
Unity Real Time 2

User Guide for Expert QC Data Management

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Table of Contents

Chapter 1: Getting Started	1
Welcome	1
Benefits of Unity Real Time.....	1
Features	2
Charts and Reports.....	2
Qualitative Results.....	2
Bench and Supervisor Review.....	2
Westgard (SPC) Rules and Settings Options	2
Lab, Lot, Test, and Panel Configuration.....	2
Multi Test Data Entry	2
Security/Administration.....	2
RiliBÄK 2008 Requirements	3
Contact Bio-Rad	3
Software Support.....	3
QC Program Representative.....	3
Organization of this Guide.....	3
Program Hints	4
Menu Bar and Menus.....	4
Toolbar	4
Buttons	4
OK Button vs. Apply Button.....	5
Help Buttons	5
Check Boxes	5
Lists	5
Options	5
Tabs	6
Unavailable Items	6
Typographical Styles and Conventions.....	6
Software Items	6
Keyboard Keys.....	7
Notes, Tips, Important, and Permission Notes.....	7
Note.....	7
Tip	7
Important	7
Permissions	7

Chapter 2: Introduction to Quality Control Statistics	8
What is Quality Control?	8
Requirements for the Statistical Process.....	8
How Are QC Results Used?	8
Normal and Abnormal Controls	9
Example Scenario.....	9
How Often Should Controls be Run?.....	10
Determining Frequency of QC Factors	10
CLIA Requirements	10
Basic QC Statistics	11
Useful Statistics	12
Mean.....	12
Standard Deviation (SD)	13
Calculate a Control Mean and Range	14
Standard Deviation Index (SDI)	14
Interpreting the SDI.....	15
Bias.....	15
Coefficient of Variation (CV)	16
Example Scenario.....	16
Determining an Acceptable CV	16
Coefficient of Variation Ratio (CVR)	17
Total Error (TE) and Allowable Total Error (TE_a)	17
z-score.....	17
SPC Rules	18
1-2s Rule	19
1-2.5s Rule	20
1-3s Rule	20
1-3.5s Rule	21
1-4s Rules.....	21
1-5s Rule	22
2-2s Rule	22
2 of 3-2s Rule	24
R-4s Rule.....	24
3-1s and 4-1s Rules.....	25
7-T Rule	26
N-x Rules	27
 Chapter 3: Choose and Troubleshoot a QC Procedure	 29
Recommended Steps.....	29
Determine Quality Requirements for the Test.....	30
Identify Appropriate Control Materials	31
Evaluate Test Performance.....	31
Six Sigma.....	32
Use of Six Sigma.....	33
Qualitative Evaluation of a Test's Bias and Imprecision.....	33

Identify Possible QC Procedures.....	34
Predict the Performance of the QC Procedures	34
Choose Goals Based on Required Quality	34
Select a QC Procedure.....	35
Troubleshoot QC Results	35
Good Laboratory Habits	36
Systematic Error	38
Random Error	38
Keys to a Productive Review of the Laboratory Quality System.....	39
Issues to Consider	39
 Chapter 4: Unity Real Time Basics	40
Essential Startup Tasks for New Users.....	40
Start the Software and Log On.....	40
Log Off the Software	41
Exit the Software	42
Configure QC Items	42
Current Lab, Panel, Instrument, Lot, and Test	43
Lab Navigation Tree.....	43
Example Lab Navigation Tree.....	43
Panel Navigation Tree	44
Example Panel Navigation Tree	44
Instrument Navigation Tree	44
Example Instrument Navigation Tree	44
Search the Navigation Tree.....	45
Adjust Column Widths	46
Toolbar	47
Toolbar Buttons.....	47
Customize the Toolbar.....	49
Keyboard Shortcuts.....	51
Menus and Functions	53
Resource “Shortcuts”	56
Functions and Where to Find Them	57
Download Adobe Reader.....	63
Update the License.....	63
Automatic License Updates	63
Update the License with an XML File	63
 Chapter 5: User Profiles, Passwords, and Permissions	64
Overview	64
Add, Edit, and Delete Users.....	65
Add a User.....	65
Edit a User	67
Delete a User	67

Assign Lab Numbers to Users	68
Passwords.....	69
Password Requirements	69
Group Login ID and Password	69
Password Expiration.....	69
Set a Password Expiration	70
Change a Password	70
User Permissions	71
Administration/Setup Permissions	71
Database Permissions.....	72
Data Permissions	72
Rules and Settings Permissions	73
Labs, Lots, Tests, and Panels Permissions	73
Data Handling Permissions	74
Data Review Permissions	75
RiliBÄK Permissions	75
Set Up User Permissions.....	75
Operator Setup.....	76
Assign Operator Initials and Shifts	76
Chapter 6: Labs and Lots.....	78
Lab Numbers.....	78
Types of Lab Numbers	78
Primary Lab Number	78
Additional Lab Number.....	79
Affiliated Lab Number.....	79
Add and Update Lab Numbers.....	79
Add a Lab Number	79
Update Lab Number Information	80
Duplicate a Lab Number.....	80
Open and Closed Lab Numbers.....	81
Close a Lab Number	82
Open a Lab Number	82
Arrange the Order of Lab Numbers	83
Adjust the Column Widths.....	83
Delete a Lab Number	84
Lot Numbers	85
Add a Bio-Rad Lot Number.....	85
Add a Non-Bio-Rad Lot Number.....	86
Duplicate a Lot Number	87
Items Automatically Duplicated	87
Optional Items When Duplicating	87
Duplicate a Bio-Rad Lot Number.....	88
Duplicate a Non-Bio-Rad Lot Number	89
Edit a Bio-Rad Lot Number	89

Edit a Non-Bio-Rad Lot Number	90
Copy a Lot Number.....	91
Closed and Open Lot Numbers.....	91
Close a Lot Number	92
Open a Closed Lot Number	92
Arrange the Order of Lot Numbers	93
Adjust the Column Widths.....	93
Delete a Lot Number	94
Lot Expiration Notifications	94
 Chapter 7: Tests.....	 95
Overview	95
Add Tests	97
Direct Methods of Adding Tests.....	97
Indirect Methods of Adding Tests	97
Add Tests Manually	97
Add Non-Bio-Rad Qualitative Tests with Qualitative Responses.....	99
Instrument Setup.....	100
Add Tests with Instrument Setup.....	100
Add Tests with a Code of “Other”	102
Duplicate Tests.....	102
Update Tests	103
Update a Test.....	103
Close and Open Tests	104
Close a Test	104
Open a Test.....	104
Arrange the Order of Tests.....	105
Adjust the Column Widths.....	106
Delete Tests.....	106
Delete a Test	107
Test Settings.....	108
Select Test Settings.....	108
Evaluation Mean and SD.....	109
Overview of Evaluation Mean and SD Options	109
Fixed vs. Floating	109
Use Bio-Rad elInsert data to set a fixed mean and/or fixed SD/CV.....	110
Manually Set a Custom Fixed Mean and/or Fixed SD/CV	111
Use Floating Statistics to Set a Fixed Mean and/or Fixed SD/CV	112
Set a Floating Mean and/or SD	113
Set Up an Expected Response	115
VITROS Slide Generation Numbers.....	115
Change the VITROS Slide Generation Number	115
Update the VITROS Slide Generation Number.....	117

Chapter 8: Panels and Data Groups	118
Panels	118
Create a Panel and Add Tests	118
Sort Tests in a Panel.....	119
Rename a Panel.....	120
Remove Tests from a Panel	120
Sort Panel Names	121
Delete a Panel	121
Data Groups	122
Overview of Data Groups	122
Month or Group Data Entry Configuration for all Tests	123
Enable or Disable Data Groups for a Single Test.....	123
Define a Data Group.....	123
Edit a Data Group	124
Data Group Statistics	124
 Chapter 9: SPC Rules and Analytical Goals.....	 125
Overview of SPC Rules	125
Notes About Rule Evaluation	126
Example 1	126
Example 2	127
Example 3	127
Rule Status	128
SPC Rules Precedence When Showing Rule Violations	129
SPC rules precedence is determined by several factors.	129
Select SPC Rules	130
Select SPC Rules at the Test Level.....	130
Select SPC Rules at the Lot Level	131
Summary of SPC Rules	132
Overview of Analytical Goals	134
Target Values/Data Ranges	134
Consensus Groups	135
Calculate the Mean	135
Performance Goals	136
Rule Status for Analytical Goals.....	137
Retrospective Evaluation with the Levey-Jennings Chart	138
Levey-Jennings with Analytical Goal View Selection.....	138
Levey-Jennings with Analytical Goal and Analytical Goal Limits	
Selections.....	139
Imprecision-BV	141
Configure Imprecision-BV.....	141
Total Error-BV	142
View Consensus Information	142
Configure Total Error-BV.....	143
Apply to TE _a	144

Medical Relevance.....	145
Configure Medical Relevance	145
Apply to TE _a	146
State of the Art	147
View Consensus Information	147
Configure State of the Art.....	148
 Chapter 10: Enter Data.....	 149
Overview	149
Overview of the Single Test Data Entry Dialog Boxes	150
Set and Change the Date for Data Entry	158
Set Date Feature	158
Use the Set Date Feature	158
Change the Date and Time for a Row of Data	160
Navigate the Single Test Data Entry Dialog Boxes	161
Overview of Single Test Point Data Entry.....	162
Enter Single Test Point Data.....	164
Overview of Single Test Summary Data Entry.....	165
Enter Single Test Summary Data.....	166
Overview of Qualitative Data Entry	167
Enter Qualitative Data	167
Overview of Multi Test Data Entry.....	168
Overview of Multi Test Point Data Entry.....	169
Overview of Multi Test Summary Data Entry	170
Enter Multi Test Data.....	170
 Chapter 11: Manage Data	 172
Overview	172
Data Entry Permissions.....	173
Edit Data, Date, and Time.....	173
Edit Data	174
Edit the Date and Time.....	174
Change a Data Point's Accepted/Rejected Status	175
Change the Accepted/Rejected Status of a Data Point.....	176
Insert Data.....	177
Insert a Data Row	177
Delete Data.....	178
Delete a Row of Data from the Data Entry Dialog Boxes.....	178
 Chapter 12: Review and Annotate Data	 179
Overview	179
About the Bench Review and Supervisor Review	180
Analytical Goal and Rule Violations Displayed.....	180
Summary of the Bench Review and Supervisor Review	180

Overview of the Bench Review and Supervisor Review Process.....	181
Perform a Bench Review or Supervisor Review.....	182
Select a Data Set for Review	182
Review Data.....	183
View a Levey-Jennings Chart	183
View the Data Entry Dialog Box	183
Add Documentation	183
Manually Accept or Reject Data in the Review	184
Document the Review	184
Save and Transmit.....	185
Warning Messages.....	186
Automatic or Require Action	186
Expected Tests Message	187
InstantQC	187
Refresh the Review Window.....	188
Manage Columns	188
Manage Expected Tests	189
Overview of the Data Review Report	190
Create the Data Review Report	190
Data Analysis Grid	192
Examples of Comparisons with the Data Analysis Grid	192
View the Data Analysis Grid	192
Select a Data Analysis Grid Template	192
Select Levels.....	193
Configuration Detail Preview	193
Column Colors	193
Data Analysis Grid Columns	194
Data Set Configuration	195
Configure the TE _a (Allowable Total Error)	196
Configure Alerts.....	199
Export the Data Analysis Grid.....	199
Print the Data Analysis Grid	199
Create a New Data Analysis Grid Template.....	199
Create a New Template Based on an Existing Template	200
Update an Existing Data Analysis Grid Template.....	200
Configure Data Set A	200
Configure Data Set B	201
Configure Data Set B2	203
Configure the General tab	203
Data Analysis Grid Formulas.....	204
Action Log and Actions.....	205
Add a Custom Action	205
Edit an Action.....	206
Sort the Action Log	206
Suppress an Action.....	206
Unsuppress an Action	207

Delete an Action.....	207
Setup Action Filter.....	208
Automatic Action Logs	208
When and where the messages will appear	209
Set Up Automatic Action Logs	209
Turn Off Automatic Action Logs.....	209
View an Action in the Data Entry Dialog Boxes	209
Add an Action in the Data Entry Dialog Boxes	210
Add an Action in the Bench Review and Supervisor Review	210
Comments.....	210
View Comments.....	211
Add a Comment to a Row of Data	211
Add a Comment in the Bench Review and Supervisor Review.....	211
Actions and Comments by Instrument.....	212
Add an Action and/or Comment by Instrument	212
Require Audit Trail Comments.....	213
Turn on Require Audit Trail Comments.....	213
Turn Off the Require Audit Trail Comments Function.....	213
 Chapter 13: Unity Real Time Charts	215
Overview	215
Keyboard Shortcuts.....	216
Levey-Jennings Chart	217
How to Use the Levey-Jennings Chart	217
Create a Levey-Jennings Chart	217
Change the Status of a Data Point on a Levey-Jennings Chart.....	218
Customize the Levey-Jennings Chart	219
Customize the Levey-Jennings Chart for Qualitative Tests	222
Customize the Levey-Jennings Chart Legend.....	223
Multi-LJ Chart.....	224
Create a Multi-LJ Chart	224
Customize the Multi-LJ Chart.....	225
Create a Multi-LJ Template.....	226
Update a Multi-LJ Template.....	227
Delete a Multi-LJ Template	227
Bar Chart.....	228
Create a Bar Chart	228
Customize the Bar Chart	229
Customize the Bar Chart for Qualitative Tests	230
Youden Chart	231
How to Use the Youden Chart.....	231
Create a Youden Chart.....	231
Customize the Youden Chart.....	232
Yundt Chart	233
SDI Information	233

