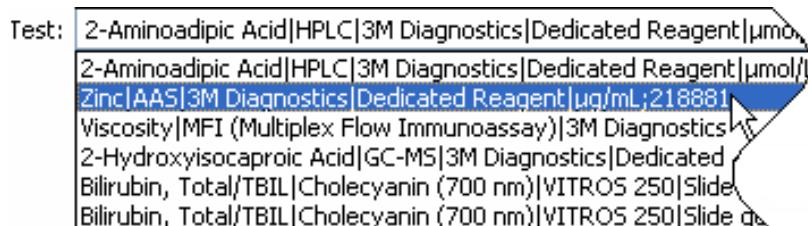
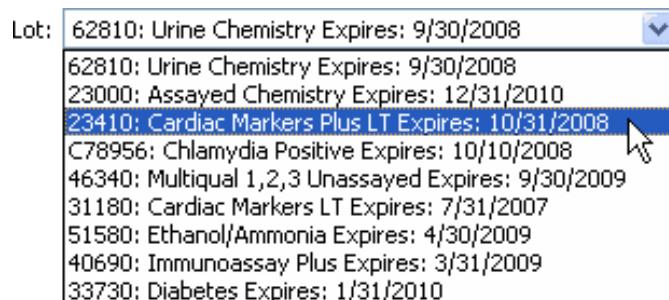
Current Lab, Panel, Lot, and Test

Select lab numbers, panels, lot numbers, and tests from lists in **UnityWeb**. The current lab, lot, and test selections determine the active lab, lot, and test. For example, selecting a test in a **Data Entry** dialog box and then clicking **Go to Chart** displays the Levey-Jennings Chart for the selected test.

Select the appropriate lab number from the **Lab** list to access a lot for the lab number.

Select the appropriate lot number from the **Lot** list to access a test for the lot number.

Example Lists

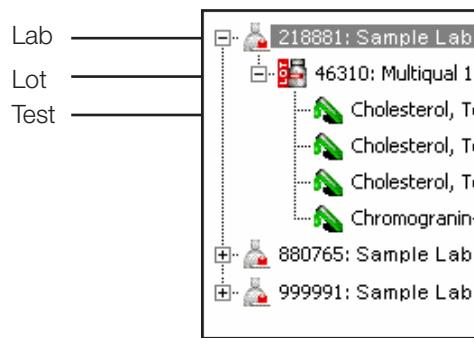


Understand the Navigation Tree

UnityWeb uses a navigation tree in some areas of the software. The navigation tree represents the hierarchy of labs, lots, and tests.

- Selecting a lab number determines the current lab.
- Selecting a lot number determines the current lab and lot.
- Selecting a test determines the current lab, lot, and test.

Example of the Navigation Tree



- Click + (plus sign) to the left of the lab number to view the lots.
- Click + (plus sign) to the left of the lot number to view the tests.

UnityWeb Tabs and Functions

UnityWeb organizes software functions by different tabs. Click each tab to access different functions of the software.

UnityWeb tabs	
Tab	Items
Configure	<ul style="list-style-type: none"> • Lab • Lot • Test • Panel <ul style="list-style-type: none"> – Add – Update/Sort Tests – Delete/Rename/Sort Panel Name • Rules/Settings <ul style="list-style-type: none"> – Rules – Fixed Mean and SD – Settings
Data Entry	<ul style="list-style-type: none"> • Single Test Point Data Entry • Single Test Summary Data Entry • Multi Test Point Data Entry • Multi Test Summary Data Entry • WebConnect <ul style="list-style-type: none"> – WebConnect Home – WebConnect History – WebConnect Transformer – WebConnect Rejection Log – WebConnect File Import Monitor
Review	<ul style="list-style-type: none"> • Bench Review

UnityWeb tabs	
Tab	Items
Charts	<ul style="list-style-type: none">• Levey-Jennings• Multi-LJ• Bar• Youden• Options<ul style="list-style-type: none">– General– Header– Levey-Jennings– Bar– Youden
Reports	<ul style="list-style-type: none">• Data Review• General<ul style="list-style-type: none">– Point Data Report– Summary Data Report– Statistical Report• Supervisor's Report<ul style="list-style-type: none">– Supervisor's Report– Operator Report• Audit Trail• Listings<ul style="list-style-type: none">– Labs– Lots– Tests– Panels– Test Code Report

UnityWeb tabs	
Tab	Items
Advisors	<ul style="list-style-type: none"> • Westgard Advisor <ul style="list-style-type: none"> – Existing QC Rules – Lab Data and Group Stats – Configure TEa – Design QC Rules – Preferences
Tools	<ul style="list-style-type: none"> • Security <ul style="list-style-type: none"> – Administrator – Update License – Change Password • Unity Interlab <ul style="list-style-type: none"> – Send Data to Bio-Rad • Utilities <ul style="list-style-type: none"> – Export – Condense – Reconcile – Delete Range of Data – Operator Setup – Configure Action Logs – Action/Comment by Instrument – View Rejection Log – Import Settings • Setup <ul style="list-style-type: none"> – Configure UnityWeb – Unity Interlab Reports

Functions and Where to Find Them

Functions and where to find them
Action Logs
Location: Tools Utilities Configure Action Logs
See: "Actions" on page 138
Actions/Comments by Instrument
Location: Tools Utilities Action/Comment by Instrument
See: "Actions and Comments by Instrument" on page 143
Add Users
Location: Tools Security Administrator
See: "Add a User" on page 62
Audit Trail
Location: Reports Audit Trail
See: "Audit Trail Report" on page 168
Automatic Action Logs
Location: Tools Setup Configure UnityWeb Automatic action logs
See: "Automatic Action Logs" on page 141
Automatic Transmission, Bench Review
Location: Tools Setup Configure UnityWeb Data review transmission (for Instant QC)
See: "Activate Transmission for InstantQC" on page 172
Automatic Transmission, Monthly
Location: Tools Setup Configure UnityWeb Automatic monthly transmission
See: "Activate Automatic Monthly Transmission" on page 172
Bench Review
Location: Review Bench Review
See: "Bench Review" on page 134
Change Password
Location: Tools Security Change Password
See: "Change a Password" on page 65

Functions and where to find them	
Charts, Bar	<p>Location: Charts Bar</p> <p>See: “Bar Chart” on page 155</p>
Charts, Levey-Jennings	<p>Location: Charts Levey-Jennings</p> <p>See: “Levey-Jennings Chart” on page 151</p>
Charts, Options	<p>Location: Charts Options</p> <p>See: “General Chart Options” on page 147</p>
Charts, Youden	<p>Location: Charts Youden</p> <p>See: “Youden Chart” on page 157</p>
Condense Data	<p>Location: Tools Utilities Condense</p> <p>See: “Condense Data” on page 58</p>
Configure, Lab	<p>Location: Configure Lab</p> <p>See: “Add and Update Lab Numbers” on page 70</p>
Configure, Lot	<p>Location: Configure Lot</p> <p>See: “Lots” on page 73</p>
Configure, Panel	<p>Location: Configure Panel</p> <p>See: “Create a Panel and Add Tests” on page 92</p>
Configure, Rules/Settings	<p>Location: Configure Rules/Settings</p> <p>See: “Select SPC Rules” on page 84 and “Select Test Settings” on page 85</p>
Configure, Test	<p>Location: Configure Test</p> <p>See: “Add Tests” on page 81</p>

Functions and where to find them
Data Entry, Multi Test, Point Location: Data Entry Multi Test Point Data Entry See: "Multi Test Data Entry" on page 121
Data Entry, Multi Test, Summary Location: Data Entry Multi Test Summary Data Entry See: "Multi Test Data Entry" on page 121
Data Entry, Single Test, Point Location: Data Entry Single Test Point Data Entry See: "Single Test Point Data Entry" on page 114
Data Entry, Single Test, Summary Location: Data Entry Single Test Summary Data Entry See: "Single Test Summary Data Entry" on page 118
Data Review Transmission Location: Tools Setup Configure UnityWeb Data review transmission (for InstantQC) See: "Activate Transmission for InstantQC" on page 172
Delete Range of Data Location: Tools Utilities Delete range of data See: "Delete a Range of Data" on page 130
Export Location: Tools Utilities Export See: "Export Data" on page 56
Operator Setup: Location: Tools Utilities Operator Setup See: "Operator Setup" on page 66
Passwords, Change Location: Tools Security Change Password See: "Change a Password" on page 65
Password Expirations Location: Tools Security Administrator See: "Password Expiration" on page 64

Functions and where to find them	
Reconcile Data	<p>Location: Tools Utilities Reconcile</p> <p>See: “Reconcile Data” on page 66</p>
Reports, Data Review	<p>Location: Reports Data Review</p> <p>See: “Data Review Report” on page 162</p>
Reports, Listings, Labs	<p>Location: Reports Listings Labs</p> <p>See: “Listings Reports” on page 169</p>
Reports, Listings, Lots	<p>Location: Reports Listings Lots</p> <p>See: “Listings Reports” on page 169</p>
Reports, Listings, Panels	<p>Location: Reports Listings Panels</p> <p>See: “Listings Reports” on page 169</p>
Reports, Listings, Tests	<p>Location: Reports Listings Tests</p> <p>See: “Listings Reports” on page 169</p>
Reports, Listings, Test Code Report	<p>Location: Reports Listings Test Code Report</p> <p>See: “Listings Reports” on page 169</p>
Reports, Operator Report	<p>Location: Reports Supervisor’s Report Operator Report</p> <p>See: “Operator Report” on page 167</p>
Reports, Point Data Report	<p>Location: Reports General Point Data Report</p> <p>See: “Point Data Report” on page 163</p>
Reports, Statistical Report	<p>Location: Reports General Statistical Report</p> <p>See: “Statistical Report” on page 165</p>

Functions and where to find them
Reports, Summary Data Report
Location: Reports General Summary Data Report
See: “Summary Data Report” on page 164
Reports, Supervisor’s Report
Location: Reports Supervisor’s Report Supervisor’s Report
See: “Supervisor’s Report” on page 166
Require Audit-Trail Comments
Location: Tools Setup Configure UnityWeb Require audit-trail comments
See: “Require Audit Trail Comments” on page 145
Send Data to Bio-Rad
Location: Tools Unity Interlab Send Data to Bio-Rad
See: “Submit Data Manually” on page 171
Transmission, Automatic Monthly
Location: Tools Setup Configure UnityWeb Automatic monthly transmission
See: “Activate Automatic Monthly Transmission” on page 172
Transmission, from Data Review
Location: Tools Setup Configure UnityWeb Data review transmission (for InstantQC)
See: “Activate Transmission for InstantQC” on page 172
Transmission, Manual
Location: Tools Unity Interlab Send Data to Bio-Rad
See: “Submit Data Manually” on page 171
Unity Interlab Report Frequency and Language
Location: Tools Setup Unity Interlab Reports
See: “Configure Unity Interlaboratory Report Frequency” on page 56
Update License
Location: Tools Security Update License
See: “Update the License” on page 51
Westgard Advisor online
Location: Advisors Westgard Advisor
See: “Westgard Advisor online” on page 222

Download Adobe Reader

UnityWeb requires installation of the free Adobe Reader 5.5 or later. Follow these steps to install Adobe Reader.

- 1 Open an Internet browser window and navigate to <http://www.adobe.com>.
- 2 Click **Downloads**.
- 3 Click **Get Adobe Reader**.
- 4 Follow the instructions on the screen to install Adobe Reader.

System Requirements

- Internet browser (Microsoft Internet Explorer 6.0 or higher, Mozilla Firefox 2.0 or later, or Internet Explorer: Mac 4.5 or later).
- Broadband internet access for best results.
- Adobe Reader 5.5 or higher. (For information about downloading Adobe Reader, see “Download Adobe Reader” on page 51.)

Update the License

There are two ways to update the license for UnityWeb:

- Via the Internet
- XML license file from Bio-Rad

Update the License via the Internet

- 1 Click the **Tools** tab.
- 2 Click **Security**.
- 3 Click **Update License**.



- 4 Click **Get License**.
- 5 Follow the instructions on the screen to update the license.

The Welcome page appears after the license is updated.

Update the License via an XML File

- 1 Click the **Tools** tab.
- 2 Click **Security**.
- 3 Click **Update License**.



- 4 Click **Browse**.
- 5 Navigate to the location of the XML file.
- 6 Click **Open**.
- 7 Click **Upload**.

The Welcome page appears after the license is updated.

Upgrade to UnityWeb

If your laboratory has been using a previous version of Bio-Rad QC software, contact your Bio-Rad QC Program Representative to upgrade to Unity Real Time online or UnityWeb 2.0.

Previous Software	Upgrade to Unity Real Time online	Upgrade to UnityWeb 2
UnityWeb 1	✓	✓
QC OnCall	✓	✓
Unity Real Time	✓	✓
Unity Desktop	✓	✓



Note: Upgrading from Unity-PC and Unity Plus/Pro is not recommended.

Configure UnityWeb

UnityWeb provides different configuration options allowing for customization of the software. For details about the different configuration options, see the following sections:

- Data entry configuration (page 54)
- Actions/comments (page 54)
- Notifications (page 55)
- Transmission (page 55)

Configure UnityWeb

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Click the **Configure UnityWeb** tab.
- 4 Select the configuration options.
- 5 Click **Save**.

Data Entry Configuration

- **Current data**

This option controls the **Summary Statistics** shown on the **Single Test Point Data Entry** dialog box and the **Single Test Summary Data Entry** dialog box.

- **Month**

The **Summary Statistics** show the laboratory current calendar month and cumulative statistics.

Month is the default selection.

- **Group**

The **Summary Statistics** show the current data group and laboratory cumulative statistics.



Note: Select and clear the **Group** check box on the **Single Test Point Data Entry** dialog box and the **Single Test Summary Data Entry** dialog box to switch between month and group **Summary Statistics**.

Actions and Comments

- **Automatic action logs**

Select this check box for the **Action** dialog box to automatically open every time a user enters a point violating an active SPC rule set to reject.

- **Require action logs**

Select this check box for the **Action** dialog box to automatically open every time a user enters a point violating an active SPC rule set to reject. Users cannot close, cancel, or exit the **Action** dialog box until an action is added.

- **Require audit-trail comments**

Select this check box for the **Audit-Trail Comment** dialog box to appear whenever the software applies an Audit Trail Event. Users cannot close, cancel, or exit the **Audit-Trail Comment** dialog box until a comment is added.

See “Audit Trail Events” on page 240 for a list of events that generate an audit trail.

View Database Information

Information about the database appears on the first screen after logging in.

Resource updates		
Lot:	10/13/2007	Biological Variation: 6/8/2007
Analyte:	10/13/2007	Mean/CV for Peer: 10/15/2007
Method:	10/13/2007	Mean/CV for Method: 10/16/2007
Instrument:	10/13/2007	Mean/CV for All Labs: 10/16/2007
Reagent:	10/13/2007	
Unit:	10/13/2007	Instrument Setup: 10/12/2007
Temperature:	10/13/2007	



Note: Access this information at any time by clicking on the UnityWeb icon in the upper left hand corner.

Notifications

Select the **Notifications** check box and a message appears each time you open **Data Entry** dialog box for a test in a lot expiring in 30 or fewer days. Within the **Data Entry** dialog box, select the **Do not display this message again** check box to stop the message from appearing.

Transmission

- **Data review transmission (for InstantQC)**

Select this check box and point data is sent to the Unity Interlaboratory Program from the Bench Review for inclusion in InstantQC.

- **Automatic monthly transmission**

Select this check box and monthly data is automatically sent to the Unity Interlaboratory Program on the selected day of the month.



Note: If using the **Automatic monthly transmission** feature, the UnityWeb software must be running in order to submit data.

Configure Unity Interlaboratory Report Frequency

Specify the report frequency (monthly, quarterly, or never) and language for the following Unity Interlaboratory Reports:

- Laboratory Performance Overview Report
- Laboratory Comparison Report
- Laboratory Histogram Report

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Click the **Unity Interlab Reports** tab.
- 4 Select the report frequency for the **Laboratory Performance Overview** from the list.
- 5 Select the report frequency for the **Laboratory Comparison Report** from the list.
- 6 Select the report frequency for the **Laboratory Histogram** from the list.
- 7 Select the report **Language** from the list.
- 8 Click **Save**.

Database Basics

UnityWeb provides the following database utilities:

- Export data (page 56)
- Condense data (page 58)
- Reconcile data (page 59)
- Delete a range of data (page 59)

Export Data

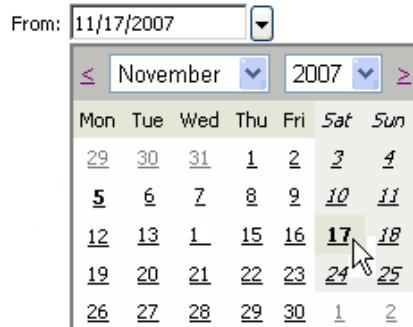
Data in UnityWeb can be exported to formats compatible with popular business software such as Microsoft Access, Microsoft Excel, and Microsoft Word.

Data can be exported to the following formats:

- Crystal Reports (RPT)
- Adobe Acrobat (PDF)
- Microsoft Excel 97–2000 (XLS)
- Microsoft Excel 97–2000 - Data Only (XLS)

- Microsoft Word (RTF)
- Microsoft Word - Editable (RTF)
- Rich Text Format (RTF)

- 1 Log in as a user with the **Export data** permission.
- 2 Click the **Tools** tab.
- 3 Click **Utilities**.
- 4 Click **Export**.
- 5 Select the lab number from the **Lab number** list for the data to export or select **All**.
- 6 Select the lot number from the **Lot number** list for the data to export or select **All**.
- 7 Select the test from the **Test** list for the data to export or select **All**.
- 8 Select the option for the type of file to export:
 - **Text file**
This option creates a file for use with word processing software. UnityWeb uses American Standard Code for Information Interchange (ASCII) characters for exporting text files.
 - **Delimited file**
This option creates a file for use with database or spreadsheet software.
 - **Import file**
This option creates a UnityWeb standard import file.
- 9 Click the arrow located to the right of the **From** date and select a beginning date for the data to export.



- 10 Click the arrow located to the right of the **To** date and select an ending date for the data to export.
- 11 Select the type of data you want to export:
 - **Point Data**
 - **Summarized Data**
- 12 Click **OK**.

The **Download** dialog box appears.

- 13 Click **Download**.

A **File Download** dialog box appears.

- 14 Click **Open** to view the file. Click **Save** to save the file.

Condense Data



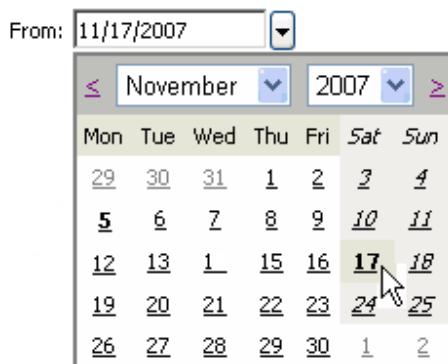
Important: You cannot reverse the condense data process. Bio-Rad recommends exporting the data prior to condensing. See “Export Data” on page 56 for more information.

Condensing data converts individual point data for each calendar month into a single summarized entry. Condensing data conserves disk space. Condensing data removes data points from the **Single Test Point Data Entry** dialog box and adds them to the **Single Test Summary Data Entry** dialog box.



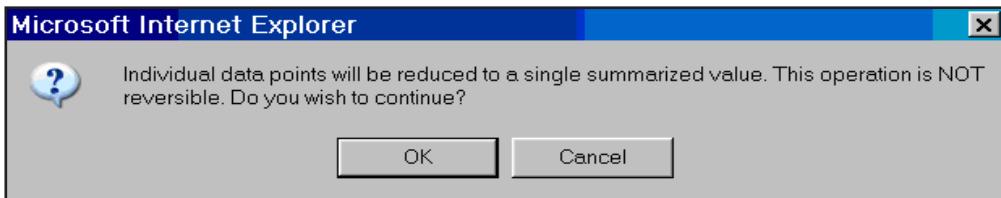
Note: Condensing data does not change the monthly summarized data values; therefore, it is not necessary to resubmit condensed data to Bio-Rad.

- 1 Log in as a user with the **Condense data** permission.
- 2 Click the **Tools** tab.
- 3 Click **Utilities**.
- 4 Click **Condense**.
- 5 Click the arrow located to the right of the **From** date and select a beginning date for the data.



- 6 Click the arrow located to the right of the **To** date and select an ending date for the data.
- 7 Select the **Lab** or **Panel** option for the data.
- 8 Select the lab number or panel name from the **Lab** or **Panel** list.
- 9 If using the **Lab** option, select the lot number from the **Lot number** list or select **All**.
- 10 Select the test from the **Test** list or select **All**.
- 11 Click **OK**.

A message appears asking for confirmation to condense data.



- 12 Click **OK**.

A message appears indicating the condensing of data is complete.



- 13 Click **OK**.

Reconcile Data



Important: The Reconcile Data feature is for special use only. Do not reconcile data unless given specific instructions from your Bio-Rad Software Support Representative.

The Reconcile Data feature creates a file including all of the laboratory data in the software. Use this feature to send quality control data to Bio-Rad in rare circumstances.

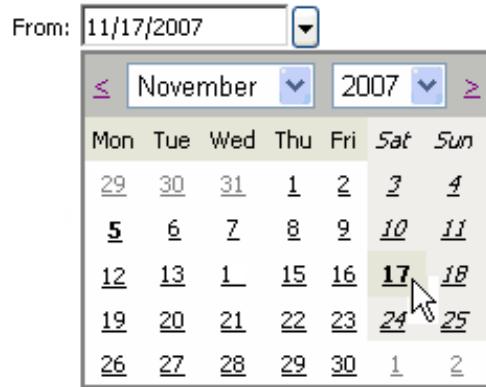
When reconciling data, the file replaces any existing data in the Unity Interlaboratory Program. Reconcile data for a lab number, lot number, or all labs in the database.

Delete a Range of Data



Important: Deleting a range of data permanently removes the data from the software. Bio-Rad recommends exporting the data before deleting. See "Export Data" on page 56 for more information.

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Delete range of data**.
- 4 Click the arrow located to the right of the **From** date and select a beginning date for the range of data.



- 5 Click the arrow located to the right of the **To** date and select an ending date for the data.
- 6 Select the lab number from the **Lab number** list or select **All**.
- 7 Select the lot number from the **Lot number** list or select **All**.
- 8 Select the test from the **Test** list or select **All**.
- 9 Click **OK**.

A message appears asking for confirmation of the data deletion.

- 10 Click **OK**.

A message appears indicating the data deletion is complete.



- 11 Click **OK**.

User Profiles and Security

In This Chapter

Define, Modify, and Delete Users.....	61
Passwords	63
User Permissions.....	65

Define, Modify, and Delete Users

UnityWeb uses user profiles with passwords and permissions to control individual user access to program features. Each user should have an assigned user name and password. Menu items and buttons for which a user does not have permission are either not displayed or appear dimmed.



Note: Only administrators and users with the **Manage users** permission can create, modify, and delete users.

In the **Administrator** dialog box, you can:

- Define, modify, and delete user profiles for individual users including their passwords and permissions.
- Select the **Administrator** check box to create users with all permissions.
- Define password expiration periods.



Note: A check mark in the **Administrator** check box automatically selects all user permissions. See “User Permissions” on page 65 for a description of user permissions.

The **User profile** section of the **Administrator** dialog box consists of the **User ID**, **User name**, **Password**, **Initials**, the **Password expires on** feature, and **Assign Lab Numbers**.

- The **User ID** can contain any combination of letters and numbers up to 80 characters.
- The **User name** can contain any combination of letters and numbers up to 80 characters.
- The **Password** can contain between 1 and 20 characters and can consist of any combination of letters and numbers. See “Password Requirements” on page 63 for more information.
- The **Initials** appear in the **OP** column of the data entry screen and identify the user (operator) who manually entered the data. User initials are also added to actions and comments.
- Set a specific expiration date for the user profile with the **Password expires on** feature.
- Define the lab number access for the user profile with the **Assign Lab Numbers** feature.

Add a User

- 1 Log in as a user with the **Manage users** permission.
 - 2 Click the **Tools** tab.
 - 3 Click **Security**.
 - 4 Click **Administrator**.
 - 5 Click **New**.
 - 6 Type the **User ID**, **User name**, **Password**, and **Initials** of the user in the **User profile** section.
 - 7 Select the **Set password expiration period to** check box and select an expiration period from the list to set a password expiration for the user. See “Password Expiration” on page 64 for more information.
 - 8 Select an option to apply the expiration period:
 - **Applied to this user only**
 - **Applied to all users**
 - 9 Select the individual permissions for the user.
 - To select a permission, select the check box next to the permission.
 - To remove a permission, clear the check box.
-  **Note:** Select the **Administrator** check box to give the new user access to all available software functions. See “User Permissions” on page 65 for more information about all permissions.
- 10 Click **OK**.
 - 11 Click **Assign Lab Numbers**.
 - 12 Select the user to assign the lab number(s) to from the **Operator** list.
 - 13 Select the lab numbers to assign to the user.
 - 14 Click **OK**.
 - 15 Click **New** and repeat steps 5-14 to add another user.

Modify a User



Note: The **User ID** field cannot be modified.

- 1 Log in as a user with the **Manage users** permission.
- 2 Click the **Tools** tab.
- 3 Click **Security**.
- 4 Click **Administrator**.
- 5 Select the user to modify from the **User ID** list.

- 6 Change the user's profile and permissions as needed.
 - To select a permission, select the check box next to the permission.
 - To remove a permission, clear the check box.



Note: Select the **Administrator** check box to give the user access to all available software functions. See “User Permissions” on page 65 for more information about all permissions.

- 7 Click **OK**.

Delete a User



Note: Deleting a user removes the associated **User ID** and **Password** from the **Login** and **Administrator** dialog boxes. The user's initials remain in the **OP** column of the **Data Entry** dialog box for any data the user previously entered and elsewhere in UnityWeb where they were recorded (actions, comments, audit trail, etc.)

- 1 Log in as a user with the **Manage users** permission.
- 2 Click the **Tools** tab.
- 3 Click **Security**.
- 4 Click **Administrator**.
- 5 Select the user to delete from the **User ID** list.
- 6 Click **Delete**.
A message appears asking for confirmation of the user deletion.
- 7 Click **OK**.

Passwords

Password Requirements

- Passwords can contain between 1 and 20 characters.
- Passwords can contain any combination of letters and numbers.
- By default, the password expiration period is set to **3 months**. Passwords can be set to expire in three, six, or nine months.

Group Login ID and Password

Bio-Rad provides an assigned Group Login ID and Password.

The Group Login ID is set up with **Administrator** permissions and allows new users initial access to the software. After creating additional users, delete this user or change the password.



Note: At least one user must have **Administrator** permissions. If only one user has **Administrator** permissions, you cannot delete this user or clear the **Administrator** check box until another user with **Administrator** permissions is set up.

Additional users can be given **Administrator** permissions as needed. However, giving all, or even most, users **Administrator** permissions eliminates the security precautions gained by using passwords.

Password Expiration

Users with the **Manage users** permission can set passwords to expire after a set period of time.



Tip: Use of this feature is entirely optional. However, using this feature is helpful for adding security or satisfying regulatory requirements.

Set the password expiration period when adding new users. Modify existing users by adding or changing the expiration period. When applying a password expiration period, apply it to the current user or to all users.



Tip: If every user has the same expiration period, it is easier to specify the expiration one time and apply it to all users. In addition, specifying **Never** as the expiration period and applying it to all users is a convenient way to cancel the use of the password expiration feature.

Set a Password Expiration

- 1 Log in as a user with the **Manage users** permission.
- 2 Click the **Tools** tab.
- 3 Click **Security**.
- 4 Click **Administrator**.
- 5 Select the applicable user from the **User ID** list.
- 6 Select the **Set password expiration period to** check box and select a time period from the list:
 - **Never**
 - **3 months**
 - **6 months**
 - **9 months**
- 7 Select an option to apply the password expiration:
 - **Applied to this user only**
 - **Applied to all users**

- 8 Click **OK**.

Change a Password



Note: All users, regardless of permissions, can change their own password.

- 1 Click the **Tools** tab.
- 2 Click **Security**.
- 3 Click **Change Password**.
- 4 Type the old password.
- 5 Type the new password.
- 6 Type the new password again to confirm.
- 7 Click **OK**.

User Permissions

Set up specific user permissions to restrict a user's access to specific software features and functions.



Important: At least one user must be set up with Administrator permissions. The Administrator permission provides access to all features and functions of the software.

User permissions are divided into the following groups:

- **Administration/Setup** permissions (page 66)
- **Data Review** permissions (page 66)
- **Database** permissions (page 66)
- **Rules and settings** permissions (page 67)
- **Labs, lots, tests, and panels** permissions (page 67)
- **Data handling** permissions (page 67)
- **Data** permissions (page 68)

Administration/Setup Permissions

Manage Users

Users with this permission can:

- Create new users and set password expiration periods.
- Modify existing user profiles.
- Modify an existing user's permissions.
- Delete users.
- Access the Operator Report.

Edit Action Log

Users with this permission can add, update, or delete pre-defined action logs.

Edit Setup Options

Users with this permission can make changes on the **Setup** dialog box. See “Configure UnityWeb” on page 53 for more information.

Operator Setup

Users with this permission can define the operator initials to appear on the data entry screen for imported data if the transformed file does not contain operator initials.

Data Review Permissions

Users with this permission can approve data from the Bench Review. When transmitting data from the Bench Review to the Unity Interlaboratory Program, the data appears on www.QCNet.com (in an InstantQC Report or Chart) after processing by the Unity Interlaboratory Program.

Database Permissions

Condense Data

Users with this permission can condense data. See “Condense Data” on page 58 for more information.



Important: The **Condense data** feature is for special use only. Bio-Rad recommends limiting user access to this feature.

Reconcile Data

Users with this permission can reconcile data. See “Reconcile Data” on page 59 for more information.



Important: The **Reconcile data** feature is for special use only. Bio-Rad recommends limiting user access to this feature.

Rules and Settings Permissions

Users with this permission can:

- Make changes to test settings (including changing the number of levels in use, decimal places, setting fixed means and SDs, and changing the number of points before rule evaluation).
- Specify settings by lot number.
- Make changes to the SPC rule profile for tests.
- Specify SPC rule profiles by lot number.
- Access the Westgard Advisor online (optional feature).



Note: Users without this permission can access Westgard Advisor online (optional feature) but cannot apply rules.

Labs, Lots, Tests, and Panels Permissions

Manage Labs/Lots/Tests

Users with this permission can:

- Add, update, close, delete, and duplicate Bio-Rad lab numbers.



Note: You cannot delete the primary lab number.

- Add, edit, delete, open, and close lot numbers.
- Add, delete, update, open, and close tests.
- Use the Instrument Setup feature.

Manage Panels

Users with this permission can add, update, sort, delete, and rename panels.

Data Handling Permissions

Communicate with Unity Interlab

Users with this permission can send data to the Unity Interlaboratory Program.

Export Data

Users with this permission can manually export data.

Data Permissions

Edit All Data

Users with this permission can enter new data and edit any line of data in the **Data Entry** dialog box.

Edit Last Line

Users with this permission can enter new data and edit the last line of data in the **Data Entry** dialog box.



Important: When a user edits any line but the last line of data, the data is not evaluated against any SPC rule(s).

Enter New Data Only

Users with this permission can enter new data but cannot edit or delete any data.

View Data Only

Users with this permission can view data on the **Data Entry** dialog box but cannot enter, edit, or delete data.

Set Up User Permissions

- 1 Log in as a user with the **Manage users** permission.
- 2 Click the **Tools** tab.
- 3 Click **Security**.
- 4 Click **Administrator**.
- 5 Select the check box or option for each applicable permission.
- 6 Click **OK**.

Labs and Lots

In This Chapter

Labs	69
Lots.....	73

Labs

UnityWeb uses a six-digit lab number provided by Bio-Rad to uniquely identify your laboratory and associated data. In order to use UnityWeb, you must have a primary lab number.



Important: Two instruments of the same type must be set up in separate lab numbers. A lab number can only be assigned by Bio-Rad. If you need additional lab numbers, contact your Bio-Rad QC Program Representative.

Types of Lab Numbers

UnityWeb uses three types of lab numbers:

- Primary lab numbers (page 69)
- Additional lab numbers (page 69)
- Affiliated lab numbers (page 70)

Primary Lab Number

The first lab number set up in UnityWeb is the primary lab number. The primary lab number can be closed but not deleted. (See “Close a Lab Number” on page 72 for more information.) The primary lab number appears highlighted in green in the **Open labs** dialog box. If you need to change your primary lab number, contact your Bio-Rad QC Program Representative.

Additional Lab Numbers

You can use additional lab numbers in UnityWeb. For example, you can use a different lab number for each instrument or different lab numbers to identify different departments or shifts.



Important: Two instruments of the same type must be set up in separate lab numbers. A lab number can only be assigned by Bio-Rad. If you need additional lab numbers, contact your Bio-Rad QC Program Representative.

Affiliated Lab Numbers

If you belong to a group of laboratories and want your Unity Interlaboratory Reports based on combined lab numbers, contact your Bio-Rad QC Program Representative.

Add and Update Lab Numbers

Add a Lab Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lab**.
- 4 Click **Clear** to clear the existing fields.
- 5 Type the six-digit lab number provided by Bio-Rad in the **Lab number** field.
- 6 Type the additional information for your laboratory.



Note: An asterisk (*) identifies required fields.

- 7 Click **Add**.

The lab number appears in the **Open labs** list.

Update Lab Number Information



Note: You can change and update any information except for the lab number itself. You cannot update a closed lab number; you must first open it. See “Open a Lab Number” on page 72 for more information.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lab**.
- 4 Select the lab number you want to update in the **Open labs** list.
- 5 Type the necessary changes.
- 6 Click **Update**.

Duplicate a Lab Number

Duplicating a lab number creates a copy of the lab information and all open lots and tests. The SPC rule settings are duplicated for all open tests. You can choose if you want to duplicate fixed means and/or fixed SDs.



Note: Duplicating a lab number does not duplicate QC data.

To set up several lab numbers with similar information, create the primary lab number and duplicate the lab number. Edit information for the duplicated lab number as needed.



Note: You cannot duplicate a closed lab number; you must first open it. See “Open a Lab Number” on page 72 for more information.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
 - 2 Click the **Configure** tab.
 - 3 Click **Lab**.
 - 4 Select the lab number to duplicate in the **Open labs** list.
 - 5 Click **Duplicate**.
 - 6 Type the new target lab number in the **Target lab number** field.
 - 7 Select the **Duplicate fixed mean** check box to duplicate the fixed mean for all open tests.
 - 8 Select the **Duplicate fixed SD** check box to duplicate the fixed SD for all open tests.
 - 9 Click **OK**.
- The new lab number appears in the **Open labs** list.
- 10 If needed, edit the duplicated lab information. See “Update Lab Number Information” on page 70 for more information.

Open and Close Lab Numbers

Lab numbers can be open or closed. Open lab numbers are available for data entry and submission. Results for their lot numbers appear on your Unity Interlaboratory Reports. Closed lab numbers are not available for data entry nor submission. However, the data for closed lab numbers remain in the UnityWeb database. Reopen a closed lab number at any time.

Close a Lab Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lab**.
- 4 Select the lab number you want to close in the **Open labs** list.
- 5 Click **Close**.

The lab number moves to the **Closed labs** list.

Open a Lab Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lab**.
- 4 Select the lab number you want to open in the **Closed labs** list.
- 5 Click **Open**.

The lab number moves to the **Open labs** list.

Delete Lab Numbers



Important: Deleting a lab number permanently deletes all data for all tests in the lab number. Information in the deleted lab number cannot be retrieved. Bio-Rad recommends closing the lab number to make it inactive rather than deleting the lab number. See “Close a Lab Number” on page 72 for more information. You can also export the lab data to another file before deleting it. See “Export Data” on page 56 for more information.



Note: Only open lab numbers can be deleted. See “Open a Lab Number” on page 72 for more information.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lab**.
- 4 Select the lab number you want to delete in the **Open labs** list.
- 5 Click **Delete**.

A message appears asking for confirmation of the lab number deletion.

- 6 Click **OK**.

Lots

UnityWeb uses Bio-Rad and non-Bio-Rad lots. However, Unity Interlaboratory Reports are available for Bio-Rad control products only.

Bio-Rad master lot numbers consist of five digits ending in zero. The lot number for Bio-Rad control products is located on the outside of the control product box, on the control product label, and in the package insert.

The final zero of the master lot number is changed to a number to identify each individual control level (for example, 1, 2, or 3 designating level 1, level 2, or level 3).

Example Bio-Rad Master Lot Number:	45550
Level 1:	45551
Level 2:	45552
Level 3:	45553

Add a Bio-Rad Lot

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the Bio-Rad control name from the **Control name** list.
- 6 Select the master lot number for the control from the **Lot number** list.



Tip: Only unexpired lot numbers in the same product group appear in the **Lot number** list.

- 7 Click **Add**.
The new lot number appears at the bottom of the **Open lots** list.
- 8 To add additional lots, repeat steps 5–7.

Add Non-Bio-Rad Lots

UnityWeb can be used for intralaboratory performance tracking of non-Bio-Rad control products. UnityWeb reports and charts are available, but Unity Interlaboratory Reports are not available for non-Bio-Rad control products.

Non-Bio-Rad lot numbers can contain up to 15 characters, which can be a mixture of numbers, letters, and symbols. However, you cannot assign a Bio-Rad lot number to a non-Bio-Rad control.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.

- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select **Other** from the **Control name** list in the **Lot information** section.
- 6 Click **Add**.
- 7 Define the control name in the **Control name** field.
- 8 Type the lot number in the **Master lot number** field.
- 9 Type the manufacturer name in the **Manufacturer** field.
- 10 Select the matrix from the **Matrix** list.
- 11 Click the up or down arrow located to the right of the **Levels** field and select the number of levels for the control.