Interpreting CV with the Yundt Chart	234
Interpreting Bias and Linearity with the Yundt Chart.....	235
Create a Yundt Chart.....	236
Customize the Yundt Chart	237
General Chart Options	238
Fill Background	238
Select the Fill Background.....	238
Grid Lines and Color	239
Select Grid Lines and Color.....	239
Show Legend.....	240
Header Options.....	241
Select Chart Header Options.....	241
Lines Options.....	242
Graph Against Options	244
Graph Against Your Laboratory	244
Graph Against the Consensus Group	245
Save and Print Charts.....	246
 Chapter 14: Unity Real Time Intralaboratory Reports.....	248
Overview	248
Point Data Report	250
Create a Point Data Report	251
Summary Data Report	253
Create a Summary Data Report	254
Statistical Report	256
Create a Statistical Report.....	256
Supervisor's Report	258
Create a Supervisor's Report.....	259
Operator Report	261
Create an Operator Report.....	262
Measurement Uncertainty Report	263
Create a Measurement Uncertainty Report.....	263
Audit Trail Report	265
Create an Audit Trail Report.....	266
Labs Listing Report	267
Create a Labs Listing Report	268
Lots Listing Report	269
Create a Lots Listing Report	270
Tests Listing Report.....	271
Create a Test Listings Report	272
Panels Listing Report	273
Create a Panels Listing Report.....	273
Test Code Report	274
Create a Test Code Listings Report.....	275
Transmission Data Summary Report	276

Create a Transmission Data Summary Report	277
Print and Export Reports	277
Export Reports.....	277
Print with SAP Crystal Reports.....	278
Add a Signature to Report Reviews	278
 Chapter 15: Submit Data to the Unity Interlaboratory Program.....	279
Overview	279
Submit Data Manually	280
Activate Automatic Monthly Transmission	281
Submit Data from the Bench Review or Supervisor Review.....	281
Activate Transmission for InstantQC.....	281
 Chapter 16: Unity Interlaboratory Reports.....	282
Overview	282
Monthly Reports.....	283
Comprehensive Reports.....	283
Affiliated Reports	283
Qualitative Reports	283
InstantQC Reports	284
Consensus Groups	284
View, Print, and Save Interlaboratory Reports	284
Print Interlaboratory Reports.....	285
Save Interlaboratory Reports	285
Monthly Reports	285
Monthly Evaluation Report	285
How to Use This Report	285
Rejection Limits for the Mean	286
Rejection Limits for the CV	286
Laboratory Performance Overview Report	287
How to Use This Report	287
Laboratory Comparison Report.....	288
How to Use This Report	288
Laboratory Histogram Report	290
How to Use This Report	290
Statistical Profile Report	291
How to Use This Report	291
Laboratory 2SD and 3SD Ranges	291
Summary Statistics	291
Frequency Histograms	292
Percentile Distribution Table.....	293
How to Use This Report.....	293
Bias and Imprecision Histogram Report	293
How to Use This Report	293

Comprehensive Reports	295
Worldwide Report.....	295
How to Use This Report.....	295
Manufacturer Report.....	296
How to Use This Report.....	296
Affiliated Reports.....	297
Affiliated Laboratory Comparison Report.....	297
How to Use This Report.....	297
Affiliated Laboratory Comparison Report: Abbreviated Summary.....	299
How to Use This Report.....	299
Affiliated Data Exception Report	300
How to Use This Report	300
Qualitative Reports	302
Qualitative Urinalysis Report	302
Urine Chemistry Report.....	302
Microscopic Report	303
Qualitative Blood Typing/Serum Indices Reports.....	304
Qualitative Worldwide Report	304
InstantQC Reports.....	305
Advantages of InstantQC Reports	305
How to Use This Report	305
View InstantQC Reports	306
 Chapter 17: Regulatory Requirements and Reports.....	307
Overview	307
CLIA Requirements.....	308
CAP Accreditation Requirements	312
ISO 15189 Requirements.....	322
 Chapter 18: Westgard Advisor.....	325
Overview	325
Flowchart of the Westgard Advisor Process.....	327
Allowable Total Error (TE _a)	328
Allowable Total Error (TE _a) Options.....	328
Configure the Allowable Total Error (TE _a)	330
Preferences	331
Data Requirements	331
Customize Data Requirements.....	332
Grid Display Options	332
View Existing QC Rules	333
View Lab Data and Group Statistics.....	333
Design QC Rules	334
Consensus Groups	335
Generate Rules with the Westgard Advisor Wizard	335

Generate Rules with the Advanced Option	338
Generate Rules with the Westgard Advisor Defaults	339
View the Data Grid Tab	340
View OPSpecs Chart	341
OPSpecs Chart Components.....	342
How to Interpret OPSpecs Chart.....	344
When Westgard Advisor Recommends a Maximum QC Procedure.....	345
View Sigma Metrics Chart.....	345
Components of a Sigma Metrics Chart	346
Advanced Tool.....	347
Westgard Advisor Report.....	348
Apply Rules with Westgard Advisor.....	349
Apply Rules.....	349
Delete Historical Rules Suggestions.....	350
 Chapter 19: Using RiliBÄK	351
Overview	351
Part A.....	352
Part B	352
Analytes Listed in Table B1	352
Internal Quality Control Requirements.....	353
Analytes Not Listed on Table B1	354
Set Up RiliBÄK Permissions	355
Getting Started with RiliBÄK	356
Add RiliBÄK Tests	356
RiliBÄK Settings.....	358
RiliBÄK Target Value and Deviation.....	358
Analyte Listed on Table B1	358
Analytes Not Listed on Table B1	359
Settings.....	360
Enter Data	361
Data Entry Grid	361
Control Cycle Screen	361
RiliBÄK Evaluation of Individual Results	361
Calculation of Internal Laboratory Error Limits.....	362
Assessment of Control Cycles.....	362
Administrative Buttons	363
Charts	363
Accuracy and Precision.....	364
Accuracy	364
Precision.....	364
Accuracy + Precision	365
Levey-Jennings Chart.....	365
RiliBÄK Reports	365
Cyclus Report	366

Create a Cyclus Report	367
Negative Cyclus Report.....	368
Create a Negative Cyclus Report.....	369
LIME Report.....	369
Create a LIME Report	370
Graphic LIME Report.....	371
Create a Graphic LIME Report	371
Point Data Report	372
Create a Point Data Report	372
Graphic Point Data Report	373
Supervisor's Report.....	373
Create a Supervisor's Report.....	373
Summary Data Report.....	375
Create a Summary Data Report	375
Target Report	376
Create a Target Report	376
Test Overview Report	377
Create a Test Overview Report	377
 Chapter 20: Unity Real Time Database	378
Log On To the Database	378
Default Database Log On	378
Change the Database at Log On.....	379
Log On To a Different Database.....	380
View and Update Database Information	380
View Database Information.....	381
Update the Database Automatically	382
Update the Database from QCNet.com.....	383
Database Utilities	383
Export Data.....	384
Condense Data	385
Reconcile the Database	386
Delete a Range of Data	387
Move Data	389
Backup and Restore the Database	390
Overview	390
Before You Start	391
Start the Utility	391
Perform a Manual Backup.....	391
Set Up a Scheduled Backup	393
Select the Frequency of the Backup.....	396
One-Time Occurrence	396
Daily Backup	397
Weekly Backup.....	398
Monthly Backup.....	399

Select the Backup Folder	401
Restore the Database.....	404
Manually Back Up or Restore the Database Remotely.....	406
Manually Back Up the Database Remotely.....	406
Manually Restore the Database Remotely	408
View the Activity Log	410
 Chapter 21: Install Unity Real Time	412
Introduction	412
Overview	412
Functional Components of Unity Real Time.....	413
Software Components	413
Application Environment.....	413
Unity Real Time Client System Requirements.....	414
Getting Started with Installation.....	415
Application Deployment.....	415
Virtual Environments.....	415
Unity Real Time Database Compatibility and Settings	416
Unity Real Time Database Sizing Recommendations	419
Small Scale Implementation Specifications	419
Medium Scale Implementation Specifications.....	419
Enterprise Level Implementation Specifications	419
Scalability.....	420
Reliability	420
Unity Real Time Network and Interface Requirements.....	421
Security and Access Control Information	422
Database Security	422
Application Security.....	422
Encryption.....	422
Integration with Enterprise Access Control (LDAP).....	422
Anti-Virus Integration	422
Client System Permissions	423
User Roles	423
Auditing.....	423
Vulnerability	423
Unity Real Time Disaster Recovery and Backups	423
Backing Up the Database.....	423
Disaster Recovery	423
Unity Real Time Certifications and Regulations.....	425
Unity Real Time Development Life Cycle	425
Change Management and Testing	425
Software Quality Assurance.....	425
Unity Real Time Support	426
Description of Software Support.....	426
Level of Support.....	426

Response Time	426
After-Hours Work	426
Training	426
Upgrades	427
Customer Assistance	427
Remote/VPN Access.....	427
On-Site Visits	427
Temporary “Work-Around(s)”	427
Software Solution.....	427
Enhancement.....	428
Software Support Hours and Contact Info	428
Updating and Upgrading the Software.....	428
Automatic Updating	428
Microsoft Compatibility.....	428
Update Notification.....	428
Frequency of Updates.....	429
 Chapter 22: Configure Unity Real Time	430
Overview	430
Configure Data Entry.....	431
Configure Actions and Comments	432
Select Actions and Comments	432
Configure Database Updates.....	433
Select Database Update Options	434
Configure Product Updates	434
Configure Notifications.....	435
Expired Lot Notification	435
Connectivity Notification	435
Configure Transmission.....	435
Configure License Updates.....	436
Configure the Report Format	436
Configure Proxy Server Settings.....	437
Configure Unity Interlaboratory Report Frequency and Language.....	437
 Chapter 23: Supplemental Information	439
Action Log Messages	439
Audit Trail Events	440
Rejection Log Messages.....	443
 Chapter 24: References.....	445
Articles	445
Books.....	446
Guidelines.....	446

Glossary	447
License Agreement.....	463
License.....	463
Subscription or Charge Based Content and/or Services	464
Warranty Information.....	465
User Content	465
Personal Information	466
Storage and Loss of Use, and Limitation of Liability	466
Indemnification	466
Proprietary Information.....	466
Export Restrictions	466
Severability	467
Applicable Laws	467
Trademark Notices.....	467

Getting Started

In This Chapter

Welcome	1
Features	2
Contact Bio-Rad	3
Organization of this Guide.....	3
Program Hints	4
Typographical Styles and Conventions.....	6
Notes, Tips, Important, and Permission Notes.....	7

Welcome

Welcome to Unity Real Time, the expert quality control (QC) data management software from Bio-Rad. 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. Unity Real Time provides data access, analysis, review, management, storage, and reporting.

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

Benefits of Unity Real Time

- Facilitates compliance with regulatory and accreditation requirements (for example, ISO 15189 and CLIA).
- Enables participation in the Unity Interlaboratory Program for external peer comparison.
- Recommends and implements optimum quality control rules when used with the optional Westgard Advisor module.
- Provides high-quality statistical process control with comprehensive audit trails.
- Facilitates prospective (bench-level) and supervisory quality control data review.
- Provides advanced data analysis charts and reports.
- Enables the consolidation of quality control management into one platform.
- Reduces non-essential retesting with Analytical Goals options.

Features

Charts and Reports

There are a variety of interlaboratory charts and reports available in Unity Real Time. The Multi-LJ chart allows users to create and save a template of tests for future comparison, as well as compare multiple tests on a single chart.

The Data Analysis Grid allows users to simultaneously compare the statistics from several instruments against each other, as well as to the Unity Peer group statistics.

Qualitative Results

Unity Real Time allows customers to configure expected qualitative responses and evaluate results in a simple statistical process control scheme. There are two qualitative charts and two qualitative reports available in Unity Real Time.

Bench and Supervisor Review

Bench and Supervisor Review are critical laboratory workflow features that streamline the QC data review process for both real-time accept/reject decisions and for periodic supervisory data review. Unity Real Time enhancements enable laboratories to enforce entering corrective actions for QC failures before completing the Bench Review and/or Supervisor Review and to detect when expected tests are not present on the review screens.

Westgard (SPC) Rules and Settings Options

Improved configuration management of Westgard (SPC) rules, fixed means and standard deviations (SDs), and other settings.

Lab, Lot, Test, and Panel Configuration

Several enhancements make the configuration of labs, lots, and tests easier.

Multi Test Data Entry

Users can now enter data for multiple tests on a single screen, saving time when entering data manually.

Security/Administration

Unity Real Time service pack 7 supports Microsoft SQL Server 2017 Express and Microsoft SQL Server 2019 which provide security and administration features.

RiliBÄK 2008 Requirements

Unity Real Time includes improvements for German laboratories that are required to follow the RiliBÄK 2008 requirements.

Contact Bio-Rad

Software Support

United States: 1-800-854-6737, extension 3

Canada: 1-800-361-1808

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.

QC Program Representative

For questions related to your peer group reports, call 1-800-854-6737, extension 4.

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.

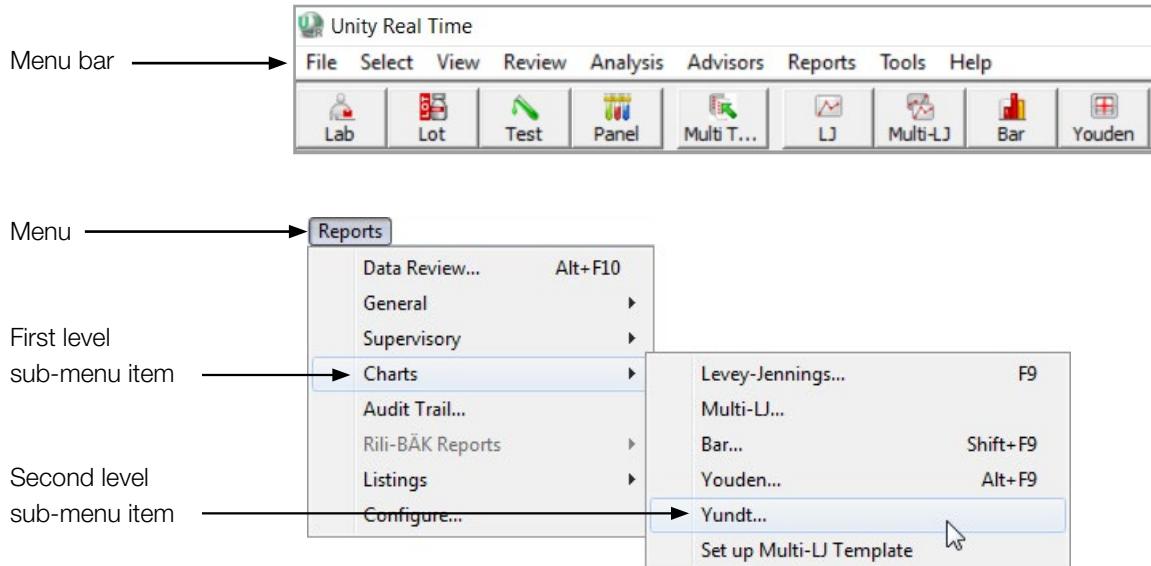
The major function of Unity Real Time is to manage QC data. Therefore, QC information appears first in this guide, the specifics of using the software appear next, and setup instructions appear last.

Program Hints

Unity Real Time contains common software elements you have probably used with other software. Each element provides a specific function for performing different actions.

Menu Bar and Menus

Access to software functions in Unity Real Time are organized by different menus and sub-menus. Click each menu on the menu bar and select a sub-menu to access different functionality of the software.



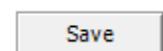
Toolbar

The Unity Real Time toolbar contains toolbar buttons. Click a toolbar button to access different functionality of the software. See “Toolbar” on page 47 for more information.



Buttons

Click a button to initiate an action.



OK Button vs. Apply Button

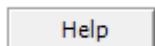
Some dialog boxes in Unity Real Time contain an **OK** button and an **Apply** button.

- Clicking the **OK** button saves any changes made and closes the dialog box.
- Clicking the **Apply** button saves any changes made and leaves the dialog box open.



Help Buttons

Some dialog boxes in Unity Real Time contain a **Help** button. The **Help** button is a link to the **Unity Real Time 2 User Guide** section that discusses topics related to the current dialog box.



Check Boxes

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



Lists

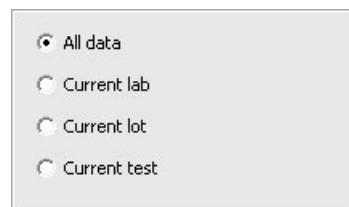
A list has a down-pointing arrow next to it. Click the arrow to open the list and make a selection.

Lot number:



Options

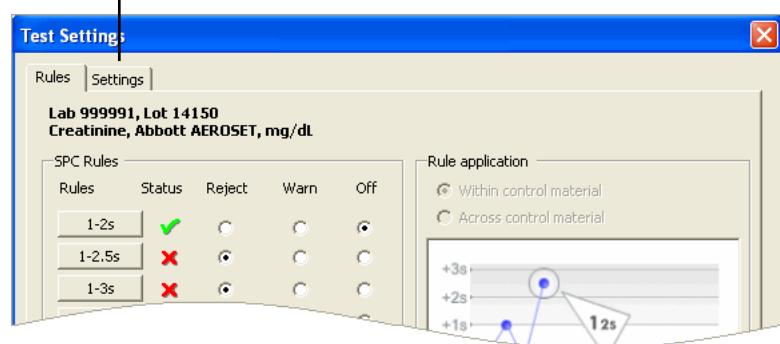
A round button is used to select one of a group of options. Unlike check boxes, only one option can be selected at a time.



Tabs

Click a tab to access a specific area within a dialog box.

Tab



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.



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

Items on the screen such as tabs, menu items, dialog boxes, buttons, options, and check boxes appear in bold.

Software Item	Example
Button	Click Save .
Check box	Select the Overlay levels check box.
Dialog box	Comments added in the data entry dialog box do not appear on the Audit Trail Report.
Menus and menu items	Click the Reports menu and then click Data Review .
Option	Select the All data option.
Tab	Click the Point Data tab.

Keyboard Keys

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

Notes, Tips, Important, and Permission Notes

This guide uses notes, tips, important, and permission 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. 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. 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. For example:



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

Permissions

A Permissions note provides information regarding specific user permissions needed to manage or use a feature in the software.



You must have the “Manage lots/tests” permission to perform this function.

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 is a process that uses surrogate patient samples and statistical process control to monitor the reliability of the testing process and the trustworthiness of the patient test results produced.

Requirements for the Statistical Process

- Regular testing of quality control products along with patient samples.
- Comparison of quality control results to specific statistical limits (ranges).

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

How Are QC Results Used?

QC results are used to validate the reliability of patient test results. Once the test system is validated, patient results can then be used for diagnosis, prognosis, or treatment planning. For example, when a patient's serum is assayed (tested) for potassium, the test result shows how much potassium (concentration) is present in the blood. This result is then used by the physician to determine whether the patient has a low, normal, or high potassium.

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. The question of reliability for most testing can be resolved by regular use of quality control materials and statistical process control.

Perform QC testing 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
	Dec 02	4.1	7.0
	Dec 03	4.0	6.9
	Dec 04	4.2	7.1
	Dec 05	4.1	7.0
	Dec 06	4.1	7.0
	Dec 07	4.2	8.0
			4.2, 4.0, 3.8, 5.0, 5.8, 4.2 3.8, 4.4, 4.6, 3.9, 4.6, 4.4, 3.9 4.4, 3.9, 3.7, 4.7, 4.7, 5.6, 4.2, 3.7, 4.3 4.7, 5.6, 4.2, 3.7, 4.3 4.3, 4.3, 4.1, 4.3 4.6, 4.4, 5.5, 3.8, 3.2 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.

How Often Should Controls be Run?

Ideally, controls should be assayed with each analytical run and placed randomly through the run to detect analytical imprecision. Controls should also have assay values within clinically significant ranges.

Determining Frequency of QC Factors

- Instrument, reagent, and method reliability
- The clinical application of the test result (for example, will incorrect patient results pose risk?)
- Amount of time available to retrieve and correct a result in error (for example, will result be acted upon immediately after it is reported?)
- Training and competency of test operators

Use of multiple levels of control allows for better laboratory decisions regarding analytical error and validity of the run. (Clinical and Laboratory Standards Institute, C24 Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, Wayne PA.)

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.

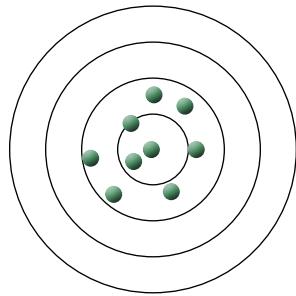


Note: As with any government regulation, these requirements can change.

Basic QC Statistics

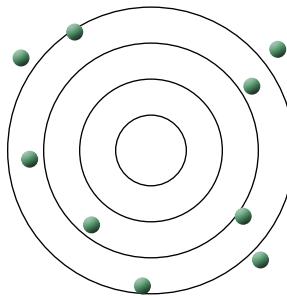
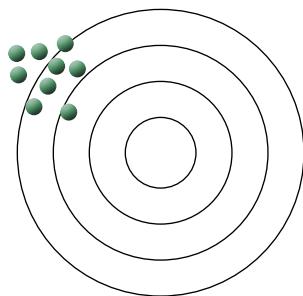
A total QC system must control both trueness and precision. The goal is for a test to have both low bias and low imprecision. Problems with imprecision are less likely to cause analytical failure in the modern laboratory due to computerization and mechanization of the analytical process. Therefore, bias 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 next 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 Unity Real Time performs these calculations, it is useful to understand the calculations, which include:

- Mean (page 12)
- Standard Deviation (page 13)
- Standard Deviation Index (page 14)
- Bias (page 15)
- Coefficient of Variation (page 16)
- Coefficient of Variation Ratio (page 17)
- Total Error and Allowable Total Error (page 17)
- z-score (page 17)

Mean

The mean is defined as the arithmetic average of a set of data points.

The mean describes the “central tendency” of the data set. In the clinical laboratory, the mean identifies the “target value” of a set of data points, usually QC or patient data.

The mean is the fundamental statistic used for comparison or for calculation of other statistics. The Clinical and Laboratory Standards Institute’s Guidance for statistical quality control (C24-Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions) recommends that at least 20 data points collected from 20 or more “separate” runs be used to establish laboratory target values for control materials. Laboratories should establish their own target values using manufacturer assay values only as guides.

Provisional target values may be established by running 20 replicates in less than 20 runs, but the provisional values must be replaced once data from 20 separate runs is accumulated. The following formula is used 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 quantifies the degree of dispersion of data points about the mean and is used to set limits upon which control result acceptability is determined. Quality control data often exhibit a “normal” or Gaussian distribution around the mean.

In a Guassian distribution:

- 68.3% of values are within ± 1.0 standard deviation of the mean.
- 95.5% of values are within ± 2.0 standard deviations of the mean.
- 99.7% of values are within ± 3.0 standard deviations of the mean.

The following formula is used 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



Note: You can create a Levey-Jennings chart to visually review data points plotted against a $\pm 3SD$ range. See “Levey-Jennings Chart” on page 217 for more information.

Standard deviation is also valuable when comparing methods or evaluating new instruments. A method or instrument with a low standard deviation produces consistent results. The lab using an instrument or method which has high standard deviations will have less certainty about the accuracy of diagnosis or the effectiveness of treatment because of test result variability. In other words, high standard deviations (poor precision, greater variability) can affect the integrity of all results. The method or instrument selected should provide a standard deviation which is medically acceptable.

Calculate a Control Mean and Range

- 1 Collect a minimum of 20 data points for each level of control.
 - Obtain data points from 20 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.



Note: 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 a guideline 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)

Another statistic which is helpful to evaluate performance is the standard deviation index (SDI). This statistic, which is usually obtained by participation in an external QC or proficiency testing program, is used to compare a laboratory's results to its consensus group. The Bio-Rad Unity Interlaboratory Program uses the consensus group value as the target value. The following formula is used to calculate the SDI:

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

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. Bias is expressed as a percentage. The following formula is used to calculate bias:

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

Coefficient of Variation (CV)

The coefficient of variation (CV) is a measure of variability. The CV is useful for comparisons of precision at different concentrations as long as the materials used are similar and CVs are determined under similar conditions. This statistic is commonly used to compare manufacturer claims, College of American Pathology (CAP) survey results, and peer group QC reports. It can also be used as a part of the internal quality control system when performing patient precision testing. The following formula is used 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%.

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. The following formula is used to calculate the CVR:

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

The CVR appears on the Data Analysis Grid and on several Unity Interlaboratory Reports.

See “Data Analysis Grid” on page 192. See “Chapter 16: Unity Interlaboratory Reports” on page 282.

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

Total error and allowable total 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. The following formula is used to calculate the TE:

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



Note: Unity Real Time uses a z-factor of 1.65 which corresponds to a 95% confidence interval.

TE_a specifications are available from several sources as described in “Determine Quality Requirements for the Test” on page 30. After choosing a TE_a , calculate the TE budget. The following formula is used to calculate the TE budget:

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

With the optional Westgard Advisor, you can choose a TE_a and the software will suggest 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. The following formula is used 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 2.3 SD away from the expected mean. The z-score appears on the Single Test Point Data Entry dialog box in Unity Real Time.

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. Rule combinations are selected by the laboratory and should be based on the quality required and the laboratory performance for each analytical method. The overall objective is to obtain a high probability of error detection and a low frequency of false rejection 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 Rule

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.