Note: You can specify up to nine levels; however, the software limits the test evaluation to four levels on non-Bio-Rad controls.

- 12 Click the arrow located to the right of the **Expiration date** and select an expiration date from the calendar.



Note: The default expiration date is one year from the last day of the current month.

- 13 Click **OK**.

The lot number appears at the bottom of the **Open lots** list.

Duplicate Lots

Duplicating a lot is helpful when switching to a new control material lot number. Both Bio-Rad and non-Bio-Rad open lot numbers can be duplicated. When duplicating a lot, the new lot number is set up exactly the same as the old lot number; however, the new lot number does not contain any QC data.

Items Automatically Duplicated

When duplicating a lot, UnityWeb duplicates the:

- Open tests within the lot (closed tests are not duplicated).
- Test settings (levels in use, decimal places, and so on).
- Rule selections for SPC rules.

Optional Items When Duplicating

If using the following optional items, you can choose if you want to duplicate them:

- Fixed mean
- Fixed SD

Duplicate a Bio-Rad Lot Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot number you want to duplicate in the **Open lots** list.
- 6 Click **Duplicate**.
- 7 Select the new lot number from the **New lot number** list.



Tip: Only unexpired lot numbers in the same product group appear in the list.

- 8 Select the appropriate check box for each parameter to duplicate:
 - **Fixed means**
 - **Fixed SDs**
- 9 Click **OK**.

The new lot number appears at the bottom of the **Open lots** list.

- 10 Repeat steps 4–9 to duplicate the lot number in each lab number.

Duplicate a Non-Bio-Rad Lot Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot number you want to duplicate in the **Open lots** list.
- 6 Click **Duplicate**.
- 7 Type the new lot number in the **Master lot number** field.
- 8 Click the arrow located to the right of the **Expiration date** and select an expiration date from the calendar.
- 9 Select the appropriate check field for each parameter to duplicate:
 - **Fixed means**
 - **Fixed SDs**
- 10 Click **OK**.

The new lot number appears at the bottom of the **Open lots** list.

- 11 Repeat steps 4–10 to duplicate the lot number in each lab number.

Edit Lot Numbers

You can edit both Bio-Rad and non-Bio-Rad lot numbers, even if the lot contains data. Editing a lot copies all test information, including test data to a new lot number you select. Only edit a lot if you realize that a lot number was defined in error and the lot number needs to be corrected.

Edit a Bio-Rad Lot Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot number you want to edit in the **Open lots** list.
- 6 Click **Edit**.
- 7 Select the new lot number from the **New Lot Number** list.
- 8 Click **OK**.

The previous lot number is replaced with the new lot number. The new lot number appears at the bottom of the **Open lots** list.

Edit a Non-Bio-Rad Lot Number and Expiration Date

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot number you want to edit in the **Open lots** list.
- 6 Click **Edit**.
- 7 Type the new lot number in the **Master Lot Number** box.
- 8 Edit the expiration date if needed.
- 9 Click **OK**.

The previous lot number is replaced with the new lot number. The new lot number appears at the bottom of the **Open lots** list.

Close and Open Lots

Unexpired and expired lot numbers can appear in the **Open lots** list or **Closed lots** list and can be toggled between the two lists.

Open and unexpired lot numbers are available for data entry and submission. Results appear on your Unity Interlaboratory Reports.

Closed lots are not available for data entry nor submission. However, the data for closed lots remains in the UnityWeb database. Open a closed lot to view, print, or change data.

Close a Lot



Tip: If you are no longer running tests on a lot, you can close the lot. A closed lot is ignored by the software although the data remains in the database.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click **Configure**.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot you want to close in the **Open lots** list.
- 6 Click **Close Lot**.

The lot moves to the bottom of the **Closed lots** list.

Open a Closed Lot

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click **Configure**.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot you want to open in the **Closed lots** list.
- 6 Click **Open Lot**.

The lot moves to the bottom of the **Open lots** list.

Arrange and Sort Lots



Tip: For convenience, rearrange the order of lots in the **Open lots** list and **Closed lots** list.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click **Configure**.

- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot you want to arrange in the **Open lots** list or **Closed lots** list.
- 6 Click the up and down arrows to move the lot up or down in the list.
- 7 Repeat steps 5 and 6 to sort other lots.

Delete Lot Numbers



Important: Deleting a lot number permanently removes all data for all tests under the lot number. Information in the deleted lot number cannot be retrieved. Bio-Rad recommends closing the lot number to make it inactive rather than deleting the lot number. See “Close a Lot” on page 77 for more information. You can also export the lot data to another file before deleting it. See “Export Data” on page 56 for more information.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click **Configure**.
- 3 Click **Lot**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot you want to delete in the **Open lots** list or **Closed lots** list.
- 6 Click **Delete**.
A message appears asking for confirmation of the lot number deletion.
- 7 Click **OK**.

Lot Expiration Notifications

You can configure the software to notify you when opening the Data Entry dialog box for a test in a lot expiring in 30 days or less. This is a convenient way to make sure your lots and software stay current.

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Select the **Expired lot notification** check box in the **Notifications** section.
- 4 Click **Save**.

Tests

In This Chapter

Overview	79
Add Tests	81
Test Rules and Settings	84
Duplicate Tests	86
Update Tests	86
Close and Open Tests	87
Sort Tests	88
Delete Tests.....	89
VITROS Slide Generation Numbers	90

Overview

UnityWeb defines tests using six parameters. In combination with the lab number and lot numbers, these codes uniquely identify your data in the Unity Interlaboratory Program.

The six test parameters are:

- **Analyte**

The analyte is the constituent being measured (for example, albumin, calcium, glucose, and so on).

- **Instrument/Kit**

The instrument or kit used to test the analyte.



Note: When using RIA kits, code for the kit rather than the gamma counter.

- **Reagent type**

- **Dedicated reagent or kit**

Choose **Dedicated reagent or kit** when the reagent manufacturer is the same as the instrument or kit manufacturer. For VITROS instruments using slide generation numbers, choose **Dedicated reagent or kit** and type the slide generation number in the **VITROS slide generation number** field.

- **Alternate formulation/standardization**

Alternate formulation/standardization is the applicable reagent selection when using a dedicated

reagent and a manufacturer update or revision of the product results in a shift of the quality control data.

Your Bio-Rad QC Program Representative may request using this option to ensure your data is in the correct consensus group. For example, this selection is applicable when a manufacturer has introduced a new formulation reagent or standardization. This designation will be used until all of the existing formulation is consumed or removed from the market. Once this occurs, you will be directed by your Bio-Rad QC Program Representative to move your data to the Dedicated reagent or kit category.

- **Factored**

Factored is applicable when quality control data is mathematically altered to simulate results obtained on another instrument or at another temperature.

- **More reagents**

More reagents is applicable when using a reagent that is not supplied by the instrument or kit manufacturer. Select **More reagents** and then select a reagent from the list. Select **Other** if the reagent does not appear in the list.



Note: Unity Interlaboratory Reports are not available for reagents using a reagent code of **Other**. Bio-Rad recommends using **Other** only on a temporary basis until the appropriate reagent is added to the code list. Contact your Bio-Rad QC Program Representative to have codes added to the code list.

- **Method**

Only methods Bio-Rad considers “valid” for the selected analyte appear in the list. If the method does not appear, contact your Bio-Rad QC Program Representative.

- **Unit of measure**

Only units Bio-Rad considers “valid” for the selected analyte appear in the list. If your unit does not appear, contact your Bio-Rad QC Program Representative.

- **Temperature**

For enzymes, choose an available temperature. For all other analytes, the temperature defaults to “no temperature” and cannot be changed.

Add Tests

Add tests to UnityWeb both directly and indirectly. Direct methods include manually adding tests and using the Instrument Setup feature. Indirect methods include duplicating labs, duplicating lots, changing the VITROS slide generation number, and the import of test configuration information when using a Bio-Rad connectivity solution such as WebConnect 2.

Direct Methods of Adding Tests

When manually adding tests or using the Instrument Setup method, the new tests appear in the **Open tests** list of the **Test** dialog box.

When manually defining tests, select the test parameters from lists in the **Test** dialog box. When using Instrument Setup, UnityWeb supplies the codes based on information in the **Unity Method Guide for Selected Instruments**.

Indirect Methods of Adding Tests

The following functions create tests in the background:

- Duplicating labs or lots

When duplicating a lab, its associated open lots and their open tests are duplicated. When duplicating a lot, its associated open tests are duplicated. Closed lots and closed tests are not duplicated.

- Changing the VITROS slide generation number

Changing VITROS slide generation number creates a new test with the new slide generation number.

- Connectivity software

Tests are automatically configured in UnityWeb 2 when data transformed with Bio-Rad connectivity software is imported.

Add Tests Manually

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab number** list.
- 5 Select the lot for which to add a test from the **Lot** list.
- 6 Select the analyte from the **Analyte** list.
- 7 Select the instrument/kit from the **Instrument/Kit** list.
- 8 Select a **Reagent type**:
 - **Dedicated reagent or kit**

Select this option if the reagent manufacturer and the instrument/kit manufacturer are the same.

- **Alternate formulation/standardization**



Note: The **Alternate formulation/standardization** option is not commonly used. Do not select this option unless instructed to do so by your Bio-Rad QC Program Representative.

- **Factored**

Select this option when the QC data is mathematically altered to simulate results obtained on another instrument or at another temperature.

- **More reagents**

Select this option when using a reagent that is not supplied by the instrument manufacturer. Select **More reagents** and then select a reagent from the list. Select **Other** if the reagent does not appear in the list.



Note: Unity Interlaboratory Reports are not available for reagents using a reagent code of **Other**. Bio-Rad recommends using **Other** only on a temporary basis until the appropriate reagent is added to the code list. Contact your Bio-Rad QC Program Representative to have codes added to the code list.

- 9 Select the method for the test from the **Method** list.
- 10 Select the unit of measure from the **Unit of measure** list.
- 11 Select the temperature from the **Temperature** list.



Note: Temperature applies to enzymes only. For other analytes, **No temperature** is automatically selected and cannot be changed.

- 12 Click **Add**.

The new test appears at the bottom of the **Open tests** list.

Add Tests with Instrument Setup

Instrument Setup is a convenient way to add a group of tests performed on an instrument. Instrument Setup creates tests and all test parameters based on information in the Bio-Rad **Unity Method Guide for Selected Instruments**.



Note: Only instruments appearing in the **Unity Method Guide for Selected Instruments** are available using Instrument Setup. If the instrument does not appear, contact your Bio-Rad QC Program Representative and ask that it be added. The **Unity Method Guide for Selected Instruments** is available on www.QCNet.com. Log in to QCNet, point to **QC Documents**, and click **Method Guide**.

Limitations of Instrument Setup

- Instrument Setup configures all reagent types as **dedicated reagent or kit**. Edit the test and change the reagent type if using a different reagent.
- Instrument Setup assigns 37° C as the temperature for all enzymes. All non-enzyme tests are designated as **No temperature**.

Add Tests Using Instrument Setup



Note: Tests previously defined for the instrument in the lab/lot combination are omitted from the list.

- Log in as a user with the **Manage labs/lots/tests** permission.
- Click the **Configure** tab.
- Click **Test**.
- If you have more than one lab number, make sure the correct number appears in the **Lab** number list.
- Select the appropriate lot in the **Lots** list.
- Click **Inst. Setup**.
- Select the instrument in the **Instrument** list. Use the scroll arrows to move up and down the list as necessary.

A list appears with all available tests for the instrument and lot combination according to the **Unity Method Guide for Selected Instruments**.



Note: A message appears if no tests are available for the instrument and lot combination.

- By default, all tests have a check mark and are selected. It may be necessary to scroll to the bottom of the window to see all information.
- By default, **Conventional** unit is selected. Select the **SI** option for SI units.
 - Select and clear the check boxes so only the tests to add are selected.



Tip: The **Select None** button clears all the check boxes. The **Select All** button selects all the check boxes.

- For **VITROS instruments only**, enter the slide generation number in each of the **SG** fields.
- Click **OK**.

The new tests appear in the **Open tests** list.

Add Tests with a Code of “Other”



Note: Unity Interlaboratory Reports are not available for tests using a test code of **Other**. Bio-Rad recommends using **Other** only on a temporary basis until the appropriate analyte is added to the code list. Contact your Bio-Rad QC Program Representative to have codes added to the code list.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab** number list.
- 5 Select the appropriate lot from the **Lot** list.
- 6 Select a test parameter from each of the respective lists in the **Test information** section or select **Other** for any code that does not appear.
- 7 Click **Add**.
The **Other** dialog box appears.
- 8 Enter the test description in the corresponding fields.
- 9 Click **OK**.
The new test appears at the bottom of the **Open tests** list.

Test Rules and Settings

Select settings to customize how tests are displayed and evaluated.

Select SPC Rules



Note: See Chapter 9, “Apply QC Rules” and Chapter 18, “Westgard Advisor online” for extensive information on selecting SPC rules.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Rules/Settings**.
- 4 Click the **Rules** tab.

Select Test Settings

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Rules/Settings**.
- 4 Click the **Settings** tab.
- 5 By default, all available **Levels in use** for the control are selected. If you do not run a particular level, clear the appropriate **Levels in use** check box.



Note: Any level not in use is omitted from the **Data Entry** dialog box. This simplifies data entry.

- 6 The default decimal places for each level is 2. Type a number (0 to 4) for each level.



Note: Each level can have a different number of decimal places.

- 7 Type the number of data points that must be entered before rule evaluation begins in the **Points before rule evaluation** field. The default is 20.

Use a Fixed Mean and SD



Note: The fixed mean and SD are independent; specify a fixed mean, a fixed SD, or both.

Although the software allows the setting of a specific number of points to collect before rule evaluation begins, when using a fixed mean and fixed SD, rule evaluation begins immediately. The software continues to use the specified values until new values are specified or the value is cleared. When a fixed mean or fixed SD field is blank, UnityWeb uses the floating mean and floating SD.

Specify a Fixed Mean and SD

- 1 Click the **Configure** tab.
- 2 Click the **Rules/Settings** tab.
- 3 Click the **Fixed Mean and SD** tab.
- 4 Type a fixed mean and/or a fixed SD for each level of control material.
- 5 Select the **%** check box to calculate the SD as a percentage.
- 6 Select the **Use floating statistics** check box to use the current floating statistics to set the fixed mean and SD.
- 7 Select a time period for calculating the floating statistics.
 - **Last 30 days**
 - **Last 6 months**

- **Cumulative**
 - **Date range**
- 8 If selecting **Date range**, click the arrow located to the right of the **From** date and select a beginning date for the floating statistics.
- 9 Click the arrow located to the right of the **To** date and select an ending date for the floating statistics.
- 10 Select the **Mean and SD** check box for each level to apply to the fixed mean and fixed SD.
- 11 Click **Save**.

Duplicate Tests



Note: Individual tests cannot be duplicated. However, duplicating a lab or lot number duplicates the tests.

Update Tests

Change any test parameter for an existing test, even if the test contains QC data. This feature is useful if making a mistake when setting up a test or if your Bio-Rad QC Program Representative asks you to make a change.



Note: A qualitative test cannot be updated to a quantitative test or vice versa if data has been entered for the test.

See “Update the VITROS Slide Generation Number” on page 91 for information about updating tests using a VITROS slide generation number.

Update a Test

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test to update in the **Open tests** list.
- 7 Select the new parameters as needed (**Analyte**, **Instrument/Kit**, **Reagent type**, **Method**, **Unit of measure**, and **Temperature**).
- 8 Click **Update**.

Close and Open Tests

Closed tests and their data remain in the UnityWeb database, but they are not available for data entry and do not appear on the Unity Interlaboratory Reports. Re-open the tests at any time if needed.

Close a Test

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test to close in the **Open tests** list.
- 7 Click **Close**.

The test moves to the **Closed tests** list.

Open a Test

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test to open in the **Closed tests** list.
- 7 Click **Open**.

The test moves to the **Open tests** list.

Sort Tests

The order of the tests determines the order the tests appear for data entry and in intralaboratory reports and charts.



Tip: Rearrange the order of tests to match the printout used for data entry. This helps to speed up the data entry and review processes.

Sort Tests for a Lab Number

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test to sort in the **Open tests** or **Closed tests** list.
- 7 Click the up and down arrows to move the test up or down in the list.
- 8 Repeat steps 6 and 7 to sort other tests.

Sort Tests in a Panel

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Panel**.
- 4 Click **Update/Sort Tests**.
- 5 Select the panel to sort from the **Panel** list.
- 6 Select the test to sort in the **Selected tests** list.
 - To select consecutive tests, click the first test, press the SHIFT key on the keyboard and click the last test.
 - To select non-consecutive tests, press the CTRL key on the keyboard and click each test.
- 7 Click **Up** or **Down** to move the test up or down in the panel.
- 8 Repeat steps 6 and 7 to sort other tests.
- 9 Click **Save**.

Delete Tests

Open and closed tests can be deleted. Tests can be deleted at several levels:

- Lab

Deleting a lab also deletes its associated lots, tests, and data. See “Delete Lab Numbers” on page 72 for more information.

- Lot

Deleting a lot deletes its associated tests and data. See “Delete Lot Numbers” on page 78 for more information.

- Test



Important: Deleting a test permanently deletes all associated data from the UnityWeb database. Deleted data cannot be retrieved. Bio-Rad recommends closing the test to make it inactive while retaining the test data. A closed test remains in the database but is unavailable for data entry and is omitted from Unity Interlaboratory Reports. See “Close a Test” on page 87 for more information. You can also export the lab data to another file before deleting it. See “Export Data” on page 56 for more information.

Delete a Test

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test to delete in the **Open tests** or **Closed tests** list.



Important: There are two **Delete** buttons in the **Test** dialog box. One **Delete** button is located to the right of the **Open tests** list and the other **Delete** button is located to the right of the **Closed tests** list. The **Delete** button you click determines the test that is deleted. Be careful to click the correct button to avoid inadvertently deleting a test.

- 7 Click **Delete**.

A message appears asking for confirmation of the test deletion.

- 8 Click **OK**.

VITROS Slide Generation Numbers



Important: The Unity Interlaboratory Program uses the VITROS slide generation numbers to determine consensus groups. To ensure accurate reports, make sure the VITROS slide generation number is correct for each test.

Change the VITROS Slide Generation Number

When changing the VITROS slide generation number for a test, UnityWeb creates a new test with the new slide generation number. When changing the VITROS slide generation number, choose what to do with the old (existing test) and the range of tests for which to apply the new slide generation number.



Important: Do not use this procedure to update or correct a slide generation number. To update or correct a slide generation number, use the procedures described in “Update the VITROS Slide Generation Number” on page 91.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test with the slide generation number change in the **Open tests** list.
- 7 Click **Change Gen**.
- 8 Type the new slide generation in the **VITROS slide generation number** field.
- 9 Select an **Action** option for the old test:
 - **Retain**
Select this option to leave the existing test open and available for data entry. This is the default selection.
 - **Close**
Select this option to close the existing test and make it unavailable for data entry.
 - **Delete**
Select this option to delete the existing test.



Important: The **Delete** option permanently deletes all data for the test. The data cannot be retrieved. Bio-Rad recommends using the **Close** option to make it inactive. You can also export the data to another file before deleting it. See “Export Data” on page 56 for more information.

- 10 Select an **Apply to** option:
 - **Selected test**
Select this option to apply the new slide generation number only to the currently selected test. This is

the default selection.

- **Current lab**

Select this option to apply the new slide generation number to all identical tests in the current lab number.

- **All labs**

Select this option to apply the new slide generation number to all identical tests in the current database.

11 Click **OK**.

Update the VITROS Slide Generation Number

When updating the VITROS slide generation number, UnityWeb only updates the slide generation number for the selected test. New tests are not created and the existing test remains available for data entry, reports, and so on.

When correcting a slide generation number, update the test rather than change the slide generation number. If a slide generation number is not correct and you have already entered data for the test, updating the test corrects the problem in UnityWeb. Also, the test is updated in the Unity Interlaboratory Program the next time you transmit data.

Follow this procedure to correct a slide generation number.

- 1 Log in as a user with the **Manage labs/lots/tests** permission.
- 2 Click the **Configure** tab.
- 3 Click **Test**.
- 4 Select the lab from the **Lab** list.
- 5 Select the lot from the **Lot** list.
- 6 Select the test with the slide generation number to update in the **Open tests** list.
- 7 Enter the new slide generation number in the **VITROS slide generation number** field.
- 8 Click **Update**.

Panels and Data Groups

In This Chapter

Panels	92
Data Groups	94

Panels

A panel is a user-defined group of tests organized to simplify data entry and data review across lab and lot numbers. Panels provide a useful way to organize tests in a convenient manner such as grouping a number of different tests performed on a single instrument or the same test performed on multiple instruments.

Any number of panels can be created. Tests added to a panel can come from any lab number and lot number in the system. A single test may be added to any number of panels but can only appear once in any one panel.

When the **Data Entry** dialog box is opened for a Panel, the navigation buttons for data entry apply to the tests in the panel. (See “Navigate the Single Test Data Entry Dialog Boxes” on page 113 for more information.) The panel name appears with the current status information.



Note: Delete a panel at any time. Panels are a way of organizing tests for data entry and data review; therefore, neither tests nor data within a panel are deleted if the panel is deleted.

Create a Panel and Add Tests

- 1 Log in as a user with the **Manage panels** permission.
- 2 Click the **Configure** tab.
- 3 Click **Panel**.
- 4 Click **Add**.
- 5 Type the name for the panel in the **Panel** field.
- 6 Select the lot or test to add to the panel from the **Available tests** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 7 Click **Add** to add the selected test or to add all tests within the selected lot. The **Add All** button adds all

tests within the navigation tree regardless of what is selected.

The test(s) appear in the **Selected tests** list.

- 8 Click **Save**.

Sort Tests in a Panel

- 1 Log in as a user with the **Manage panels** permission.
- 2 Click the **Configure** tab.
- 3 Click **Panel**.
- 4 Click **Update/Sort Tests**.
- 5 Select the panel with tests to sort from the **Panel** list.
- 6 Select the test to sort in the **Selected tests** list.
 - To select consecutive tests, click the first test, press the SHIFT key on the keyboard and then click the last test.
 - To select non-consecutive tests, press the CTRL key on the keyboard and then click each test.
- 7 Click **Up** or **Down** to move the test up or down in the list.
- 8 Click **Save**.

Remove Tests from a Panel

- 1 Log in as a user with the **Manage panels** permission.
- 2 Click the **Configure** tab.
- 3 Click **Panel**.
- 4 Click **Update/Sort Tests**.
- 5 Select the panel with the test(s) to remove from the **Panel** list.
- 6 Select the test to remove from the **Selected tests** list.
- 7 Click **Remove** to remove an individual test or click **Remove All** to remove all tests in the **Selected tests** list.
- 8 Click **Save**.

Rename a Panel

- 1 Log in as a user with the **Manage panels** permission.
- 2 Click the **Configure** tab.
- 3 Click **Panel**.
- 4 Click **Delete/Rename/Sort Panel Name**.

- 5 Click the edit icon .
 - 6 Type the new name for the panel.
 - 7 Click the save icon .
- A message appears asking for confirmation of the update.
- 8 Click **OK**.

Sort Panel Names

- 1 Log in as a user with the **Manage panels** permission.
- 2 Click the **Configure** tab.
- 3 Click **Panel**.
- 4 Click **Delete/Rename/Sort Panel Name**.
- 5 Click the up or down arrow to move the panel up or down in the list.

Delete a Panel

- 1 Log in as a user with the **Manage panels** permission.
 - 2 Click the **Configure** tab.
 - 3 Click **Panel**.
 - 4 Click **Delete/Rename/Sort Panel Name**.
 - 5 Click the delete icon located to the right of the panel to delete .
- A message appears asking for confirmation of the panel deletion.
- 6 Click **OK**.

Data Groups

Categorizing tests by group name is a useful way to designate tests having something in common. For example, tests with the same lab and lot number can be grouped according to the reagent type. In this example, group all tests using a specific reagent (for example, Reagent 1) into Group 1 and all tests using another reagent (for example, Reagent 2) into Group 2. Tests can also be grouped by calibrators, the standardization matrix of a kit, and so on.

Overview of Groups

- The Month and Group options are available for point data entry and summary data entry.
- The **Current data** selection (Month or Group) in the **Data entry configuration** section of the **Setup** dialog box applies to all tests.
- On the **Single Test Point Data Entry** dialog box or the **Single Test Summary Data Entry** dialog box, select or clear the **Group** check box to switch between Month and Group. Selecting the **Group** check box changes the Summary Statistics. UnityWeb does not arrange data entry rows into groups.
- UnityWeb assigns all data points to group 0 (zero) until a data group is defined.
- If no Group is defined for a test, the Group and Cumulative summary statistics are the same.

Change the Current Data Option



Note: Toggle between Month and Group on the **Data Entry** dialog box. It is not necessary to change the **Current Data** option even if using groups.

- 1 Log in as a user with the **Edit setup options** permission.
- 2 Click the **Tools** tab.
- 3 Click **Setup**.
- 4 Click the **Configure UnityWeb** tab.
- 5 Within the **Data entry configuration** section, select the **Group** option located under **Current data**.
- 6 Click **Save**.

Define or Edit a Group

- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Data Entry** tab.
- 3 Click **Single Test Point Data Entry** or **Single Test Summary Data Entry**.
- 4 If you have more than one lab number, make sure the correct number appears in the **Lab** number list.
- 5 Select the appropriate lot in the **Lot** list.
- 6 Select the appropriate test in the **Test** list.
- 7 Select the **Group** check box.

The screen refreshes, and the **Group** column appears.

- 8 Add a group name in the **Group** column.
- 9 Click **Save**.



Note: UnityWeb assigns successive data entry rows to the same group until another group name is assigned in the **Group** column.



Tip: Type a comment to describe the group. See “Add a Comment to a Row of Data” on page 143 for more information.

Apply QC Rules

In This Chapter

Overview of Rule Evaluation.....	97
Set SPC Rules.....	99
Use a Fixed Mean and Fixed SD with SPC Rules.....	101
SPC Rules: Tabular Summary.....	103

Overview of Rule Evaluation

UnityWeb provides statistical process control (SPC) rules to monitor test performance. UnityWeb evaluates data points against the active SPC rules to determine whether to accept or reject the data. The software provides 17 different SPC rules, each of which can be set to reject, warn, or off.



Note: See “SPC Rules: Tabular Summary” on page 103 for an overview of the available SPC rules.

Laboratories perform statistical analysis using tools such as OPSpecs Charts, critical-error graphs, and power function curves as described in numerous publications. However, using the optional Westgard Advisor online automates statistical analysis and suggests rules based on a selected performance goal, historical data, and Unity Interlaboratory Program consensus group information.

Notes About Rule Evaluation

- UnityWeb rejects the entire row if any data within a run violates a SPC rule with a status of reject.
- UnityWeb excludes rejected data rows when evaluating rules between runs.

For example, a test is being evaluated using the 1-3s and 2-2s rules, both set to reject. If run four violates the 1-3s rule and run five violates the 1-2s rule, the second run is not rejected as violating the 2-2s rule.



Note: Excluding rejected data is based on the assumption the test system was evaluated in response to the rejection and the laboratory took corrective action. UnityWeb assumes subsequent data points reflect these actions.

Rule Status



Note: Only point data is evaluated against SPC rules. Data inserted or edited is not evaluated against SPC rules unless the data is on the last line of the **Data Entry** dialog box.

Set SPC rules to any of the following status:



Note: Rules set to reject or warn are the active rules for the test.

- **Reject**

UnityWeb rejects data violating the SPC rule and excludes it from the summary statistic calculations. The rule violated appears in the **Rules** column on the **Data Entry** dialog box and on intralaboratory charts and reports.

- **Warn**

UnityWeb accepts data violating the SPC rule. The rule violated appears in the **Rules** column on the **Data Entry** dialog box and on intralaboratory charts and reports.

- **Off**

UnityWeb ignores the rule when evaluating data points.

UnityWeb begins evaluating point data against SPC rules with a status of reject or warn after the test has the number of data points specified on the **Settings** tab of the **Rules/Settings** dialog box. See “Set SPC Rules” on page 99 for more information.



Note: Twenty data points is generally considered the minimum for statistical significance and therefore is the default number used in the software. Specify a fixed mean and SD to have rule evaluation begin immediately. See “Use a Fixed Mean and Fixed SD with SPC Rules” on page 101 for more information.

SPC Rules Precedence When Showing Rule Violations

For the purpose of rules precedence, SPC rules are divided into the groups shown in the columns in the table below. Rules are arranged in decreasing order of severity within each group. If a data point violates more than one rule in a group, UnityWeb shows only the most severe rule violation in the **Rules** column on the **Data Entry** dialog box and on intralaboratory reports and charts. UnityWeb evaluates the data against all active rules; however, rules are sometimes truncated in the **Rules** column on the **Data Entry** dialog box to simplify viewing.

Group	1	2	3	4	5	6	7
Least severe rule violation ↓	1-5s	2-2s	2 of 3-2s	12-x	7-T	R-4s	4-1s
	1-4s	1-2s	1-2s	10-x	—	—	3-1s
	1-3.5s	—	—	9-x	—	—	—
	1-3s	—	—	8-x	—	—	—
	1-2.5s	—	—	7-x	—	—	—
	1-2s	—	—	—	—	—	—

Set SPC Rules

UnityWeb applies a default set of SPC rules based on the number of levels available for the control product being used when a test is created. However, best practices recommend setting SPC rules for each test based on its quality requirements.

Set SPC rules at the test level and/or the lot level. However, Bio-Rad strongly recommends choosing SPC rules for each individual test. Using the optional Westgard Advisor online is the best method for configuring and applying SPC rules. See Chapter 18, “Westgard Advisor online” for more information.



Important: Best practices require laboratories to select rules on a test-by-test basis.

Set SPC Rules at the Test Level



Note: View tests by lab number or by panel. Set up a panel before selecting rules for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

- 1 Log in as a user with the **Edit test settings/rules** permission.
- 2 Click the **Configure** tab.
- 3 Click **Rules/Settings**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** or **Panel** list.
- 6 If using the **Lab** option, select the lot number from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click **Rules**.
- 9 Select an option (**Reject**, **Warn**, or **Off**) for each SPC rule.



Note: Click on the rules button to display information on rule application. If the application of the rule is within or across control materials, click on the radio button to view the applicable display.

The status of each rule is indicated in the **Status** column using the symbols shown below:

-  Reject
-  Warn
-  Off



Note: Click **Disable SPC Rules** to set all the rules to off. Click **Default Settings** to return the rules to their default settings.

10 Click **Save**.

Set SPC Rules at the Lot Level



Note: View tests by lab number or by panel. Set up a panel before selecting rules for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

- 1 Log in as a user with the **Edit test settings/rules** permission.
- 2 Click the **Configure** tab.
- 3 Click **Rules/Settings**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** or **Panel** list.
- 6 If using the **Lab** option, select the lot number from the **Lot** list.
- 7 Select a test from the **Test** list.
- 8 Click **Rules**.
- 9 Select an option (**Reject**, **Warn**, or **Off**) for each SPC rule.



Note: Click the rules button to display information on rule application. If the application of the rule is within or across control material, click the option button to view the applicable display.

The status of each rule is indicated in the **Status** column using the symbols shown below:

-  Reject
-  Warn
-  Off

10 Select the **Apply to** check box.

11 Select the appropriate option:

- Select the **This lot** option to apply the rules and/or settings to all tests in the lot, or
- Select the **All labs for this lot** option to apply the rules and/or settings to all tests run on this control material in the software.

12 Select the appropriate option to apply the changes:

- Select the **Apply Rules/Settings** option to apply the changes to both the Rules and Settings.
- Select the **Apply Rules only** option to apply the changes to the Rules only.
- Select the **Apply Settings only** option to apply the changes to the Settings only.



Note: Click **Disable SPC Rules** to set all the rules to off. Click **Default Settings** to return the rules to their default settings.

13 Click **Save**.

- The following message appears if you selected the **This lot** option in step 11:

Best practices in process control require laboratories to establish quality specifications and set appropriate process control rules (Westgard Rules) to meet those specifications for each test. In keeping with good laboratory practice, Bio-Rad recommends that, where appropriate, process control rules should be set on a test-by-test basis. Do you want to apply these SPC rules to all tests within the current lab and lot?

- The following message appears if you selected the **All labs for this lot** option in step 11:

Best practices in process control require laboratories to establish quality specifications and set appropriate process control rules (Westgard Rules) to meet those specifications for each test. In keeping with good laboratory practice, Bio-Rad recommends that, where appropriate, process control rules should be set on a test-by-test basis. Do you want to apply these SPC rules to each test in the lot for all active lab numbers?

14 Click **OK**.

Use a Fixed Mean and Fixed SD with SPC Rules

Most SPC rules evaluate data against a floating mean and standard deviation (SD). For example, the 1-3s rule evaluates if the data point is $\pm 3\text{SD}$ from the mean.

Specify a fixed mean, fixed SD, or both for each test. Fixed statistics are more sensitive than floating statistics. However, over time, cumulative statistics stabilize and can simulate a fixed statistic. Consequently, cumulative statistics provide a reasonable degree of sensitivity to shifts and trends.

Useful Facts about Fixed Mean and Fixed SD

- If using both a fixed mean and a fixed SD, UnityWeb begins SPC rule evaluation immediately, even if the test does not have the specified number of points before rule evaluation begins (default is twenty). If you do not specify both a fixed mean and a fixed SD, rule evaluation begins after the specified number of points are entered.
- When specifying a fixed mean and fixed SD, UnityWeb immediately begins using these values as the evaluation mean and SD for any new data points entered.
- UnityWeb continues using the fixed statistics until new values are specified or the values are cleared.
- When not specifying a fixed mean or fixed SD, UnityWeb uses the floating mean and/or floating SD.



Note: The fixed mean and fixed SD statistics are for your laboratory use only. Fixed statistics are not transmitted to the Unity Interlaboratory Program and do not appear on Unity Interlaboratory Reports.

- Duplicate the fixed means and/or fixed SDs when duplicating from the existing to the new lot number as described in “Duplicate Lots” on page 74.
- If you prefer, UnityWeb allows the use of a fixed percentage as the SD.

Set a Fixed Mean and/or Fixed SD

- 1 Log in as a user with the **Edit test settings/rules** permission.
- 2 Click the **Configure** tab.
- 3 Click **Rules/Settings**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or the panel name from the **Lab** or **Panel** list.
- 6 If using the **Lab** option, select the lot number from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click the **Fixed Mean and SD** tab.
- 9 Type a **Fixed mean** and/or **Fixed SD** for each level of control material.
- 10 If using a fixed percentage for the SD, select the **%** check box and type the desired percentage value in the **Fixed SD** field.



Note: The fixed mean and fixed SD are independent of each other. Fixed statistics do not have to be used for all levels. A fixed mean can be set without a fixed SD and vice versa.

- 11 Click **Save**.

Set Floating Statistics as a Fixed Mean and/or Fixed SD

- 1 Log in as a user with the **Edit test settings/rules** permission.
- 2 Click the **Configure** tab.
- 3 Click **Rules/Settings**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or the panel name from the **Lab** or **Panel** list.
- 6 If using the **Lab** option, select the lot number from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click the **Fixed Mean and SD** tab.
- 9 Select the **Use floating statistics** check box and select an option for the floating statistics:
 - **Last 30 days**
 - **Last 6 months**
 - **Cumulative**
 - **Date range**
- 10 If using **Date range**, enter a **From** date and a **To** date.
- 11 Select the **Apply to** check boxes indicating the levels where you want to apply the floating statistics.



Note: The **Fixed mean** and **Fixed SD** fields auto-populate based on the selections made.

- 12 Click **Save**.

SPC Rules: Tabular Summary

The following table summarizes the SPC rules available in UnityWeb. See “SPC Rules” on page 18 for more information.

Rule	Error type	When violated	Notes
1-2s	Random or systematic	A single control observation is outside the $\pm 2\text{SD}$ limit.	When used as a rejection rule, 1-2s yields a high proportion of false rejections.
1-2.5s	Random or systematic	A single control observation is outside the $\pm 2.5\text{SD}$ limit.	N/A

Rule	Error type	When violated	Notes
1-3s	Random or the beginning of large systematic	A single control observation is outside the $\pm 3SD$ limit.	While a value outside $\pm 3SD$ may be statistically significant, it may not be biologically or medically relevant due to the fact that modern laboratory instruments are often more precise than what is needed medically.
1-3.5s	Random and may also indicate systematic	One control value exceeds the mean $\pm 3.5SD$.	This rule is applied within the run only.
1-4s	Random and may also indicate systematic	One control value exceeds the mean $\pm 4SD$.	This rule is applied within the run only.
1-5s	Random and may also indicate systematic	One control value exceeds the mean $\pm 5SD$.	This rule is applied within the run only.
2-2s	Systematic	Two consecutive QC results are outside the $\pm 2SD$ limit on the same side of the mean.	N/A
2 of 3-2s	Systematic	Two of three levels of control within the same run exceed $\pm 2SD$ on the same side of the mean.	This rule is a variation of the 2-2s rule and is applicable when testing three or more levels of control material.
R-4s	Random	There is at least a $\pm 4SD$ difference between control values within a single run.	Bio-Rad software uses the exact within-run difference between control values to determine if R-4s is violated.
3-1s	Systematic	Three consecutive results exceed $\pm 1SD$ on the same side of the mean.	N/A
4-1s	Systematic	Four consecutive results exceed $\pm 1SD$ on the same side of the mean.	N/A
7-T	Systematic	Seven consecutive data points for a single level of control show either a “strict” increasing or decreasing pattern.	A “strict” increasing pattern is defined as a series of points that increase incrementally from the previous point (each point greater than the last) without a break in the pattern. A “strict” decreasing pattern is the same pattern in the opposite direction.