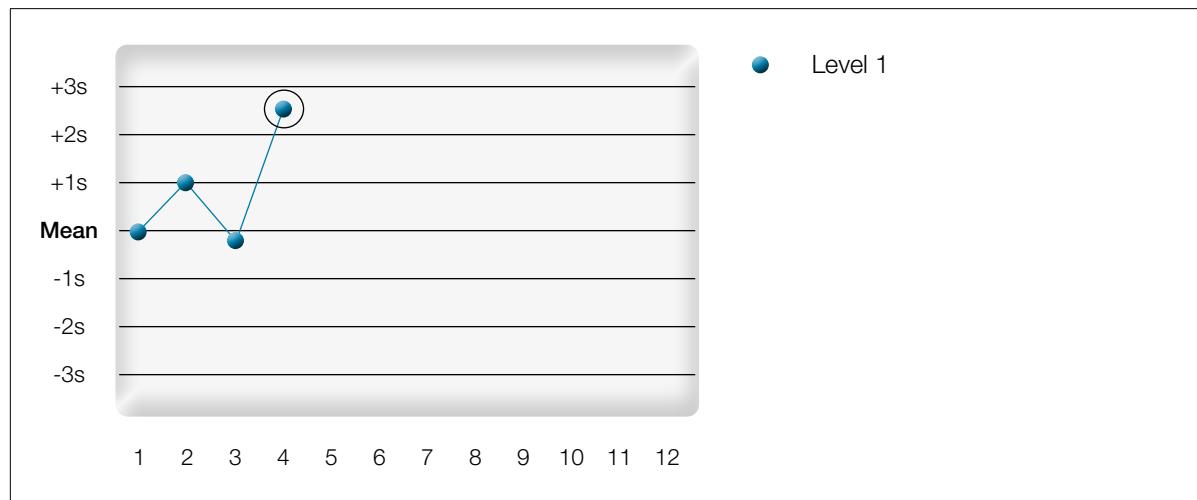
The 1-2s rule was originally designed as a warning rule for manual application of the Westgard rules. If one control measurement within a run exceeds the mean $\pm 2SD$ in a manual application of Westgard rules, evaluate other controls in the run (within the run) and in previous runs (across runs) before 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.

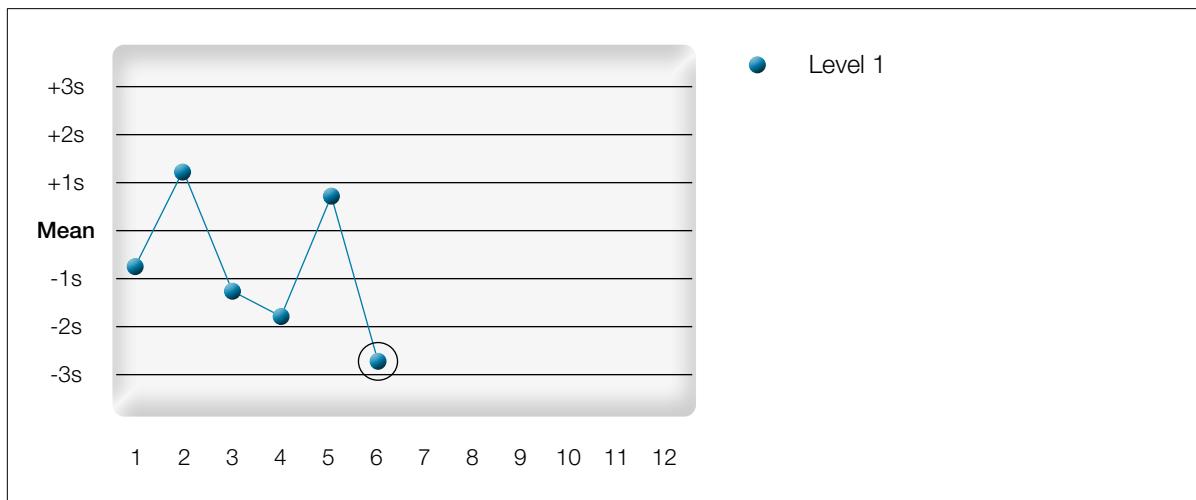
These false rejections result in the unnecessary repeat of patient samples, the waste of labor and materials, and the unnecessary delay of patient results.

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



1-2.5s Rule

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 $\pm 2.5\text{SD}$ limit.

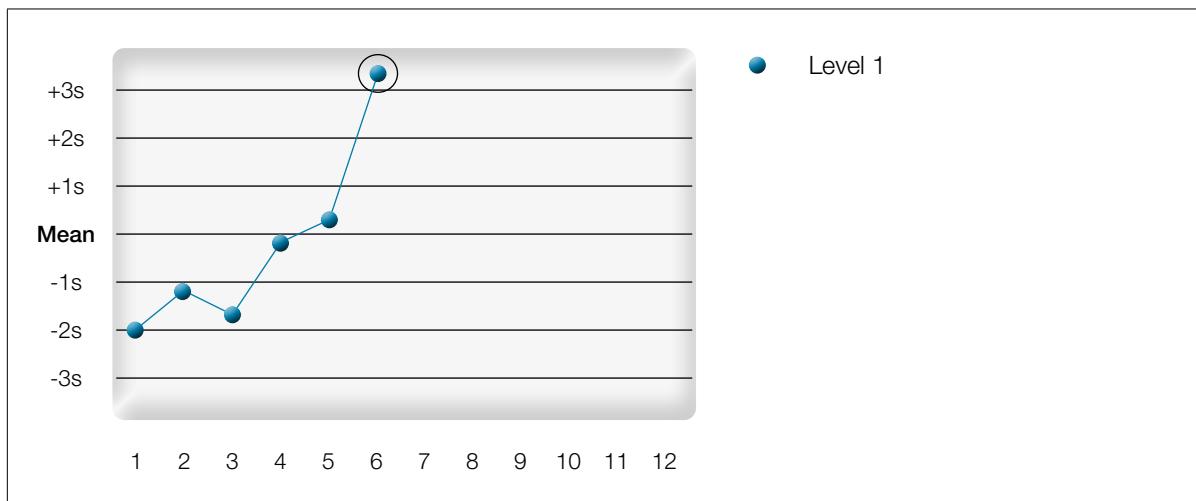


1-3s Rule

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

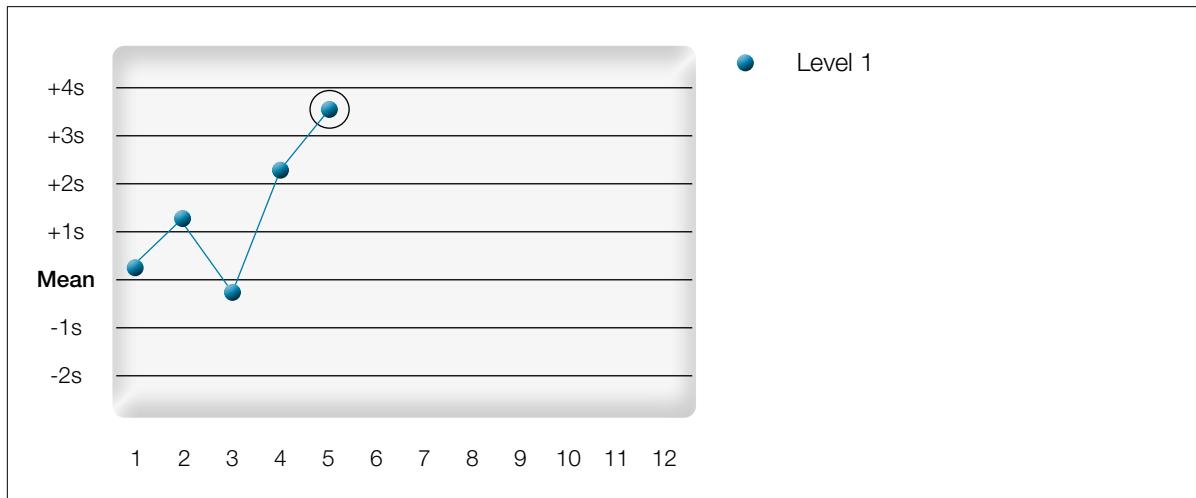
While a value outside $\pm 3\text{SD}$ may be statistically significant, it may not be biologically or medically relevant due to the fact that modern laboratory instruments are often more precise than what is needed medically. Therefore, depending upon the quality required for a test, a value outside of $\pm 3\text{SD}$ may or may not be acceptable. See Chapter 3, “Select a QC Procedure” on page 35 for more information about selecting QC rules.

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



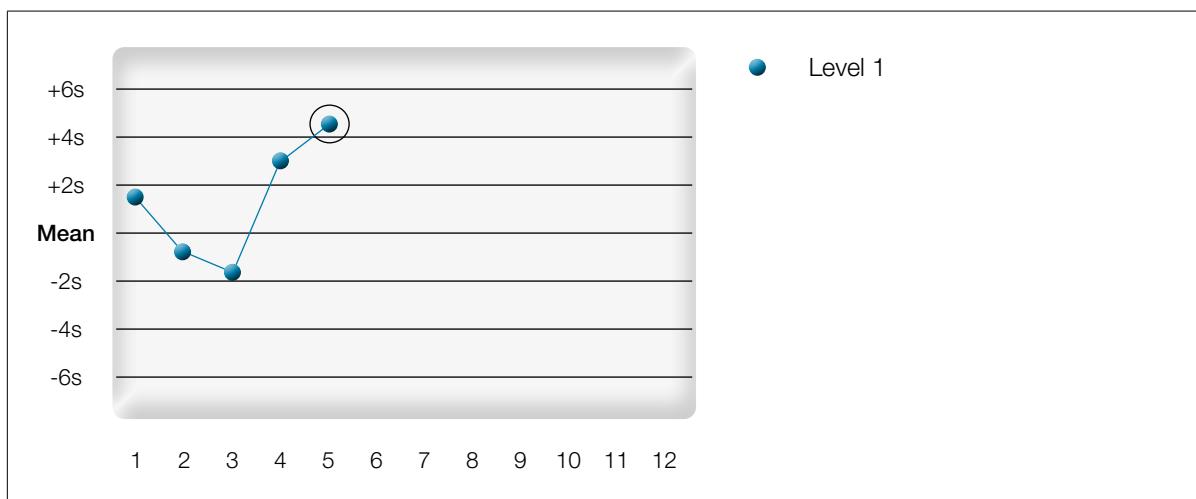
1-3.5s Rule

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



1-4s Rules

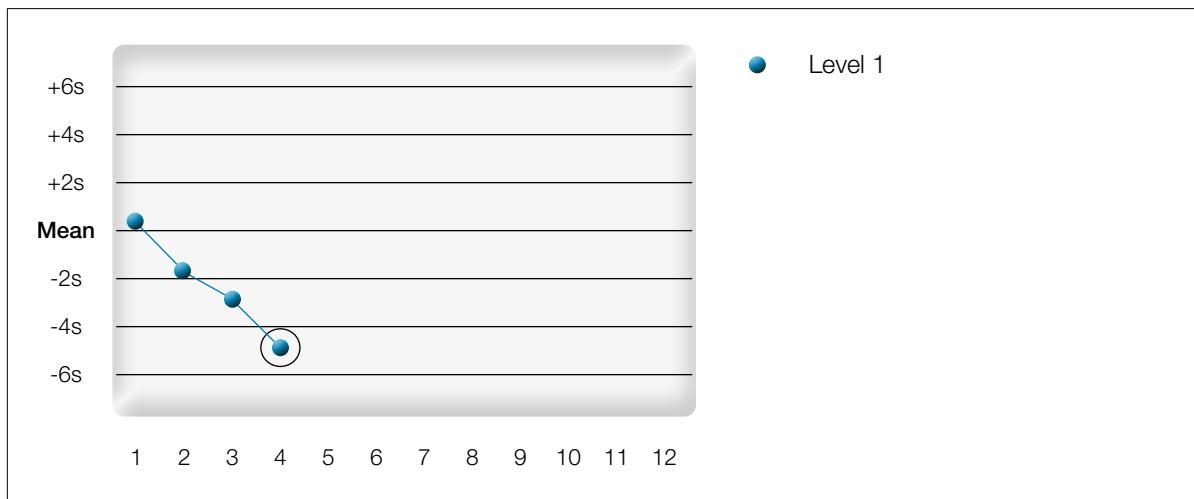
Violation of the 1-4s rule indicates random error and may also point to systematic error. When this rule is used, the run is considered out of control when one control value exceeds the mean $\pm 4\text{SD}$. This rule is applied within the run only. The following figure shows a Levey-Jennings chart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



1-5s Rule

Violation of this rule indicates random error and may also point to systematic error. When this rule is used, 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 Rule

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:

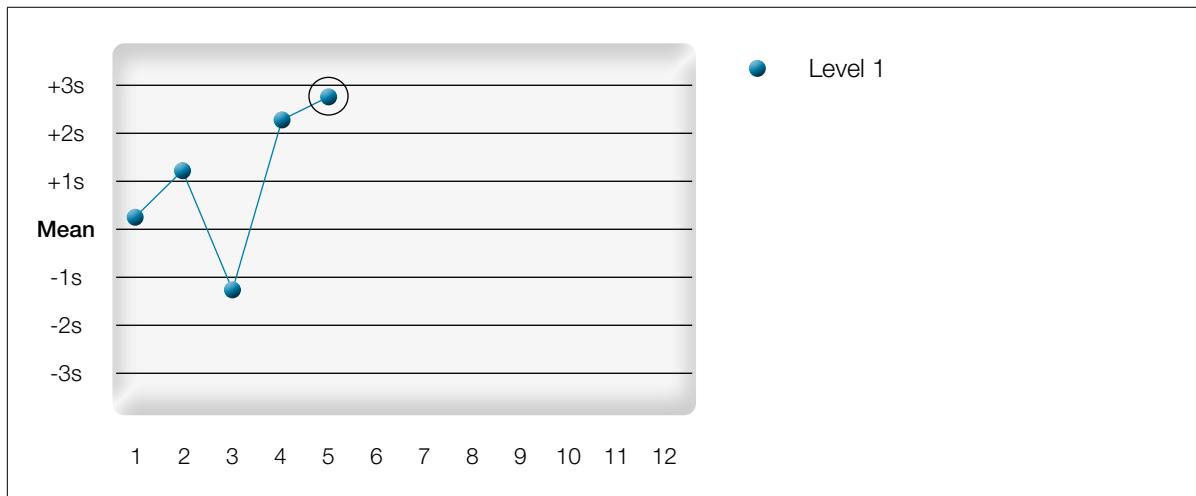
- Within run violation
Two control values in the same run are $>2SD$ on the same side of the mean. Violation of the within run application indicates systematic error is present and potentially affecting the entire analytical curve.
- Across run violation
Two consecutive values across runs are $>2SD$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