Rule	Error type	When violated	Notes
7-x, 8-x, 9-x	Systematic	X number of consecutive results on the same side of the mean.	Because of the extreme sensitivity of these rules, they should be used sparingly, if at all.
10-x	Systematic	Ten consecutive results on the same side of the mean.	This rule has a lower probability for false rejection than do the 7-x, 8-x, and 9-x rules.
12-x	Systematic	Twelve consecutive results on the same side of the mean.	This rule has a lower probability for false rejection than do the 7-x, 8-x, 9-x, and 10-x rules.

Enter Data

In This Chapter

Overview	106
Overview of the Single Test Data Entry Dialog Boxes	107
Data Entry Features	111
Single Test Point Data Entry	114
Qualitative Data Entry	119
Multi Test Data Entry.....	121

Overview

Manual data entry is a basic feature of UnityWeb. Alternatively, use one of Bio-Rad's connectivity solutions to automatically import data from an instrument, Laboratory Information System (LIS), or other data management system for which Bio-Rad has an interface.



Note: Contact your Bio-Rad Account Manager for more information on Connectivity Solutions.

UnityWeb provides data entry for the following:

- Single Test Point Data Entry (page 114)
- Single Test Summary Data Entry (page 118)
- Qualitative Data Entry (page 119)
- Multi Test Data Entry (page 121)



Note: This guide uses the term qualitative to refer to both qualitative and semi-quantitative results.

Overview of the Single Test Data Entry Dialog Boxes

UnityWeb Single Test data entry dialog boxes share a common look and consist of the following areas:

- Lab, panel, lot, and test information (page 107)
- Command buttons and options (page 108)
- Data entry grid (page 109)
- Paging arrows (page 110)
- Summary statistics (page 110)
- Group statistics (page 111)
- Fixed Mean and SD (page 111)

Lab, Panel, Lot, and Test Information

The screenshot shows the UnityWeb Single Test Point Data Entry dialog box. At the top, there are tabs for "Single Test Point Data Entry", "Single Test Summary Data Entry", "Multi Test Data Entry", and "WebConnect™". Below the tabs are several icons and a toolbar with buttons for "Lab" (radio button selected), "Panel", and other functions like "Print", "Save", and "Edit".

1 Lab: 999988: RXL2, VITROS 350, Access2 [dropdown] Lot: 40690: Immunoassay Plus Expires: 3/31/2009 [dropdown]

2 Test: Fructosamine|EIA|Roche Cobas Integra|Dedicated Reagent|μmol/L;999988: RXL2, VITROS 350, Access2;40690[149] [dropdown]

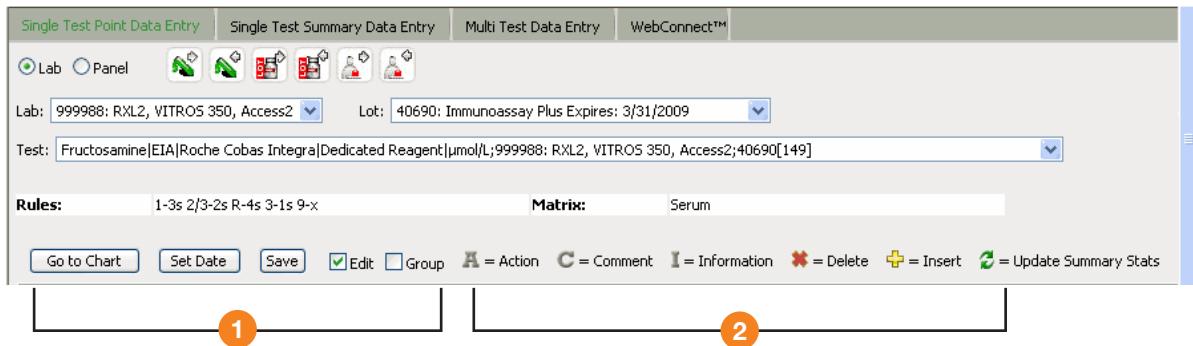
3 Rules: 1-3s 2/3-2s R-4s 3-1s 9-x **4** Matrix: Serum

5 Buttons at the bottom: Go to Chart, Set Date, Save, Edit, Group, Action (A), Comment (C), Information (I), Delete (X), Insert (+), Update Summary Stats (U).

The top section of the dialog box shows the following information:

- 1** Lab number and laboratory description or panel
- 2** Lot number, control product description, and control product expiration date
- 3** Test information including analyte name, method, instrument, VITROS slide generation number (if applicable), reagent, unit, and temperature
- 4** Current rules, if applicable
- 5** Matrix

Command Buttons and Options



1 Command buttons and options

- **Go to Chart**

Click **Go to Chart** to view a Levey-Jennings Chart for the test (**Single Test Point Data Entry** dialog box only). See “View a Levey-Jennings Chart” on page 112 for more information.

- **Set Date**

Click **Set Date** to use the Set Date feature. See “Use the Set Date Feature” on page 111 for more information.

- **Save**

Click **Save** to save data.

- **Edit** check box

Select the **Edit** check box to enter or edit data (**Single Test Point Data Entry** dialog box only).

- **Group** check box

Select the **Group** check box to view the Summary Statistics based on the Group and cumulative statistics. See “Data Groups” on page 94 for more information about data groups.

Clear the **Group** check box to view the Summary Statistics based on monthly and cumulative statistics. See “Summary Statistics” on page 110 for more information.

2 Edit Data Key

Each data entry row provides the ability to edit data as follows:

- Click  to add an action to the row of data or to view any existing actions. A green arrow appears in the column when an action has been added . Actions are only available for point data.
- Click  to add a comment to the row of data or to view any existing comments. A green arrow appears in the column when a comment has been added .
- Click  or the **Information** link to view extended information about the test:

Floating mean/SD

(the evaluation mean and/or SD used to evaluate the row of data if floating statistics are used)

Fixed mean/SD

(the evaluation mean and/or SD used to evaluate the row of data if fixed statistics are used)

Rules

(the SPC rules used to evaluate the row of data)

Bench Review

(the person who reviewed the row of data, if applicable, in Bench Review)

- Click  or the **Delete** link to delete a row of data.
- Click  or the **Insert** link to insert a row of data.
- Click  or the **Update** link to update the Summary Statistics.

Data Entry Grid

Manual data is entered and imported data appears in the data entry grid rows and columns.

Each type of data (point and summary) has its own data entry grid. See the following sections for more information:

- Point data entry grid (page 114)
- Summary data entry grid (page 118)

Paging Arrows

UnityWeb groups rows of data into pages based on the number of rows that can be displayed at a time. Click the paging arrows to move through pages of data or select a page number from the list.

Go to first row



Go to previous page



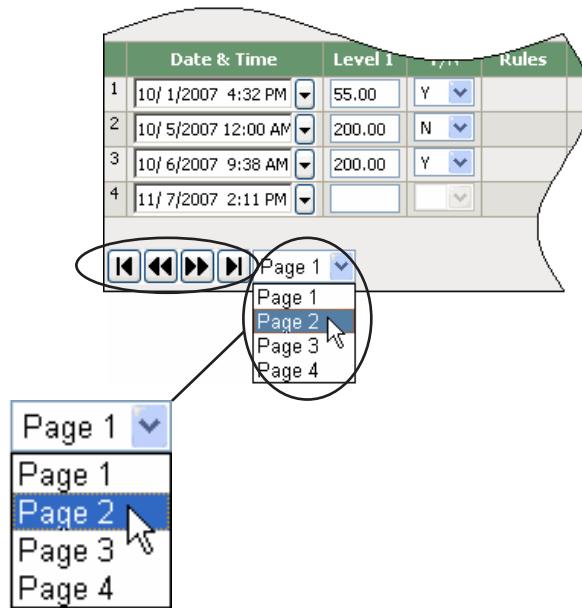
Go to next page



Go to last row



Select a page from the list



Summary Statistics

The Summary Statistics shows the monthly and cumulative mean, monthly and cumulative standard deviation (SD), monthly and cumulative coefficient of variation (CV), and monthly and cumulative number of points.



Tip: Set the default statistics to **Summary** or **Group**. See “Data Entry Configuration” on page 54 for more information.

Example of Summary Statistics

Summary Statistics as of 11/16/2007 10:05:00 AM						
	Month	Cumulative	Month	Cumulative	Month	Cumulative
Mean	179.00	177.52	0.00	0.00	192.20	192.00
SD	2.92	3.91	0.00	0.00	2.95	3.91
CV	1.63	2.20	0.00	0.00	1.53	2.04
Points	5	23	0	0	5	26

Group Statistics

If data groups are set up, select the **Group** check box to view group and cumulative statistics. (See “Data Groups” on page 145 for more information.) The Group Statistics shows the group and cumulative mean, group and cumulative SD, group and cumulative CV, and group and cumulative number of points.



Tip: Set the default statistics to **Summary** or **Group**. See “Data Entry Configuration” on page 54 for more information.

Example of Group Statistics

	Group	Cumulative	Group	Cumulative	Group	Cumulative
Mean	179.00	177.52	0.00	0.00	192.20	192.00
SD	2.92	3.91	0.00	0.00	2.95	3.91
CV	1.63	2.20	0.00	0.00	1.53	2.04
Points	5	23	0	0	5	26

Fixed Mean and SD

The fixed mean and fixed SD (if specified) appear below the Summary Statistics (**Single Test Point Data Entry** dialog box only). These statistics do not change as you select different rows of data. See “Fixed Statistics” on page 115 for more information.



Note: The fixed mean and fixed SD apply to point data only.

Data Entry Features



Note: Enter data by lab number or by panel. Set up a panel before entering data for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

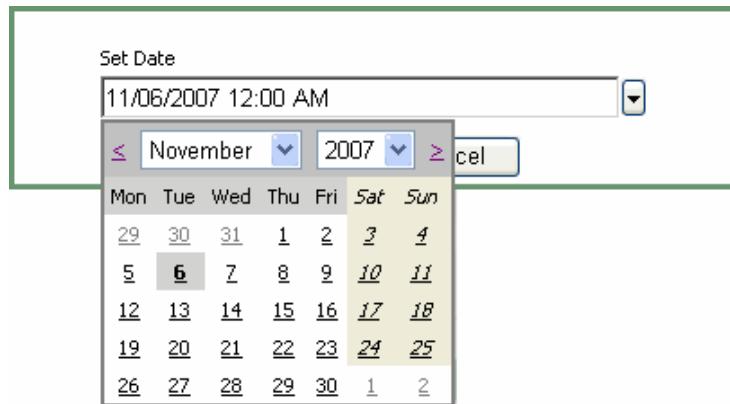
Use the Set Date Feature

The Set Date feature is useful when manually entering several days of data. After the date is set, UnityWeb increments the date by one day each time a new row of data is added. UnityWeb continues to increment the date by one day until you exit the software.

- 1 Click the **Data Entry** tab.
- 2 Click **Set Date**.
 - Click any part of the date and type over to edit the date for the first date of data entry, or



- Click the arrow located to the right of the date and select a date from the calendar for the first date of data entry.



- Within the calendar click to go to the previous month.
- Within the calendar click to go to the next month.

3 Enter data.

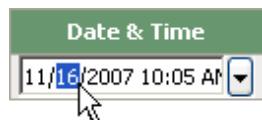
The date increments by one day each time you add a new row.

4 Click **Save**.

Change the Date and Time for a Row of Data

Changing the date or time for a data entry row only applies to the current row. For example, after editing the date and time of the last data entry row, the next row added contains the current date-time.

- Click any part of the date and type over to edit the date:



View a Levey-Jennings Chart

When working in the **Single Test Point Data Entry** dialog box, click **Go to Chart** to view a Levey-Jennings Chart for the test. Display one chart at a time.

View Rules and Settings

When working in the **Single Test Point Data Entry** dialog box:

- The current active SPC rules appear on the **Rules** line.
- The fixed mean and fixed SD (if specified) appear below the Summary Statistics.
- Click the **Information** link to view historical information for a row of data, including the SPC rules active when the data point was entered.

Navigate the Single Test Data Entry Dialog Boxes

In the **Single Test Point Data Entry** and **Single Test Summary Data Entry** dialog boxes, navigate by clicking the buttons described below:



To...	Click...
Go to the next test	
Go to the previous test	
Go to the next lot (available only if the Lab option is selected)	
Go to the previous lot (available only if the Lab option is selected)	
Go to the next lab (available only if the Lab option is selected)	
Go to the previous lab (available only if the Lab option is selected)	
Go to the next panel (available only if the Panel option is selected)	
Go to the previous panel (available only if the Panel option is selected)	

Clicking any of the navigation buttons will:

- Close the current **Data Entry** dialog box.

- Open the **Data Entry** dialog box for the next or previous item.

Single Test Point Data Entry

Use the **Single Test Point Data Entry** dialog box to enter individual data points. If using SPC rules, the data is evaluated against the SPC rules.

Single Test Point Data Entry Grid

The point data entry grid consists of rows and columns where manually entered data and imported data appears.

1	2	3	4	5	6	7	8								
	Date & Time	Level 1	Y/N	Rules	z	Level 2	Y/N	Rules	z	Level 3	Y/N	Rules	z	OP	Group
1	11/1/2007 12:00 AM	10.00	Y		0.00	17.00	Y		0.00	3.00	Y		0.00	JL	1 A
2	11/2/2007 12:00 AM	12.00	N	R-45	2.00	13.00	N	2-25 2	-2.67	2.00	N	2-25 2	-2.00	JL	1 A*
3	11/3/2007 12:00 AM	10.00	Y		0.00	15.50	Y		-1.00	3.00	Y		0.00	JL	2 F
4	11/4/2007 12:00 AM	9.50	Y		-0.50	16.00	Y		-0.67	2.90	Y		-0.20	JL	0
5	11/5/2007 12:00 AM	10.00	Y		0.00	13.70	Y	1-25[W]	-2.20	2.80	Y		-0.40	JL	0
6	11/15/2007 7:31 AM													JL	0

1 Row number

UnityWeb numbers rows consecutively. If inserting or deleting a row of data, the software renames the rows to maintain a consecutive order. (UnityWeb does not number runs within a day.)

2 Date & Time

Date and time the data was manually entered. The testing date and time appears for imported data.

3 Level (1, 2, 3)

The fields where the QC values are typed when manually entering data. Values for imported data also appear in these fields.

4 Y/N

If using SPC rules, this column indicates if the data point was accepted (Y) or rejected (N) according to the active rule(s). UnityWeb automatically rejects a row of data if a data point within the row violates a SPC rule with a status of reject. Users with the **Edit data** permission can manually change the accept/reject status of a data point. See “Data Permissions” on page 68 for more information.

5 Rules

Shows any active SPC rules the data point violated. If using multiple rules, UnityWeb only shows the most serious rule violation. See “SPC Rules Precedence When Showing Rule Violations” on page 98 for more information.

6

z

The z-score indicates the number of standard deviations between a result and the expected mean. The z-score calculation begins after the specified number of points, before rule evaluation begins, are entered. See “Select Test Settings” on page 85 for more information.

7

OP

For manual data entry, this column shows the initials of the user logged into the software at the time data was entered. For imported data, this column shows the initials defined in the import file, if any. If initials are not defined in the import file, this column shows the initials defined in the Operator Setup. If initials are not defined in the Operator Setup, this column shows two asterisks (**). See “Operator Setup” on page 131 for more information about Operator Setup.

8

Group

Group designation, if specified.

Fixed Statistics

The fixed mean and/or fixed SD appear below the Summary Statistics. If fixed statistics are not specified, the evaluation mean and SD fields are blank. Click the **Information** link to view the evaluation mean and SD after the specified number of points have been entered. Each level within a control material can have different combinations of fixed and floating statistics.

A fixed mean and fixed SD can be specified independently. There are four combinations as follows:

- Floating Mean/Floating SD (page 116)
- Floating Mean/Fixed SD (page 116)
- Fixed Mean/Fixed SD (page 116)
- Fixed Mean/Floating SD (page 117)

Important Facts

- The evaluation mean and SD appear for each control level.
- If either statistic is floating, rule evaluation begins after the specified number of points have been entered.
- SPC rule evaluation begins with the first data point if both statistics are fixed.

Floating Mean/Floating SD

The following figure illustrates information for a data point without a fixed mean or fixed SD specified.

	Level 1	Level 2
Fixed Mean/SD	--/-	--/-
Floating mean	<input type="text"/>	<input type="text"/> Floating SD

- Rule evaluation begins after entering the specified number of points.
- The fixed mean/SD areas are blank because fixed statistics have not been specified.

Floating Mean/Fixed SD

The following figure illustrates information for a Level 1 data point with a floating mean and fixed SD. Rule evaluation begins after the specified number of points are entered.

	Level 1	Level 2
Fixed Mean/SD	--/0.47	--/-
Floating mean	<input type="text"/>	<input type="text"/> Fixed SD

Fixed Mean/Fixed SD

The following figure illustrates information for a Level 1 and Level 2 data point with a fixed mean and fixed SD. Rule evaluation begins with the first data point entered after defining the fixed mean and SD.

	Level 1	Level 2
Fixed Mean/SD	4.60/0.69	3.10/0.47
Fixed mean	<input type="text"/>	<input type="text"/> Fixed SD

Fixed Mean/Floating SD

The following figure illustrates information for a Level 1 data point with a fixed mean and a floating SD. Rule evaluation begins after the specified number of points are entered.

	Level 1	Level 2
Fixed Mean/SD	0.47/-	--/-

Fixed mean _____ Floating SD



Enter Single Test Point Data

- 1 Click the **Data Entry** tab.
- 2 Click **Single Test Point Data Entry**.
- 3 Select the lab number or panel name from the **Lab** or **Panel** list.
- 4 If using the **Lab** option, select the lot number from the **Lot** list.
- 5 Select the test from the **Test** list.
- 6 Click **Set Date**.
 - Click any part of the date and type over to edit the date for the first date of data entry, or
 - Click the arrow located to the right of the date and select a date from the calendar for the first date of data entry.
- 7 Click in the first **Level** field and type the value for the level.
- 8 Press the TAB or ENTER key on the keyboard to go to the next **Level** field.
- 9 Repeat steps 7 and 8 as needed to enter data for all levels.

When pressing the TAB or ENTER key on the keyboard in the last level of the row, UnityWeb:

- Goes to the first field on the next row.
 - Evaluates the data points against active SPC rules and indicates the rule status (accept, warn, reject).
 - Updates the Summary Statistics.
- 10 Continue entering data for the test.
 - 11 Click **Save** after all data has been entered for the test.
 - 12 Click the appropriate navigation button to continue entering data for other labs, lots, and tests. Make sure to click **Save** before navigating to ensure the data is saved.



Note: See “Navigate the Single Test Data Entry Dialog Boxes” on page 113 for information about navigation buttons.

- 13 Repeat steps 7–9 to continue entering data for the test.

Single Test Summary Data Entry

Entering single test summary data includes entering the mean, SD, and number of points for each level for a calendar month. You can choose to enter summary data if using quality control evaluation on an instrument or LIS for daily quality control. Entering summary data allows participation in the Unity Interlaboratory Program.



Note: You can enter point and summary data for the same test. If doing so, the Summary Statistics include both types of data.

- Data entered as summary data is not evaluated by SPC rules.
- Only the Bar Chart is available for summary data.



Note: If viewing a Levey-Jennings, Multi-LJ, or Youden Chart for a test with only summary data, the chart displays but does not contain data points.

- The Set Date feature can be used for summary data. However, the date does not increment by month, but instead increments by one day. See “Use the Set Date Feature” on page 111 for more information.
- Comments are available for summary data.
- Actions are not available for summary data.

Summary Data Entry Grid

The summary data entry grid consists of rows and columns where manually entered data and imported data appears.

1	Date & Time	Mean 1	SD	Points	Mean 2	SD	Points	OK
2	1 11/16/2007 6:25 AM ▾							3

1 Row number

UnityWeb numbers rows consecutively. If inserting or deleting a row of data, the software renames the rows to maintain a consecutive order.

2 Date & Time

Date and time the data was manually entered. The date assigned for imported data is either the first or last day of the month depending on how the Bio-Rad connectivity software is configured.

3 Mean, SD, Points per level

The fields where the values for the mean, SD, and number of points are typed when manually entering data. Values for imported data also appear in these fields.

Enter Single Test Summary Data

- 1 Click the **Data Entry** tab.
- 2 Click **Single Test Summary Data Entry**.
- 3 Select the lab number or panel name from the **Lab** or **Panel** list.
- 4 If using the **Lab** option, select the lot number from the **Lot** list.
- 5 Select the test from the **Test** list.
- 6 Click **Set Date**.
 - Click any part of the date and type over to edit the date for the first date of data entry, or
 - Click the arrow located to the right of the date and select a date from the calendar for the first date of data entry.
- 7 Click in the first **Mean** field and type the value for the mean.
- 8 Press the TAB or ENTER key on the keyboard to go to the **SD** field.
- 9 Type the value for the **SD**.
- 10 Press the TAB or ENTER key on the keyboard to go to the **Points** field.
- 11 Type the number of points.
- 12 Repeat steps 8–12 as needed to enter data for all levels.
- 13 Click **Save**.
- 14 Click the appropriate navigation button to continue entering data. Make sure to click **Save** before navigating to ensure the data is saved.



Note: See “Navigate the Single Test Data Entry Dialog Boxes” on page 113 for information about navigation buttons.

Qualitative Data Entry



Note: Enter qualitative data manually or import it in the same way as quantitative data.

UnityWeb provides the capability to enter qualitative and semi-quantitative data. Submit data for Bio-Rad urinalysis controls to Bio-Rad for comparison in the Unity Interlaboratory Program.



Note: The Urinalysis Report is optional. Contact your Bio-Rad QC Program Representative to request this report.

Qualitative data entry is available for the following Bio-Rad controls:

- Autoimmune

- Qualitative Urine Toxicology
- Urinalysis

The software contains all valid results for qualitative and semi-quantitative tests. When entering qualitative data, select the appropriate result from the list for each level of control. Add actions and comments to any row of qualitative data.

Enter Qualitative Data



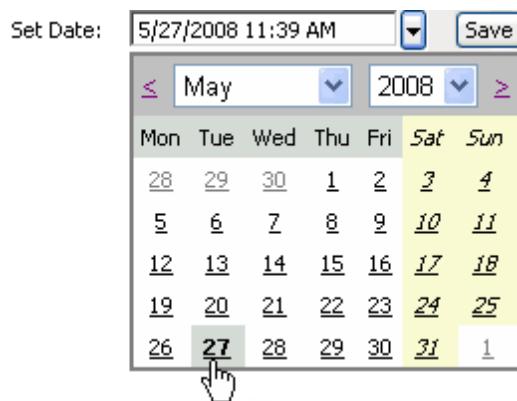
Note: Qualitative data is not evaluated against SPC rules.

- 1 Click the **Data Entry** tab.
- 2 Click **Single Test Point Data Entry**.



Note: Qualitative data can only be entered on the **Single Test Point Data Entry** dialog box.

- 3 Select the lab number or panel name from the **Lab** or **Panel** list.
- 4 If using the **Lab** option, select the lot number from the **Lot** list.
- 5 Select the test from the **Test** list.
- 6 Click the down arrow located to the right of **Set Date** and select a starting date for data entry.



- 7 Select the result for the qualitative data from the appropriate **Level** list.

Entered Date	Level 1	Level 2	Level 3
11/20/2007 1:53:41 PM	<input type="button" value="▼"/> 5.0 5.5 6.0 6.5 7.0 7.5 ≥8.0	<input type="button" value="▼"/>	<input type="button" value="▼"/>

- 8 Repeat step 7 until all results are entered.

9 Click **Save**.

10 Click the appropriate navigation button to continue entering data.



Tip: See “Navigate the Single Test Data Entry Dialog Boxes” on page 113 for information about navigation buttons.

Send Qualitative Data to the Unity Interlaboratory Program

Qualitative and semi-quantitative data, including urinalysis data, is transmitted to the Unity Interlaboratory Program the same as quantitative data. Urinalysis data is due at the same time as all other data for inclusion in the Unity Interlaboratory Program.



Note: The Urinalysis Report is optional. Contact your Bio-Rad QC Program Representative to request this report.

See Chapter 15, “Send Data to the Unity Interlaboratory Program” for more information about submitting data to Bio-Rad.

Multi Test Data Entry

Multi Test data entry provides a convenient way to enter a day's worth of data for all tests in a lot. Use Multi Test data entry for point and summary data.

Multi Test Data Entry Information

The top section of the **Multi Test Data Entry** dialog box shows the following:

<input checked="" type="radio"/> Lab <input type="radio"/> Panel 1 Lab: 244909: Sample Lab 244909 <input type="button" value="▼"/> 4 Level: <input checked="" type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 6 Enter by: <input checked="" type="radio"/> Row <input type="radio"/> Level	2 Lot: 40710: Immunoassay Plus <input type="button" value="▼"/> 3 Set Date: 11/12/2007 <input type="button" value="▼"/> 5 Display: <input checked="" type="checkbox"/> Analyte <input checked="" type="checkbox"/> Method <input checked="" type="checkbox"/> Instrument <input type="checkbox"/> Reagent <input type="checkbox"/> Unit <input type="checkbox"/> Temperature 7 Show <input type="text" value="4"/> previous data rows (0 to 4)
<input type="button" value="Save"/>	

1 Lab number and laboratory description or panel

2 Control material name and lot number

3 Set Date

Click to use the Set Date feature. See “Use the Set Date Feature” on page 111 for more information.

4 Level check boxes

By default, all levels set up in UnityWeb are selected and available for data entry. To remove a level, clear the appropriate **Level** check box.

5 Display check boxes

Note: Make sure the Reagent check box is selected to view VITROS slide generation numbers.

Select or clear the check boxes to customize the information appearing on the data entry grid. Available options are:

- **Method**
- **Instrument**
- **Reagent**
- **Unit**
- **Temperature**



Note: The **Analyte** option is selected by default and cannot be cleared.

6 Enter by options:

- **Row**

Use the **Row** option to enter data for all levels for a single test (left to right).

- **Level**

Use the **Level** option to enter data for all tests by level (top to bottom).

7 Show previous data rows.

Type a number for the previous rows of data to show in the data entry grid. This is helpful for visually comparing previous data with the current data.

10/31/2007 12:00:00 AM	4.12	4.50	10.10	A	C*
11/1/2007 12:00:00 AM	3.59	3.69	10.20	A	C
11/2/2007 12:00:00 AM	4.12	4.20	9.89	A	C
11/3/2007 12:00:00 AM	4.20	4.60	10.30	A	C
11/12/2007 12:00:00 AM				A	C

Multi Test Data Entry Grid

The Multi Test data entry grid consists of rows and columns where manually entered data and imported data appears.



Note: The illustration below shows an example of the Multi Test Point data entry grid. Click the **Multi Test Summary Data Entry** to enter summary data.

Test Information	Entered Date	Level 1	Level 2	Level 3	A	C
Acetaminophen Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Digoxin Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Gentamicin Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Phenobarbital Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Phenytoin (Dilantin) Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Salicylate Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Theophylline Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C
Tobramycin Beckman Coulter LX 20	11/13/2007 3:07:57 PM				A	C

1 Entered Date

Date and time the data was manually entered. The testing date and time appears for imported data.

2 Level (1, 2, 3)

The fields where the QC values are typed when manually entering data. Values for imported data also appear in these fields.

3 Test information

The information appearing depends on the **Display** options selected. See “Display check boxes” on page 122 for more information.

Enter Multi Test Data

- 1 Click the **Data Entry** tab.
- 2 Click **Multi Test Point Data Entry** or **Multi Test Summary Data Entry**.
- 3 Select the lab number or panel name from the **Lab** or **Panel** list.
- 4 If using the **Lab** option, select the lot number from the **Lot** list.
- 5 Click **Set Date** and click the calendar icon located to the right of the date and select the date to use for the first date of data entry.



- 6 Select test entry configurations:
 - Level
 - Display
 - Enter by
 - Show number of rows of previous data
- 7 Enter data.
- 8 Click **Save**.

Manage Data

In This Chapter

Overview	125
Edit Data, Date, and Time.....	126
Change a Data Point's Accepted/Rejected Status	128
Insert Data.....	129
Delete Data	130
Operator Setup.....	131

Overview

Change Data

Occasionally, edits to previously entered or imported data may need to be made. In UnityWeb it is possible to edit data. However, when edits are made, the software does not re-evaluate the edited data against any statistical process control (SPC) rules unless the edited data is on the last line of all data entered. The following list summarizes the actions which can be performed:

- Edit a value
- Edit the date/time associated with a value
- Change the accepted or rejected status of a data point (point data entry only)
- Insert a value
- Delete data
- Delete a range of data

Data Entry Permissions

Data entry permissions determine the extent to which edits can be made to existing data:

- Users with the **Edit all data** permission can change any value.
- Users with the **Edit last line of data** permission can change only the last line of data.
- Users with the **Enter new data only** permission or **View data only** permission cannot make any changes to existing data.

When edits are made to data, UnityWeb sends the edits to the Unity Interlaboratory Program the next time data is submitted.

Edit Data, Date, and Time

Data results and the date-times associated with the results can be edited. If editing point data, UnityWeb automatically adds a comment to the row stating “Inserted data is not evaluated against QC rules.”



Note: This comment is not added for summary or qualitative data because summary and qualitative data are not evaluated against SPC rules.

Unless using the Set Date feature, UnityWeb assigns manually entered data to the current date and time based on the computer clock. The date and time can be edited; however, data points must be in ascending date and time order. If an edited date and time violates this requirement, UnityWeb displays a message stating **Invalid-date-range**.

Edit Data

- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Data Entry** tab.
- 3 Click the appropriate data entry dialog box:
 - **Single Test Point Data Entry**
 - **Single Test Summary Data Entry**



Note: You cannot edit previously saved data from the **Multi Test Point Data Entry** dialog box or the **Multi Test Summary Data Entry** dialog box.

- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** list or **Panel** list.
- 6 If using the **Lab** option, select the lot from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click in the field of the data to be edited.
- 9 Highlight the existing data and type in the new data.



Note: For point data only, UnityWeb automatically adds a comment to the row noting edited data is not evaluated against SPC rules. A green arrow appears in the **C** column designating the comment has been added.

- 10 Click **Save**.

Edit the Date and Time

- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Data Entry** tab.
- 3 Click the appropriate Data Entry dialog box, depending on the data to edit:
 - **Single Test Point Data Entry**
 - **Single Test Summary Data Entry**



Note: You cannot edit previously saved data from the **Multi Test Point Data Entry** dialog box or the **Multi Test Summary Data Entry** dialog box.

- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** list or **Panel** list.
- 6 If using the **Lab** option, select the lot from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 To edit the date, click the part of the date to edit and type over the date:



- 9 To edit the time, click the part of the time to edit and type over the time:



- 10 Click **Save**.



Note: You can edit the date and time; however, data points must be in ascending date and time order. If an edited date and time violates this requirement, UnityWeb displays a message stating **Invalid-date-range**.

Change a Data Point's Accepted/Rejected Status

UnityWeb automatically accepts or rejects point data based on the active statistical process control (SPC) rules. When data violates a SPC rule set to reject, an **N** appears in the **Y/N** column.



Point accepted—Included in monthly and cumulative statistics. Will be included in monthly submission statistics for Unity Interlaboratory Reports.

Point rejected—Not included in monthly or cumulative statistics. Will not be included in monthly submission for Unity Interlaboratory Reports.



Note: SPC rule evaluation is by run rather than level. If any data point in a run violates a rejection rule, UnityWeb rejects the entire row of data.

If manually changing an **N** to a **Y**, UnityWeb updates the summary statistics. Conversely, if manually changing a **Y** to an **N**, UnityWeb updates the summary statistics to exclude the value.

Change the Accepted/Rejected Status



Note: Only point data is evaluated by SPC rules. Summary and qualitative data screens do not have a **Y/N** column.

- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Data Entry** tab.
- 3 Click **Single Test Point Data Entry**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** list or **Panel** list.
- 6 If using the **Lab** option, select the lot from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click the arrow located to the right of the **Y** or **N** and change the status.
- 9 Click **Save**.

Insert Data

A row of data can be inserted between existing rows of point data, summary data, and qualitative data.

Note the following when inserting data:

- Only one row of data can be inserted at a time.
- Inserted point data is not evaluated against statistical process control (SPC) rules. UnityWeb automatically adds a comment noting inserted data is not evaluated against SPC rules. A green arrow appears in the **C** column designating the comment has been added.
- UnityWeb inserts the row above the selected row and assigns the row the same date and time. You can edit the date and time; however, data points must be in ascending date and time order. If an edited date and time violates this requirement, UnityWeb displays a message stating **Invalid-date-range**.

Insert a Data Row

- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Data Entry** tab.
- 3 Click the appropriate **Data Entry** dialog box:
 - **Single Test Point Data Entry**
 - **Single Test Summary Data Entry**
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** list or **Panel** list.
- 6 If using the **Lab** option, select the lot from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click  (plus sign) or the **Insert** link located to the right of the row to be inserted.

A new row appears.
- 9 If necessary, edit the date and time of the row maintaining the sequential date and time order.
- 10 Type the data for the new row.



Note: For point data only, UnityWeb automatically adds a comment to the row noting inserted data is not evaluated against SPC rules. A green arrow appears in the **C** column designating the comment has been added.

- 11 Click **Save**.

Delete Data

UnityWeb provides two ways to delete data:

- By row in the **Data Entry** dialog box (page 130)
- A range of data (page 130)

Delete a Row of Data from the Data Entry Dialog Box

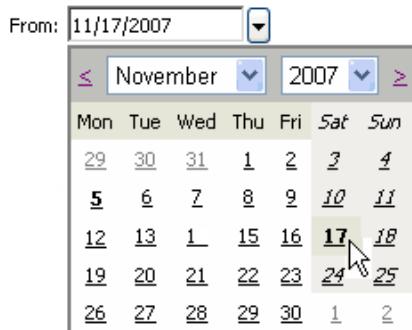
- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Data Entry** tab.
- 3 Click the appropriate **Data Entry** dialog box:
 - **Single Test Point Data Entry**
 - **Single Test Summary Data Entry**
- 4 Select the **Lab** or **Panel** option.
- 5 Select the lab number or panel name from the **Lab** list or **Panel** list.
- 6 If using the **Lab** option, select the lot from the **Lot** list.
- 7 Select the test from the **Test** list.
- 8 Click  or the **Delete** link located to the right of the row to be deleted.
A message appears asking for confirmation of the deletion.
- 9 Click **OK**.
- 10 Click **Save**.

Delete a Range of Data



Important: Deleting a range of data permanently deletes the data from the software. Deleted data cannot be retrieved. Bio-Rad recommends exporting the data to another file before deleting it. See “Export Data” on page 56 for more information.

- 1 Log in as a user with the **Edit all data** permission.
- 2 Click the **Tools** tab.
- 3 Click **Utilities**.
- 4 Click **Delete Range of Data**.
- 5 Click the arrow located to the right of the **From** date and select a beginning date for the range of data to be deleted.



- 6 Click the arrow located to the right of the **To** date and select an ending date for the range of data to be deleted.
- 7 Select a lab from the **Lab number** list or select **All** to delete all data from UnityWeb for the date range selected.
- 8 Select a lot from the **Lot number** list or select **All**.
- 9 Select a test from the **Test** list or select **All**.
- 10 Click **OK**.

A message appears asking for confirmation of the deletion.

- 11 Click **OK**.

Operator Setup

UnityWeb allows the specification of operator initials for imported data. UnityWeb uses the following cascade when importing data to determine the initials to appear in the **OP** column of the **Data Entry** dialog box:

- UnityWeb places initials contained in the import file in the **OP** column.
- UnityWeb uses any initials defined in **Operator Setup** if the import file does not contain initials.
- UnityWeb places two asterisks in the **OP** column, indicating the operator is unknown, when the import file does not contain any initials nor are initials defined in **Operator Setup**.

Click the **Tools** tab, click **Utilities**, and then click **Operator Setup** to open the **Operator Setup** dialog box. From the dialog box the following options are available:

- Choose how to assign operator initials; **All data, Labs and Lots**, or **Instrument**.
- Specify the number of work **Shifts** (from one to eight) in use in your lab.



Important: Set the number of **Shifts** before making other selections. The numbers in the **Shift** column list will be limited to this number.

- Make selections from the lists to assign **Operator** initials.

(Different columns appear depending on your choice of how to define operator initials.)

Operator Setup Shifts

The default setting is one; however, you can define up to eight shifts per day and assign a different operator to each shift. The setting for shifts is global and applies to all tests in the database.

UnityWeb divides the 24-hour day evenly among the number of shifts set.

Review and Annotate Data

In This Chapter

Overview	134
Bench Review	134
InstantQC	137
Actions and Comments	137
Require Audit Trail Comments.....	145

Overview

UnityWeb provides features to simplify documentation of QC review:

- Bench Review (page 134)
- InstantQC (page 137)
- Actions and Comments (page 137)
- Audit Trail Comments (page 145)

Bench Review

Regulatory agencies frequently require the documentation of QC data review. The Bench Review simplifies this process and provides an electronic trail of the review:

- Bench Review

The laboratory personnel performing the testing reviews QC results before verifying patient results.

Using Bench Review, data points violating a statistical process control (SPC) rule with a status of “reject” are highlighted in red and data points violating a SPC rule with a status of “warn” are highlighted in yellow. The following warning appears if any data point violates an active SPC rule.



One or more data points violate an evaluation rule.

In addition, the Bench Review sends data to Bio-Rad for inclusion in InstantQC Reports and Charts on www.QCNet.com for prospective data review.