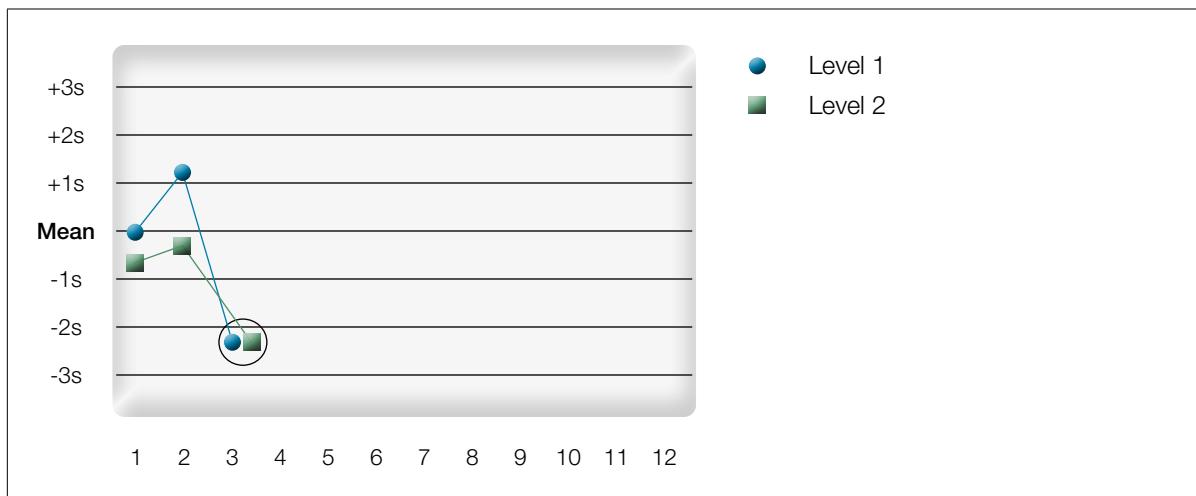
Note: This rule also applies to tri-level (three level) controls. Whenever any two of the three levels violate the criteria for this rule within the run, unacceptable systematic error may be present and must be resolved.

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

2-2s Rule Within Run Violation

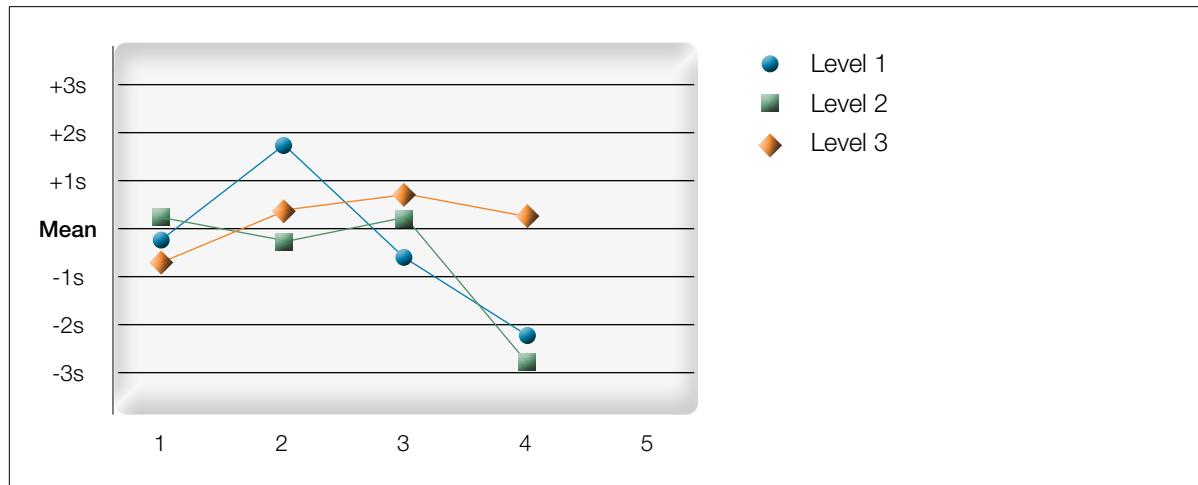


2-2s Rule Across Run Violation



2 of 3-s Rule

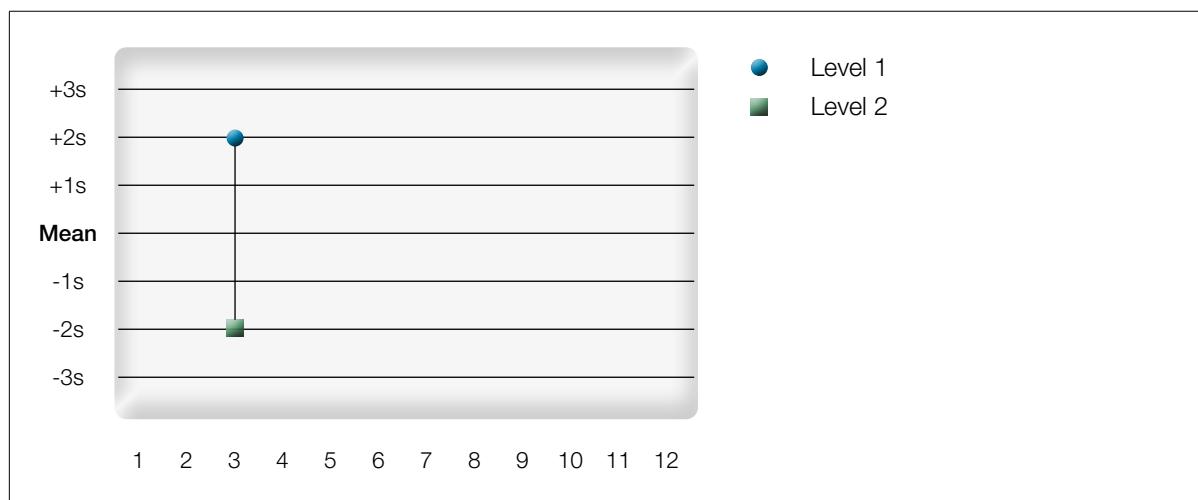
This is a variation of the 2-2s rule and detects systematic errors. It is triggered when any two of all three levels of control in a run exceed 2SD on the same side of the mean. The following figure shows a Levey-Jennings chart with two points violating the 2 of 3-s rule.



R-4s Rule

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 4 SD 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 +2.8 SD above the mean and Level 2 is -1.3 SD below the mean. The total difference between the two control levels is greater than 4 SD ($+2.8\text{SD} - (-1.3\text{SD}) = 4.1\text{ SD}$). The following figure shows a Levey-Jennings chart with two points violating the R-4s rule.



3-1s and 4-1s Rules

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

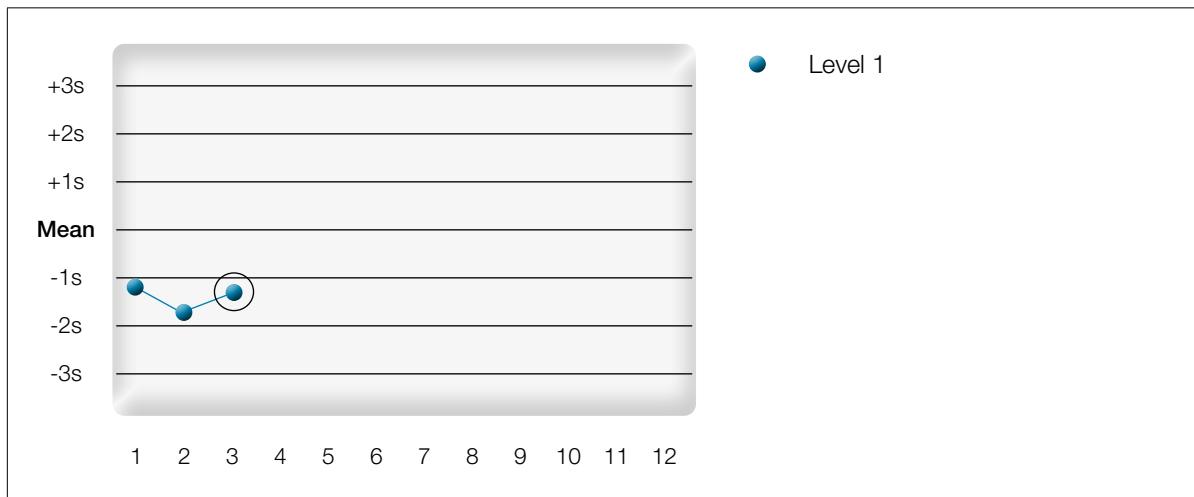
- Greater than 1SD.
- On the same side of the mean.

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

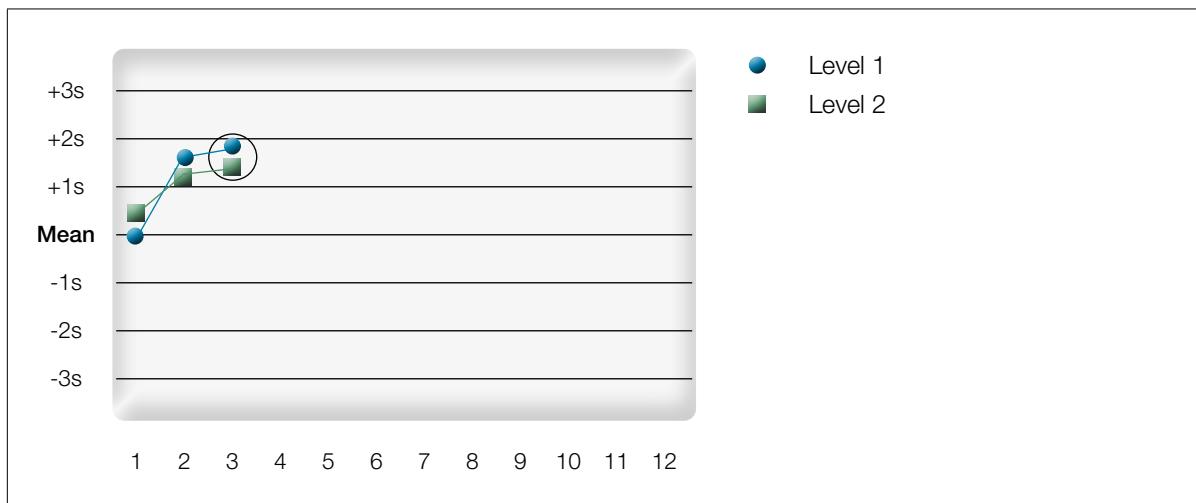
- Within a control level (for example, all Level 1 control results).
Violations within a control level indicate systematic bias in a single area of the method curve.
- Across control levels (for example, Level 1, 2, and 3 control results in combination).
Violations across control levels indicate systematic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

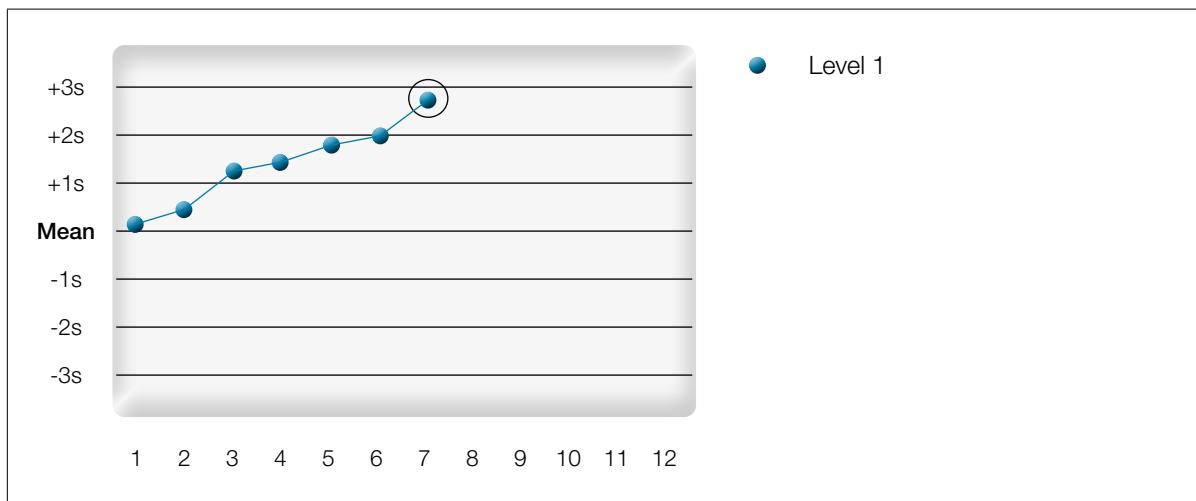


4-1s Rule Across Control Levels



7-T Rule

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.