Note: By default, data transmission from the Bench Review for InstantQC Reports and Charts is activated. See “Activate Transmission for InstantQC” on page 172 for more information.

UnityWeb documents the Bench Review using the Data Review Report which you can print or save to a file. See “Data Review Report” on page 162 for more information.

Perform Bench Review



Note: Bench Review is restricted to users with the **Bench Review** permission. See “User Permissions” on page 65 for more information.

The major steps of Bench review are:

- Select a data set (page 135).
- Review the data (page 136).
- Indicate review of all data points or individual data points (page 134).
- Save the review and, optionally, send data to the Unity Interlaboratory Program for inclusion in InstantQC Reports and Charts on www.QCNet.com (page 137).

Select a Data Set



Note: Create Bench Review by lab number or by panel. Set up a panel before selecting a data set for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

- 1 Log in as a user with the **Bench review** permission.
- 2 Click the **Review** tab.
- 3 Click **Bench Review**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select the option for the data to review:

- **All data**

By default, the **All data** option is selected. The Bench Review shows all data, regardless if the data violated any active SPC rules.

- **Suspect data**

The Bench Review shows only rejected data points and data points violating an active (reject or warn) SPC rule.



Note: Click the appropriate option to switch between **All data** and **Suspect data**.

- 6 Select a lab number from the **Lab number** list or select **All**.
- 7 Select a lot number from the **Lot number** list or select **All**.

- 8 Select an instrument from the **Instrument** list or select **All**.
 - UnityWeb shows the data in the selected data set and includes any items selected in the **Show Columns** dialog box (value, evaluation mean, evaluation standard deviation (SD), and/or any attached actions and comments). See “Manage Columns” below for more information.
 - Data violating a SPC rule with a status of reject is highlighted in red.
 - Data violating a SPC rule with a status of warn is highlighted in yellow.
 - Data not violating a SPC rule but within the same run as a data point violating a SPC rule with a status of reject or warn is highlighted in white.
 - Non-suspect data or accepted runs are highlighted in white.
- 9 Continue with the next section, “Review Data.”

Review Data

- 1 Click  located to the left of a test to view a Levey-Jennings Chart for the test.
- 2 Click  located to the left of a test to open the **Data Entry** dialog box for the test.
 - Change Y/N
 - Add a comment or action
- 3 Close the Levey-Jennings Chart or **Data Entry** dialog box to return to the data review.

Manage Columns

Customize the data shown on the Bench Review.

- 1 On the **Bench Review** dialog box, click **Manage Columns**.
- 2 On the **Show Columns** dialog box, select a check box to display the corresponding column in the Bench Review, or clear a check box to hide the column.
- 3 Click **OK**.

Document the Review

Document the review according to the **All data** option.

All Data Option

- 1 Select the **All data** option:
 - Click **Review Current Page** to indicate review of all data points on the page.
 - Click the individual **Reviewed** check box located to the left of the test to indicate review of the data in the row.
- 2 Click **Save** or **Save and Transmit** depending on the transmission option selected for InstantQC. See “Save and Transmit” on page 137 for more information.

- 3 Repeat steps 1 and 2 until all data on each page has been reviewed.

Save and Transmit

When each page of the Bench Review is complete, click **Save** or **Save and Transmit**. The **Data review transmission** check box selection in the **Setup** dialog box (on page 55) determines which button appears. By default, the **Data review transmission** check box is selected.

- If the check box is selected, the **Save and Transmit** button appears and data is saved to the Data Review Report and sent to the Unity Interlaboratory Program for inclusion in InstantQC Reports and Charts on www.QCNet.com.
- If the check box is cleared, the **Save** button appears and data is saved to the Data Review Report but is not sent to the Unity Interlaboratory Program for inclusion in InstantQC Reports and Charts on www.QCNet.com.

InstantQC

Utilize InstantQC Reports and Charts to compare your results to the results of other laboratories at any time, without any applicable deadlines for data submission. Accessed from www.QCNet.com, InstantQC Reports and Charts provide easy access to peer group comparison statistics.

Due to the rapid report turnaround times, InstantQC is particularly useful for troubleshooting problems with test system performance as they occur. Clicking **Save and Transmit** sends Bench Review data to the Unity Interlaboratory Program. The reviewed data points appear on InstantQC Reports and Charts on www.QCNet.com after a short processing time.



Note: See “InstantQC Reports and Charts” on page 197 for more information.

Actions and Comments

UnityWeb provides features to simplify documentation of QC review:

- Actions (page 138)
- Comments (page 142)
- Actions and comments by instrument (page 143)
- Audit Trail Comments (page 145)

Actions

UnityWeb includes a library of commonly used actions. These pre-defined messages help standardize the documentation of the steps taken to correct an error situation. Customize actions for optimal use in your laboratory.

The  symbol next to an action in the Action(s) list indicates the action is in use. You cannot edit or delete used actions. Therefore, Bio-Rad recommends reviewing the list of pre-defined actions prior to use. See “Action Log Messages” on page 239 for more information.

If using actions, the actions appear in the following:

- Bench Review
- Data Entry dialog boxes
- Point Data Report
- Data Review Report
- Supervisor Report
- Levey-Jennings Chart



Note: The Levey-Jennings Chart must be configured to show actions. See “Select Levey-Jennings Chart Options” on page 152 for more information.

View Actions

If an action is added to a row of data in any of the **Data Entry** dialog boxes, a green arrow appears to the right of the **A** in the **A** Column:  . Position the mouse over the  to view the comment.

Configure Actions

Add a Custom Action



Note: Only a user with the **Edit action log** permission can add a new custom action to the Action Log. Bio-Rad recommends limiting the number of users with the **Edit action log** permission. This prevents an abundance of non-standard actions which is important when reviewing reports and the Levey-Jennings Chart.

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Configure Action Logs**.
- 4 Clear the existing text and type the text for the custom action in the **Action(s)** box.
- 5 Click **Add**.

The action is added in alphabetical order. The software assigns a code number to the action based on the next available number.

Edit an Action



Note: Only a user with the **Edit action log** permission can edit an action. A  symbol next to an action in the **Action(s)** list indicates the action is in use and cannot be edited.

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Configure Action Logs**.
- 4 Select the action to edit in the **Action(s)** list.
- 5 Edit the text in the **Action(s)** field.
- 6 Click **Update**.

The edited action appears in the **Action(s)** list.

Delete an Action



Note: Only a user with the **Edit action log** permission can edit an action. A  symbol next to an action in the **Action(s)** list indicates the action is in use and cannot be deleted.

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Configure Action Logs**.
- 4 Select the action to delete in the **Action(s)** list.
- 5 Click **Delete**.

The edited action is removed from the **Action(s)** list.

Add, Edit, and Delete Actions in the Data Entry Dialog Boxes

Add an Existing Action to a Row of Data

- 1 Click in the **A** column of the row in the **Data Entry** dialog box to add the action.
The **Action** dialog box appears.



Note: Make sure the **Edit** check box is selected if nothing occurs when clicking **A**.

- 2 Locate the action to add in the **Action(s)** list and click  to apply the action.
The selected action appears in the **Existing Action** dialog box.



Tip: If necessary, click the page numbers to page through the **Action(s)** list.

- 3 Click **OK**.

The action is added to the row of data.

- 4 Click **Save**.

Add a New Action to a Row of Data



Note: Only a user with the **Edit action log** permission can add a new action to a row of data.

- 1 Click in the **A** column of the row in the **Data Entry** dialog box to add the action.

The **Action** dialog box appears.



Note: Make sure the **Edit** check box is selected if nothing occurs when clicking **A**.

- 2 Click .



Tip: Regardless of where in the list you add an action, the software arranges actions in alphabetical order.

- 3 Type the text for the new action.

- 4 Click .

A message appears asking for confirmation.

- 5 Click **OK**.

- 6 Select the action to add in the **Action(s)** list and click  to apply the action.



Tip: If necessary, click the page numbers to page through the **Action(s)** list.

- 7 Click **OK**.

The action is added to the row of data.

The action is added in alphabetical order in the **Action(s)** list. The software assigns a code number to the action based on the next available number.

Edit the Action List from the Data Entry Dialog Box



Note: Only a user with the **Edit action log** permission can edit an action in a row of data.

- 1 Click in the **A** column of the row in the **Data Entry** dialog box to edit the action.



Note: The  symbol next to an action indicates the action is in use. You cannot edit used actions.

The **Action** dialog box appears.



Note: Make sure the **Edit** check box is selected if nothing occurs when clicking **A**.

- 2 Select the action to edit in the **Action(s)** list.



Tip: If necessary, click the page numbers to page through the **Action(s)** list.

- 3 Click .

- 4 Edit the text for the action.

- 5 Click .

A message appears asking for confirmation.

- 6 Click **OK**.

Delete an Action from the Action List from the Data Entry Dialog Box



Note: Only a user with the **Edit action log** permission can delete an action from a row of data.

- 1 Click in the **A** column of any data entry row in the **Data Entry** dialog box.



Note: The symbol next to an action indicates the action is in use. You cannot delete used actions.

The **Action** dialog box appears.



Note: Make sure the **Edit** check box is selected if nothing occurs when clicking **A**.

- 2 Select the action to delete in the **Action(s)** list.



Tip: If necessary, click the page numbers to page through the **Action(s)** list.

- 3 Click .

A message appears asking for confirmation.

- 4 Click **OK**.

Automatic Action Logs



Note: Automatic action logs are only available for manually entered point data.

Use Automatic Action Logs to require the addition of an action whenever a user enters a data point violating a SPC rule set to reject.

Set Up Automatic Action Logs



Note: Only a user with the **Edit setup options** permission can set up automatic action logs.

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Click the **Configure UnityWeb** tab.
- 4 Select the **Automatic action logs** check box in the **Actions/comments** section.
- 5 Select the **Require action logs** check box.
- 6 Click **Save**.

Turn Off Automatic Action Logs



Note: Only a user with the **Edit setup options** permission can turn off automatic action logs.

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Click the **Configure UnityWeb** tab.
- 4 Clear the **Automatic action logs** check box in the **Actions/comments** section.
- 5 Click **Save**.

Comments

A comment is text added to a data point for documentation purposes. Adding a comment is an easy way to detail events or actions in the laboratory that effect quality control data.

Using comments together with actions provides a good method for documenting changes in the test system or steps taken in response to a rule violation. For example, when performing corrective maintenance, add a comment to the “**Maintenance: corrective**” action to describe the specific maintenance performed.

When added, comments appear in the following locations:

- Bench Review
- Data Entry dialog boxes
- Point Data Report
- Data Review Report
- Supervisor Report



Note: Once a comment is added, it cannot be deleted.

View Comments

If a comment is added to a row of data in any of the **Data Entry** dialog boxes, a green arrow appears to the right of the **C** in the **C** column: . Position the mouse over the to view the comment.

Add a Comment to a Row of Data

- 1 Click in the **C** column of the row in the **Data Entry** dialog box to add the comment.



Note: Existing comments for the row appear in the **Existing Comment** list.

The **Comment** dialog box appears.



Note: The symbol next to an action indicates the action is in use. You cannot delete used actions.

- 2 Type the comment in the **New comment** field and click **OK**.
- 3 Click **Save**.

Actions and Comments by Instrument

Simplify the documentation process by adding an action or comment one time and applying it to all tests performed on an instrument.



Tip: This is a time saver for documenting actions such as instrument maintenance and calibration which apply to all tests performed on an instrument.

Actions and comments by instrument can be applied to:

- Instrument
Applies the action/comment to all tests (including all lab and lot numbers) performed on the instrument regardless of how many instruments of the same model are in the laboratory.
- Lab number
Applies the action/comment to all tests performed on the selected instrument/lab number combination.
- Lot number
Applies the action/comment to all tests performed in the selected instrument/lab number/lot number combination.



Note: If there is not any data within the selected date-range and scope, the software inserts a blank data row and adds the actions/comments to the blank row.

Add an Action by Instrument

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Action/Comment by Instrument**.
- 4 Select the **Action** check box.
- 5 Click **Add**.
- 6 Select the action to add to the instrument in the **Action(s)** list.
- 7 Repeat step 6 to add another action.
- 8 Click **Apply**.
- 9 Click **Close**.
- 10 Click the up or down arrows located to the right of the **Start date** to select a beginning date for the action.
- 11 Click the up or down arrows located to the right of the **End date** to select an ending date for the action.
- 12 Select the instrument, lab number, or lot number in the **Scope** tree.
 - Click + (plus sign) to the left of the instrument to view the labs.
 - Click + (plus sign) to the left of the lab number to view the lots.
- 13 Click **Save**.

Add a Comment by Instrument

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Action/Comment by Instrument**.
- 4 Select the **Comment** check box.
- 5 Click in the comment box and type the comment.
- 6 Click the up or down arrows located to the right of the **Start date** to select a beginning date for the comment.
- 7 Click the up or down arrows located to the right of the **End date** to select an ending date for the comment.
- 8 Select the instrument, lab number, or lot number in the **Scope** tree.
 - Click + (plus sign) to the left of the instrument to view the labs.
 - Click + (plus sign) to the left of the lab number to view the lots.
- 9 Click **Save**.

Add an Action and Comment by Instrument

- 1 Click the **Tools** tab.
- 2 Click **Utilities**.
- 3 Click **Action/Comment by Instrument**.
- 4 Select the **Action** check box.
- 5 Click **Add** to open the **Action(s)** dialog box.
- 6 Select the action to add in the **Action(s)** list.
- 7 Click **Apply**.
- 8 Click **Close**.
- 9 Select the **Comment** check box.
- 10 Click in the comment box and type the comment.
- 11 Click the up or down arrows located to the right of the **Start date** to select a beginning date for the action and comment.
- 12 Click the up or down arrows located to the right of the **End date** to select an ending date for the action and comment.
- 13 Select the instrument, lab number, or lot number in the **Scope** tree.
 - Click + (plus sign) to the left of the instrument to view the labs.
 - Click + (plus sign) to the left of the lab number to view the lots.
- 14 Click **Save**.

Require Audit Trail Comments

The Audit Trail keeps track of events that can change how data points are evaluated. Audit Trail Events are automatically applied by the software. For example, the software applies the **Data inserted** Audit Trail Event when inserting a row of data. UnityWeb includes a library of Audit Trail Events. See “Audit Trail Events” on page 240 for more information.

Configure the software to require the addition of a comment whenever the software applies an Audit Trail Event.

Require Audit Trail Comments



Note: Only a user with the **Edit setup options** permission can require audit trail comments.

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Click the **Configure UnityWeb** tab.
- 4 Select the **Require audit trail comments** check box in the **Actions/comments** section.
- 5 Click **Save**.

Turn Off the Require Audit Trail Comments Feature



Note: Only a user with the **Edit setup options** permission can turn off require audit trail comments.

- 1 Click the **Tools** tab.
- 2 Click **Setup**.
- 3 Click the **Configure UnityWeb** tab.
- 4 Clear the **Require audit trail comments** check box in the **Actions/comments** section.
- 5 Click **Save**.

UnityWeb Charts

In This Chapter

Overview	147
General Chart Options.....	147
Save and Print Charts.....	150
Levey-Jennings Chart.....	151
Multi-LJ Chart.....	154
Bar Chart.....	155
Youden Chart	157

Overview

UnityWeb provides a variety of charts for investigating, troubleshooting, and documenting review of suspect data. The following charts are available:

- Levey-Jennings Chart (page 151)
- Multi-LJ Chart (page 154)
- Bar Chart (page 155)
- Youden Chart (page 157)

General Chart Options

There are a variety of options available for customizing charts. Some options apply to all charts and some options apply only to specific charts.

For information about options that apply to specific charts, see the section for the specific chart:

- Levey-Jennings Chart options (page 152)
- Bar Chart options (page 156)
- Youden Chart options (page 157)

Fill Background

Fill background for the $\pm 1\text{SD}$, $\pm 2\text{SD}$, and $\pm 3\text{SD}$ ranges apply to all charts.



Important: UnityWeb shows data points violating a statistical process control (SPC) rule with a status of “warning” in orange and data points violating a SPC rule with a status of “reject” in red. Therefore, Bio-Rad recommends not using orange or red for fill colors as it could make these data points difficult to see.

Select Fill Background

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **General**.
- 4 Select the **Show background** check box.
- 5 Click (ellipsis button) for the **SD Fill** and select the background color from the palette.
- 6 Repeat step 5 for each **SD Fill** color.
- 7 Click **Save**.



Note: Click **Default** to return to the default settings.

Grid Lines and Color

The grid lines designate $\pm 1\text{SD}$, $\pm 2\text{SD}$, and $\pm 3\text{SD}$ above and below the mean and apply to the following charts:

- Levey-Jennings Chart
- Multi-LJ Chart
- Youden Chart



Note: You can edit the grid line dash style and color.

Edit Grid Lines and Color

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **General**.
- 4 Select the **SD grid line dash style** from the list.
- 5 Click (ellipsis button) for the **SD grid line color** and select the color from the palette.
- 6 Repeat steps 4 and 5 to change each **SD grid line dash style** and **SD grid line color**.

- 7 Click **Save**.



Note: Click **Default** to return to the default settings.

Chart Header Options

Customize chart headers to contain specific information. The selections apply to all charts.



Note: Header options are for customization only. Regardless of the options selected, the size of the header is always the same.

Example of a Chart Header

Levey-Jennings Chart for SPC Rules	Period: 04/26/2007 – 06/25/2007
Lab: 99999, Your Lab Name, Lab Contact, Lab Department	
Lot: 14130, Assayed Chemistry, Serum, Bio-Rad, 03/31/2008	
Potassium, ISE indirect, Beckman Coulter LX 20, Dedicated Reagent, mmol/L, No Temperature	
Cum Mean/SD: [1] 2.04/0.07, [2] 3.78/0.06, Fixed Mean/SD: [1] 2.00/0.10, [2] 3.80/0.10	
Graph against: Your laboratory, Current lab number, Evaluation Mean/SD	
19. Maintenance: semi-annual	

Available Header Options

• Lab number	• Unit
• Lab name	• Temperature name
• Contact	• Lot number
• Department	• Lot name
• Analyte name	• Lot expiration date
• Method name	• Product manufacturer
• Instrument name	• Matrix
• Reagent name	• Print date

Select Chart Header Options

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **Header**.
- 4 Select the check box for each item to appear in the chart header.
- 5 Clear the check box to omit an item from the chart header.
- 6 Click **Save**.



Note: The software applies the selection(s) to all charts. Click **Default** to return to the default settings.

Save and Print Charts

- 1 Click **Save/Print** after creating the chart.
- 2 Select the range of data for the chart from the **Range** list.



Note: The **Range** list is not available for the Multi-LJ Chart.

The range of available data for the chart depends on the **Lab** or **Panel** option when the chart was created.

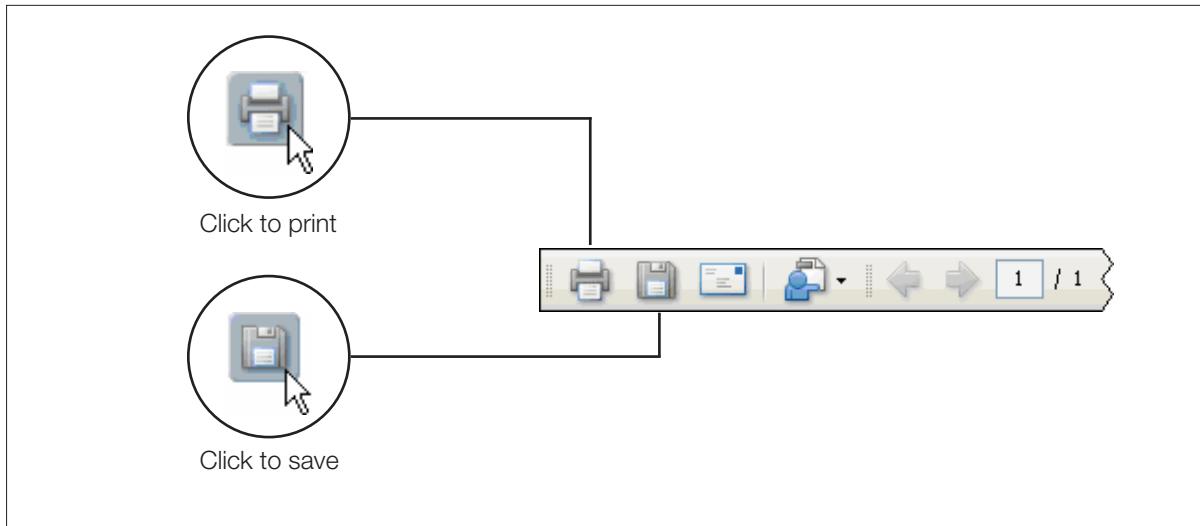
- **Lab** options
 - **Current Test**
 - **Current Lot**
 - **Current Lab**
 - **All Data**
- **Panel** options
 - **Current Panel**
 - **All Data**

- 3 Select the **Print background color** check box to print the chart background as it appears on the screen.



Tip: To conserve toner when printing charts, clear the **Print background color** check box.

- 4 Click **OK**.
- The chart opens in a separate window in PDF format.
- 5 Click the appropriate icon to print or save the chart.



Note: Depending on the version of Adobe Reader installed on your computer, the icons may look slightly different.

Levey-Jennings Chart

UnityWeb uses fixed statistics, if defined. Otherwise, the software uses cumulative statistics.



Note: The Levey-Jennings Chart plots laboratory data points for a specified time period against the fixed or cumulative (floating) mean $\pm 3SD$ range of a user defined data set.

How to Use the Levey-Jennings Chart

Using statistics to evaluate QC values assumes new control measurements have a similar distribution to past measurements while the system is stable and the distribution of values is Gaussian (normal).

Using these assumptions, 95.5% of values should be within $\pm 2SD$ of the mean and 99.7% of values should be within $\pm 3SD$ of the mean. A value outside $\pm 3SD$ of the mean would be expected only 0.3% of the time when the system is stable.

The Levey-Jennings Chart is helpful to visually identify these data points as well as shifts (sudden changes) and trends (gradual changes) in laboratory data.

Select Levey-Jennings Chart Options



Note: The options selected for a Levey-Jennings Chart also apply to the Multi-LJ Chart.

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **Levey-Jennings**.
- 4 Select the **Days on charts** option.
 - The default is 60 days.
 - Select a number from 1 to 90.
- 5 Select the **X-axis type**:

- **Date**

The X-axis shows a vertical column for each day. Each data point collected during that day appears in this column so the individual data points appear to be stacked.

Selecting the **Include point representing mean of data points for the day** check box adds a large point representing the daily mean and shows the individual data points as smaller points.

- **Sequence**

Each data point appears in its own column.



Note: Selecting the **Sequence** option makes the **Include point representing mean of data points for the day** check box unavailable.

- 6 Select the **Action** check box to include an action (if any) in the Levey-Jennings Chart header. The action number and description appear in the chart header and at the top of the chart corresponding to the date of the action.

Action number and
description _____ →

Levey-Jennings Chart for SPC Rules - Period D
Lab 99999, Your Lab Name, Lab Contact, Lab ID
Lot 14130, Assayed Chemistry, Serum, Bio-Rad
Potassium, ISE indirect, Beckman Coulter LX
Cum MeanSD: [1] 2.04±0.07, [2] 3.78±0.06
Graph against: Your laboratory, Current lab
19. Maintenance: semi-annual

- 7 Each control level has a default symbol to represent the level's data. To change the default symbol, select a **Symbol** for each **Level point** from the list.



Tip: The different symbols help visually distinguish the levels when printing in black and white. An arrow represents data points that are off the scale, regardless of the level symbol selected.

- 8 Select the **Size** for each **Symbol**.
 - The default is 6.
 - Select a size from 1 to 10 (pixels).

- 9 Select the **Fill** check box to select a fill color for each level symbol.



Tip: The different colors help visually distinguish the levels when viewing the chart on a color monitor.

- 10 Click (ellipsis button) for the fill and select the background color from the palette.



Important: UnityWeb shows data points violating a statistical process control (SPC) rule with a status of “warning” in orange and data points violating a rule with a status of “reject” in red. Therefore, Bio-Rad recommends not using orange or red for fill colors as it could make these data points difficult to see.

- 11 Select the **Connect line** check box to draw a line connecting the data points on the chart.

- 12 Repeat steps 7 through 11 as needed for each level.



Note: The line connects the mean of the points for the day and only appears if the **Include point representing mean of data points for the day** check box is selected.

- 13 Click **Save**.



Note: Click **Default** to return to the default settings.

Levey-Jennings Chart Legend



Note: The Levey-Jennings Chart legend also applies to the Multi-LJ Chart.

The Levey-Jennings Chart contains an optional legend with the symbol and color for each level of control. Select an option to display the legend at the top or bottom of the chart. By default, the legend appears above the chart.

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **General**.
- 4 Select the **Show legend** check box.
- 5 Select the option for where the legend will appear on the chart:
 - **Display on top**
 - **Display on bottom**
- 6 Click **Save**.



Note: Click **Default** to return to the default settings.

Other Options

There are other options that apply to the Levey-Jennings Chart. See the following sections for more information:

- “Fill background” (page 148)
- “Grid Lines and Color” (page 148)
- “Chart Header Options” (page 149)

Create a Levey-Jennings Chart

- 1 Click the **Charts** tab.
- 2 Click **Levey-Jennings**.
- 3 Select the **Lab** or **Panel** option.
- 4 Select the lab number or panel name from the **Lab** or **Panel** list depending on the option selected in step 3.
- 5 If using the **Lab** option, select the lot from the **Lot** list.
- 6 Select the test from the **Test** list.
- 7 Click the arrow located to the right of the **From** (date) and select a beginning date for the data on the chart.
- 8 Click the arrow located to the right of the **To** (date) and select an ending date for the data on the chart.
- 9 By default, the **Overlay levels** check box is selected. Clear the **Overlay levels** check box to view each level on a separate chart.
- 10 By default, all levels are selected for the chart. To remove a level, clear the appropriate **Level** check box.
- 11 To save or print the chart, see “Save and Print Charts” on page 150.

Multi-LJ Chart

The Multi-LJ Chart provides an easy way to compare tests, such as the same analyte run on two different instruments or on two different lot numbers of control material. The Multi-LJ Chart shows a Levey-Jennings Chart for up to 18 tests.

Select Multi-LJ Chart Options



Note: The options selected for a Levey-Jennings Chart also apply to the Multi-LJ Chart. See “Select Levey-Jennings Chart Options” on page 152 for more information.

Create a Multi-LJ Chart

- 1 Click the **Charts** tab.
- 2 Click **Multi-LJ**.
- 3 Click the **Lab** or **Panel** tab.
- 4 In the **Lab** or **Panel** navigation tree, select up to 18 tests to display on the chart.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 5 Click **Plot**.
- 6 By default, all levels set up in UnityWeb are selected for the chart. To remove a level, clear the appropriate **Level** check box.
- 7 To change the arrangement of the individual charts:
 - Click  to view the charts in a single column.
 - Click  to view the charts in two columns.
- 8 To save or print the chart, see “Save and Print Charts” on page 150.

Bar Chart

The Bar Chart shows the laboratory mean for 13 months plotted against one of the following:

- Cumulative mean (if no fixed mean is specified)

The Bar Chart is overlaid onto the cumulative mean $\pm 3SD$ range. The cumulative mean determines the scale of the Y-axis (mean $\pm 3SD$).

- Fixed mean (if a fixed mean is specified)

The Bar Chart is overlaid onto the fixed mean $\pm 3SD$ range specified for the test. The fixed mean determines the scale of the Y-axis (mean $\pm 3SD$).

The Bar Chart also shows the SD, CV, and number of points for each monthly mean.



Tip: The Bar Chart plots monthly means against a $\pm 3SD$ range. Therefore, the Bar Chart is helpful to visualize long-term shifts and trends.

Select Bar Chart Options

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **Bar**.
- 4 Select the **Months on charts** option.
 - The default is 13 months.
 - Select a number from 1 to 13.
- 5 Click  (ellipsis button) for the **Level Fill** and select a color from the palette.
- 6 Repeat step 5 for each level.
- 7 Click **Save**.

Other Options

There are other options that apply to the Bar Chart. See the following sections for more information:

- “Fill background” (page 148)
- “Chart Header Options” (page 149)

Create a Bar Chart



Note: Create a Bar Chart by lab number or by panel. Set up a panel before creating a chart for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

- 1 Click the **Charts** tab.
- 2 Click **Bar**.
- 3 Select the **Lab** or **Panel** option.
- 4 Select the lab number or panel name from the **Lab** or **Panel** list, depending on the option selected in step 3.
- 5 If using the **Lab** option, select the lot from the **Lot** list.
- 6 Select a test for the chart from the **Test** list.
- 7 Click the arrow located to the right of the **From** (date) and select a beginning date for the data on the chart.
- 8 Click the arrow located to the right of the **To** (date) and select an ending date for the data on the chart.
- 9 By default, all levels set up in UnityWeb are selected for the chart. To remove a level, clear the appropriate **Level** check box.
- 10 To save or print the chart, see “Save and Print Charts” on page 150.

Youden Chart

The Youden Chart is a graphical representation used to plot paired data (Level 1 and Level 2, Level 1 and Level 3, and so on) for a given time period on an X- and Y-axis.



Note: The Youden Chart can be used for any two levels of a control material.

Data points are plotted on the graph and fall within one of four fields:

- Within $\pm 1\text{SD}$ of the mean
- Within $\pm 2\text{SD}$ of the mean
- Within $\pm 3\text{SD}$ of the mean
- Outside $\pm 3\text{SD}$ of the mean

How to Use the Youden Chart

The center of the Youden Chart represents the optimum target. The more tightly points are clustered around the center of the target, the better the precision of the control levels.



Tip: When viewing a Youden Chart, pause the mouse pointer on an individual data point to view the two associated values, date and time, any SPC rules violations, and any attached actions or comments.

Select Youden Chart Options

- 1 Click the **Charts** tab.
- 2 Click **Options**.
- 3 Click **Youden**.
- 4 Select the **Days on charts** option:
 - The default is 60 days.
 - Select a number from 1 to 90.
- 5 Select the **Symbol** for the **Point**.
- 6 Select the **Size** for the **Symbol**.
 - The default is 6.
 - Select a size from 1 to 10 (pixels).
- 7 Select the **Fill** check box to select a fill color for the point symbol.
- 8 Click (ellipsis button) and select the fill color from the palette.



Important: UnityWeb shows data points violating a statistical process control (SPC) rule with a status of “warning” in orange and data points violating a rule with a status of “reject” in red. Therefore, Bio-Rad recommends not using orange or red for fill colors as it could make these data points difficult to see.

Other Options

There are other options that apply to the Youden Chart. See the following sections for more information:

- “Fill background” (page 148)
- “Grid Lines and Color” (page 148)
- “Chart Header Options” (page 149)

Create a Youden Chart



Note: Create a Youden Chart by lab number or by panel. Set up a panel before creating a chart for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

- 1 Click the **Charts** tab.
- 2 Click **Youden**.
- 3 Select the **Lab** or **Panel** option.
- 4 Select the lab number or panel name from the **Lab** or **Panel** list.
- 5 If using the **Lab** option, select the lot from the **Lot** list.
- 6 Select a test from the **Test** list.
- 7 Click the arrow located to the right of the **From** (date) and select a beginning date for the data on the chart.
- 8 Click the arrow located to the right of the **To** (date) and select an ending date for the data on the chart.
- 9 By default, all levels set up in UnityWeb are selected for the chart. To remove a level, clear the appropriate **Level** check box.
- 10 To save or print the chart, see “Save and Print Charts” on page 150.

UnityWeb Reports

In This Chapter

Overview	159
Save and Print Reports.....	160
Data Review Report.....	162
Point Data Report.....	163
Summary Data Report.....	164
Statistical Report	165
Supervisor's Report	166
Operator Report	167
Audit Trail Report	168
Listings Reports.....	169

Overview

UnityWeb intralaboratory reports are a valuable addition to the monthly Unity Interlaboratory Reports. The following UnityWeb reports are available creation at any time:

- Data Review Report (page 162)
- Point Data Report (page 163)
- Summary Data Report (page 164)
- Statistical Report (page 165)
- Supervisor's Report (page 166)
- Operator Report (page 167)
- Audit Trail Report (page 168)
- Listings reports (page 169)

Save and Print Reports

Reports appear in Crystal Report format after clicking **Show report**.

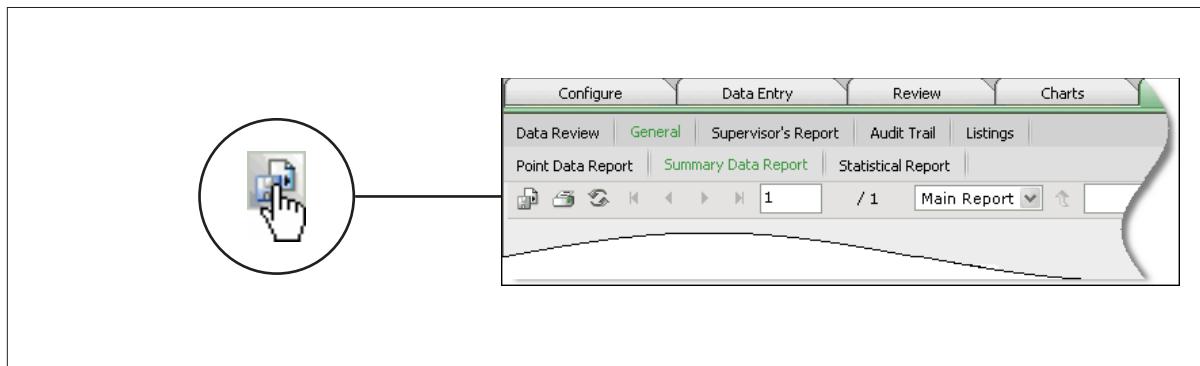
Save Reports



Note: The following directions apply to Exporting the Report to a PDF format. Depending on the version of Adobe Reader installed on the computer, the icons may look slightly different.

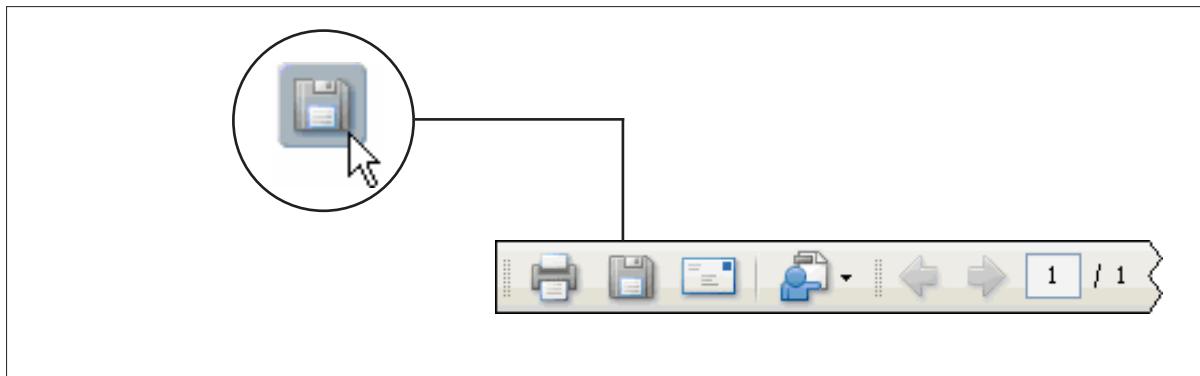
The report appears in Crystal Report format after clicking **Show report**.

- 1 Click the export icon.



The **Export the Report** dialog box appears in a separate window.

- 2 Select a format for the report from the **File Format** list.
 - Crystal Reports (RPT)
 - Adobe Acrobat (PDF)
 - Microsoft Excel 97-2000 (XLS)
 - Microsoft Excel 97-2000 - Data Only (XLS)
 - Microsoft Word (RTF)
 - Microsoft Word - Editable (RTF)
 - Rich Text Format (RTF)
- 3 Select the **Page Range** option.
- 4 Click **OK**.
- 5 Click the save icon.



The **Save a Copy** dialog box appears.

- 6 Navigate to the desired location on the hard drive or network.
- 7 Click **Save**.

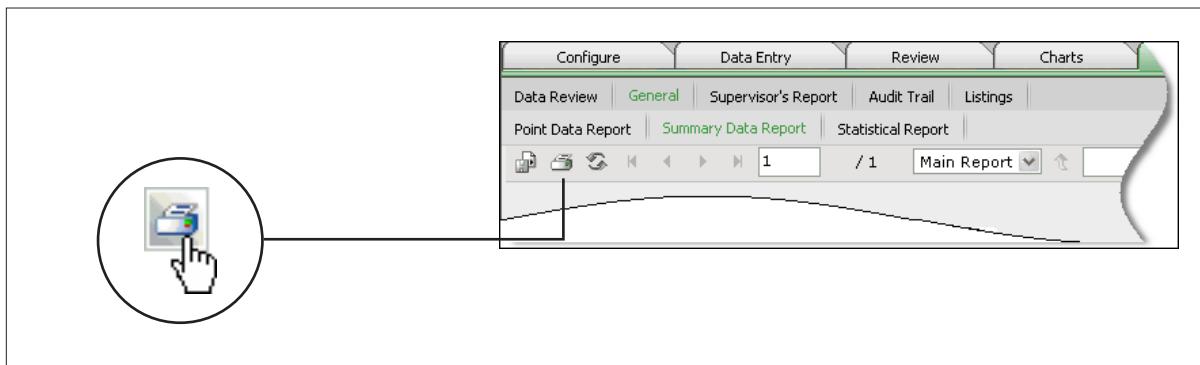
Print Reports



Note: Depending on the version of Adobe Reader installed on the computer, the icons may look slightly different.

The report appears in Crystal Report format after clicking **Show report**.

- 1 Click the printer icon.

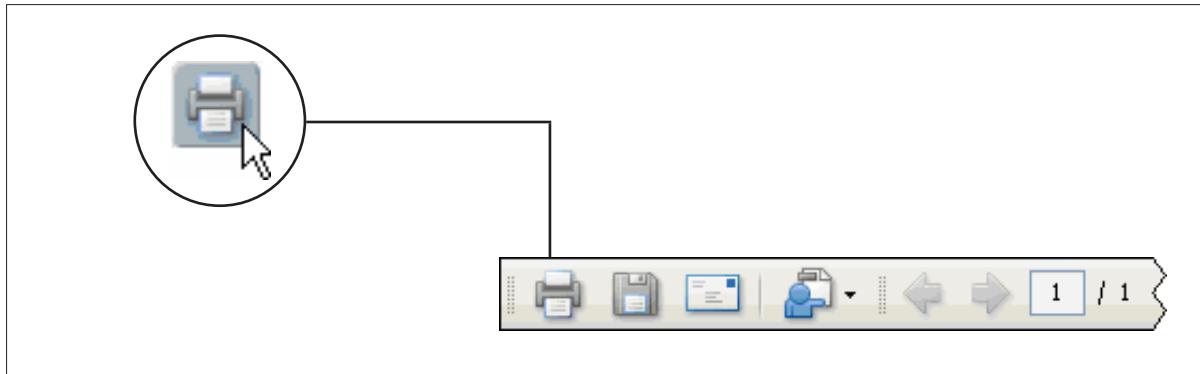


The **Print the Report** dialog box appears in a separate window.

- 2 Select the **Page Range** option.
- 3 Click **OK**.

The report appears in PDF format in a new window.

- 4 Click the printer icon.



The **Print** dialog box appears.

- 5 Select the appropriate options for the printer and click **OK**.

Document Report Reviews

At the end of each report is a signature line and a section to document corrective actions needed.



Note: UnityWeb does not support electronic signatures. However, you can use a third-party software product such as Adobe Reader.

Data Review Report

The Data Review Report documents the review of point data from the Bench Review.

The Data Review Report contains the following information for each data point:

- Date/time
- Operator initials
- Value (result)
- Attached actions and comments, if any
- Accept/reject status
- Initials of the person performing Bench Review, if available
- Date/time of the Bench Review

Create a Data Review Report

- 1 Click the **Reports** tab.
- 2 Click **Data Review**.
- 3 Select the lab number from the **Lab** list.
If using **All Labs**, go to step 6.
- 4 Select the lot number from the **Lot** list.
If using **All Lots**, go to step 6.
- 5 Select the instrument from the **Instrument** list or select **All Instruments**.
- 6 Click the arrow located to the right of the **From** date and select a beginning date for the report.
- 7 Click the arrow located to the right of the **To** date and select an ending date for the report.
- 8 Click **Show report**.
- 9 To save or print the report, see “Save and Print Reports” on page 160.

Point Data Report

The Point Data Report is useful for reviewing all point data for a specific date range such as a month or quarter. Data entered as summary data does not appear on the report.

Point Data Report Options



Note: Create the Point Data Report by lab number or by panel. Set up a panel before creating a report for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

Create a Point Data Report

- 1 Click the **Reports** tab.
- 2 Click **General**.
- 3 Click **Point Data Report**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select a test in the navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 6 Click the arrow located to the right of the **From** date and select a beginning date for the report.
- 7 Click the arrow located to the right of the **To** date and select an ending date for the report.

- 8 Select an option for the data in the report from the **Report range** list.



Note: The **Report range** options depend on the option selected in step 4.

- 9 Click **Show report**.
- 10 To save or print the report, see “Save and Print Reports” on page 160.

Summary Data Report

The Summary Data Report shows the monthly and cumulative mean, SD, CV, and number of data points for each test in the selected data set. These statistics combine both point and summary data and provide a quick way to review large amounts of data.

Summary Data Report Options



Note: Create the Summary Data Report by lab number or by panel. Set up a panel before creating a report for the panel. See “Save and Print Reports” on page 160 for more information.

Create a Summary Data Report

- 1 Click the **Reports** tab.
- 2 Click **General**.
- 3 Click **Summary Data Report**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select a test in the navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 6 Click the arrow located to the right of the **From** date and select a beginning date for the report.
- 7 Click the arrow located to the right of the **To** date and select an ending date for the report.
- 8 Select an option for the data in the report from the **Report range** list.



Note: The **Report range** options depend on the option selected in step 4.

- 9 Click **Show report**.
- 10 To save or print the report, see “Save and Print Reports” on page 160.

Statistical Report

The Statistical Report shows the percentage of point data that did not violate any active statistical process control (SPC) rule. The Statistical Report is a helpful overview of how well the laboratory is meeting its performance goals. The report shows:

- Cumulative statistics for the test.
- Statistics for each calendar month.

Statistical Report Options



Note: Create the Statistical Report by lab number or by panel. Set up a panel before creating a report for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

Create a Statistical Report

- 1 Click the **Reports** tab.
- 2 Click **General**.
- 3 Click **Statistical Report**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select a test in the navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 6 Click the arrow located to the right of the **From** date and select a beginning date for the report.
- 7 Click the arrow located to the right of the **To** date and select an ending date for the report.
- 8 Select an option for the data in the report from the **Report range** list.



Note: The **Report range** options depend on the option selected in step 4.

- 9 Click **Show report**.
- 10 To save or print the report, see “Save and Print Reports” on page 160.

Supervisor's Report

Use the Supervisor's Report to view data points that:

- Violate a rejection rule.
- Violate a warning rule.
- Have an attached action or comment.

Supervisor's Report Options



Note: Create the Supervisor's Report by lab number or by panel. Set up a panel before creating a report for the panel. See "Create a Panel and Add Tests" on page 92 for more information.

Create a Supervisor's Report

- 1 Click the **Reports** tab.
- 2 Click **Supervisor's Report**.
- 3 Click **Supervisor's Report**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select a test in the navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 6 Click the arrow located to the right of the **From** date and select a beginning date for the report.
- 7 Click the arrow located to the right of the **To** date and select an ending date for the report.
- 8 Select an option for the data in the report from the **Report range** list.



Note: The **Report range** options depend on the option selected in step 4.

- 9 By default, the **Reject** check box is selected. Clear the **Reject** check box to exclude rejected data from the report.

To view additional data:

 - Select the **Warn** check box.
 - Select the **Action or Comment** check box.
- 10 Click **Show report**.
- 11 To save or print the report, see "Save and Print Reports" on page 160.

Operator Report

The Operator Report shows the following statistics for each test separated by operator:

- Mean
- SD
- CV
- Number of data points



Note: The Operator Report is only available to users with the **Manage users** permission.

Operator Report Options



Note: Create the Operator Report by lab number or by panel. Set up a panel before creating a report for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

Create an Operator Report

- 1 Click the **Reports** tab.
- 2 Click **Supervisor’s Report**.
- 3 Click **Operator Report**.
- 4 Select the **Lab** or **Panel** option.
- 5 Select a test in the navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of the lot number to view the tests.
- 6 Click the arrow located to the right of the **From** date and select a beginning date for the report.
- 7 Click the arrow located to the right of the **To** date and select an ending date for the report.
- 8 Select an option for the data in the report from the **Report range** list.



Note: The **Report range** options depend on the option selected in step 4.

- 9 Click **Show report**.
- 10 To save or print the report, see “Save and Print Reports” on page 160.

Audit Trail Report

The Audit Trail Report is a convenient tool to identify events that changed how data points were evaluated. When first creating the Audit Trail Report, the report contains all events for all labs, lots, and tests. Filter the report by any of the following criteria:

- Date range
- Lab number
- Lot number
- Test
- Event

Audit Trail Events

The **Event** list contains auditable events that have been performed. The following information appears for each event:

- Initials of the person performing the auditable event.
- Original value or setting.
- New value or setting.
- Comments entered in the **Audit Trail Comment** dialog box.



Note: When Audit Trail comments are required, the **New Comment** dialog box appears whenever users perform an action triggering an Audit Trail Event. See “Require Audit Trail Comments” on page 145 for more information.

Create an Audit Trail Report

- 1 Click the **Reports** tab.
- 2 Click **Audit Trail**.

The Audit Trail report appears and shows all events for all labs, all lots, and all tests.

- 3 Complete any of the following steps to narrow the information in the report.



Note: The Audit Trail report refreshes on the screen with each selection made. Click **Show report** to save or print the report after any selection. See “Save and Print Reports” on page 160.

- 4 Click the arrow located to the right of the **Start** date and select a beginning date for the report.
- 5 Click the arrow located to the right of the **End** date and select an ending date for the report.
- 6 Select a lab number from the **Lab number** list to narrow the report by lab.
- 7 Select a lot number from the **Lot number** list to narrow the report by lot.
- 8 Select a test from the **Test information** list to narrow the report by test.

- 9 Select an event from the **Event** list to narrow the report by event.
- 10 Click **Show report**.
- 11 To save or print the report, see “Save and Print Reports” on page 160.

Listings Reports

The Listings Reports are helpful to view all the information set up in the UnityWeb software. Listings Reports are available for the following information:

- **Labs**
Shows all lab numbers, organized by open and closed lab numbers.
- **Lots**
Shows all open lab numbers and associated lot numbers, whether open or closed.
- **Tests**
Shows all lab numbers (open and closed) and associated tests organized by lot number. Closed lots and associated tests are not shown.
- **Panels**
Shows all panels with associated tests organized by lab number and lot number.
- **Test Code Report**
The Test Code Report shows the Unity codes for each test based on the specified criteria. This report includes the Unity codes for the:
 - Analyte
 - Method
 - Instrument/kit
 - Reagent
 - Unit
 - Temperature

Listings Report Options



Note: Create a Listings Report by lab number or by panel. Set up a panel before creating a report for the panel. See “Create a Panel and Add Tests” on page 92 for more information.

Create a Listings Report

- 1 Click the **Reports** tab.
- 2 Click **Listings**.
- 3 Click the type for the Listings Report:
 - **Labs**
 - **Lots**
 - **Tests**
 - **Panels**
 - **Test Code Report**
- 4 To save or print the report, see “Save and Print Reports” on page 160.

Send Data to the Unity Interlaboratory Program

In This Chapter

Overview	171
Submit Data Monthly	171
Submit Data from the Bench Review	172

Overview

Comparing your data to other laboratories worldwide is a major benefit of the Bio-Rad Unity Interlaboratory Program. The Unity Interlaboratory Program provides a variety of reports to help meet regulatory requirements. (See Chapter 16, “Unity Interlaboratory Reports” for more information.) There are two options for submitting data to the Unity Interlaboratory Program:

- Submit data monthly (page 171)
- Submit data from the Bench Review (page 172)

Submit Data Monthly

Submit monthly data manually or by using the automatic monthly transmission feature. Monthly transmission ensures data is transmitted for inclusion in monthly Unity Interlaboratory Reports.



Note: Using the automatic monthly transmission feature ensures all data is sent for inclusion in the monthly Unity Interlaboratory reports. Bio-Rad recommends activating automatic monthly Unity transmission to ensure data is sent on time.

Submit Data Manually

Send data manually at any time even if using the automatic monthly transmission feature.

- 1 Log in as a user with the **Communicate with Unity Interlab** permission.
- 2 Click the **Tools** tab.
- 3 Click **Unity Interlab**.
- 4 Click **Send Data to Bio-Rad**.

A message appears asking for confirmation of the data submission.

- 5 Click **OK**.

Activate Automatic Monthly Transmission



Note: If using the automatic monthly transmission feature, the UnityWeb software must be running in order to submit data.

- 1 Log in as a user with the **Edit setup options** permission.
- 2 Click the **Tools** tab.
- 3 Click **Setup**.
- 4 Click **Configure UnityWeb**.
- 5 Select the **Automatic monthly transmission** check box within the **Transmission** section.
The **Day of the month** list becomes available.
- 6 Select the day of the month for automatic transmission to occur from the **Day of the month** list.



Note: The day of the month options are 1 through 7. As a general rule, you must send your data to Bio-Rad by the fifth business day of the following month. Data received after the 7th is late.

- 7 Click **Save**.

Submit Data from the Bench Review

To receive InstantQC Reports, submit point data from the Bench Review. If entering only point data, substitute the InstantQC transmission for monthly transmission. See Chapter 12, “Review and Annotate Data” for more information about Bench Review.

Activate Transmission for InstantQC

- 1 Log in as a user with the **Edit setup options** permission.
- 2 Click the **Tools** tab.
- 3 Click **Setup**.
- 4 Click **Configure UnityWeb**.
- 5 Select the **Data review transmission (for InstantQC)** check box within the **Transmission** section.
- 6 Click **Save**.



Note: UnityWeb sends point data to the Unity Interlaboratory Program each time a Bench Review is approved. After a short processing time, the data appears on the InstantQC Reports on www.QCNet.com.

Unity Interlaboratory Reports

In This Chapter

Overview	174
Monthly Reports	176
Comprehensive Reports	184
Optional Reports	187
Affiliated Reports	190
Urinalysis Report	195
InstantQC Reports and Charts.....	197

Overview

Unity Interlaboratory Reports show comparative results between laboratories and are used to determine values and assess test methods. Unity Interlaboratory Reports help ensure the reliability and precision of test systems and improve laboratory analytical performance.

Laboratories participating in the Unity Interlaboratory Program submit data on a monthly basis for each control product tested. This data is combined with data from other laboratories worldwide using the same consensus group. The Unity Interlaboratory Program generates reports for all data submitted by the monthly due date. A notification e-mail is sent when Unity Interlaboratory Reports are available on www.QCNet.com. (See page 176 for more information about Consensus groups.)



Important: As a general rule, data must be sent to Bio-Rad by the fifth business day of the following month. Reports are not automatically generated for data received after the due date. Contact your Bio-Rad QC Program Representative to request late reports.

The Unity Interlaboratory Program provides the following types of reports:

- Monthly reports
- Comprehensive reports
- Optional reports
- InstantQC reports

Monthly Reports

The Unity Interlaboratory Program automatically generates the following reports for each month you submit your data. These reports compare your laboratory data to the data of your consensus group.

- Monthly Evaluation Report (page 177)
- Data Rejection Report (page 178)
- Bias and Imprecision Histogram Report (page 183)

The Unity Interlaboratory Program generates the following reports according to the frequency (monthly, quarterly, or never) specified in UnityWeb.

- Laboratory Performance Overview Report (page 179)
- Laboratory Comparison Report (page 180)
- Laboratory Histogram Report (page 182)



Note: See “Configure Unity Interlaboratory Report Frequency” on page 56 for more information.

Comprehensive Reports

The Unity Interlaboratory Program provides the following comprehensive reports. These reports show comparative data for all Peer and Method group statistics.

- Worldwide Report (page 184)
- Manufacturer Report (page 186)

Optional Reports



Note: Additional optional reports are available by request. Contact your Bio-Rad QC Program Representative for more information.

- Statistical Profile Report (page 187)
- Affiliated Reports (page 190)
- Urinalysis Report (page 195)

InstantQC Reports and Charts



Note: When sending data to the Unity Interlaboratory Program from Bench Review, the reviewed data points appear on InstantQC Reports and Charts on www.QCNet.com after a short processing time. See “InstantQC Reports and Charts” on page 197 for more information.

- InstantQC Report (page 198)
- InstantQC Chart (page 199)

Consensus Groups

The Unity Interlaboratory Program consists of the following consensus groups:

- **Peer** (most specific)

The Peer consensus group is the ideal group for comparison. It is composed of all laboratories using the same instrument, lot number, level, reagent, analytical method, units, and temperature of a test.

- **Method** (next specific)

Choose the Method consensus group when there is an insufficient number of laboratories in the Peer group. It is composed of all laboratories using the same lot number, level, analytical method, units, and temperature of a test.

- **All Labs** (least specific)

The All Labs consensus group is composed of data from all laboratories using the same lot number, level, units, and temperature of a test.

View and Print Interlaboratory Reports

- 1 Start an Internet browser window and navigate to www.QCNet.com.
- 2 Log on with your **QCNet user ID** and **Password**.
- 3 Point to **Unity Interlab** and then click **Unity Reports**.
- 4 Point to **Reports**, and then click **My Reports**.
- 5 Make selections for the lab number, lot number, report type, and period. The selected report appears in Adobe Reader.
- 6 Click the printer icon.
The **Print** dialog box appears.
- 7 Select the appropriate options for the printer and click **OK**.

Monthly Reports



Important: As a general rule, data must be sent to Bio-Rad by the fifth business day of the following month. Reports are not automatically generated for data received after the due date. Contact your Bio-Rad QC Program Representative to request late reports.

Monthly Evaluation Report

The Monthly Evaluation Report provides an overview of your laboratory performance for the month.

How to Use This Report

The Monthly Evaluation Report:

- Validates your monthly laboratory performance compared to the consensus group.
- Identifies when your laboratory's monthly performance does not statistically compare with or was not accepted into the Unity database.
- Notifies your laboratory when your laboratory's data was not received in time for the standard worldwide comparison. Late reports are available upon request from your Bio-Rad QC Program Representative.
- Contains a signature line and a section to document corrective actions needed. Alerts you when your SDI (a peer-based measure of bias) or CVR (a peer-based measure of imprecision) exceeds threshold limits. The default threshold is 2.0 for both CVR and SDI. These limits can be customized upon request.

Example Monthly Evaluation Report

BIO-RAD		Monthly Evaluation Multiqual 1, 2, 3 Unassayed			Lot 10000																															
Lab 001234	QC Coordinator Associated Regional Laboratory 123 Main Street Anytown, NY, 12345-6789				Data For: 05-2007 Lot Exp: 08-31-2009 Printed: 05-31-07 Page 1	Unity™ <small>Interlaboratory Programs</small>																														
<p>Dear Customer,</p> <p>Attached are your QC reports for the month of 05-2007. Based on comparisons to the reported peer group, the parameters listed below may require investigation or review.</p>																																				
<table border="1"> <thead> <tr> <th>AST (ASAT/GOT)</th> <th>Monthly:</th> <th>SDI</th> <th>CVR</th> <th># Labs</th> <th># Points</th> </tr> </thead> <tbody> <tr> <td>UV without P5P</td> <td>Level 1</td> <td>-0.83</td> <td>0.88</td> <td>25</td> <td>5853</td> </tr> <tr> <td>Roche MODULAR</td> <td>Level 2</td> <td>-0.85</td> <td>0.58</td> <td>14</td> <td>3850</td> </tr> <tr> <td>Dedicated Reagent</td> <td>Level 3</td> <td>-2.03</td> <td>1.00</td> <td>25</td> <td>2300</td> </tr> <tr> <td>U/L 37°C</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>							AST (ASAT/GOT)	Monthly:	SDI	CVR	# Labs	# Points	UV without P5P	Level 1	-0.83	0.88	25	5853	Roche MODULAR	Level 2	-0.85	0.58	14	3850	Dedicated Reagent	Level 3	-2.03	1.00	25	2300	U/L 37°C					
AST (ASAT/GOT)	Monthly:	SDI	CVR	# Labs	# Points																															
UV without P5P	Level 1	-0.83	0.88	25	5853																															
Roche MODULAR	Level 2	-0.85	0.58	14	3850																															
Dedicated Reagent	Level 3	-2.03	1.00	25	2300																															
U/L 37°C																																				

Data Rejection Report

The Data Rejection Report identifies data that has been rejected and therefore excluded from the Unity Interlaboratory Program.

How to Use This Report

The Unity Interlaboratory Program does not include data outside of a standard statistical range based on the previous month's consensus group standard deviation. The rejected data points are not included in cumulative statistics or in statistical comparisons. If a rejection is due to data entered in error, correct the error and Unity Interlaboratory Reports can be regenerated upon request to your Bio-Rad QC Program Representative.

Data points may be rejected for two reasons:

- Based on consensus group mean or coefficient of variation (CV) the data points lie outside the standard statistical window.
- An incorrect code (for example, invalid unit, invalid method, and so on) was used when reporting data.

Limits for the Mean

- Mean \leq 5.0

The allowable statistical window is $\pm 4SD$ from the previous month's consensus group cumulative mean.

- Mean $>$ 5.0

The allowable statistical window is $\pm 3SD$ from the previous month's consensus group cumulative mean.

Limits for the CV

- Data is rejected when your CV is $\geq 40\%$.
- Data is accepted when your CV is $< 40\%$.



Note: The window of acceptable values appears below the rejected values on the report. The CV limit may be different for some analytes.

Example Data Rejection Report

Data Rejection Report Urine Chemistry		Lot 10000													
BIO-RAD	Lab 001234 QC Coordinator Associated Regional Laboratory 123 Main Street Anytown, NY, 12345-6789	Data For: 05-2007 Lot Exp: 08-31-2009 Printed: 05-31-06 Page 1													
<p>Dear Customer,</p> <p>The following data was not used as a part of the Unity™ worldwide statistical database. Please refer to your manual for a detailed explanation of rejection criteria.</p>															
<table border="1"> <thead> <tr> <th>Analyte / Date</th> <th>Level</th> <th>Mean</th> <th>SD</th> <th>CV</th> <th># Points</th> </tr> </thead> <tbody> <tr> <td>Potassium ISE indirect Roche Hitachi Systems (USA) Dedicated Reagent mEq/L</td> <td>05-2007</td> <td>Level 2 Acceptable values are between 3.688 – 4.262</td> <td>5.22</td> <td>0.07</td> <td>----</td> <td>16</td> </tr> </tbody> </table>			Analyte / Date	Level	Mean	SD	CV	# Points	Potassium ISE indirect Roche Hitachi Systems (USA) Dedicated Reagent mEq/L	05-2007	Level 2 Acceptable values are between 3.688 – 4.262	5.22	0.07	----	16
Analyte / Date	Level	Mean	SD	CV	# Points										
Potassium ISE indirect Roche Hitachi Systems (USA) Dedicated Reagent mEq/L	05-2007	Level 2 Acceptable values are between 3.688 – 4.262	5.22	0.07	----	16									

Laboratory Performance Overview Report

The Laboratory Performance Overview Report shows your monthly bias and imprecision for a test compared to the Peer and Method consensus groups.



Tip: The monthly standard deviation index (SDI) is a peer-based measure of bias. The monthly coefficient of variation ratio (CVR) is a peer-based measure of imprecision.

How to Use This Report

The SDI and CVR are combined as X-Y coordinates located within one of three performance zones shown by increased levels of shading:

- No shading - Acceptable performance.
- Slight shading - Acceptable to marginal performance.
May indicate the need to investigate test system bias and imprecision.
- Darkest shading - Marginal performance.
May need to perform a corrective action.

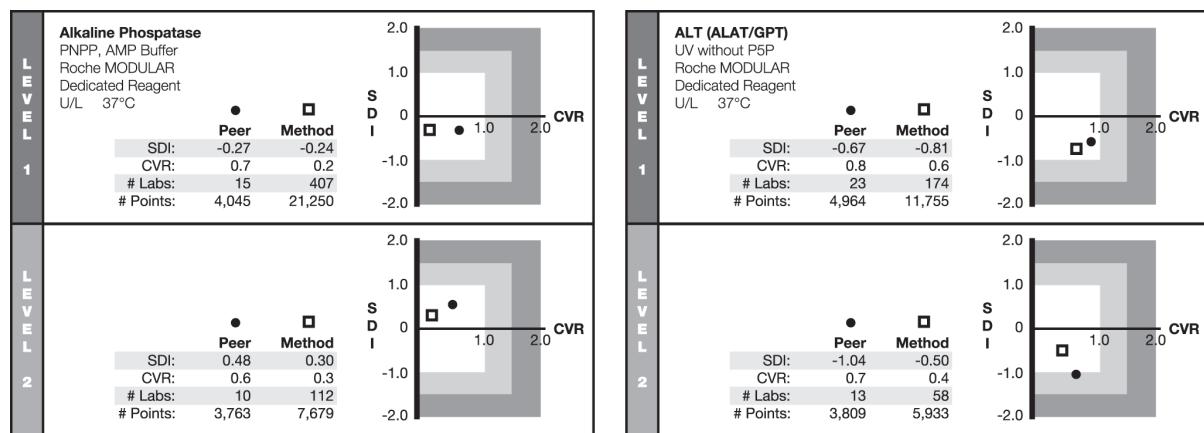
- Outside of graph  - Unacceptable performance.

Requires corrective action.

The center of the graph (SDI and CVR both equal to zero) represents perfect agreement between your laboratory's values and your consensus group (Peer or Method) statistics. Your bias and imprecision increase as your values move further away from the center of the graph.

The report contains a signature line and a section to document corrective actions needed.

Example Laboratory Performance Overview Report



Laboratory Comparison Report

The Laboratory Comparison Report allows you to compare your results to those of the Peer and Method consensus groups. This report includes many vital statistics and is often the very first report reviewed by Unity participants.

For VITROS instruments, the Laboratory Comparison Report provides statistics for your laboratory, Peer group, and Method group based on the slide generation numbers you report.



Note: Method group statistics may not be available for all analytes.

How to Use This Report

For each test, the report contains the following monthly and cumulative statistics:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Number of points
- Coefficient of variation ratio (CVR) for the Peer and Method consensus groups

- Standard deviation index (SDI) for the Peer and Method consensus groups

The Laboratory Comparison Report also shows the monthly and cumulative Peer and Method group statistics for:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Number of points reported
- Number of labs reported

Example Laboratory Comparison Report

Laboratory Comparison Report Multiqual 1, 2, 3 Unassayed						Lot 10000				
Lab 001234			QC Coordinator Associated Regional Laboratory 123 Main Street Anytown, NY, 12345-6789			Data For: 05-2007 Lot Exp: 08-31-2009 Printed: 05-31-07 Page 1				
BIO-RAD										
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 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.										
Analyte	Methods	Units	Temp	Level 1	Level 2	Level 3				
Instrument / Kit	Reagent			Mon	Cum	Mon	Cum	Mon	Cum	
Alkaline Phosphatase										
PNPP, AMP Buffer	U/L	37° C								
Roche MODULAR										
Dedicated Reagent										
Your Lab				Mean	36.01	36.97	141.1	141.4	289.5	290.2
				SD	0.870	1.33	1.99	2.26	3.82	4.52
				CV	2.4	3.6	1.4	1.6	1.3	1.6
				(Peer) CVR	0.7	0.8	0.6	0.6	0.4	0.4
				(Method) CVR	0.2	0.3	0.3	0.3	0.1	0.2
				(Peer) SDI	-0.27	0.00	0.48	0.37	0.96	1.13
				(Method) SDI	-0.24	-0.21	0.30	0.27	0.24	0.20
				# Points	534	2501	534	2503	24	136
Peer Group				Mean	36.35	36.97	139.5	139.9	280.8	278.5
Roche MODULAR				SD	1.28	1.58	3.32	4.02	9.10	10.31
				CV	3.5	4.3	2.4	2.9	3.2	3.7
				# Points	4045	21643	3763	17254	504	5602
				# Labs	35	40	22	34	31	37
Group Values by Method				Mean	37.07	38.02	138.8	138.8	283.6	285.0
				SD	4.36	4.90	7.56	9.81	24.98	25.56
				CV	11.8	12.9	5.4	7.1	8.8	9.0
				# Points	21250	298501	7679	86655	16468	267886
				# Labs	407	612	112	196	383	588

Laboratory Histogram Report

The Laboratory Histogram shows information for each analyte you have reported for the past 12 months. The histogram has a bar for each calendar month as well as a cumulative bar. Each level of control has a separate bar chart. The Laboratory Histogram plots your monthly means against the current cumulative Peer group mean $\pm 2SD$ range. For each bar, the Laboratory Histogram shows:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Number of points

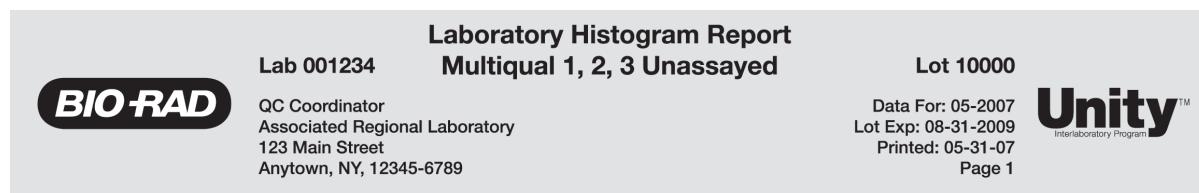
How to Use This Report

The Laboratory Histogram provides a visual comparison of your laboratory's performance to your consensus group over time. This report helps identify shifts (abrupt changes in values) and trends (gradual changes in values).

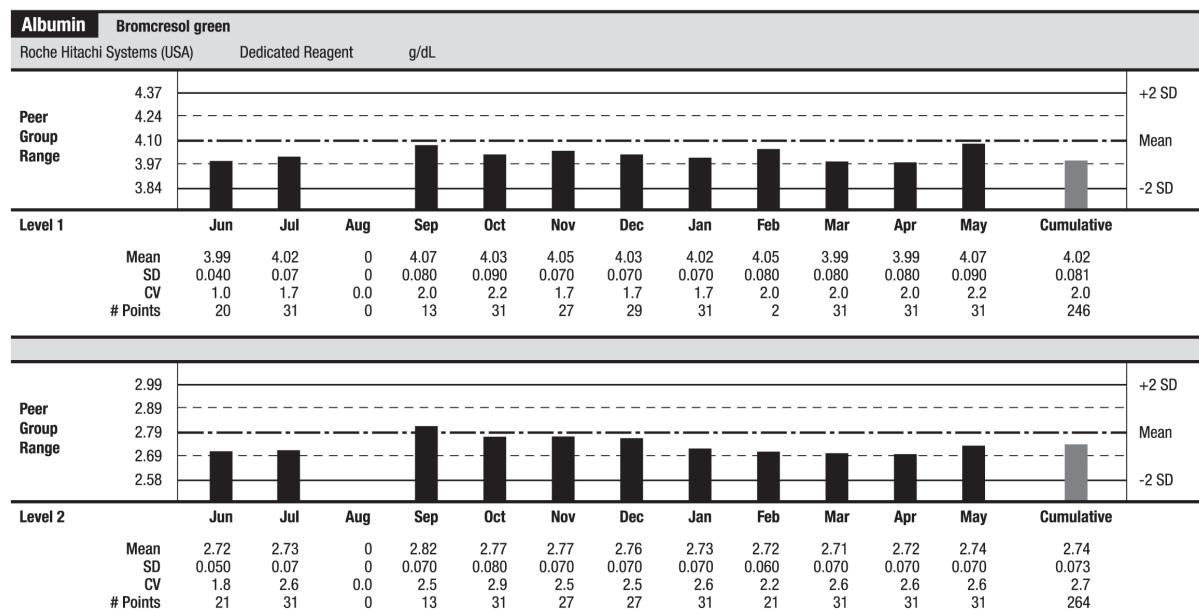


Note: If a month does not have any data points, then either there were not any values submitted, values were submitted late, or submitted values were outside of the statistical range and therefore rejected by the Unity Interlaboratory Program. If data points were rejected by the Unity Interlaboratory Program, a description appears on the Data Rejection Report.

Example Laboratory Histogram Report



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 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.



Bias and Imprecision Histogram Report

The Bias and Imprecision Histogram Report was developed based on the work of Dr. Carmen Ricos, and others in *Clinica Chimica Acta* in 2004. This report provides a graphical representation of your laboratory's bias and coefficient of variation (CV) for a lot number of Bio-Rad control product. Your monthly CV is represented as a bar and your bias is represented as a diamond with lines connecting each diamond.

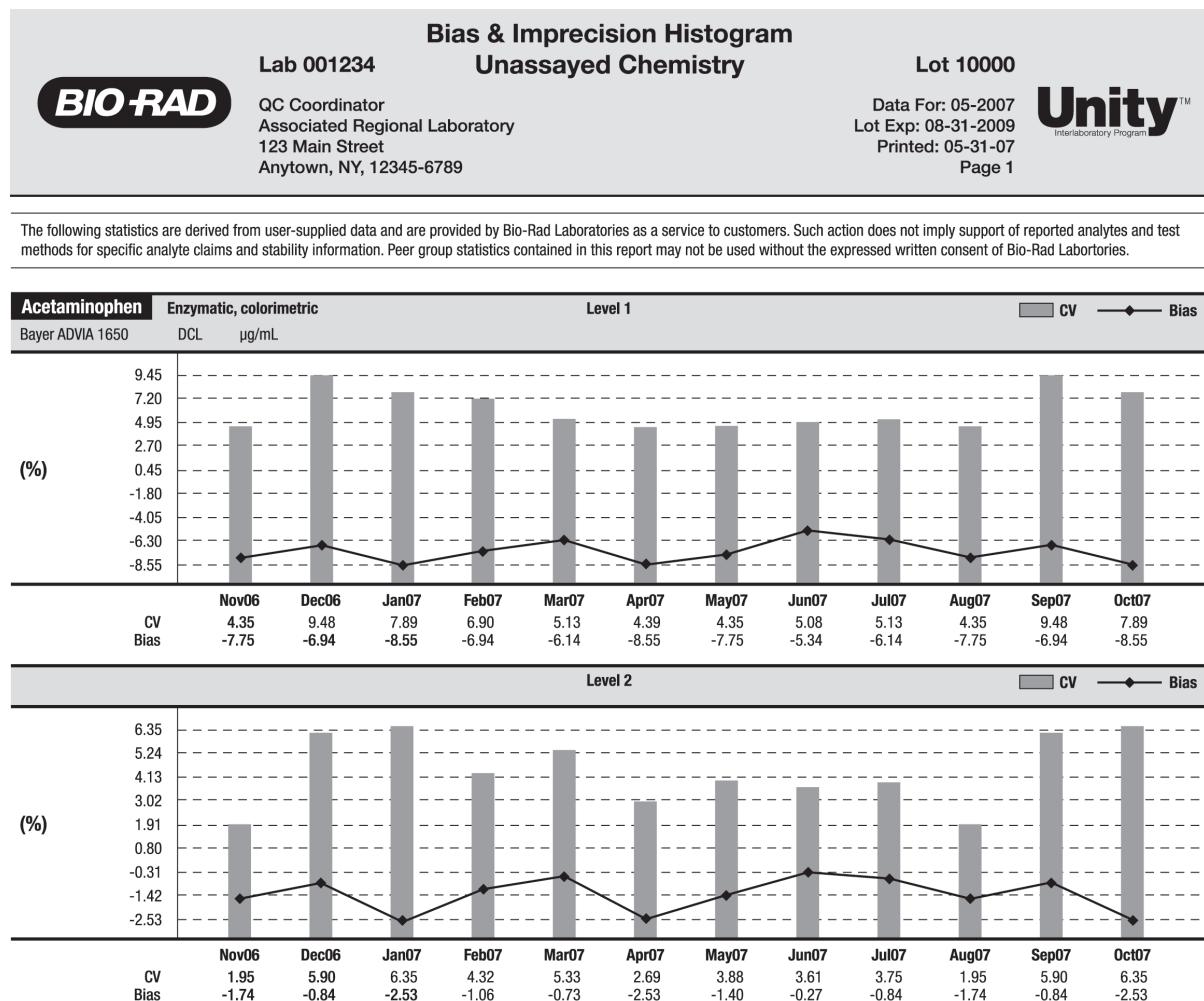
How to Use This Report

The primary use of the Bias and Imprecision Histogram is to detect changes in performance over time and to identify if changes in performance are due to bias, imprecision, or both.

Although you can use this report to detect abnormal CV or bias, the Bias and Imprecision Histogram Report does not contain specific thresholds for allowable bias or allowable imprecision.

The determination of whether a shift in performance is meaningful or problematic can be made from other metrics, including the standard deviation index (SDI) or coefficient of variation ratio (CVR) provided on the Laboratory Comparison Report or by using biological variation values for allowable bias and imprecision.

Example Bias and Imprecision Report



Comprehensive Reports

Worldwide Report

The Worldwide Report summarizes all data submitted to the Unity Interlaboratory Program. This report is available for each lot number of Bio-Rad control product.

How to Use This Report

The Worldwide Report is a good reference to use when starting a new lot number. Compare your first few data points against the consensus group already using the lot number. The Worldwide Report is also a good reference to use when evaluating a new instrument, kit, or method.

The Worldwide Report is updated every month and includes:

- All Peer group and Method group statistics.
- All tests (including all instruments, all methods, and so on) reported to the Unity Interlaboratory Program by all laboratories reporting on the same lot number.
- Monthly and cumulative statistics (mean, standard deviation, coefficient of variation, number of points, and number of laboratories) for each level of control.

Example Worldwide Report

		Worldwide Report Unassayed Chemistry				Lot 10000		
		Conventional Units						
				Data For: 05-2007	Lot Exp: 08-31-2009	Printed: 05-31-07		
				Page 1				
Analyte	Methods	Units	Temp					
	Instrument / Kit			Level 1		Level 3		
	Reagent			Mon	Cum	Mon		
Glucose						Cum		
Hexokinase		ng/mL						
Abbott AEROSET / ARCHITECT (c8000, ci8200, i2000)				Mean	87.48	87.15		
Abbott MULTIGENT				SD	2.05	2.19		
				CV	2.3	2.5		
				# Points	1331	9214		
				# Labs	39	50		
Dade Behring Dimension Series				Mean	86.23	86.71		
Dedicated Reagent				SD	2.11	2.07		
				CV	2.4	2.4		
				# Points	8679	71244		
				# Labs	220	273		
Olympus AU 400 / 600 / 640 / 2700 / 5400				Mean	87.47	87.69		
Dedicated Reagent				SD	1.83	2.00		
				CV	2.1	2.3		
				# Points	5726	49827		
				# Labs	31	36		
Roche MODULAR (ISE, D, P, E170)				Mean	87.23	87.65		
Dedicated Reagent				SD	1.91	2.02		
				CV	2.2	2.3		
				# Points	2014	13623		
				# Labs	26	26		

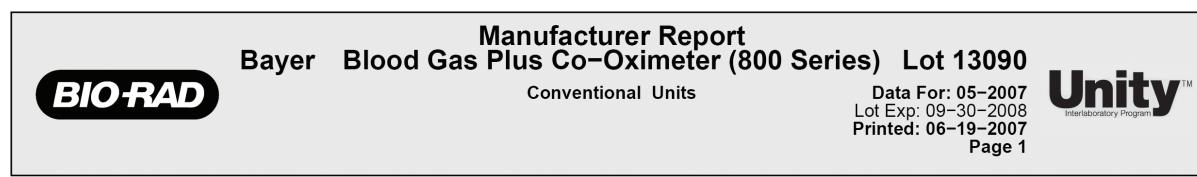
Manufacturer Report

The Manufacturer Report is a modified format of the Worldwide Report. The Manufacturer Report is identical to the Worldwide Report except it lists only the statistics for a particular manufacturer's instruments. The Manufacturer Report is updated every month.