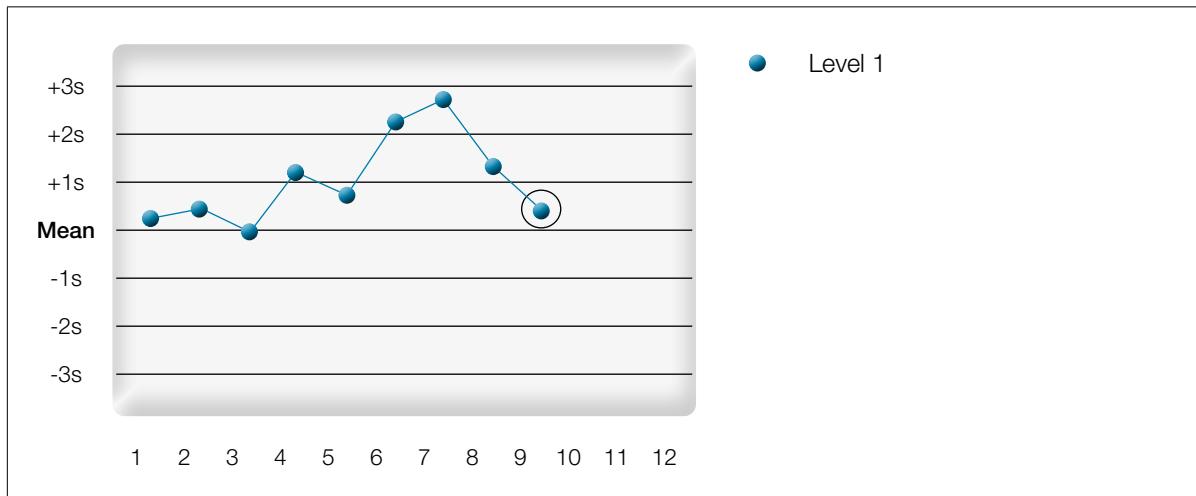
Each of these rules has two applications:

- 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.

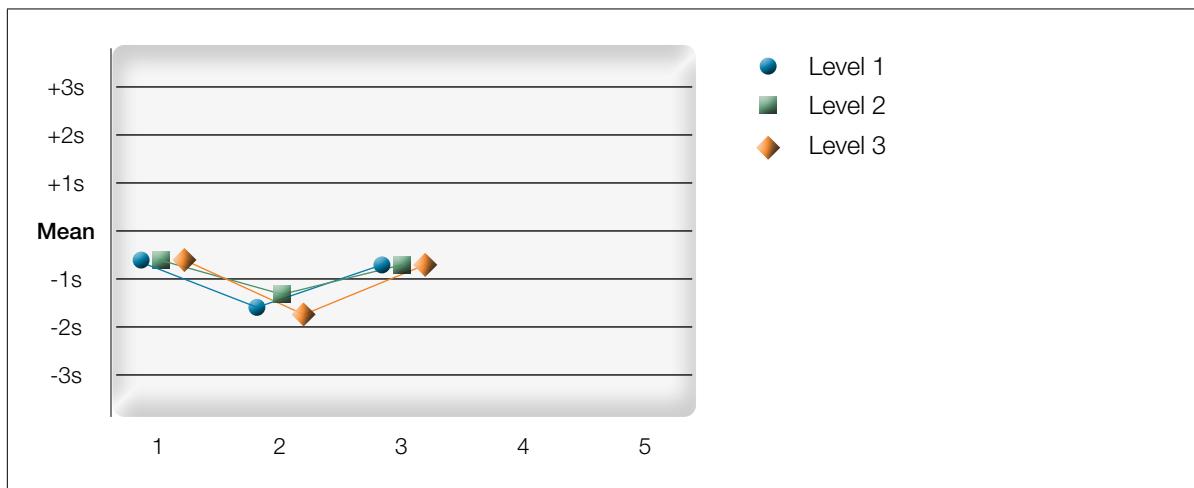
The 7-x control rule is far more sensitive to analytical bias than the 12-x rule. The chance of finding seven consecutive control observations on one side of the mean is much higher than finding twelve.

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 Rule Within a Control Level



9-x Rule Across Control Levels



Choose and Troubleshoot a QC Procedure

In This Chapter

Recommended Steps.....	29
Determine Quality Requirements for the Test.....	30
Identify Appropriate Control Materials	31
Evaluate Test Performance	31
Identify Possible QC Procedures.....	34
Predict the Performance of the QC Procedures	34
Choose Goals Based on Required Quality	34
Select a QC Procedure.....	35
Troubleshoot QC Results.....	35
Good Laboratory Habits	36
Keys to a Productive Review of the Laboratory Quality System.....	39

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 (page 30).
- 2 Identify appropriate control materials to use (page 31).
- 3 Evaluate test performance (page 31).
- 4 Identify possible QC procedures (page 34).
- 5 Predict the performance of the identified QC procedures (page 34).
- 6 Choose goals based on the required quality (page 34).
- 7 Select a QC procedure (page 35).

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 makes the complex task of choosing the appropriate SPC rules easier. See “Chapter 18: Westgard Advisor” on page 325 for more information.

Determine Quality Requirements for the Test

How good does a test need to be? Answering this question will help determine the allowable total 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 Control 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). Unity Real Time uses the following formula to calculate the laboratory total error (TE) at a 95% ($p < 0.05$) confidence interval:

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

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). The Data Analysis Grid in Unity Real Time and several Unity Interlaboratory Reports contain these statistics.



Important: 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 allowable total 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
$\pm 2\text{SD}$	4.55	45,500
$\pm 3\text{SD}$	0.27	2,700
$\pm 4\text{SD}$	0.0063	63
$\pm 5\text{SD}$	0.000057	0.57
$\pm 6\text{SD}$	0.0000002	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.

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:

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



Note: The optional Westgard Advisor 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	$\text{TE}_a > \text{bias} + 4 \text{ SD}$
3-sigma process	$\text{TE}_a > \text{bias} + 3 \text{ SD}$
2-sigma process	$\text{TE}_a > \text{bias} + 2 \text{ SD}$



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 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 Report. See “Westgard Advisor Report” on page 348 for more information.

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.

OPSspecs Charts and sigma values are available in the optional Westgard Advisor and provide information about a test’s maximum allowable bias (inaccuracy) and imprecision. See “Chapter 18: Westgard Advisor” on page 325 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 Control Materials” on page 31.
- 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, type, size, and frequency of the errors).
- The practicality of the QC procedure working for the laboratory.

The optional Westgard Advisor is an excellent tool for assisting in the design of QC procedures. While considering the selected quality specifications, Westgard Advisor makes recommendations for the SPC rules to apply and the number of control samples to run. See “Chapter 18: Westgard Advisor” on page 325 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 systematic error and the probability that the procedure will produce false rejections.

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



Tip: 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 (Ped).

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 Ped (probability of error detection), and Pfr (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.



Tip: The optional Westgard Advisor 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:

-  Inspect the control charts or rules violated to determine type of error.
-  Relate the type of error to possible causes.
-  Consider factors in common on multi test systems.
-  Relate the problem to recent changes.
-  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 39 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 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 laboratory's 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 when using the 1-3s rule). 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.



Tip: Unity Real Time provides reports and charts that are useful for problem solving, especially for unusual problems.

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

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 allowable total 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.

Unity Real Time Basics

In This Chapter

Essential Startup Tasks for New Users.....	40
Configure QC Items.....	42
Current Lab, Panel, Instrument, Lot, and Test.....	43
Adjust Column Widths.....	46
Toolbar	47
Keyboard Shortcuts.....	51
Menus and Functions	53
Functions and Where to Find Them	57
Download Adobe Reader	63
Update the License	63

Essential Startup Tasks for New Users

Bio-Rad provides your laboratory with a group login ID and password for Unity Real Time. This default administrator login allows new users first-time access to the software.



Note: See Chapter 5, “User Profiles, Passwords, and Permissions” for more information about adding additional users, changing passwords, and setting up user permissions.

Start the Software and Log On

- 1 Double-click the Unity Real Time shortcut located on your computer desktop.

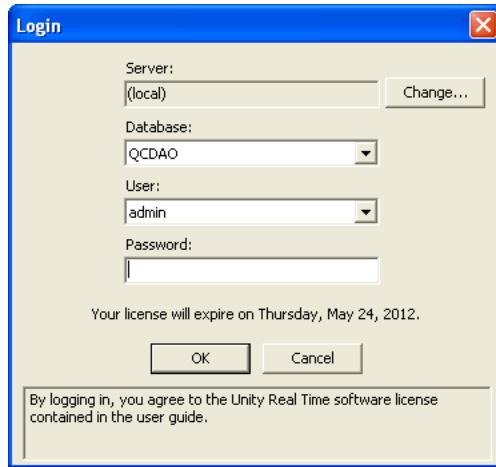


The **Login** dialog box appears.



Note: If the **Login** dialog box does not appear, click the **Tools** menu, point to **Security**, and then click **Login**.

- 2 The group login ID provided by Bio-Rad appears in the **User** list.



- 3 Type the password in the **Password** field.
4 Click **OK**.



Note: See Chapter 5, “User Profiles, Passwords, and Permissions” for more information about adding additional users, changing passwords, and setting up user permissions.

Log Off the Software



Important: Make sure you save your data before you log off the software. Data that was not saved is lost when you log off the software.

Use one of the following methods to log off the software:

- Click  located on the toolbar.
- Click the **Tools** menu, point to **Security**, and then click **Logoff**.
- Press SHIFT+F2 on the keyboard.



Note: You can add or remove the **Logoff** toolbar button. See “Search fields” on page 45 for more information.

The software remains open on the computer but is not active when you log off. The Login dialog box appears indicating the software is available for a user to log on.

Exit the Software



Important: Make sure you save your data before you log off the software. Data that was not saved is lost when you log off the software.

Click the **File** menu and then click **Exit**. The software completely closes when you exit the software.

Configure QC Items

You must perform the following tasks before you can enter QC data.

- 1 Add a lab number. See Chapter 6, “Labs and Lots.”
- 2 Add lot numbers. See Chapter 6, “Labs and Lots.”
- 3 Add tests. See Chapter 7, “Tests.”
- 4 Arrange the order of tests. See Chapter 7, “Tests.”

Current Lab, Panel, Instrument, Lot, and Test

Unity Real Time uses navigation trees to represent the hierarchy of labs, panels, and instruments and their related lots and tests set up in the software. There are three types of navigation trees you can use:

- Lab navigation tree
- Panel navigation tree
- Instrument navigation tree

Lab Navigation Tree

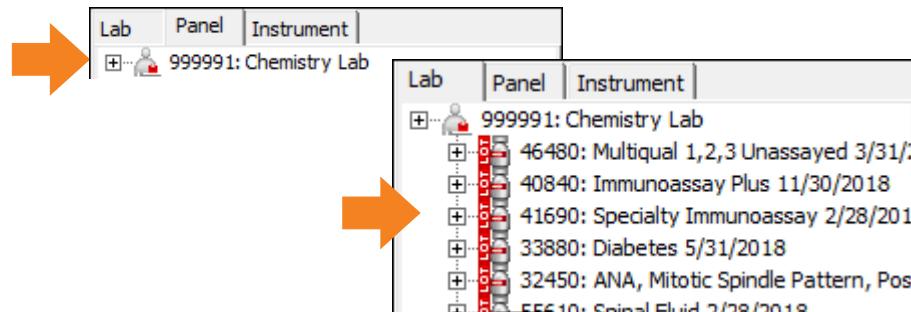
The Lab navigation tree shows the lab, lot, and test combinations.

- 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 Lab Navigation Tree

Click + (plus sign) located to the left of a lab number to expand the lab number and view the lots.

Click + (plus sign) to the left of a lot number to expand the lot and view the tests.



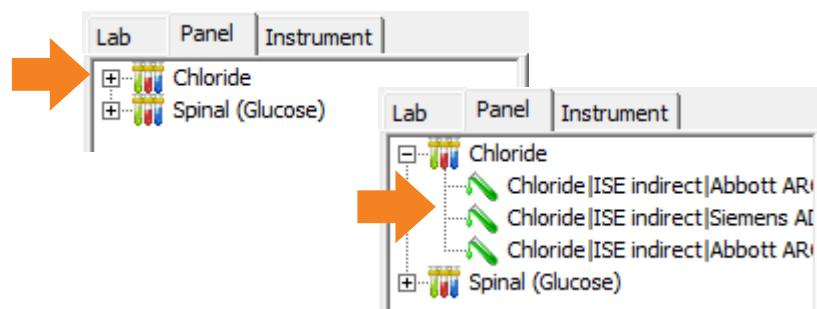
Panel Navigation Tree

The Panel navigation tree shows panel and test combinations.

- Selecting a panel name determines the current panel.
- Selecting a test determines the current panel and test.

Example Panel Navigation Tree

Click + (plus sign) to the left of a panel name to expand the panel and view the tests.



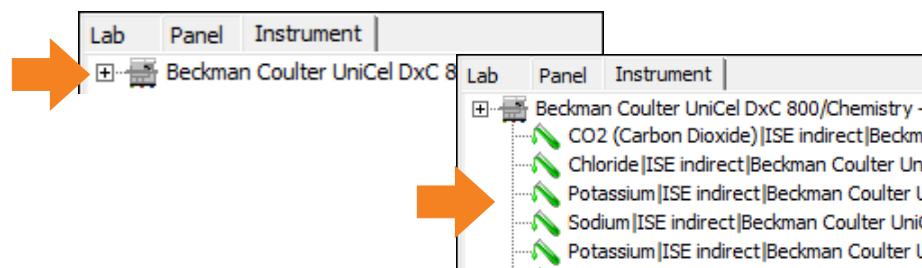
Instrument Navigation Tree

The Instrument navigation tree shows the instrument and test combinations.