How to Use This Report

The Manufacturer Report is a good reference to use when evaluating a new instrument, kit, or method.

Example Manufacturer Report



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 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.

Analyte Method Units Temp Instrument/Kit Reagent	Level 1		Level 2		Level 3	
	Mon	Cum	Mon	Cum	Mon	Cum
HGB (Hemoglobin, Total)						
Photometric g/dL						
Bayer Diagnostics 845						
Dedicated Reagent	Mean	0	8.05	0	12.50	0
	SD	0	0.086	0	0.124	0
	CV	0.0	1.1	0.0	1.0	0.0
	# Points	0	204	0	168	0
	# Labs	0	2	0	1	0
Bayer Diagnostics 855						
Dedicated Reagent	Mean	0	8.09	0	12.57	0
	SD	0	0.077	0	0.118	0
	CV	0.0	1.0	0.0	0.9	0.0
	# Points	0	206	0	231	0
	# Labs	0	2	0	2	0
Bayer Diagnostics 860						
Dedicated Reagent	Mean	12.89	13.10	0	20.33	34.32
	SD	0	0.131	0	0.237	0.005
	CV	0.0	1.0	0.0	1.2	0.0
	# Points	1	91	0	105	2
	# Labs	1	1	0	1	1
Bayer Diagnostics 865						
Dedicated Reagent	Mean	0	8.08	0	12.59	0
	SD	0	0.092	0	0.105	0
	CV	0.0	1.1	0.0	0.8	0.0
	# Points	0	98	0	82	0
	# Labs	0	2	0	2	0
HHb (Hemoglobin, Reduced)						

Optional Reports

Statistical Profile Report



Note: The Statistical Profile Report is optional. Contact your Bio-Rad QC Program Representative to request this report.

The Statistical Profile Report allows you to compare your laboratory's statistics to the Peer, Method, and All Labs consensus group statistics for selected time periods. The Statistical Profile Report also provides two histograms summarizing how your laboratory's mean and coefficient of variation (CV) compare to the range of mean and range of CVs calculated for each consensus group.

How to Use This Report

The Statistical Profile Report contains four major sections:

- Laboratory 2SD and 3SD Ranges
- Summary Statistics
- Frequency Histograms
- Percentile Distribution Table

Laboratory 2SD and 3SD Ranges

The Statistical Profile Report includes your laboratory's $\pm 2\text{SD}$ and $\pm 3\text{SD}$ ranges for the current quarter and this year.

Example Laboratory 2SD and 3SD Ranges

 BIO-RAD	Statistical Profile Unassayed Chemistry	Lot 10000
Lab 001234	QC Coordinator Associated Regional Laboratory 123 Main Street Anytown, NY, 12345-6789	Data For: 05-2007 Lot Exp: 08-31-2009 Printed: 05-31-07 Page 1
<small>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 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.</small>		

Albumin
 Roche MODULAR
 Bromcresol green
 g/dL
 Dedicated Reagent

	Your Lab 2s Range	Your Lab 3s Range
This Quarter	3.93 – 4.21	3.86 – 4.27
This Year	3.86 – 4.29	3.76 – 4.40

Summary Statistics

The Statistical Profile Report includes summary statistics for your laboratory and the Peer, Method, and All Labs consensus groups for the current quarter and the year.

Example Summary Statistics

	Summary Statistics (This Quarter)				Summary Statistics (This Year)			
	Your Lab	Peer Group	Method Group	All Labs	Your Lab	Peer Group	Method Group	All Labs
Median	N/A	4.10	4.07	3.83	N/A	4.10	4.08	3.83
Mean	4.07	4.10	4.07	3.84	4.08	4.10	4.08	3.84
SD	0.07	0.09	0.09	0.09	0.11	0.08	0.09	0.08
CV	1.68	2.28	2.37	2.34	2.62	2.02	2.15	2.22
/ Lab Bias /	N/A	0.77	0.04	5.92	N/A	0.64	0.12	6.20
# Labs	1	35	219	960	1	33	223	988
# Points	227	3468	28248	103592	238	3009	33254	113082

Frequency Histograms

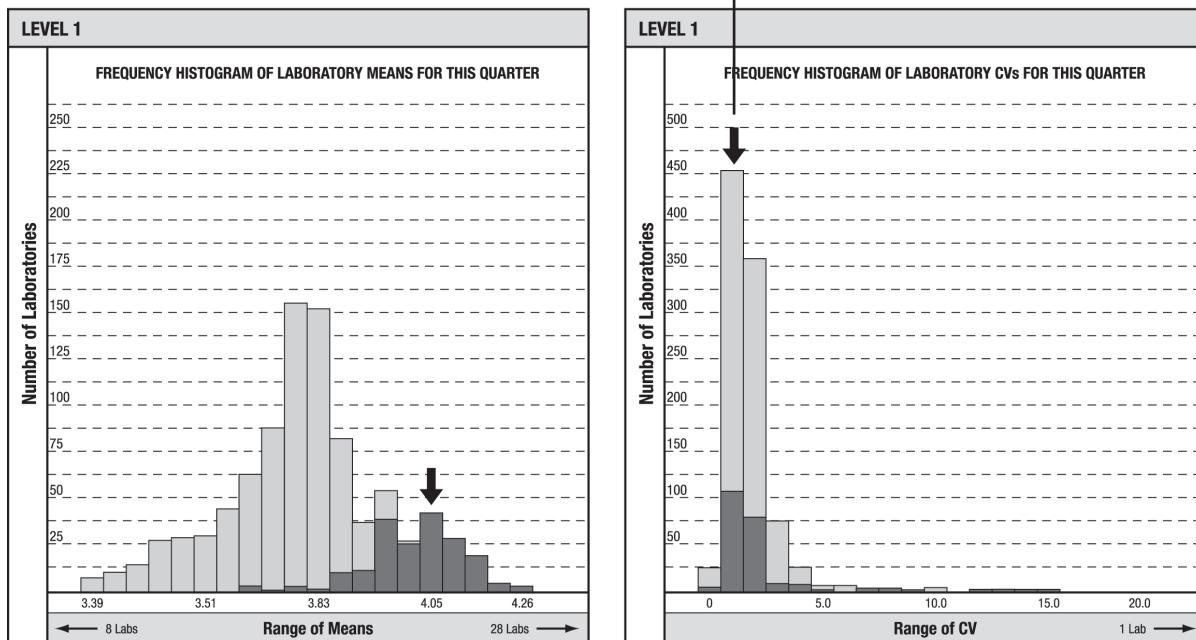
The frequency histogram section of the Statistical Profile Report contains two frequency histograms which show the location of:

- Your laboratory's means for the quarter plotted on the range of means for the Method and All Labs consensus groups.
- Your laboratory's coefficient of variation (CV) for the quarter plotted on the range of CVs for the Method and All Labs consensus groups.

Each histogram has an arrow indicating your laboratory's mean and CV values.

Example Frequency Histogram

The arrow represents your laboratory's performance so you can visually determine where your laboratory fits in the distribution of consensus groups means and CVs.



Example Percentile Distribution Table

		Percentile Distribution																			
		This Quarter										This Year									
		10°	20°	30°	40°	Median 50°	60°	70°	80°	90°	95°	10°	20°	30°	40°	Median 50°	60°	70°	80°	90°	95°
Peer	/Bias/	0.31	0.68	1.14	1.30	1.52	1.86	2.13	2.59	2.86	3.21	0.25	0.47	0.54	0.83	1.10	1.64	2.13	2.75	3.74	1.97
	SD	0.07	0.06	0.09	0.09	0.10	0.10	0.10	0.11	0.14	0.14	0.06	0.06	0.07	0.08	0.08	0.08	0.10	0.11	0.13	0.07
	CV	1.51	1.91	2.14	2.26	2.30	2.33	2.41	2.62	3.29	3.51	1.41	1.53	1.70	1.87	1.90	1.94	2.56	2.68	3.03	1.60
Method	/Bias/	0.37	0.58	0.98	1.35	1.74	2.17	2.65	4.35	7.38	11.85	0.38	0.63	1.00	1.55	1.90	2.30	3.31	4.55	7.37	12.27
	SD	0.05	0.06	0.07	0.07	0.08	0.09	0.10	0.11	0.13	0.18	0.05	0.06	0.06	0.07	0.08	0.08	0.09	0.10	0.11	0.15
	CV	1.23	1.45	1.65	1.84	1.99	2.19	2.41	2.63	3.13	4.62	1.14	1.34	1.52	1.70	1.85	1.96	2.23	2.51	2.83	3.83
All Labs	/Bias/	1.47	3.14	4.79	5.51	6.31	7.10	8.15	9.99	12.83	14.98	1.58	3.62	5.39	6.14	6.70	7.35	8.46	10.58	13.12	15.01
	SD	0.05	0.06	0.07	0.07	0.08	0.08	0.09	0.10	0.13	0.15	0.05	0.06	0.07	0.07	0.07	0.08	0.09	0.10	0.12	0.15
	CV	1.33	1.53	1.71	1.86	2.01	2.19	2.45	2.75	3.34	4.06	1.27	1.45	1.59	1.78	1.93	2.14	2.39	2.73	3.15	3.86

Affiliated Reports



Note: Affiliated Reports are optional. Contact your Bio-Rad QC Program Representative to request Affiliated Reports.

Affiliated Reports allow a group of laboratories to compare results, essentially creating their own consensus group. The Unity Interlaboratory Program provides the following Affiliated Reports:

- Affiliated Laboratory Comparison Report (page 190)
- Affiliated Laboratory Comparison Report: Abbreviated Summary (page 192)
- Affiliated Data Exception Report (page 193)



Note: It is likely an affiliated group's standard deviation index (SDI) and coefficient of variation ratio (CVR) will be different from the Bio-Rad consensus groups since the affiliated group most likely has more in common than the Bio-Rad consensus groups. For example, the laboratories in an affiliated group probably use the same reagent or calibrator lots.

Affiliated Laboratory Comparison Report

The Affiliated Laboratory Comparison Report summarizes the performance of each participating affiliated laboratory in a single report. Statistics are provided for your laboratory and all affiliated laboratories and include:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Coefficient of variation ratio (CVR) and Standard deviation index (SDI)
 - Lab to Peer Group

- Lab to Lab Group (affiliated group)
- Number of points



Tip: If your laboratories report results in both conventional and SI units, request this report in one or the other unit rather than both.

How to Use This Report

This report is designed for the Laboratory Manager or Quality Control Coordinator who is responsible for multiple sites. Use this report to compare multiple instruments made by the same manufacturer, across or within multiple sites.



Note: Each participating affiliated laboratory, Laboratory Manager, or Quality Control Coordinator can request to receive this report.

Example Affiliated Laboratory Comparison Report

Affiliated Laboratory Comparison Report			
Lab 001234	Unassayed Chemistry	Lot 00000	
BIO-RAD QC Coordinator Associated Regional Laboratory 123 Main Street Anytown, NY, 12345-6789		Data For: 01-2006 Lot Exp: 08-31-2008 Printed: 03-31-2006 Page 1	

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 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.

Analyte Methods Instrument / Kit Lab	Units Reagent	Level 1		Level 2		
		Mon	Cum	Mon	Cum	
This is an unassayed product for which there are no insert values.						
Glucose	Glucose oxidase, hydrogen peroxide (Trinder)	mg/dL				
VITROS 250 / 500 / 700						
Slide Generation #32						
254890 Associated Regional Laboratory	Mean	92.11	88.24	283.9	278.0	
	SD	1.95	2.39	5.52	5.45	
	CV	2.1	2.7	1.9	2.0	
	# Points	24	270	24	270	
Lab to Peer Group	CVR	0.8	0.9	1.0	0.9	
	SDI	2.52	0.20	1.69	0.27	
Lab to Lab Group	CVR	0.5	1.0	0.8	1.0	
	SDI	0.93	0.52	0.79	0.67	
252458 Memorial Medical Center Laboratory	Mean	88.54	88.16	277.2	276.1	
	SD	2.87	2.93	5.01	6.19	
	CV	3.2	3.3	1.8	2.2	
	# Points	34	408	36	432	
Lab to Peer Group	CVR	1.2	1.1	0.9	1.0	
	SDI	0.88	0.17	0.41	-0.03	
Lab to Lab Group	CVR	0.7	0.9	0.7	0.9	
	SDI	-0.14	-0.02	-0.30	-0.07	

Affiliated Laboratory Comparison Report: Abbreviated Summary

This report is designed for a quick review and focuses on key statistics to provide a performance summary for multiple laboratories. This report summarizes the performance of each participating affiliated laboratory in a single report. For each test, this report shows:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Number of points
- Coefficient of variation ratio (CVR) compared to the Peer, Method, and Affiliated consensus groups
- Standard deviation index (SDI) compared to the Peer, Method, and Affiliated consensus groups



Tip: If laboratories report results in both conventional and SI units, request this report appear in one or the other unit rather than both.

How to Use This Report

Use this report to statistically compare your laboratory to the Peer, Method, and Affiliated consensus groups. This report is designed for the Laboratory Manager or Quality Control Coordinator who is responsible for multiple sites.



Note: Each participating affiliated laboratory, Laboratory Manager, or Quality Control Coordinator can request to receive this report.

Example Affiliated Laboratory Comparison Report: Abbreviated Summary

Bilirubin, Direct/BC (DBIL) mg/dL cont.		Level 1								Level 2											
		Mean	SD	CV	CVR (Peer)	CVR (Method)	CVR (Affiliate)	SDI (Peer)	SDI (Method)	SDI (Affiliate)	Mean	SD	CV	CVR (Peer)	CVR (Method)	CVR (Affiliate)	SDI (Peer)	SDI (Method)	SDI (Affiliate)		
Lab	Instrument																				
170278	Associated Regional Lab 1 Roche Hitachi Systems (USA)	0.30	0.00	0.00	0.00	0.00	0.14	-0.40	0.50	1.17	3.42	0.45	0.15	0.68	-0.33	-0.63	0.34				
		0.00	0.00	31						0.04	31										
170293	Associated Regional Lab 5 Roche Hitachi Systems (USA)	0.30	0.00	0.00	0.00	0.00	0.14	-0.40	-0.50	1.20	0.00	0.00	0.00	0.00	0.00	-0.54	0.86				
		0	1							0	1										
194633	Associated Regional Lab 8 Roche Hitachi Systems (USA)	0.26	7.69	0.53	0.32	1.01	-0.79	-0.90	-1.32	1.14	7.02	0.92	0.30	1.40	-0.66	-0.73	-0.17				
		0.02	22							0.08	22										
227703	Associated Regional Lab 2 Roche Hitachi Systems (USA)	0.30	3.33	0.23	0.14	0.43	0.14	-0.40	0.50	1.12	3.57	0.47	0.16	0.72	-0.88	-0.79	-0.52				
		0.10	23							0.04	23										
Diazotization		Mean	SD	CV	# Points	# Labs				Mean	SD	CV	# Points	# Labs							
Dedicated Reagent	Peer	0.294	0.043	14.63	1690	25				1.20	0.091	7.58	1619	24							
	Method	0.332	0.080	24.10	12121	317				1.37	0.317	23.14	11676	303							
	Affiliate	0.289	0.022	7.61	77	4				1.15	0.058	5.04	77	4							

Affiliated Data Exception Report

For all laboratories within the affiliated laboratory consensus group, this report shows any analyte:

- Exceeding a specified standard deviation index (SDI) or coefficient of variation ratio (CVR) warning limit compared to the consensus group.
- Rejected by the Unity Interlaboratory Program.
- Containing a suspected coding error such as invalid unit, invalid method, and so on.

How to Use This Report

This report, in combination with the other Affiliated Reports, is ideal for a Laboratory Manager or Quality Control Coordinator who manages multiple sites or multiple instruments of the same make and model.



Note: Each participating affiliated laboratory, Laboratory Manager, or Quality Control Coordinator can request to receive this report.

Example Affiliated Data Exception Report

Affiliated Data Exception Report Multiqual 1, 2, 3 Unassayed			Lot 00000
BIO-RAD	Lab 001234	QC Coordinator Associated Regional Laboratory 123 Main Street Anytown, NY, 12345-6789	Data For: 01-2006 Lot Exp: 08-31-2008 Printed: 03-31-2006 Page 1

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 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.

SDI AND CVR WARNING

The following data exceeded prescribed SD or CVR warning limits when compared to the consensus group.

131876 Associated Regional Lab

Chloride
ISE indirect
Beckman Coulter CX Series
Dedicated Reagent
mEq/L

04-2007	Level 1	Lab Mean = 81.00	Lab SD = 0.900	Lab CV = 1.11%	Lab # Points = 32	Lab # Labs = N/A
		Peer Mean = 80.14	Peer SD = 1.76	Peer CV = 2.20%	Peer # Points = 2257	Peer # Labs = 46
		Method Mean = 75.85	Method SD = 2.55	Method CV = 3.15%	Method # Points = 22027	Method # Labs = 387
		Affiliate Mean = 81.00	Affiliate SD = 0.900	Affiliate CV = 1.11%	Affiliate # Points = 32	Affiliate # Labs = 1

Method SDI = 2.02

Acceptable values are between 0 – 2.00

DATA REJECTION

The following data was not used as a part of the Unity™ worldwide statistical database.

987654 Associated Regional Lab 1

Albumin
Bromcresol purple
Beckman Coulter CX Series
Dedicated Reagent
g/L No Temperature

04-2007	Level 1	Lab Mean = 2.5	Lab SD = 0.05	Lab CV = 2.0%	Lab # Points = 29
Acceptable Mean values are between 20.9979 – 26.2313					

480921 Associated Regional Lab 2

Albumin
Bromcresol purple
Beckman Coulter CX Series
Dedicated Reagent
g/L No Temperature

04-2007	Level 3	Lab Mean = 4.2999	Lab SD = 0.06	Lab CV = 1.39%	Lab # Points = 24
Acceptable Mean values are between 38.5843 – 44.7415					

Urinalysis Report



Note: The Urinalysis Report is optional. Contact your Bio-Rad QC Program Representative to request this report.

Customers submitting data for a Bio-Rad urinalysis product to the Unity Interlaboratory Program receive a qualitative report consisting of the following:

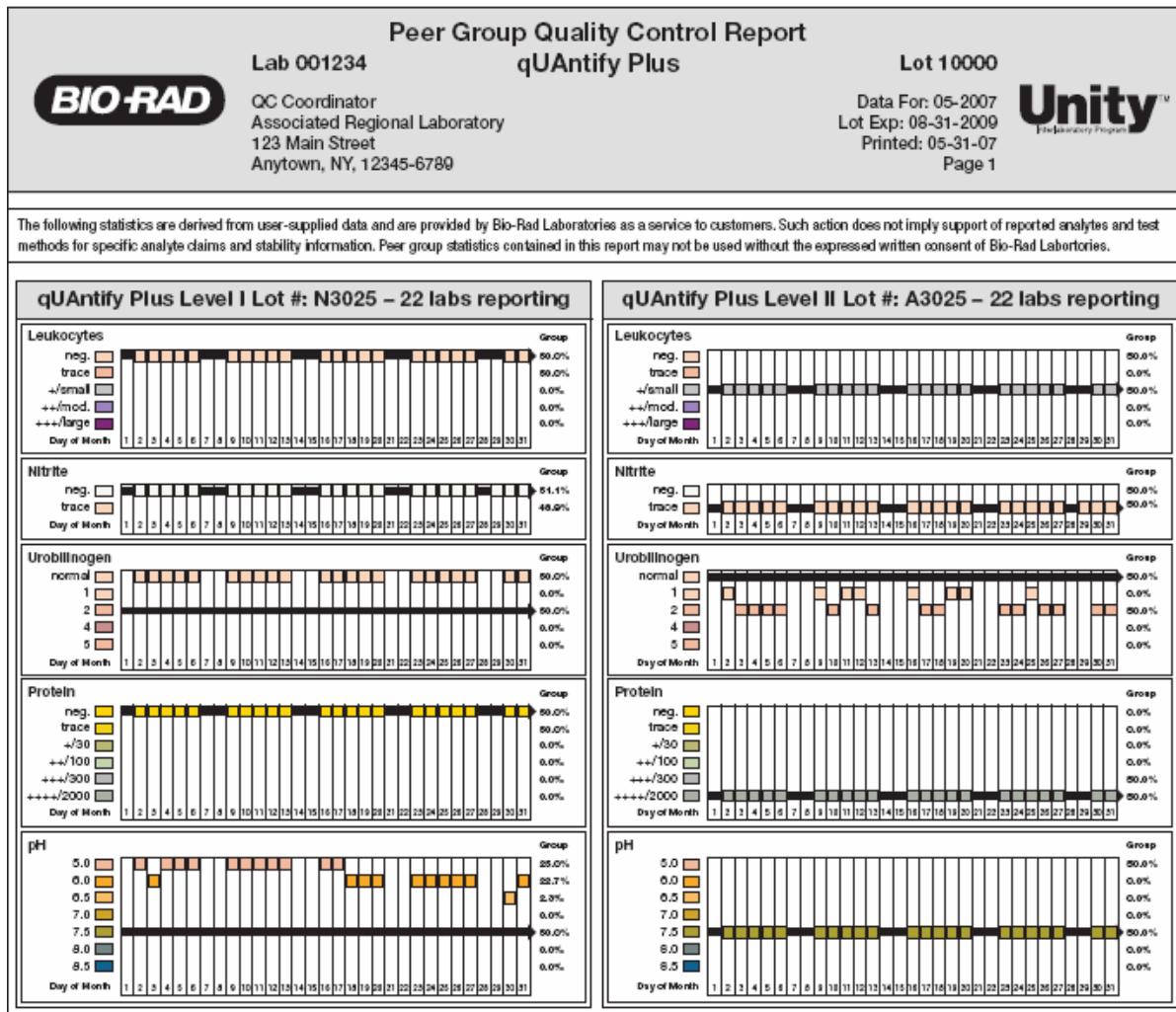
- Cover page
- Dual level chemistry report for each instrument submitted
- Dual level microscopy report for each data entry set submitted

The Urinalysis Report displays only one set of results per day. If submitting multiple sets, this report includes the one with the most recent date-time stamp.

Chemistry Section

The chemistry section of the Urinalysis Report provides a simulation of the laboratory responses versus a simulation of the group responses using the visual color changes of reagent strips. On this report, arrows identify the majority group response. The following figure shows a portion of the report.

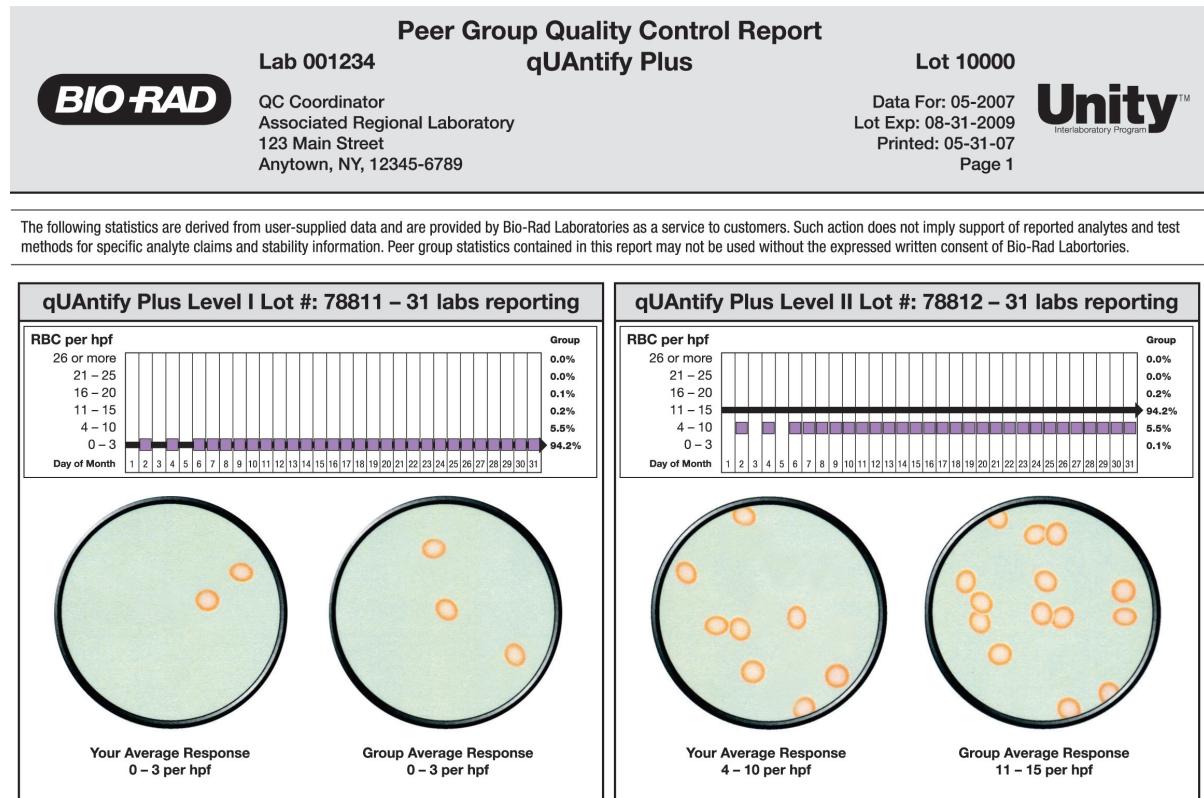
The complete report includes leukocytes, nitrite, urobilinogen, protein, pH, blood, specific gravity, ketone, bilirubin, glucose, and hCG.



Microscopy Section

Graphics on the report simulate your average response and the group's average response. Your daily responses appear above the graphics with an arrow to indicate the majority group response.

The following figure shows a portion of the report. The complete report includes RBC, WBC, and crystals.



InstantQC Reports and Charts



Note: When sending data to the Unity Interlaboratory Program from Bench Review, the reviewed data points appear on InstantQC Reports and Charts on www.QCNet.com after a short processing time. See “InstantQC” on page 137 for more information.

InstantQC Reports

The InstantQC Report is provided in HTML format. Select from a list of **Period**, **Group Type**, and **Group By** options using the lists provided.

Lab	Lot	Period	Group Type	Group By									
100014	40650 - Immunoassay Plus	1 Month	Worldwide	Peer									
Analyte	Your Lab for: 1 Month by Peer							Worldwide for: 1 Month by Peer					
	Level	Mean	SD	CV%	#Pts	SDI	Bias%	TEB%	Mean	SD	CV%	#Pts	#Labs
Ferritin Electrochemiluminescence (ECL), ng/mL, No Temperature Roche Elecsys Dedicated Reagent 5/3/2007 – 6/1/2007	1	31.44	0.76	2.4	30	-0.12	-1.07	29.74	31.78	2.81	8.84	78	37
	3	419.88	9.22	2.19	31	-0.2	-1.65	30.15	426.92	34.6	8.1	76	36
hCG, Total Electrochemiluminescence (ECL), mIU/mL, No Temperature Roche Elecsys Dedicated Reagent 5/3/2007 – 6/1/2007	1	4	0.31	7.86	31	0.2	7.53	N/A	3.72	1.41	37.93	18	37
	3	234.05	4.25	1.82	31	-0.58	-2.94	N/A	241.13	12.13	5.03	11	35
TSH Electrochemiluminescence (ECL), pIU/mL, No Temperature Roche Elecsys Dedicated Reagent 5/3/2007 – 6/1/2007	1	0.77	0.01	1.58	32	-1	-4.94	27.54	0.81	0.04	4.97	111	45
	3	16.31	0.18	1.13	33	-1.31	-5.89	27.23	17.33	0.78	4.52	127	42

Comparison Statistics Shown:

- SDI: a measurement of your bias compared to your selected consensus group
- Bias: a measurement of how far your observed value is from the target value
- TEB%: a measurement of your total error (bias and imprecision) compared to the total allowable error limits based on biological variation

How to Use This Report

This report provides summary statistics based on your selections for your laboratory and the consensus group. Comparison statistics between your laboratory and selected consensus groups are also provided.

View InstantQC Reports

- 1 Start an Internet browser window and navigate to www.QCNet.com.
- 2 Log on with your QCNet User ID and password.
- 3 Point to **Unity Interlab** and then click **Unity Reports**.
- 4 Point to **Reports**, point to **InstantQC**, and then click **Reports**.
- 5 Make a selection from each of the following lists:
 - **Lab**
 - **Lot**
 - **Period-1 day, 7 days, 30 days, 1 month, 3 months, 6 months**
 - **Group Type-Worldwide, Country, Affiliate**

- **Group By-Peer, Method, All Labs**

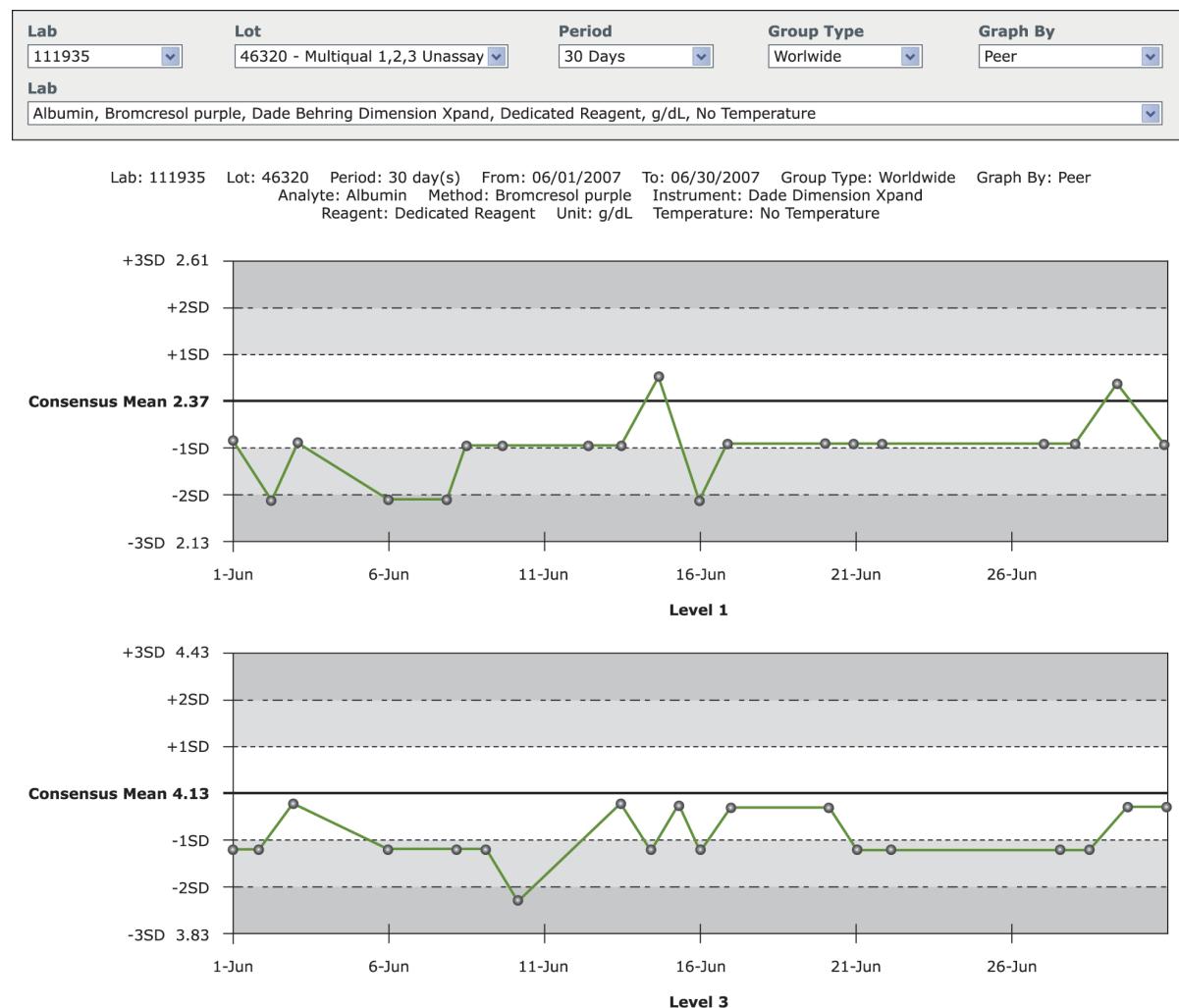
The selected report appears.

InstantQC Chart

The InstantQC Chart plots your data points for your selected date range against your selected consensus group's mean and $\pm 3SD$ range.

How to Use This Report

The InstantQC Chart is provided in HTML format. This allows you to select from a list of **Period**, **Group Type**, and **Group By** options using the lists provided.



View InstantQC Charts

- 1 Start an Internet browser window and navigate to www.QCNet.com.
- 2 Log on with your QCNet User ID and password.
- 3 Point to **Unity Interlab** and then click **Unity Reports**.
- 4 Point to **Reports**, point to **InstantQC**, and then click **Charts**.
- 5 Make a selection from each of the following lists:
 - **Lab**
 - **Lot**
 - **Period-1 day, 7 days, 30 days**
 - **Group Type-Worldwide, Country, Affiliate**
 - **Graph By-Peer, Method, All Labs**

The selected chart appears.

Regulatory Requirements and Reports

In This Chapter

Overview	201
CLIA Requirements.....	201
CAP Accreditation Requirements.....	208
ISO 15189 Requirements	220

Overview

Comparing your data to other laboratories worldwide is a major benefit of the Bio-Rad Unity Interlaboratory Program. The Unity Interlaboratory Program provides a variety of reports to help meet regulatory requirements. (See Chapter 16, “Unity Interlaboratory Reports” for more information.)

UnityWeb also provides a variety of intralaboratory reports and charts to help meet regulatory requirements. (See Chapter 13, “UnityWeb Charts” and Chapter 14, “UnityWeb Reports” for more information.)

The following pages show available reports and charts and their recommended use according to Clinical Laboratory Improvement Amendments (CLIA), College of American Pathologists (CAP), and International Organization for Standardization (ISO) 15189.

CLIA Requirements



Note: The information in this section is extracted and paraphrased from Part III Department of Health and Human Services, Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, 42 CFR Part 493 Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications, Final Rule, Friday, January 24, 2003.

CLIA Requirements—Paraphrased	
Requirement:	Have a record of test system performance.
• Intralaboratory Reports and Charts:	
Point Data Report	
Summary Data Report	
Supervisor's Report	
Operator Report	
Data Review Report	
Levey-Jennings Chart	
• Unity Interlaboratory Reports:	
Monthly Evaluation Report	
Data Rejection Report	
Laboratory Performance Overview	
Laboratory Comparison Report	
Laboratory Histogram Report	
Bias and Imprecision Histogram	
Statistical Profile Report	
Affiliated Data Exception Report	
Affiliated Laboratory Comparison Report	
• InstantQC Reports and Charts:	
InstantQC Report	
InstantQC Chart	

CLIA Requirements—Paraphrased
<p>Requirement:</p> <p>Monitor the accuracy of the analytical process.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts: Levey-Jennings Chart• Unity Interlaboratory Reports: Monthly Evaluation Report Laboratory Performance Overview Laboratory Comparison Report Laboratory Histogram Report Bias and Imprecision Histogram Statistical Profile Report Affiliated Data Exception Report Affiliated Laboratory Comparison Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart

CLIA Requirements—Paraphrased
<p>Requirement:</p> <p>Monitor the precision of the analytical process.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts: Levey-Jennings Chart• Unity Interlaboratory Reports: Monthly Evaluation Report Laboratory Performance Overview Laboratory Comparison Report Laboratory Histogram Report Bias and Imprecision Histogram Statistical Profile Report Affiliated Data Exception Report Affiliated Laboratory Comparison Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart
<p>Requirement:</p> <p>Detect immediate errors.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts: Point Data Report Supervisor's Report Operator Report Data Review Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart

CLIA Requirements—Paraphrased
<p>Requirement:</p> <p>Establish or verify the criteria for acceptability of all control materials.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts: Levey-Jennings Chart• Unity Interlaboratory Reports: Monthly Evaluation Report Data Rejection Report• InstantQC Reports and Charts: InstantQC Chart
<p>Requirement:</p> <p>Establish statistical parameters for each batch and lot number of control materials.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts: Summary Data Report Levey-Jennings Chart• Unity Interlaboratory Reports: Laboratory Comparison Report Statistical Profile Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart
<p>Requirement:</p> <p>Document all control procedures performed.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts: Data Review Report Point Data Report Supervisor's Report Levey-Jennings Chart• InstantQC Reports and Charts: InstantQC Chart

CLIA Requirements—Paraphrased
<p>Requirement:</p> <p>Document that at least once each day patient specimens are assayed or examined, test two control materials of different concentrations.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Data Review ReportPoint Data ReportSummary Data ReportLevey-Jennings Chart• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC Chart
<p>Requirement:</p> <p>For blood gas analyses, document that one sample of control material is tested each eight hours of testing using a combination of control materials that include both low and high values on each day of testing.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Data Review ReportPoint Data Report
<p>Requirement:</p> <p>Evaluate and define the relationship between test results for the same analyte using different methodologies, instruments, or testing sites.</p>
<ul style="list-style-type: none">• Unity Interlaboratory Reports:<ul style="list-style-type: none">Affiliated Data Exception ReportAffiliated Laboratory Comparison Report
<p>Requirement:</p> <p>Document all corrective actions taken as a result of QC.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Data Review ReportPoint Data ReportSupervisor's Report• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation Report

CLIA Requirements—Paraphrased	
Requirement:	Document all analytic systems assessment activities.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<p>Data Review Report</p> <p>Point Data Report</p> <p>Supervisor's Report</p>
<ul style="list-style-type: none">• Unity Interlaboratory Reports:	<p>Monthly Evaluation Report</p> <p>Laboratory Performance Overview</p> <p>Laboratory Comparison Report</p> <p>Laboratory Histogram Report</p> <p>Bias and Imprecision Histogram</p> <p>Statistical Profile Report</p>
Requirement:	Document that, over time, control material testing is rotated among all operators who perform the test.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<p>Data Review Report</p> <p>Point Data Report</p> <p>Supervisor's Report</p> <p>Levey-Jennings Chart</p>
Requirement:	Document that control material testing is performed after a complete change of reagent, major preventive maintenance, or when any critical part is replaced.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<p>Data Review Report</p> <p>Point Data Report</p> <p>Supervisor's Report</p>

CAP Accreditation Requirements



Note: The information in this section is extracted and paraphrased from requirements published by the College of American Pathologists and the Joint Commission on Accreditation of Healthcare Organizations.