- Selecting an instrument determines the current instrument.
- Selecting a test determines the current instrument and test.

Example Instrument Navigation Tree

Click + (plus sign) to the left of the instrument to expand the instrument and view the tests.

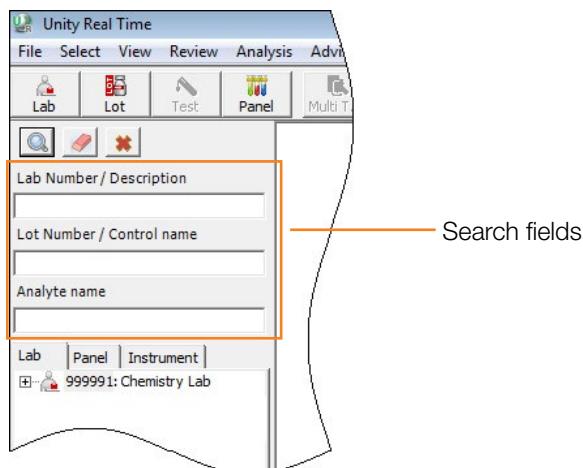


Search the Navigation Tree

The navigation tree has a search feature that lets you search for specific items.



Note: This is a helpful feature when searching for a test if the navigation tree is not in a specific order. The search feature can also be used when trying to find all instances of a test across multiple labs and lots.

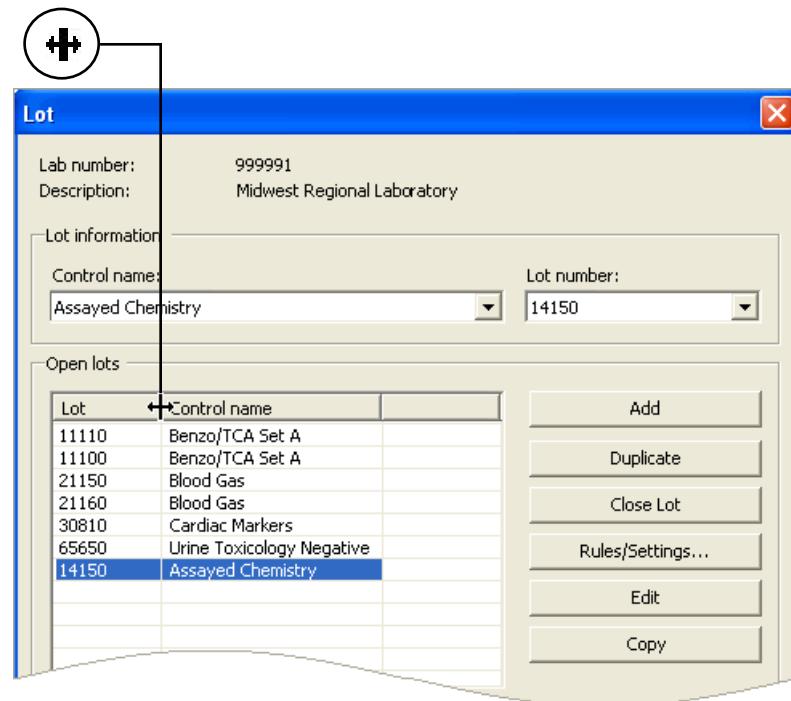


- Click the magnifying glass .
- Enter the item for which you want to search in the appropriate field.
- Click the magnifying glass  again.
- Click  to return to the full navigation tree.

Adjust Column Widths

There are areas of the Unity Real Time software you can adjust as needed to view more information. For example, you can adjust the width of the columns in the Lot dialog box as necessary for ease of viewing.

- 1 Position the pointer on a line in the column heading so the pointer changes to a cross arrow .



- 2 Click the left mouse button and drag the line to the width you want.

Toolbar

The Unity Real Time toolbar is made up of buttons you click to access specific program features and functions. You can position your mouse over a button to view a brief description. The default toolbar contains the most commonly used buttons. However, you can customize the toolbar to contain the buttons you want.



Note: You can configure the toolbar individually for each user according to the user ID or for all users.

Toolbar Buttons

The following describes the toolbar buttons available in Unity Real Time. An asterisk (*) indicates the button appears on the toolbar by default.



Note:

- An asterisk (*) indicates the button appears on the toolbar by default.
- Bold lines around the rows indicate button groups for arrangement and sorting.

Button	Description
 Lab	Lab *
 Lot	Lot *
 Test	Test *
 Panel	Panel *
 Multi T...	Multi Test data Entry *
 Single ...	Single Test data Entry
 LJ	Levey-Jennings chart *
 Multi-LJ	Multi-LJ chart *
 Bar	Bar chart *
 Youden	Youden chart *
 Yundt	Yundt chart
 Data A...	Data Analysis Grid
 Statisti...	Statistical Report
 Supervi...	Supervisor Report
 Data R...	Data Review Report
 Point D...	Point Data Report
 Summa...	Summary Data Report
 Operat...	Operator Report

Toolbar Buttons (continued)	
Button	Description
 Bench ...	Bench Review
 Supervi...	Supervisor Review
 SPC Rules *	SPC Rules *
 RiliBÄK...	RiliBÄK Rules
 AG Rules *	AG Rules *
 Evaluat...	Evaluation Mean/SD *
 Send/R...	Send/Receive Data
 Westgard	Westgard Advisor
 Rejecti...	Rejection Log *
 Help *	Help *
 User G...	User Guide
 Logoff	Logoff *

Customize the Toolbar

- 1 Click the **View** menu and then click **Toolbar**.
 - The Toolbar dialog box appears.
 - The current toolbar buttons appear at the top of the dialog box.
 - The available buttons appear in the **Available** list on the left of the dialog box.
 - The selected buttons appear in the **Selected** list on the right of the dialog box.
- 2 Select an option for the size of the toolbar and buttons:
 - Large toolbar

- Small toolbar



Note: The small toolbar takes up less room. However, the large toolbar contains labels on each button which may be useful while you become familiar with the program.

3 Add one or more buttons to the toolbar:

- Add a single button:

Select the button in the **Available** list and click **Add ->**.

- Add multiple consecutive buttons:

Select the first button in the **Available** list you want to add, press and hold the SHIFT key on the keyboard, and then click the last button you want to add. Click **Add ->**.

- Add multiple non-consecutive buttons:

Hold down the CTRL key on the keyboard and select each button in the **Available** list you want to add. Click **Add ->**.

4 Remove one or more buttons from the toolbar:

- Remove a single button:

Select the button in the **Selected** list and click **<- Remove**.

- Remove multiple consecutive buttons:

Select the first button in the **Selected** list you want to remove, hold down the SHIFT key on the keyboard, and then click the last button you want to remove. Click **<- Remove**.

- Remove multiple non-consecutive buttons:

Hold down the CTRL key on the keyboard and select each button in the **Selected** list you want to remove. Click **<- Remove**.



Note: Click **Default** if you want to return to the default toolbar settings.

5 Sort buttons on the toolbar:

- From the **Selected List** column, click and drag a row and place it as desired in the list order.



Note: Sorting of buttons can only be done within the selected button's group. (i.e. Charts must stay in the chart group but can be re-ordered within the group. Group sections themselves cannot be reorganized.)

6 Select an option to apply the settings:

- Apply to all users
- Apply to current user

7 Click **OK**.

Keyboard Shortcuts

The information below shows keyboard shortcuts available when using Unity Real Time. A keyboard shortcut allows you to quickly access an area of the software by pressing a keyboard key or a combination of keyboard keys.

The two keys you press on the keyboard are shown with a plus sign [+] between them. For example, press the CTRL key and the F2 key simultaneously to open the Bench Review.



Note: You must first select a test in the navigation tree before using any keyboard shortcut.

Function	Keyboard Shortcut
Lab dialog box	ALT+F3
Lot dialog box	CTRL+F3
Panel dialog box	SHIFT+F3
Test dialog box	F3
Bench Review	CTRL+F2
Supervisor Review	F2

Log Off and Exit the Software	Keyboard Shortcut
Log off the software	SHIFT+F2
Exit the software	ALT+F4
Import	Keyboard Shortcut
Import utility	F12
Reports	Keyboard Shortcut
Point Data Report	CTRL+F9
Supervisor Report	CTRL+F10
Data Review Report	ALT+F10
Statistical Report	SHIFT+F10

Keyboard Shortcuts (continued)	
Data Entry	Keyboard Shortcut
Next test	F5
Previous test	SHIFT+F5
Next lot	F6
Previous lot	SHIFT+F6
Next lab number	F7
Previous lab number	SHIFT+F7
Next panel	F8
Previous Panel	SHIFT+F8
Save	CTRL+s

Charts	Keyboard Shortcut
Levey-Jennings Chart	F9
Youden Chart	ALT+F9
Bar Chart	SHIFT+F9

Viewing Charts	Keyboard Shortcut
Go to the next test	F5
Go to the previous test	SHIFT+F5
Go to the next lot (Lab navigation tree only)	F6
Go to the previous lot (Lab navigation tree only)	SHIFT+F6
Go to the next lab (Lab navigation tree only)	F7
Go to the previous lab (Lab navigation tree only)	SHIFT+F7
Go to the next panel (Panel navigation tree only)	F8
Go to the previous panel (Panel navigation tree only)	SHIFT+F8

Menus and Functions

Unity Real Time organizes software functions by different menus. The following shows the functions for each menu.

Menu	Submenu(s)
File	<ul style="list-style-type: none"> • Save/Print Chart • Exit
Select	<ul style="list-style-type: none"> • Lab
	<ul style="list-style-type: none"> • Lot
	<ul style="list-style-type: none"> • Test <ul style="list-style-type: none"> » Test » Single Test Data Entry » Multi Test Data Entry » Rules/Settings » Evaluation Mean/SD » RiliBÄK Rules » GOST Settings » Analytical Goals
	<ul style="list-style-type: none"> • Panel
View	<ul style="list-style-type: none"> • Status Bar • Refresh • Toolbar
Review	<ul style="list-style-type: none"> • Bench Review • Supervisor Review
Analysis	<ul style="list-style-type: none"> • Data Set Configuration • Data Analysis Grid
Advisors	<ul style="list-style-type: none"> • Westgard
Reports	<ul style="list-style-type: none"> • Data Review
	<ul style="list-style-type: none"> • General <ul style="list-style-type: none"> » Point Data Report » Summary Data Report » Statistical Report
	<ul style="list-style-type: none"> • Supervisory <ul style="list-style-type: none"> » Supervisor's Report » Operator Report
	<ul style="list-style-type: none"> • Measurement Uncertainty

Menus and Functions (continued)		
Menu	Submenu(s)	
Reports (continued)	<ul style="list-style-type: none"> • Charts <ul style="list-style-type: none"> » Levey-Jennings » Multi-LJ » Bar » Youden » Yundt » Set up Multi-LJ Template • Audit Trail 	
	<ul style="list-style-type: none"> • RiliBÄK Reports <ul style="list-style-type: none"> » Cyclic Accuracy Report » Cyclic Precision Report » LIME Report » Graphic LIME Report » Supervisor's Report » Point Data Report » Summary Data Report » Target Report 	
	<ul style="list-style-type: none"> • Listings <ul style="list-style-type: none"> » Labs » Lots » Tests » Panels » Test Code Report 	
	<ul style="list-style-type: none"> • GOST <ul style="list-style-type: none"> » Repeatability » Imprecision Bias » Rejection Log 	
	<ul style="list-style-type: none"> » Configure 	
Tools	<ul style="list-style-type: none"> • Security <ul style="list-style-type: none"> » Login » Logoff » Administrator » Update License » Change Password • Unity Interlab <ul style="list-style-type: none"> » Send/Receive Data » Update Database » Write Transmission Files » View Transmission Log 	

Menus and Functions (continued)	
Menu	Submenu(s)
Tools (continued)	<ul style="list-style-type: none"> • Utilities <ul style="list-style-type: none"> » Export » Import <ul style="list-style-type: none"> • Import Data • View Rejection Log • Delete Rejection Log » Condense » Reconcile » Archive/Restore » Operator setup » Delete Range of Data » Extract for Unity Next » Move Data
	<ul style="list-style-type: none"> • Actions and Comments <ul style="list-style-type: none"> » Configure Action Logs » Setup Action Filter » Action/Comment by Instrument
	<ul style="list-style-type: none"> • Setup
Help	<ul style="list-style-type: none"> » Help Topics » Bio-Rad on the Web » QCNet on the Web » Unity Support on the Web » About Unity Real Time » User Guide

Resource “Shortcuts”

Unity Real Time provides shortcuts to a number of resources that are useful. These shortcuts are displayed along the bottom of the main window. Click the appropriate globe icon  to quickly access the resource.



Note: This same area will display the server IP address, database address, and the current user with their “Edit” permissions.