CAP Accreditation Requirements—Paraphrased

Requirement:

Document validation of new reagent lots or shipments of reagents.

- **Intralaboratory Reports and Charts:**

Point Data Report

Summary Data Report

Supervisor's Report

Operator Report

Data Review Report

Levey-Jennings Chart

Requirement:

Document calibration or recalibration when controls fail to meet established criteria.

- **Intralaboratory Reports and Charts:**

Point Data Report

Supervisor's Report

Data Review Report

CAP Accreditation Requirements—Paraphrased
Requirement:
Use data to make changes to improve performance and patient safety.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportOperator ReportData Review ReportLevey-Jennings Chart• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation ReportData Rejection ReportLaboratory Performance OverviewLaboratory Comparison ReportLaboratory Histogram ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Data Exception ReportAffiliated Laboratory Comparison Report• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC Chart

CAP Accreditation Requirements—Paraphrased
<p>Requirement:</p> <p>For quantitative tests, document use of control materials at more than one concentration (level) at least daily.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportData Review ReportLevey-Jennings Chart• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC Chart
<p>Requirement:</p> <p>For numeric QC data, document calculation of QC statistics at specified intervals to define analytic imprecision.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Summary Data Report• Unity Interlaboratory Reports:<ul style="list-style-type: none">Laboratory Comparison ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Laboratory Comparison Report• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC ReportInstantQC Chart

CAP Accreditation Requirements—Paraphrased	
Requirement:	Demonstrate that QC and instrument maintenance are performed and evaluated.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<p>Point Data Report</p> <p>Supervisor's Report</p> <p>Data Review Report</p>
<ul style="list-style-type: none">• Unity Interlaboratory Reports:	<p>Monthly Evaluation Report</p>
<ul style="list-style-type: none">• InstantQC Reports and Charts:	<p>InstantQC Chart</p>
Requirement:	Document verification results of controls for acceptability before reporting patient test results.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<p>Point Data Report</p> <p>Supervisor's Report</p> <p>Data Review Report</p> <p>Levey-Jennings Chart</p>
Requirement:	For hematology, document testing of two different stabilized control specimens and record results during each 24 hours of analyzer use.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<p>Point Data Report</p> <p>Summary Data Report</p> <p>Supervisor's Report</p> <p>Data Review Report</p> <p>Levey-Jennings Chart</p>
<ul style="list-style-type: none">• InstantQC Reports and Charts:	<p>InstantQC Chart</p>

CAP Accreditation Requirements—Paraphrased
<p>Requirement:</p> <p>If commercially assayed controls are used for hematology instruments, verify the target values (mean and QC ranges).</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts: Operator Report• Unity Interlaboratory Reports: Laboratory Comparison Report Laboratory Histogram Report Statistical Profile Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart
<p>Requirement:</p> <p>If unassayed controls are used in hematology, establish a statistically valid target mean and range for each lot by repetitive analysis.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts: Operator Report• Unity Interlaboratory Reports: Laboratory Comparison Report Laboratory Histogram Report Statistical Profile Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart

CAP Accreditation Requirements—Paraphrased
Requirement: Fully define and document tolerance limits (numeric and nonnumeric) for all hematology and coagulation control procedures.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts: Point Data Report Summary Data Report Supervisor's Report Operator Report Data Review Report Levey-Jennings Chart• InstantQC Reports and Charts: InstantQC Chart
Requirement: Monitor precision data for significant changes.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts: Levey-Jennings Chart• Unity Interlaboratory Reports: Monthly Evaluation Report Data Rejection Report Laboratory Performance Overview Laboratory Histogram Report Bias and Imprecision Histogram Affiliated Data Exception Report Affiliated Laboratory Comparison Report• InstantQC Reports and Charts: InstantQC Report InstantQC Chart

CAP Accreditation Requirements—Paraphrased	
Requirement:	Document review and assessment of quality control data at least monthly.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<ul style="list-style-type: none">Summary Data ReportSupervisor's ReportLevey-Jennings Chart
<ul style="list-style-type: none">• Unity Interlaboratory Reports:	<ul style="list-style-type: none">Monthly Evaluation ReportData Rejection ReportLaboratory Performance OverviewLaboratory Comparison ReportLaboratory Histogram ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Data Exception ReportAffiliated Laboratory Comparison Report
<ul style="list-style-type: none">• InstantQC Reports and Charts:	<ul style="list-style-type: none">InstantQC ReportInstantQC Chart
Requirement:	Verify manufacturer's calibrations with control materials appropriate for the system.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<ul style="list-style-type: none">Data Review Report
Requirement:	Document that the photo-optical coagulation testing system (for PT, aPTT, and so on) is checked with two different levels of control material during each eight hours of patient testing and each time there is a change in reagents.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<ul style="list-style-type: none">Point Data ReportSupervisor's ReportData Review Report

CAP Accreditation Requirements—Paraphrased
<p>Requirement:</p> <p>Document that the manual coagulation system is checked with two different levels of control material in duplicate during each eight hours of patient testing and each time there is a change of reagents.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSupervisor's ReportData Review Report
<p>Requirement:</p> <p>Document ongoing evaluation of (QC) records, instrument maintenance and function, temperature, etc.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Data Review Report• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation ReportLaboratory Performance Overview• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC Chart
<p>Requirement:</p> <p>Organize and present QC data so that it can be evaluated daily by the technical staff to detect problems, trends, etc.</p> <ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportLevey-Jennings Chart• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC ReportInstantQC Chart

CAP Accreditation Requirements—Paraphrased
<p>Requirement:</p> <p>Document that at least one quality control specimen for pH, pCO₂, and pO₂ (tonometered sample or liquid control material) is tested at least every eight hours of operation when patient specimens are tested.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSupervisor's ReportData Review Report
<p>Requirement:</p> <p>Document that control materials for pH, pCO₂, and pO₂ represent both high and low values on each day of patient testing.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSupervisor's ReportData Review ReportLevey-Jennings Chart• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC ReportInstantQC Chart
<p>Requirement:</p> <p>Document that one sample of control material for pH, pCO₂, and pO₂ is included each time patient samples are tested, except for automated instruments that internally calibrate at least once every 30 minutes of use.</p>
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSupervisor's ReportData Review Report

CAP Accreditation Requirements—Paraphrased	
Requirement:	Document the review for acceptability of quality control results.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportOperator ReportData Review ReportLevey-Jennings Chart• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation ReportLaboratory Performance OverviewBias and Imprecision Histogram	

CAP Accreditation Requirements—Paraphrased	
Requirement:	Collect and analyze pertinent data to monitor and assess performance.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:	<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportOperator ReportData Review ReportLevey-Jennings Chart
<ul style="list-style-type: none">• Unity Interlaboratory Reports:	<ul style="list-style-type: none">Monthly Evaluation ReportData Rejection ReportLaboratory Performance OverviewLaboratory Comparison ReportLaboratory Histogram ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Data Exception ReportAffiliated Laboratory Comparison Report
<ul style="list-style-type: none">• InstantQC Reports and Charts:	<ul style="list-style-type: none">InstantQC ReportInstantQC Chart

CAP Accreditation Requirements—Paraphrased
Requirement:
Use data to identify unwanted trends.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportOperator ReportData Review ReportLevey-Jennings Chart• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation ReportData Rejection ReportLaboratory Performance OverviewLaboratory Comparison ReportLaboratory Histogram ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Data Exception ReportAffiliated Laboratory Comparison Report• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC ReportInstantQC Chart

ISO 15189 Requirements

ISO 15189 Requirements
Requirement:
Design internal quality control systems to verify the intended quality of results.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportOperator ReportData Review ReportLevey-Jennings Chart• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation ReportData Rejection ReportLaboratory Performance OverviewLaboratory Comparison ReportLaboratory Histogram ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Data Exception ReportAffiliated Laboratory Comparison Report• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC ReportInstantQC Chart

ISO 15189 Requirements
Requirement:
Provide staff members with clear and easily understood information on which to base technical and medical decisions.
<ul style="list-style-type: none">• Intralaboratory Reports and Charts:<ul style="list-style-type: none">Point Data ReportSummary Data ReportSupervisor's ReportOperator ReportData Review ReportLevey-Jennings Chart• Unity Interlaboratory Reports:<ul style="list-style-type: none">Monthly Evaluation ReportData Rejection ReportLaboratory Performance OverviewLaboratory Comparison ReportLaboratory Histogram ReportBias and Imprecision HistogramStatistical Profile ReportAffiliated Data Exception ReportAffiliated Laboratory Comparison Report• InstantQC Reports and Charts:<ul style="list-style-type: none">InstantQC ReportInstantQC Chart

Westgard Advisor online

In This Chapter

Overview	222
Configure Westgard Advisor online	223
Generate Rules with Westgard Advisor online.....	227
Apply Rules with Westgard Advisor online	231
Westgard Advisor online Report.....	232
Delete Historical Suggestions	234
OPSpecs Chart	234

Overview

Westgard Advisor online is an optional feature of UnityWeb that identifies the tests needing improvement and the tests routinely achieving the required quality. Westgard Advisor online uses the following information to recommend statistical process control (SPC) rules, and the number of control samples per run:

- Data for the test
- A selected TE_a
- A selected consensus group

The consensus group can be a date range of the laboratory's data or a Unity Interlaboratory consensus group (Peer, Method, or All Labs).

Using Westgard Advisor online, it is possible to generate rules based on different combinations of these selections, display the OPSpecs Chart, and apply the suggested SPC rules.

Westgard Advisor online always provides suggestions. However, if a method has poor performance, Westgard Advisor online is not able to recommend a set of SPC rules that will solve performance problems. When no multirule meets the quality specification, Westgard Advisor online reports a maximum QC condition and recommends all available multirules.



Note: The rules suggested by Westgard Advisor online are recommendations only. Conditions in the laboratory may make some rules impossible to use.

View Existing QC Rules

- 1 Click the **Advisors** tab.
- 2 Click **Existing QC Rules**.

The **Existing QC Rules** dialog box shows the rules currently applied.



Note: If SPC rules have not been previously generated and applied using Westgard Advisor online, the default rules appear based on the levels of control material set up in UnityWeb.

- 3 If more than one lab number is set up in the software, select a lab from the **Lab Number** list to view the existing rules for another lab number.
- 4 If more than one lot number is set up in the software, select a lot from the **Lot Number** list to view the existing rules for another lot number.

View Lab Data and Group Statistics

- 1 Click the **Advisors** tab.
- 2 Click **Lab Data and Group Stats**.
- 3 Select a lab number from the **Lab number** list.
- 4 Select a lot number from the **Lot number** list.
- 5 Select a test from the **Test** list.
- 6 Select an option for the data:
 - **Lab Data**
Shows the mean, coefficient of variation (CV), and number of points for each available level by calendar month for the selected lab number and test.
 - **Group Statistics**
Shows the cumulative mean, coefficient of variation (CV), Bias (%), number of labs, and number of points for the laboratory and the mean, coefficient of variation (CV), Bias (%), number of labs, and number of points for each consensus group from the Unity Interlaboratory Program.

Configure Westgard Advisor online

Before generating rules for a test, configure the quality requirements (total allowable error) for the test and specify the data requirements.

Total Allowable Error (TE_a) Options

Westgard Advisor online uses a default TE_a for each test. To change the default TE_a , choose one of the following TE_a options.



Note: Not all options are available for all tests.

- $\pm 3SD$ limits based on the data for the test
- Biological Variation (BV) Desirable
- Biological Variation (BV) Minimum
- Biological Variation (BV) Optimal
- CLIA (USA)
- QMP-LS (Canada–Ontario)
- RCPA limits (Australia)



Note: Limits such as BV, CLIA, QMP-LS, and RCPA are only available when published.

- User Defined
- Tightest (smallest TE_a available)
- Loosest (largest TE_a available)
- State of the Art based on the median coefficient of variation (CV) of a selected consensus group

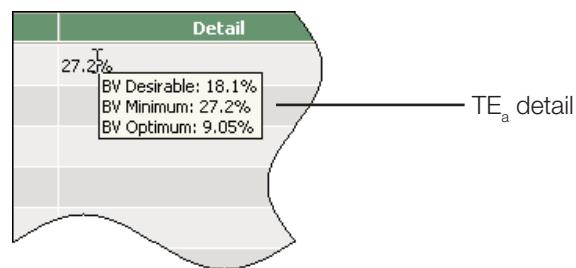


Note: When generating rules, Westgard Advisor online displays a message if statistics are not available for a consensus group.

View TE_a Details

- 1 Click the **Advisors** tab.
- 2 Click **Configure TEa**.
- 3 In the **Detail** column, position the mouse on top of the detail.

The values for the TE_a selection appear in a box.



Configure the TE_a for an Analyte

- 1 Click the **Advisors** tab.
- 2 Click **Configure TEa**.

Each analyte appears with the current TE_a selection.



Note: An asterisk (*) indicates the default TE_a options.

- 3 Select a TE_a from the list to change the default TE_a for the analyte.



Note: Limits such as BV, CLIA, QMP-LS, and RCPA are only available when published.

- 4 Click **Save**.



Note: Westgard Advisor online uses the TE_a selections when generating rules with the Wizard or the Advanced method. If using the Default method, Westgard Advisor online uses the default TE_a options regardless of the selections made.

Configure the TE_a for All Analytes

- 1 Click the **Advisors** tab.
- 2 Click **Configure TEa**.

Each analyte appears with the current TE_a selection.



Note: An asterisk (*) indicates the default TE_a options.

- 3 Select a TE_a from the list located to the left of **For All Analytes**.



Note: Limits such as BV, CLIA, QMP-LS, and RCPA are only available when published.

- 4 Click **For All Analytes** to apply the TE_a selection to all analytes for which it is available.



Note: If the TE_a is not available for the analyte (for example CLIA limits for zinc), the existing selection remains unchanged.

- 5 Click **Save**.



Note: Westgard Advisor online uses the TE_a selections when generating rules with the Wizard or the Advanced method. If using the Default method, Westgard Advisor online uses the default TE_a options regardless of the selections made.

Return TE_a Selections to the Default

- 1 Click the **Advisors** tab.
- 2 Click **Configure TEa**.

Each analyte appears with the current TE_a selection.



Note: An asterisk (*) indicates the default TE_a options.

- 3 Click **Set All to Default**.



Note: Westgard Advisor online uses the TE_a selections when generating rules with the Wizard or the Advanced method. If using the Default method, Westgard Advisor online uses the default TE_a options regardless of the selections made.

- 4 Click **Save**.

Data Requirements

Westgard Advisor online provides a default set of data requirements to use for suggesting rules; however, you can customize data requirements.



Important: Westgard Advisor online will not generate rules for a test until the minimum data requirements are met.

- Lab data points (default—minimum of 20)
- Consensus group data points (default—minimum of 100)
- Consensus group labs (default—minimum of 5)



Note: See “View Lab Data and Group Statistics” on page 223 to view consensus group data. If consensus group data does not appear for a test or if the consensus group is unexpectedly small, confirm that the test parameters (analyte, instrument, method, and so on) are correct. If necessary, update the test. See “Update Tests” on page 86 for more information.

Specify Data Requirements

- 1 Click the **Advisors** tab.
- 2 Click **Preferences**.
- 3 Type the minimum number of data requirements in each of the **Minimum Number** boxes.
- 4 Click **Save**.



Note: Click **Default** to return to the default settings.

Grid Display Options

Grid Display Options determine the information appearing on the **Design QC Rules** dialog box. The software provides a default set of options; however, you can customize Grid Display Options.

Select Grid Display Options

- 1 Click the **Advisors** tab.
- 2 Click **Preferences**.
- 3 Select the check box for each item to appear on the **Design QC Rules** dialog box. Clear the check box to remove an item.
- 4 Click **Save**.



Note: Click **Default** to return to the default settings.

Generate Rules with Westgard Advisor online

There are three methods for generating SPC rules with Westgard Advisor online:

- Westgard Advisor online Wizard

Westgard Advisor online guides you through the process by presenting a series of dialog boxes from which you select options.



Tip: The Westgard Advisor online Wizard contains text in each dialog box explaining the options. As a result, it is a good method to use when unfamiliar with Westgard Advisor online.

- Advanced option

Westgard Advisor online displays a single dialog box for selecting all options.



Tip: This advanced option is a good choice when familiar with Westgard Advisor online since this option does not provide any explanatory text.

- Defaults

Westgard Advisor online generates rules based on its default options. The default selections are:

- Peer consensus group
- 6-months (date range for data)
- Smallest TE_a



Note: Changes cannot be made when using the default method.

Consensus Groups

Westgard Advisor online uses consensus groups from the Unity Interlaboratory Program to calculate performance estimates.



Note: Westgard Advisor online will not be able to generate rules for a test if there are not any statistics available for the selected consensus group.

The following consensus groups are available:

- **Peer** (most specific)

The Peer consensus group is the ideal group for comparison. It is composed of all laboratories using the same instrument, lot number, level, reagent, analytical method, units, and temperature of a test.

- **Method** (next specific)

Choose the Method consensus group when there is an insufficient number of laboratories in the Peer group. It is composed of all laboratories using the same lot number, level, analytical method, units, and temperature of a test.

- **All Labs** (least specific)

The All Labs consensus group is composed of data from all laboratories using for the same lot number, level, units, and temperature of a test.

Use the Westgard Advisor online Wizard

1 Click the **Advisors** tab.

2 Click **Design QC Rules**.

3 Select the lab number from the **Lab number** list.

4 Select the lot number from the **Lot number** list.

5 Click the **Generate Rule Suggestions** link.

The **Westgard Advisor Configure Rule Selection** dialog box appears.

6 Select the **Wizard** option and click **OK**.

7 The **Configure Rule Selection Wizard – Step 1 of 4** dialog box appears with two rule generation options:

- **All lot numbers**

Select this option to generate rules for all identical tests in all lot numbers within the lab number.

- **Specific lot number**

Select this option to generate rules only for tests within the selected lab and lot combination.

8 Click **Next**.

The **Configure Rule Selection Wizard – Step 2 of 4** dialog box appears with the following message:

What date range should be used to compute performance estimates from your laboratory data?

- 9 Click the arrow located to the right of **First Date** and select a beginning date for the range of data.



Important: The data within the **Lab Data Range** is used to compute performance estimates such as the mean and coefficient of variation (CV) of the laboratory. Select a representative sample of laboratory data that correlates with the performance expected to achieve in the future.

- 10 Click the arrow located to the right of **Last Date** and select an ending date for the range of data.

- 11 Click **Next**.

The **Configure Rule Selection Wizard – Step 3 of 4** dialog box appears with the following message:

Which level should be used to compute performance estimates from your laboratory data?

SPC rules are suggested by analyte. If testing more than one level of control, select a single level to compute performance estimates for the analyte.

- 12 Select an option for the lot:

- **By Level**

Select this option to specify a control level to use for the calculations.

The level selected is used for all tests. Select a level from the **By Level** list.

- **By Performance**

Select this option for Westgard Advisor online to evaluate performance statistics from all available levels for each analyte and select an option for the performance:

- **Highest Total Error** (resulting in conservative settings)
- **Lowest Total Error** (resulting in optimistic settings)

- 13 Click **Next**.

The **Configure Rule Selection Wizard – Step 4 of 4** dialog box appears with the following message:

Which Group do you want to compare to?

Performance estimates can include bias if a consensus group is selected for comparison. Select **This Lab** to omit bias from the performance estimates. Otherwise, select **Peer**, **Method**, or **All Labs** for the appropriate consensus group comparison.

- 14 Select a consensus group option and click **Finish**.

By default, the **Grid** option of the **Design QC Rules** dialog box appears and shows the suggested rules and other statistics.

- 15 Select the **Chart** option to view the OPSpecs Chart for the suggested rules. See “OPSpecs Chart” on page 234 for more information.

Use the Advanced Option

- 1 Click the **Advisors** tab.
 - 2 Click **Design QC Rules**.
 - 3 Select the lab number from the **Lab number** list.
 - 4 Select the lot number from the **Lot number** list.
 - 5 Click the **Generate Rule Suggestions** link.

The **Westgard Advisor Configure Rule Selection** dialog box appears.
 - 6 Select the **Advanced** option and click **OK**.

The **Westgard Advisor Advanced Rule Selection** dialog box appears.
 - 7 Select a **Lot Number Selection** option:
 - **All Lot Numbers**

Select this option to generate rules for all identical tests in all lot numbers within the lab number.
 - **Lot number NNNNN** (where NNNNN is a specific lot number)

Select this option to generate rules only for tests within the selected lab and lot combination.
 - 8 Select a **Lot Selection** option:
 - **By Level**

Select this option to specify a control level to use for the calculations and then select a level from the **By Level** list.
 - **By Performance**

Select this option for Westgard Advisor online to evaluate performance statistics from all available levels for each analyte and select an option for the performance:

 - **Use level with lowest Total Error** (resulting in optimistic settings)
 - **Use level with highest Total Error** (resulting in conservative settings)
 - 9 Click the arrow located to the right of **First Date** and select a beginning date for the range of data.
-  **Important:** The data within the **Lab Data Range** is used to compute performance estimates such as the mean and coefficient of variation (CV) of the laboratory. Select a representative sample of laboratory data that correlates with the performance expected to achieve in the future.
- 10 Click the arrow located to the right of **Last Date** and select an ending date for the range of data.
 - 11 Select a **Group** option.

Performance estimates can include bias if a consensus group is selected for comparison. Select **This Lab** to omit bias from the performance estimates. Otherwise, select **Peer**, **Method**, or **All Labs** for the appropriate consensus group comparison.
 - 12 Select a **Group Data Range** option:

- **Monthly**
- **6 months**
- **Cumulative**

13 Click **OK**.

By default, the **Grid** option of **Design QC Rules** dialog box appears and shows the suggested rules and other statistics.

14 Select the **Chart** option to view the OPSpecs Chart for the suggested rules. See “OPSpecs Chart” on page 234 for more information.

Use the Westgard Advisor online Defaults



Note: Changes cannot be made to any selections or changes when using the default method.

- 1 Click the **Advisors** tab.
- 2 Click **Design QC Rules**.
- 3 Select the lab number from the **Lab number** list.
- 4 Select the lot number from the **Lot number** list.
- 5 Click the **Generate Rule Suggestions** link.

The **Westgard Advisor Configure Rule Selection** dialog box appears.

- 6 Select the **Use Defaults** option and click **OK**.

By default, the **Grid** option of **Design QC Rules** dialog box appears and shows the suggested rules and other statistics.

7 To view the OPSpecs Chart for the suggested rules, select the **Chart** option. See “OPSpecs Chart” on page 234 for more information.

Apply Rules with Westgard Advisor online

After Westgard Advisor online generates rules, the recommendations appear in the **Suggested Rules** column on the **Design QC Rules** dialog box.

Apply Rules

- 1 Click the **Advisors** tab.
- 2 Click **Design QC Rules**.
- 3 Select the lab number from the **Lab number** list.
- 4 Select the lot number from the **Lot number** list.
- 5 Select the desired Historical Suggestion.
- 6 Make sure the **Grid** option is selected.
- 7 Click the **Apply Suggested Rules** link.

The **Westgard Advisor Apply Suggested Rules** dialog box appears and shows the statistics, existing rules, suggested rules, and performance information for each analyte.

By default, the check box located to the left of each analyte is selected. This indicates the suggested rules will be applied to each analyte.



Note: If Westgard Advisor online is unable to generate rules for a test, the check box is cleared and the **Suggested Rules** column shows the reason rules could not be generated. If there are not any rules available, the check box cannot be selected.

- 8 Clear the check box or click **Select None** to clear all check boxes. A cleared check box indicates there will not be any rules applied.
- 9 Click **Apply**.
- 10 Repeat steps 5–9 to make additional changes based on other Historical Suggestion selections.
- 11 The new rule selection(s) appear on the **Rules** tab of the **Rules/Settings** dialog box and UnityWeb evaluates new data points against the rules. (See Chapter 9, “Apply QC Rules” on page 97 for more information about the **Rules** tab.)

Westgard Advisor online Report

The Westgard Advisor online Report summarizes the options used each time SPC rules are generated with Westgard Advisor online. The Westgard Advisor online Report shows the information from the **Grid** and **Chart** options of the **Design QC Rules** dialog box. Print the report to document the selected rules.



Note: The Westgard Advisor online Report is only available for tests for which rules have previously been generated.

Print the Westgard Advisor online Report

- 1 Click the **Advisors** tab.
- 2 Click **Design QC Rules**.
- 3 Select the **Chart** option.
- 4 Click the **Print Chart** link.
- 5 The **Westgard Advisor Print Chart** dialog box appears.
- 6 Select an option for the range of tests to print:

- **Current Test**

Select this option to print the report for the selected test.

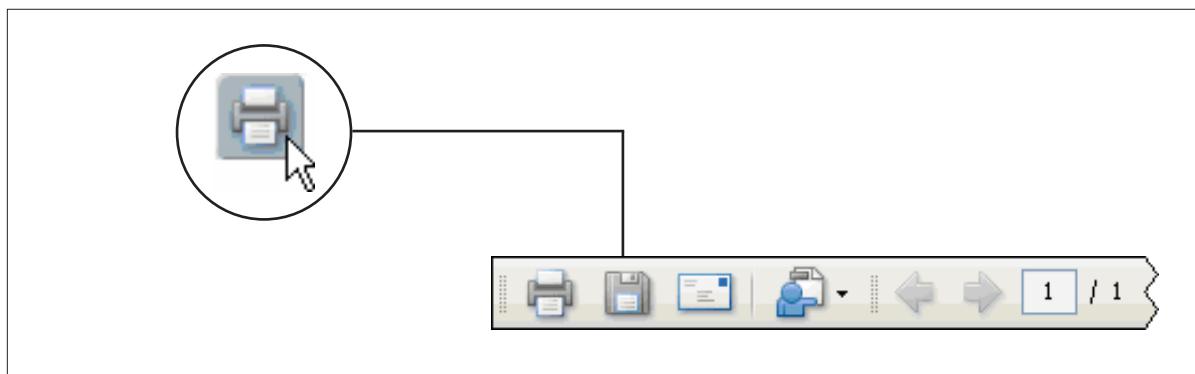
- **All Tests**

Select this option to print the report for all tests in the lot number.

- 7 Click **Print to PDF**.

The Westgard Advisor online Report appears in a separate window in PDF format.

- 8 Click the printer icon.



The **Print** dialog box appears.

- 9 Select the appropriate options for the printer and click **OK**.

Delete Historical Suggestions

Rules suggestions are saved each time SPC rules are generated using Westgard Advisor online. Delete the suggestions if they are no longer needed.



Note: Deleting historical suggestions does not delete any applied rules.

- 1 Click the **Advisors** tab.
- 2 Click **Design QC Rules**.
- 3 Select the lab number from the **Lab number** list.
- 4 Select the lot number from the **Lot number** list.
- 5 Click the **Delete Historical Suggestions** link.

A separate dialog box opens and shows the **Date Generated**, **Lab Data Range**, **Lot Selection**, and **Group**.

- 6 Select the check box located to the left of the historical selection to delete or click **Select All** to delete all historical selections.
- 7 Click **Delete**.

OPSpecs Chart

An OPSpecs (operational process specifications) Chart plots the allowable bias versus the allowable imprecision. An OPSpecs Chart describes the imprecision, bias, SPC rules, and number of runs required to assure a defined quality requirement will be achieved with a known level of analytical quality assurance (AQA). An OPSpecs Chart provides the information needed to select appropriate quality control procedures and is therefore an integral part of Westgard Advisor online.

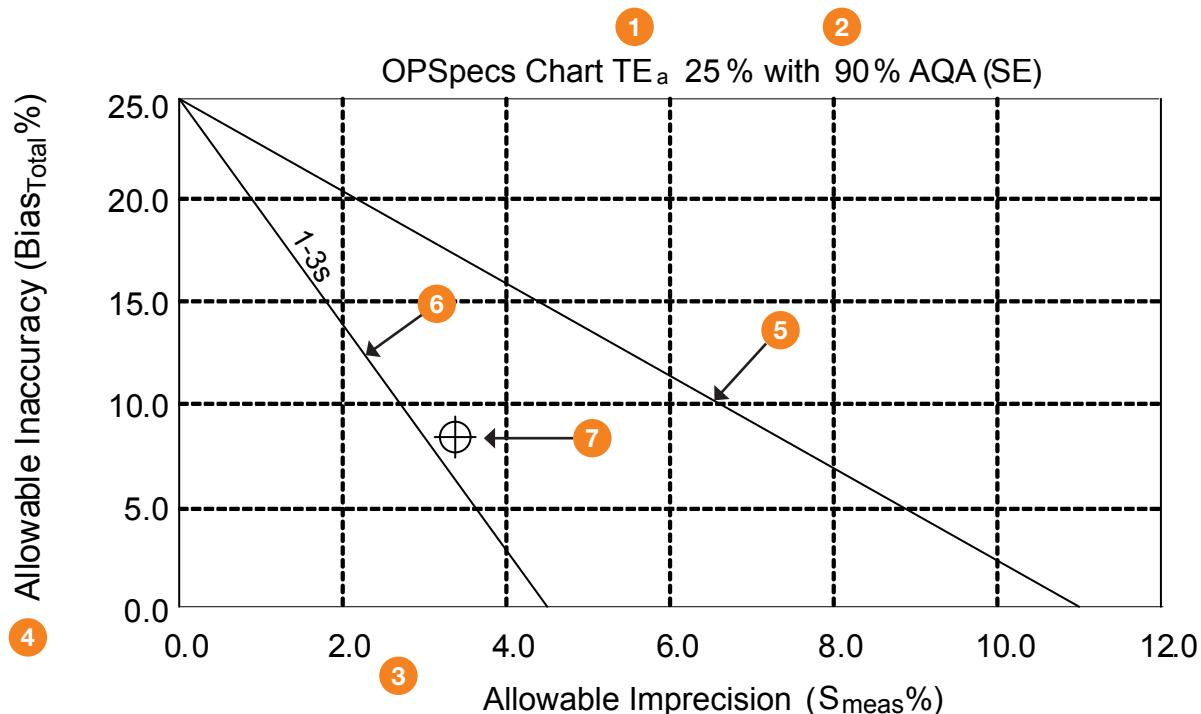
Use the OPSpecs Chart to:

- Identify an appropriate quality control procedure for a test.
- Consider how improving a test's precision and accuracy will change the **Operating Point** of the method, and therefore result in simpler and less expensive quality control.
- Estimate the maximum allowable imprecision for a test from the X-intercepts of the operating lines for the QC procedures being implemented.

Each time Westgard Advisor online generates rules for a test based on different TE_a and consensus group selections, the rules recommendations are saved. View the OPSpecs Chart for rule recommendations, compare the charts for different QC procedures, and select the most appropriate options.

OPSpecs Chart Components

An OPSpecs Chart shows the operational limits for bias and imprecision for the specified candidate QC procedure at either 90%, 50%, or 25% analytical quality assurance (AQA or error detection).



Magnesium

Bias_{meas} = 8.89% P_{fr} = 0.004
 S_{meas} = 2.95% N = 2

1 TE_a

Total allowable error. The quality requirement for the test. In the example above, the TE_a is 25%.

2 AQA (SE)

Analytical quality assurance for systematic error. The percentage of error detection. In the example above, the AQA is 90%.

3 Allowable Imprecision (x-axis)

The allowable imprecision (bias) scaled from 0 to 0.5 TE_a.

4 Allowable Inaccuracy (y-axis)

The allowable inaccuracy (bias) scaled from 0 to TE_a.

5 Maximum limits of a stable process

The highest line on the chart describes the maximum limits of inaccuracy and imprecision for a method that is perfectly stable and does not need any quality control.

6 Limits of bias and imprecision for suggested QC procedure (Operating Limits line)

The lowest line on the chart describes the limits of bias and imprecision for the suggested QC procedure with the selected quality control procedure. The line is labeled with the suggested QC rules (1-3s in the example on page 235). The **Operating Point** should be below this line.

7 Operating Point

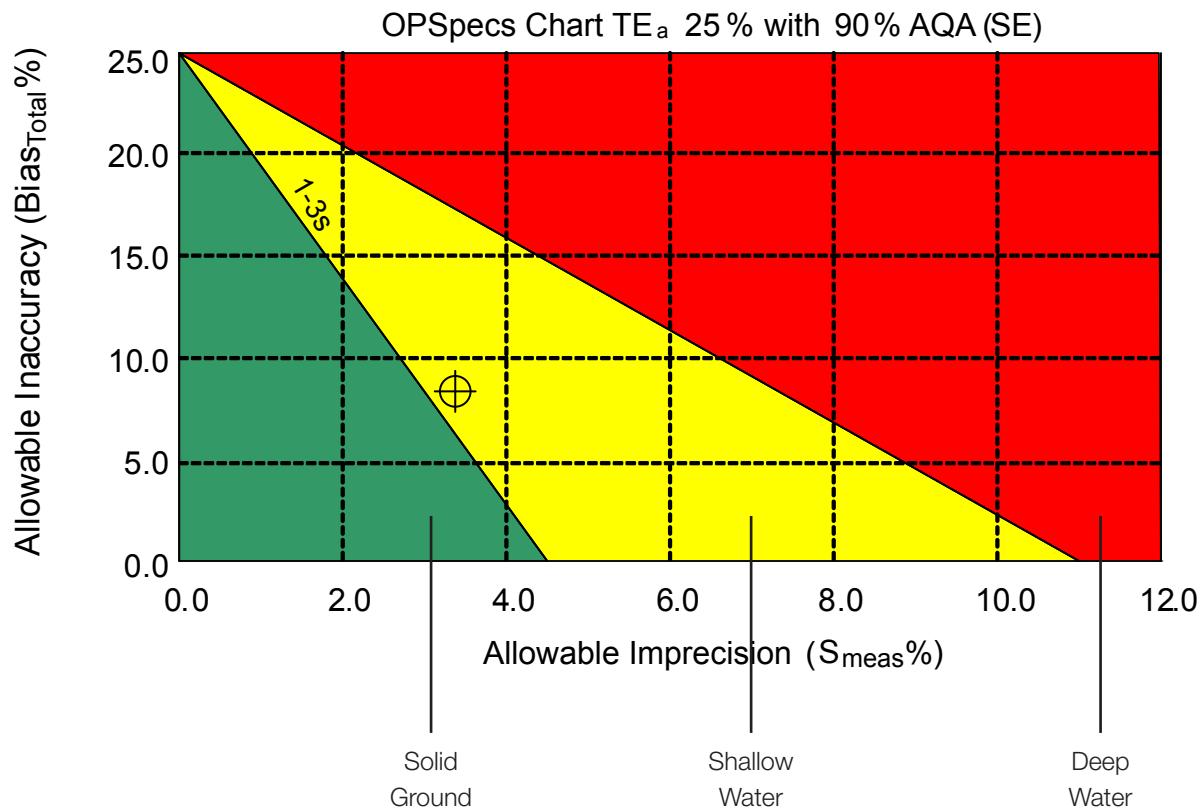
The **Operating Point** shows where the test's bias and imprecision intersect and shows the observed performance of the measurement procedure. The **Operating Point** is plotted by obtaining estimates for imprecision and inaccuracy and using them as X (imprecision) and Y (inaccuracy) coordinates on the chart.

Operational limits depend on the guarantee of quality built into the process. For example, operational limits for 90% AQA are more demanding than those for 50% AQA. Lower assurance, or lower error detection, may be acceptable for very stable testing processes with a very low frequency of errors. However, in general it is best to aim for 90% AQA.

If any of the lines in the OPSpecs Chart are above the **Operating Point**, they meet or exceed the level of quality assurance listed in the chart's title. For example, if the **Operating Limits line** is above the **Operating Point** in a 90% AQA Chart, the control rule and N (the recommended number of control determinations) corresponding to that line assures 90% or more analytical quality assurance or error detection.

How to Interpret an OPSpecs Chart

The lines on the OPSpecs Chart divide the chart into three sections.



Dr. James Westgard describes the three sections using the following terms.

- **Solid ground**

This is the area below the line for **Limits of bias and imprecision for suggested QC procedure (Operating Limits line)**. This is where the **Operating Point** should appear. The position of the **Operating Point** varies depending on the rule(s) it represents. Use different TE_a and consensus group criteria to generate multiple sets of rules. Review the OPSpecs Chart before deciding which rules to apply.

- **Shallow water**

This is the area between the **Maximum limits of a stable process** line and the **Limits of bias and imprecision for suggested QC procedure (Operating Limits line)** line representing the suggested QC procedure. If the **Operating Point** appears in this area, it is best to consider other rule combinations and try to improve the test method performance.

- **Deep water**

This is the area above the **Maximum limits of a stable process** line. If the **Operating Point** is in this area, consider other rule combinations and attempt to improve the test method performance. If the **Operating Point** is in this area, Westgard Advisor online will most likely recommend a maximum QC procedure.

When Westgard Advisor online Recommends a Maximum QC Procedure

To maximize error detection, the recommended rules for maximum QC include all available SPC rules. The recommended number of control determination (N) is also increased. If the laboratory does not have the resources to implement the recommendation, apply the most stringent rules possible. Also consider ways to improve test method performance (bias and CV). Consider replacing the method with a better one.



Important: The maximum QC procedure is not capable of 50% error detection. Do not rely on the control rules alone to provide QC for the method. Use non-statistical factors to improve QC for the test.

Supplemental Information

In This Chapter

Action Log Messages	239
Audit Trail Events	240
Rejection Log Messages	241

Action Log Messages

The following is a list of the pre-defined action messages and their code number. If you add custom action messages, the action is added in alphabetical order. The software assigns a code number to the action based on the next available number.

Action Log Messages
1 Calibrator: changed
2 Calibrator: new lot
3 Control: reconstituted new
4 Control: repeated level 1
5 Control: repeated level 2
6 Control: repeated level 3
7 Control: repeated level 4
8 Filter: performed maintenance
9 Filter: regulatory
10 Instrument: bleached
11 Instrument: calibrate
12 Instrument: electrode/cartridge change
13 Instrument: enzyme cleaner
14 Instrument: membrane changed
15 Instrument: service
16 Maintenance: corrective

Action Log Messages
17 Maintenance: daily
18 Maintenance: monthly
19 Maintenance: semi-annual
20 Maintenance: weekly
21 Mean: established new
22 Pipette: calibrate
23 Proficiency testing
24 QC: reviewed for day
25 QC: reviewed for month
26 QC: reviewed for week
27 Range: established new
28 Reagent: changed
29 Reagent: new lot
30 Test/assay repeated
31 Test: calibrate

Audit Trail Events

The following is a list of events tracked by the Audit Trail Report. See “Audit Trail Report” on page 168 for more information.

Audit Trail Events
Fixed Mean added or changed
Fixed standard deviation added or changed
Data deleted using Delete Range of Data
Number of decimal places changed
Number of points before rule evaluation changed
Data point date/time changed
Data deleted from within data entry
Data point edited
Designer lot edited
Lab profile updated

Audit Trail Events
Lot number edited after data entry
Data inserted
Accepted/rejected status changed
SPC rule change: 1-2s
SPC rule change: 1-2.5s
SPC rule change: 1-3s
SPC rule change: 2-2s
SPC rule change: 2/3-2s
SPC rule change: R-4s
SPC rule change: 3-1s
SPC rule change: 4-1s
SPC rule change: 7-T
SPC rule change: 7-x
SPC rule change: 8-x
SPC rule change: 9-x
SPC rule change: 10-x
SPC rule change: 12-x
SPC rule change: 1-3.5s
SPC rule change: 1-4s
SPC rule change: 1-5s

Rejection Log Messages

The following is a list of the messages that appear on the Rejection Log to correct errors from a connectivity solution.

Rejection Log Messages
Analyte code invalid
Create new lots if necessary disabled
Create new tests if necessary disabled
Data entry locked for this test
Date earlier than test creation date

Rejection Log Messages
Date out of range
Date out of sequence
Date/Time invalid
Failed validity check
Instrument code invalid
Invalid Day
Invalid Hour
Invalid level number
Invalid Mean
Invalid Minute
Invalid Month
Invalid number of Points
Invalid SD
Invalid Second
Invalid Time
Invalid Value
Invalid Year
Lab closed
Lab number undefined
Lot closed
Lot expired
Lot number undefined
Method code invalid
Method invalid for selected analyte
No code-fulfillment test ID defined
No Target Value defined
Reagent code invalid
Record type invalid
Result invalid
Temperature code invalid
Temperature invalid for selected analyte
Test not defined

Rejection Log Messages
Time out of sequence
Unable to create new test
Unit code invalid
Unit invalid for selected analyte

References

In This Chapter

QC References	244
---------------------	-----

QC References

Articles

- 1 Elsa F. Quam, BS, MT(ASCP), QC-The Out-Of-Control Problem, retrieved June 6, 2006, from the Basic QC Practices Lessons section of Dr. James O. Westgard's Web site at <http://www.westgard.com/lesson17.htm>.
- 2 Westgard J.O., Burnett RW. Precision requirements for cost-effective operation of analytical processes. *Clin Chem* 1990; 36:1629-1632.
- 3 Westgard, J.O. et al., Combined Shewhart-CUSUM Control Chart For Improved Quality Control In Clinical Chemistry; *CLIN. CHEM.* 23/10, 1881-1887 (1977).
- 4 Westgard, J.O.; Barry, P. L.; Hunt M.R.; Groth, T; A Multi-Rule Shewhart Chart For Quality Control In Clinical Chemistry; *CLIN. CHEM.* 27/3 493-501 (1981).
- 5 Westgard, J.O.; Koch, D.D.; Oryall, J.J.; Quam, E. F.; Feldbruegge, D. H.; Dowd, D. E.; Barry, P.L.; Selection Of Medically Useful Quality Control Procedures For Individual Tests Done In A Multi Test System; *CLIN. CHEM.* 36, 230 (1990).

Books

- 1 Cembrowski, G.S.; Carey, R.N.; Laboratory Quality Management: QC & QA, ASCP Press (1989).
- 2 Cooper G., Gillions T, Producing Reliable Test Results in the Medical Laboratory: Using a Quality System Approach and ISO 15189 to Assure the Quality of Laboratory Examination Procedures, Bio-Rad Laboratories, Inc., 2007.
- 3 Davies, O.L.; Goldsmith, P.L. Statistical Methods In Research and Production, New York (1984).
- 4 Howanitz, Peter J and Joan H., Laboratory Quality Assurance, McGraw-Hill Book Company (1987).
- 5 Weisbrot, M.D., Statistics For The Clinical Laboratory; J.B. Lippincott Company, Philadelphia (1985).
- 6 Westgard J.O. Basic QC Practices; second edition; (2002).

- 7 Westgard, J.O. Assuring the Right Quality Right. Westgard QC, Inc. Madison, WI, 2007.
- 8 Westgard, J.O., Barry Patricia L, Cost Effective Quality Control: Managing the Quality and Productivity of Analytical Processes. AACC Press 1995.
- 9 Westgard J.O. Basic Planning for Quality: Training in Analytical Quality Management for Healthcare Laboratories, Westgard Inc., 2000.

Guidelines

- 1 C24. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. Clinical and Laboratory Standards Institute, (formerly NCCLS) Wayne, PA, 2006.
- 2 National Committee for Clinical Laboratory Standards. Evaluation of precision performance of clinical chemistry devices - Second Edition; Tentative Guideline. NCCLS document EP5-T2 (ISBN 1-56238-145-8). NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania, 19805, 1992.

Glossary

accuracy

The closeness of agreement between a result and the accepted reference value. Accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

active rule

A SPC rule with a status of warn or reject.

Affiliated Data Exception Report



Note: Affiliated Reports are optional. Contact your Bio-Rad QC Program Representative to request Affiliated Reports.

For all laboratories within the affiliated laboratory consensus group, this report shows any analyte:

- Exceeding a specified SDI or CVR warning limit compared to the consensus group.
- Rejected by the Unity Interlaboratory Program.
- Containing a suspected coding error such as invalid unit, invalid method, and so on.

affiliated group

A group of laboratories in the Unity Interlaboratory Program comparing their results and essentially become their own consensus group. Contact your Bio-Rad QC Program Representative to request any of the available Affiliated Reports.

Affiliated Laboratory Comparison Report



Note: Affiliated Reports are optional. Contact your Bio-Rad QC Program Representative to request Affiliated Reports.

The Affiliated Laboratory Comparison Report summarizes the performance of each participating affiliated laboratory in a single report. Statistics are provided for your laboratory and all affiliated laboratories and include:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)

- Coefficient of variation ratio (CVR) and Standard deviation index (SDI)
 - Lab to Peer Group
 - Lab to Lab Group (affiliated group)
- Number of points

Affiliated Laboratory Comparison Report: Abbreviated Summary



Note: Affiliated Reports are optional. Contact your Bio-Rad QC Program Representative to request Affiliated Reports.

This report is designed for a quick review and focuses on key statistics to provide a performance summary for multiple laboratories. This report summarizes the performance of each participating affiliated laboratory in a single report. For each test, this report shows:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Number of points
- Coefficient of variation ratio (CVR) compared to the Peer, Method, and Affiliated consensus groups
- Standard deviation index (SDI) compared to the Peer, Method, and Affiliated consensus groups

Affiliated Reports



Note: Affiliated Reports are optional. Contact your Bio-Rad QC Program Representative to request Affiliated Reports.

Affiliated Reports allow a group of laboratories to compare results, essentially creating their own consensus group. The Unity Interlaboratory Program provides the following Affiliated Reports:

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

all labs group

One of the available Unity Interlaboratory Program consensus groups. The All Labs consensus group is composed of data from all laboratories reporting for the same lot number, level, units, and temperature of a test.

analyte

A substance or chemical constituent being analyzed such as glucose, TSH, and so on.

analytical process

A series of steps taken in the analysis or testing of patient specimens or samples.

audit trail

A secure, computer generated electronic record allowing reconstruction of the course of events relating to the creation, modification, and deletion of an electronic record.

bias

Bias measures how far an observed value is from a target value and is expressed as a percentage. Bias is determined by a reference value or estimated from an outside source such as proficiency testing results or the Bio-Rad Unity Interlaboratory Program. Use the following formula to calculate bias:

$$\text{Laboratory Bias \%} = \frac{\text{Laboratory Mean} - \text{Consensus Group Mean}}{\text{Consensus Group Mean}} \times 100$$



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]

Bias and Imprecision Histogram Report

The Bias and Imprecision Histogram Report is one of the Unity Interlaboratory Reports. This report provides a graphic representation of a laboratory's bias compared to the current cumulative consensus group mean and a laboratory's CV. On the chart, the monthly CV is represented as a bar and the bias is represented as a diamond with lines connecting each diamond. The Bias and Imprecision Histogram Report helps to detect changes in performance over time and to identify if the change in performance is due to imprecision, bias, or both.



Note: The Bias and Imprecision Histogram Report does not contain specific thresholds for allowable bias or allowable imprecision.

CLIA

Acronym for the Clinical Laboratory Improvements Amendments of 1998 which regulate laboratory practice in the United States.

CLSI

Acronym for the Clinical and Laboratory Standards Institute. Formerly the NCCLS.

consensus group

A group of laboratories submitting data to the Unity Interlaboratory Program. Carefully select a consensus group for comparison as statistical outcomes can be quite different based on the nature of the grouping. When choosing a consensus group, always choose the most specific group for which statistics are available.

The available Unity Interlaboratory Program consensus groups are:

- Peer (most specific)

The Peer consensus group is composed of all laboratories using the same instrument, lot number, level,

reagent, analytical method, units, and temperature of a test. This is the ideal group for comparison.

- Method (next specific)

The Method consensus group is composed of all laboratories using the same lot number, level, analytical method, units, and temperature of a test. Use the Method group if there is an insufficient number of laboratories in the Peer group.

- All Labs (least specific)

The All Labs consensus group is composed of data from all laboratories reporting for the same lot number, level, units, and temperature of a test.

cumulative mean

Also known as floating mean. The mean of all accepted data points entered for a test. If a fixed mean is not defined, the software uses the cumulative (floating) mean for rule evaluation.

CV (coefficient of variation)

The coefficient of variation is the standard deviation expressed as a percentage of the mean. Use the following formula to calculate the CV:

$$CV = (s \div \bar{x})$$

Where: s = standard deviation
 \bar{x} = mean

CVR (coefficient of variation ratio)

The coefficient of variation ratio compares a laboratory's precision to that of other laboratories in a consensus group. Use the following formula to calculate the CVR:

$$CVR = \frac{\text{Within Laboratory CV}}{\text{Consensus Group CV}}$$

data group

A user-defined set of data points having something in common, such as a calibrator lot. Define data groups on the **Single Test Point Data Entry** dialog box and the **Single Test Summary Data Entry** dialog box.

Data Rejection Report

The Data Rejection Report is one of the Unity Interlaboratory Reports and is only generated when data is rejected by the Unity Interlaboratory Program. The rejected data points are not included in cumulative statistics or in statistical comparisons. Data points may be rejected for two reasons:

- The data points are outside the standard statistical range, based on consensus group mean, SD range, or

CV.

- The data points were reported with an incorrect code (for example, invalid units, invalid method, and so on).

evaluation mean/SD

The mean and SD UnityWeb uses to evaluate a data point. When using cumulative (floating) statistics, these values can be different for each data point. View the evaluation statistics by clicking  for a row of data on the **Single Test Point Entry** dialog box.

fixed statistics

Fixed statistics refers to specifying (fixing) the evaluation mean and/or SD for a test.

floating mean

Also known as cumulative mean. The mean of all accepted data points entered for a test. If a fixed mean is not defined, the software uses the floating (cumulative) mean for rule evaluation.

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 SD or CV.

inactive rule

A SPC rule with a status of off.

InstantQC

An instant laboratory program option for comparing point data submitted via the Bench Review to other laboratories' data on demand. InstantQC Reports and Charts are available on www.QCNet.com.

InstantQC Chart

When sending data to the Unity Interlaboratory Program from Bench Review, the reviewed data points appear on InstantQC Reports and Charts on www.QCNet.com after a short processing time. The InstantQC Chart plots your data points for your selected date range against your selected consensus group's mean and $\pm 3SD$ range.

InstantQC Report

When sending data to the Unity Interlaboratory Program from Bench Review, the reviewed data points appear on InstantQC Reports and Charts on www.QCNet.com after a short processing time. The Comparison Statistics Shown are:

- SDI: a measurement of your bias compared to your selected consensus group.
- Bias: a measurement of how far your observed value is from the target value.
- TEB%: a measurement of your total error (bias and imprecision) compared to the total allowable error limits based on biological variation.

interlaboratory

Comparative results between laboratories used to determine values and assess test methods.

interlaboratory

Within a single laboratory.

Laboratory Comparison Report

The Laboratory Comparison Report is one of the Unity Interlaboratory Reports and shows the monthly and cumulative statistics for the laboratory, Peer group, and Method group for all tests reported. The Laboratory Performance Overview Report is automatically generated each month you submit data; however, you can specify a different report frequency. See “Configure Unity Interlaboratory Report Frequency” on page 56 for more information.

Use the Laboratory Comparison Report to compare results to those of the Peer and Method consensus groups. For VITROS instruments, the Laboratory Comparison Report provides statistics for the laboratory, Peer group, and Method group based on the slide generation numbers reported for the laboratory.

The Laboratory Comparison Report contains the following monthly and cumulative statistics for each test:

- Laboratory mean
- Laboratory SD
- Laboratory CV
- Number of points reported by the laboratory
- CVR for the Peer and Method groups
- SDI for the Peer and Method groups

The Laboratory Comparison Report also contains the monthly and cumulative Peer and Method group statistics for:

- Mean
- SD
- CV
- Number of points reported
- Number of laboratories reporting

Laboratory Histogram Report

The Laboratory Histogram Report is one of the Unity Interlaboratory Reports and is a bar chart showing up to a 12 month summary of the laboratory's monthly means against the current cumulative consensus group means $\pm 2SD$ range. The Laboratory Histogram Report is automatically generated each month you submit data; however, you can specify a different report frequency. See “Configure Unity Interlaboratory Report Frequency” on page 56 for more information.

The report shows the laboratory's mean, SD, CV, and number of points for each bar. Each level of control has a separate bar chart.

The Laboratory Histogram Report provides a visual comparison which is useful to identify shifts (abrupt changes in values) and trends (gradual changes in values).

Laboratory Performance Overview Report

The Laboratory Performance Overview Report is one of the Unity Interlaboratory Reports and allows you to visually evaluate the bias and imprecision for each test compared to the Peer and Method consensus groups on a modified Youden Chart. The Laboratory Performance Overview Report is automatically generated each month you submit data; however, you can specify a different report frequency. See “Configure Unity Interlaboratory Report Frequency” on page 56 for more information.

The SDI and CVR are combined as X-Y coordinates located within one of three performance zones designated by increased levels of shading:

- No shading
Acceptable performance.
- Slight shading
Acceptable to marginal performance. This may indicate the need to investigate test system bias and imprecision.
- Darkest shading
Outside of acceptable and marginal performance. Corrective action may be needed.
- Outside of graph 
Unacceptable performance. Requires corrective action.

The center of the graph (SDI and CVR both equal to zero) represents perfect agreement between the laboratory's values and the consensus group (Peer or Method) statistics. Bias and imprecision increase as values move further away from the center of the graph.

level

When referring to QC materials, level refers to the concentration of analytes within the control material. Controls are usually bi-level (low and high) or tri-level (low, normal, and high).

levels in use

The levels of a control product used in the laboratory (for example, level 1, level 2, level 3). Unused levels of a control material are omitted from intralaboratory and Unity Interlaboratory Reports.

Levey-Jennings Chart

A graphical chart used to plot successive quality control results, either day-to-day or run-to-run.

Manufacturer Report

The Manufacturer Report is provided through the Unity Interlaboratory Program and is a subset of the information from the Worldwide Report separated by the instrument manufacturer. The Manufacturer Report is a good reference to use when evaluating a new instrument or kit and is updated every month.

master lot number

For Bio-Rad controls, the master lot number is the 5-digit lot number, ending in zero, which includes all levels of the control product (for example, 40910). To identify the levels of a control product, the final zero is changed to the level number (for example, 40911 is level 1, 40912 is level 2, and 40913 is level 3).

matrix

The substance containing the analyte being tested (for example, serum, urine, spinal fluid, whole blood).

maximum QC

The condition existing when Westgard Advisor online is unable to suggest rules meeting your quality specification (TE_a). This condition indicates the test process has such a low process capacity (high total error) it cannot be controlled to a defined level of quality. The default maximum QC procedure is a Westgard multirule applying every possible rule.

mean

The mean for a group of data points is simply the arithmetic average. The mean provides a laboratory's best estimate of the analyte's "true" value for a specific level of control. The mean \pm a predetermined number of standard deviations represents the error expected in a test when the analytical system is stable. Use the following formula to calculate the mean:

$$\text{Mean} = \sum \frac{x_n}{n}$$

Where: s = sum

x_n = each value in the data set

n = the number of values in the data set

median

The middle value in a distribution, above and below which lie an equal number of values.

method

The way by which an analyte is measured (for example, hexokinase).

method group

One of the available Unity Interlaboratory Program consensus groups. The Method consensus group is composed of all laboratories using the same lot number, level, analytical method, units and temperature of a test. Use the Method group when there is an insufficient number of laboratories in the Peer group.

Monthly Evaluation Report

The Monthly Evaluation Report is automatically generated each month you submit data. The Monthly Evaluation Report validates the monthly laboratory performance as compared to the Peer group. This report identifies when the monthly laboratory performance does not statistically compare with or was not accepted into the Unity database. Also, the Monthly Evaluation Report notifies the laboratory when its data was not received in time for the comparison.

operating point

The point on an OPSpecs Chart representing the intersection of bias and imprecision for a test. The Operating Point represents the current performance of a test.

OPSpecs (operational process specifications) Chart

OPSpecs Charts are an integral part of Westgard Advisor online. In general, an OPSpecs Chart is a tool for assisting a laboratory to select appropriate SPC rules and the number of control measurements for a QC procedure. OPSpecs Charts are plots of the allowable inaccuracy versus allowable imprecision. The highest line on the chart describes the maximum limits for inaccuracy and imprecision for a stable process. The lower line describes operational limits with the selected QC procedure. The Operating Point appears where the accuracy and precision of the test intersect.

panel

A user-defined group of tests organized to make data entry and review easier. Create a panel to customize the organization of tests in a convenient way. For example, a panel can be created to group a number of different tests performed on a single instrument, or a panel can be created to group the same test performed on multiple instruments.

peer group

One of the available Unity Interlaboratory Program consensus groups. The Peer consensus group is composed of all laboratories using the same instrument, lot number, level, reagent, analytical method, units, and temperature of a test. This is the ideal group for comparison.

percent AQA (SE)

The percent of analytical quality assurance (AQA) for systematic error (SE) is the chance of detecting medically important systematic errors. Percent AQA (SE) is synonymous with probability of error detection (P_{ed}).

point data

A single value generated as a result of testing an analyte within a control material.

precision

A measurement of how close a set of measurements are to each other. The measurements may or may not be close to the “true” answer. See “accuracy” on page 246.

probability of false rejection (P_{fr})

A QC performance characteristic describing how often a run is rejected when there are no errors.

QC (quality control)

In the clinical laboratory, QC is a system designed to increase the probability each result report is valid and can be used with confidence by a health care provider when making diagnostic or therapeutic decisions.

random error

A random deviation from the laboratory mean. “Expected” or “acceptable” random error is generally between $\pm 3SD$ of the mean. A deviation greater than $\pm 3SD$ is considered “unacceptable” random error. Because of its random nature, this type of error is unpredictable.

range

The difference between the largest and the smallest observed value of a quantitative characteristic or statistical limit.

rejection rule

A SPC rule with a status of reject. When a data point violates a SPC rule with a reject status, the point is not accepted and is excluded from monthly and cumulative statistics and is not reported to the Unity Interlaboratory Program for consensus group comparison.

run

A set of QC values UnityWeb groups together for statistical profile rule evaluation (for example, within run and between run).

shift

A type of systematic error evidenced by an abrupt change in the mean of the control values.

SD (standard deviation)

The standard deviation measures a test's precision, or how close individual measurements are to each other. (The standard deviation does not measure bias, which requires comparing results to a target value such as the Peer consensus group.) The standard deviation provides an estimate of how repeatable a test is at specific concentrations. Test repeatability can be consistent (low standard deviation, low imprecision) or inconsistent (high standard deviation, high imprecision). Use the following formula to calculate the 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 values in the data set

SDI (standard deviation index)

The standard deviation index is a measurement of bias (how close a value is to the target value). The Unity Interlaboratory Program uses the consensus group value as the target value. Use the following formula to calculate the SDI:

$$\text{SDI} = \frac{\bar{x}_{\text{Lab}} - \bar{x}_{\text{Group}}}{s_{\text{Group}}}$$

Where: \bar{x}_{Lab} = Laboratory mean
 \bar{x}_{Group} = Consensus group mean
 s_{Group} = Consensus group standard deviation

SPC (statistical process control) rules

A set of rules which use statistics to monitor and evaluate a process. SPC rules include the original six Westgard rules as well as additional rules.

Statistical Profile Report

Note: The Statistical Profile Report is optional. Contact your Bio-Rad QC Program Representative to request this report.

The Statistical Profile Report allows you to compare your laboratory's statistics to the Peer, Method, and All Labs consensus group statistics for selected time periods. The Statistical Profile Report also provides two histograms summarizing how your laboratory's mean and CV compare to the range of mean and range of CVs calculated for each consensus group.

summary data

The mean, SD, and number of points for a data set comprised of the control material results for testing an analyte over a specific time range (for example, October 2007).

suspect data

Data points violating any SPC rule set to reject or warn.

systematic error

A trend or shift away from the laboratory mean. Small amounts of systematic error are tolerable. Systematic error remains until corrective action is taken.

TE (total error)

Total error is the overall error that may occur in a test result due to the imprecision and bias present in the testing procedure. Use the following formula to calculate the TE:

$$\text{Laboratory TE} = [\text{Laboratory Bias(\%)}] + z\text{-factor} \times (\text{Laboratory Imprecision \%})$$

TE_a specifications are available from several sources as described in “Determine Quality Requirements for the Test” on page 28.

- Total error < total allowable error = test results are generally considered reliable.
- Total error > total allowable error = corrective action should be taken as quality specifications are not being met.

TE_a (total allowable error)

Total allowable error is a quality requirement setting limits for the imprecision and bias allowable in a test result. After choosing a TE_a , the TE budget can be calculated. Use the following formula to calculate the TE_a :

$$\text{TE}_a = z\text{-score} \times (\text{Desirable Imprecision \%}) + [\text{Desirable Bias \%}]$$

trend

A type of systematic error causing a gradual, often subtle increase or decrease in control values and possibly patient results.

Urinalysis Report

Note: The Urinalysis Report is optional. Contact your Bio-Rad QC Program Representative to request this report.

Customers submitting data for a Bio-Rad urinalysis product to the Unity Interlaboratory Program receive a qualitative report consisting of the following:

- Cover page
- Dual level chemistry report for each instrument submitted
- Dual level microscopy report for each data entry set submitted

The Urinalysis Report displays only one set of results per day. If submitting multiple sets, this report includes the one with the most recent date-time stamp.

warn rule

A SPC rule with a status of warn. When a data point violates a SPC rule with a warn status, the data point is accepted and is included in monthly and cumulative statistics and is reported to the Unity Interlaboratory Program for consensus group comparison.

Westgard rules

A laboratory QC system based on a set of six core statistical rules, each having statistical power to detect random and systematic deviations from the norm.

Worldwide Report

The Worldwide Report is provided through the Unity Interlaboratory Program. The Worldwide Report contains all Peer group and Method group statistics and is a good reference to use when evaluating a new instrument or kit. The Worldwide Report includes:

- All Peer group and Method group statistics.
- All tests (including all instruments, all methods, and so on) reported to the Unity Interlaboratory Program by all laboratories reporting on the same lot number.
- Monthly and cumulative statistics (mean, SD, CV, number of points, and number of laboratories) for each level of control.

z-score

The z-score is the number of standard deviations a control result is from the expected mean. Use the following formula to calculate the z-score:

$$\text{z-score} = \frac{\text{Observed Result} - \text{Expected Mean}}{\text{Expected Standard Deviation}}$$

A z-score of ± 2.3 indicates the observed value is $\pm 2.3\text{SD}$ away from the expected mean. A data point with this z-score would violate the 1-2s rule, but not the 1-3s rule. The z-score appears on the **Single Test Point Data Entry** dialog box.

License Agreement

In This Chapter

License Agreement.....	259
Warranty Information	259
Trademark Notices	260

License Agreement

Bio-Rad hereby grants to you, and you hereby accept, a non-exclusive license to use the Unity Real Time software program ("Software"), and the related materials provided in this package. If you do not agree to the terms hereof, promptly return the Software and all other related materials provided in this package to the place of purchase. Except for the limited license granted herein, Bio-Rad owns all copyright, trade secret, patent and other proprietary rights, and all other right, title and interest, in and to the Software and related materials.

You may not copy, reproduce, or transmit any part of the Software or other related materials including but not limited to the user manual or reference guide in any form or by any means (including translation to another language, computer language, or format). For user manuals provided electronically such as a PDF file, it is permissible to print these for use by the Purchaser. You may not reverse engineer, decompile, disassemble, or otherwise reduce the Software to any human perceivable forms. You may not modify, adapt, translate, rent, lease, loan, resell for profit, transfer, export or create derivative works based upon the Software or any part thereof. You agree to keep confidential, and use your best efforts to prevent the unauthorized disclosure and use of, the contents of the Software and related materials.

The Software is licensed for use only to medical laboratories worldwide using Bio-Rad quality control products and is not for sale to the general public unless otherwise specified. The information contained in the user manual and reference guide is subject to changes and updates at Bio-Rad's discretion.

Warranty Information

The Purchaser must notify Bio-Rad of its claim of any defect. If the Software is found to be defective by Bio-Rad, Bio-Rad's sole obligation under this warranty is to remedy such defect in a manner consistent with Bio-Rad's regular business practices. For a defect which materially adversely affects the performance of the Software, Bio-Rad shall use commercially reasonable efforts to cure such defect as soon as reasonably practicable after receipt of Purchaser's notice, and for minor defects, Bio-Rad shall use commercially

reasonable efforts to correct such minor defects in the next release of its Software. If, however, Bio-Rad is unable to cure a major defect, the Purchaser's sole remedy shall be the option to cancel this Agreement, whereupon Bio-Rad shall refund only the Software fees paid, and Bio-Rad shall have no other liability whatsoever.

The warranties set forth in this Agreement are in lieu of all other representations and warranties, express or implied, including warranties of merchantability and fitness for a particular purpose, any warranty of non-infringement, and any other statutory or common-law warranty. Bio-Rad on its own behalf hereby expressly disclaims and excludes any and all such other representations and warranties. Liability of Bio-Rad to the Purchaser, if any, for breach of warranty, or any other claim relating to this Agreement shall in no event exceed the total amount of Software fees paid by the Purchaser to Bio-Rad. In no event shall Bio-Rad be liable for incidental or consequential damages (including but not limited to damages to any laboratory instruments, computer equipment or data arising from the use of the Software), loss of business or profits, special or indirect damages of any nature whatsoever, even if Bio-Rad has knowledge of the potential loss or damage. Bio-Rad accepts no responsibility for misuse of the Software or its data modifying capabilities.

Trademark Notices

DirectConnect, InstantQC, QCNet, SoftConnect, UnityWeb, Unity Interlaboratory Program, Unity Real Time, Unity Desktop, WebConnect, and Westgard Advisor are trademarks or registered trademarks of Bio-Rad Laboratories, Inc.

All other trademarks and registered trademarks used in this guide are the property of other companies.

Please consult the individual manufacturers for specific information.

Index

A

accuracy 246
action log messages 239
actions 138
actions and comments 54, 137
 by instrument 143
activate automatic monthly transmission 172
activate transmission for InstantQC 172
active rule 246
add a comment to a row of data 143
administration/setup permissions 66
Affiliated Data Exception Report 193, 246
affiliated group 246
affiliated lab numbers 70
Affiliated Laboratory Comparison Report 190, 246
 Abbreviated Summary 192, 247
Affiliated Reports 190, 247
all labs group 247
analyte 247
analytical process 247
audit trail 248
audit trail events 168, 240
Audit Trail Report 168
 create 168

B

bar chart 155
 create 156
 select options 156
basic QC statistics 11
bench review 134
 perform 135
bias 248
Bias and Imprecision Histogram Report 183, 248
buttons 5

C

CAP accreditation requirements 208
change a data point's accepted/rejected status 128
change a password 65
change data 125
change the current data option 95
change the date and time for a row of data 112
chart header options 149

check boxes 5
chemistry section 195
choose goals based on required quality 33
CLIA 248
 requirements 10
CLSI 248
command buttons and options 108
comments 142
comprehensive reports 175, 184
condense data 58
configure UnityWeb 53
consensus groups 176, 228, 248
contact Bio-Rad 2
cumulative mean 249
current lab, panel, lot, and test 41
CV 249
CVR 249

D

database permissions 66
data entry
 configuration 54
 features 111
 grid 109
 overview 106
 permissions 125
data groups 94, 249
 define or edit a group 96
 overview 95
data handling permissions 67
data management
 overview 125
data permissions 68
Data Rejection Report 178, 249
data requirements 226
data review permissions 66
Data Review Report 162
 create 163
delete a range of data 59, 130
delete a row of data from the data entry dialog box 130
delete data 130
document report reviews 162
download Adobe Reader 51

E

edit data 126

edit data, date, and time 126
edit the date and time 127
enter multi test data 124
enter qualitative data 120
enter single test point data 117
enter single test summary data 119
essential startup tasks for new users 3
evaluate test performance 29
evaluation mean/SD 250
example lists 41
export data 56

F

fill background 148
first time log in 3, 39
fixed mean and SD 111
fixed statistics 115, 250
floating mean 250
functions and where to find them 46

G

general chart options 147
good laboratory habits 34
grid display options 227
grid lines and color 148
group login ID and password 64
group statistics 111

H

historical suggestions
 delete 234
how are QC results used? 8

I

identify appropriate QC materials 29
identify possible QC procedures 32
imprecision 250
inactive rule 250
indirect methods of adding tests 81
insert data 129
InstantQC 137, 250
InstantQC chart 175, 199, 250
InstantQC Report 175, 198, 250
interlaboratory 250, 251
ISO 15189 requirements 220
issues to consider 37

K

keys to a productive review of the laboratory quality system 37

L

lab numbers

- add 70
- close 71, 72
- delete 72
- duplicate 71
- open 71, 72
- primary lab number 69
- types 69
- update information 70

Laboratory Comparison Report 180, 251

Laboratory Histogram Report 182, 251

Laboratory Performance Overview Report 179, 252

lab, panel, lot, and test information 107

labs, lots, tests, and panels permissions 67

level 252

levels in use 252

Levey-Jennings chart 151, 252

- create 154
- how to use 151
- select options 152
- view 112

license agreement 259

limitations of instrument setup 83

links 5

Listings Report 169

- create 170
- options 169

lists 6

log off the software 40

log on to the software 40

lot expiration notifications 78

lot numbers

- delete 78
- duplicate a Bio-Rad lot number 75
- duplicate a non-Bio-Rad lot number 75
- edit 76

lots 73

- add a Bio-Rad lot 73
- add non-Bio-Rad lots 73
- arrange and sort 77
- close 77

duplicate 74
open a closed lot 77

M

Manufacturer Report 186, 252
master lot number 252
matrix 253
maximum QC 253
mean 253
median 253
menu items 5
method 253
method group 253
microscopy section 196
Monthly Evaluation Report 177, 253
monthly reports 175, 176
Multi-LJ chart 154
 create 155
 select options 154
multi test data entry 121
 grid 123
 information 121

N

navigate the single test data entry dialog boxes 113
normal and abnormal controls 9
notes about rule evaluation 97
notifications 55

O

operating point 253
Operator Report 167
 create 167
 options 167
operator setup 131
OPSpecs chart 234, 254
 components 235
 how to interpret 237
optional reports 175, 187
options 5
organization of this guide 2

P

paging arrows 110
panels 92, 254
 create a panel and add tests 92

delete 94
remove tests from a panel 93
rename 93
sort names 94
passwords 63
 requirements 63
peer group 254
percent AQA (SE) 254
point data 254
Point Data Report 163
 create 163
 options 163
precision 254
predict the performance of the QC procedures 32
probability of false rejection (Pfr) 254
program hints 4

Q

QC configuration 4
QC (quality control) 254
QC references 244
qualitative data entry 119
qualitative evaluation of a test's bias and imprecision 31

R

random error 254
range 254
recalibrate 34
recommended steps for a QC system 27
regular log on and log off process 40
rejection log messages 241
rejection rule 255
require audit trail comments 145
review and annotate data
 overview 134
rule evaluation
 overview 97
rules and settings permissions 67
rule status 98
run 255

S

scroll bars and scroll arrows 6
SD 255
SDI 256
select a QC procedure 33

send qualitative data to the Unity Interlaboratory Program 121
set a fixed mean and/or fixed SD 102
set floating statistics as a fixed mean and/or fixed SD 103
shift 255
single test data entry dialog boxes
 overview 107
single test point data entry 114
single test point data entry grid 114
single test summary data entry 118
six sigma 29
sort tests 88
 for a lab number 88
 in a panel 88, 93
SPC rules 256
 1-2.5s 19
 1-2s 18
 1-3.5s 20
 1-3s 20
 1-4s 21
 1-5s 21
 2-2s 21
 2 of 3-2s 23
 3-1s and 4-1s 24
 7-T 25
 N-x rules 25
 R-4s 23
 select 84
 set 99
 at the lot level 100
 at the test level 99
 tabular summary 103
Statistical Profile Report 187, 256
Statistical Report 165
 create 165
 options 165
submit data
 from the bench review 172
 manually 171
 monthly 171
summary data 256
summary data entry grid 118
Summary Data Report 164
 create 164
 options 164
Supervisor's Report 166
 create 166

options 166
suspect data 256
systematic error 256
system requirements 51

T

tabs 4
TEa (total allowable error) 257
test rules and settings 84
tests
 add 81
 manually 81
 using instrument setup 82, 83
 with a code of “other” 84
close 87
delete 89
determine quality requirements 28
direct methods of adding tests 81
duplicate 86
open 87
overview 79
select settings 85
update 86
TE (total error) 257
total allowable error (TEa) options 224
trademark notices 260
transmission 55
 overview 171
trend 257
try a new control 34
typographical styles and conventions 2

U

unavailable items 7
understand the navigation tree 42
Unity Interlaboratory reports
 configure frequency 56
 overview 174
 view and print 176
UnityWeb charts
 overview 147
 save and print 150
UnityWeb reports
 overview 159
 print 161
 save 160

Urinalysis Report 195, 257
use a fixed mean and fixed SD with SPC rules 101
use a fixed mean and SD 85
useful facts about fixed mean and fixed SD 102
useful statistics 12
users
 add 62
 define, modify and delete 61
 delete 63
 modify 62
 permissions 65
 set up permissions 68
use the set date feature 111

V

view existing QC rules 223
view lab data and group statistics 223
view rules and settings 113
VITROS slide generation numbers 90
 change 90
 update 91

W

warn rule 258
warranty information 259
welcome 1
Westgard Advisor online
 advanced option 230
 apply rules 231, 232
 configure 223
 defaults 231
 generate rules 227
 overview 222
 wizard 228
Westgard Advisor online Report 232
 print 233
Westgard rules 258
what is quality control? 8
Worldwide Report 184, 258

Y

Youden chart 157
 create 158
 how to use 157
 select options 157

Z

z-score 258