Resource Name	Description	URL
Install Guide	This link will open the current PDF version of Unity Real Time 2 Technical Review. This document describes the technical and operational components of the software.	N/A
UnityConnect 2	This option is only available for databases that have been configured for it. If configured, the link will open the UnityConnect 2 connectivity software.	N/A
Unity Support	This link will take you directly to the Technical Support page on QCNet.com. From here you can find other resources.	https://www.qcnet.com/Support/tabid/337/language/en-US/Default.aspx
QCNet	This link will take you to the International Home page for QCNet.com. From here you can select the country and language that works for you.	https://www.qcnet.com/tabid/352/Default.aspx
Bio-Rad	This link will take you to the Bio-Rad.com website where you can find information about Bio-Rad's contributions in advancing scientific discovery.	https://www.bio-rad.com/

Functions and Where to Find Them

Actions/Comments by Instrument

- Set Up
 - Tools > Actions and Comments > Action/Comment by Instrument
 - See “Actions and Comments by Instrument” on page 212

Action Logs

- Configure
 - Tools > Actions and Comments > Configure Action Logs
 - See “Action Log and Actions” on page 205
- Automatic
 - Tools > Setup > Automatic action logs
 - See “Automatic Action Logs” on page 208

Analytical Goals

- Configure
 - Select > Tests > Analytical Goals
 - See “Overview of Analytical Goals” on page 134

Audit Trail

- Report
 - Reports > Audit Trail
 - See “Audit Trail Report” on page 265
- Require Audit Trail Comments
 - Tools > Setup > Require audit-trail comments
 - See “Require Audit Trail Comments” on page 213

Bench Review

- Perform Review > Bench Review
- See “About the Bench Review and Supervisor Review” on page 180

Functions and Where to Find Them (continued)

Charts

- Bar
 - Reports > Charts > Bar
 - See “Bar Chart” on page 228
- Levey-Jennings
 - Reports > Charts > Levey-Jennings
 - See “Levey-Jennings Chart” on page 217
- Multi-LJ
 - Reports > Charts > Multi-LJ
 - See “Customize the Multi-LJ Chart” on page 225
- Options



Note: You must open a chart before you can access the **Options** button.

- See “General Chart Options” on page 238
- See “Header Options” on page 241
- See “Customize the Levey-Jennings Chart” on page 219
- See “Graph Against Options” on page 244
- Youden
 - Reports > Charts > Youden
 - See “Youden Chart” on page 231
- Yundt
 - Reports > Charts > Yundt
 - See “Yundt Chart” on page 233

Condense Data

- Tools > Utilities > Condense
- See “Condense Data” on page 385

Data Analysis Grid

- Analysis > Data Analysis Grid
- See “Data Analysis Grid” on page 192

Functions and Where to Find Them (continued)**Data Entry**

- Multi Test Point
 - Select > Test > Multi Test Data Entry
 - See “Enter Multi Test Data” on page 170
- Multi Test Summary
 - Select > Test > Multi Test Data Entry
 - See “Enter Multi Test Data” on page 170
- Qualitative
 - See “Overview of Qualitative Data Entry” on page 167
- Single Test Point
 - Select > Test > Single Test Data Entry
 - See “Enter Single Test Point Data” on page 164
- Single Test Summary
 - Select > Test > Single Test Data Entry
 - See “Enter Single Test Summary Data” on page 166

Data Sets

- Configure
 - Analysis > Data Set Configuration
 - See “Data Set Configuration” on page 195

Export Data

- Tools > Utilities > Export
- See “Export Data” on page 384

Lab

- Select > Lab
- See “Add and Update Lab Numbers” on page 79

License

- Tools > Security > Update License
- See “Update the License” on page 63

Functions and Where to Find Them (continued)
Lot <ul style="list-style-type: none">• Select > Lot• See “Lot Numbers” on page 85
Operator Setup <ul style="list-style-type: none">• Tools > Utilities > Operator Setup• See “Operator Setup” on page 76
Panels <ul style="list-style-type: none">• Select > Panel• See “Create a Panel and Add Tests” on page 118
Passwords <ul style="list-style-type: none">• Change<ul style="list-style-type: none">– Tools > Security > Change Password– See “Change a Password” on page 70• Expiration<ul style="list-style-type: none">– Tools > Security > Administrator– See “Password Expiration” on page 69
Reconcile Data <ul style="list-style-type: none">• Tools > Utilities > Reconcile• See “Reconcile the Database” on page 386

Functions and Where to Find Them (continued)**Reports**

- Data Review
 - Reports > Data Review
 - See “Create the Data Review Report” on page 190
- Listings
 - Reports > Listings > Labs/Lots/Tests/Panels/Test Code Report
 - See “Listings Reports” on page 267
- Operator
 - Reports > Supervisory > Operator Report
 - See “Operator Report” on page 261
- Point Data
 - Reports > General > Point Data Report
 - See “Point Data Report” on page 250
- Statistical
 - Reports > General > Statistical Report
 - See “Statistical Report” on page 256
- Summary
 - Reports > General > Summary Data Report
 - See “Summary Data Report” on page 253
 - Reports > Supervisory > Supervisor’s Report
 - See “Supervisor’s Report” on page 258
- Transfer Data Summary Report
 - Tools > Unity Interlab > Send/Receive Data
 - See “Transmission Data Summary Report” on page 276

Rules/Settings

- Select > SPC Rules
- See “Select SPC Rules” on page 130 and “Test Settings” on page 108

Functions and Where to Find Them (continued)**Submit Data to Bio-Rad**

- Automatic Monthly Transmission
 - Tools > Setup > Configure Unity Real Time tab > Automatic monthly transmission
 - See “Activate Automatic Monthly Transmission” on page 281
- From Data Review (Bench/Supervisor)
 - Tools > Setup > Configure Unity Real Time tab > Data review transmission (for InstantQC)
 - See “Activate Transmission for InstantQC” on page 281
- Manually
 - Tools > Unity Interlab > Send/Receive Data
 - See “Submit Data Manually” on page 280

Supervisor Review

- Review > Supervisor Review
- See “Perform a Bench Review or Supervisor Review” on page 182

Test

- Select > Test
- See “Add Tests” on page 97

Unity Interlaboratory Reports

- Frequency and Language
 - Tools > Setup > Unity Interlab Reports tab
 - See “Configure Unity Interlaboratory Report Frequency and Language” on page 437
- Report Types
 - See “Monthly Reports” on page 285
 - See “Comprehensive Reports” on page 295
 - See “Affiliated Reports” on page 297

Users

- Add
 - Tools > Security > Administrator
 - See “Add a User” on page 65

Westgard Advisor

- Advisors > Westgard
- See “Chapter 18: Westgard Advisor” on page 325

Download Adobe Reader

Unity Real Time requires installation of the free Adobe Reader 6.0 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.

Update the License

There are two ways to update the license for Unity Real Time:

- Automatic license updates from Bio-Rad
- From an XML license file from Bio-Rad

Automatic License Updates

You can configure Unity Real Time to automatically update the license.

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Select the **Automatic license updates** check box.

Update the License with an XML File

- 1 Click the **Tools** menu, point to **Security**, and then click **Update License**.
The **Update License** dialog box appears.
- 2 Click .
The **Open** dialog box appears.
- 3 Navigate to the location of the XML file and click **Open**.
- 4 Click **Upload**.

User Profiles, Passwords, and Permissions

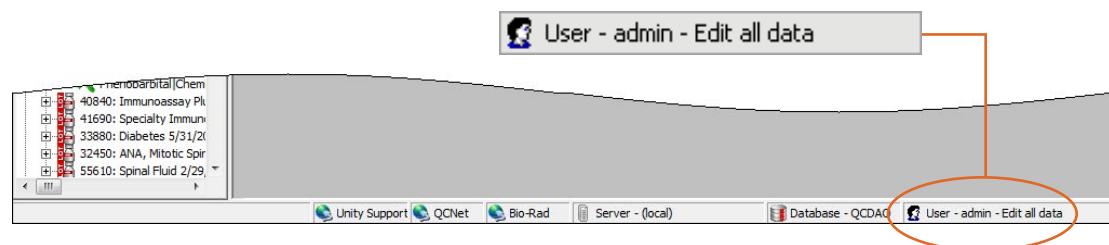
In This Chapter

Overview	64
Add, Edit, and Delete Users.....	65
Assign Lab Numbers to Users	68
Passwords	69
User Permissions.....	71
Set Up User Permissions.....	75
Operator Setup.....	76

Overview

Unity Real Time provides user profiles with passwords and permissions to control user access to program functions. Bio-Rad recommends each user 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.

The user ID and permissions for the user logged on to the software appear on the lower right of the screen. For example:



Add, Edit, and Delete Users

Add a User



You must have the “Manage users” permission to perform this function.

- 1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.

- 2 Click **New**.

The existing information in the fields clear.

- 3 Enter the user ID in the **User ID** field.



Note: The user ID can contain any combination of letters and numbers up to 80 characters.

- 4 Enter the user name in the **User name** field.



Note: The user name can contain any combination of letters and numbers up to 80 characters.

- 5 Enter the password in the **Password** field.



Note: The password can contain between 2 and 20 characters and can consist of any combination of letters and numbers. See “Password Requirements” on page 69 for more information.

- 6 Enter the user initials in the **Initials** field.



Note: The initials can contain between 1 and 4 characters. The initials appear on the lower right of the screen for the user logged on to the software and in the OP (operator) column of the Single Test Data Entry dialog boxes to identify the user who manually entered the data. User initials are also added to actions, comments, all reports, and other areas of the software where required.

- 7 Enter the minimum number of characters for the password in the **Minimum Password Length** box.



Note: The minimum password length can be between 2 and 20 characters.

8 Select the **Set password expiration period to** check box and select an expiration period from the list.

- Never (default)
- 3 months
- 6 months
- 9 months
- 12 months

See “Password Expiration” on page 69 for more information.

9 Select an option for the password expiration period:

- Applied to this user only
- Applied to all users

10 Select the individual permissions you want to give the user.

- Select the check box next to a permission to assign the permission.
- Clear the check box next to a permission to remove the permission.



Tip: Select the **Administrator** check box if you want to give the new user access to all available software functions. See “User Permissions” on page 71 for a description of permissions.

11 Click the appropriate button:

- Click **OK** to apply the user settings and close the **Administrator** dialog box.
- Click **Apply** to apply the user settings without closing the **Administrator** dialog box. This is convenient if you want to continue to add other users. You can then click **New** and repeat steps 3–11 to add the other users.



Important: Setting up user permissions is step one in giving users access to work in Unity Real Time. Step two is assigning lab numbers for them to work with. See “Assign Lab Numbers to Users” on page 68 for more information.

Edit a User



You must have the “Manage users” permission to perform this function.

- 1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.
- 2 Select the user from the **User ID** list.
- 3 Change the user profile and permissions as needed:
 - Select the check box next to a permission to assign the permission.
 - Clear the check box next to a permission to remove the permission.
- 4 Click **OK**.



Tip: Select the **Administrator** check box if you want to give the new user access to all available software functions. See “User Permissions” on page 71 for a description of permissions.

Delete a User



You must have the “Administrator” permission to perform this function.



Note: Deleting a user removes the 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 boxes for any data the user previously entered and elsewhere in the software where recorded (actions, comments, reports, audit trail, etc.).

- 1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.
- 2 Select the user from the **User ID** list.
- 3 Click **Delete**.
A message appears asking for confirmation.
- 4 Click **Yes**.
- 5 Click **OK**.

Assign Lab Numbers to Users



You must have the “Manage users” permission to perform this function.

1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.

2 Click **Assign Lab Numbers**.

The **Assign Lab Numbers** dialog box appears.

3 Select the user from the **User ID** list.

4 Select the check box for each lab number you want to assign to the user.



Tip: You can select or clear the **Lab** check box to assign or remove the user from all lab numbers.

5 Click the appropriate button:

- Click **OK** to apply the lab number(s) and close the **Assign Lab Numbers** dialog box.
- Click **Apply** to apply the lab number(s) without closing the **Assign Lab Numbers** dialog box. This is convenient if you want to continue to assign lab numbers to other users. Repeat steps 3–5 to assign lab numbers to other users. A message appears asking for confirmation if you clicked the **Apply** button.

6 Click **OK** to close the message.

7 Click **OK** to close the **Assign Lab Numbers** dialog box.

8 Click **OK** to close the **Administrator** dialog box.

Passwords

Password Requirements

- Passwords can contain between 2 and 20 characters.
- Passwords can contain any combination of letters and numbers.
- The password expiration period is set to “never” by default. Passwords can be set to expire in 3, 6, 9, 12 months, or never.

Group Login ID and Password

Bio-Rad provides a group login ID and password. This login ID is set up with Administrator permissions and allows new users initial access to the software. You can delete the group login ID or change the password after you set up additional users.



Important: At least one user must have Administrator permissions. You cannot delete the Administrator 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 and permissions.

Password Expiration

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



Note: Use of the password expiration feature is optional. However, using this feature is helpful for adding security or satisfying regulatory requirements.

You can set the password expiration period when you add new users or when you modify existing users. You can modify existing users by adding or changing the expiration period. You can apply the password expiration period to an individual user or to all users.



Tip: It is easier to specify the expiration period one time and apply it to all users if every user has the same expiration period.

Set a Password Expiration



You must have the “Manage users” permission to perform this function.

- 1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.
- 2 Select the user from the **User ID** list.
- 3 Select the **Set password expiration period to** check box and select an expiration period from the list:
 - Never (default)
 - 3 months
 - 6 months
 - 9 months
 - 12 months
- 4 Select an option to apply the password expiration period:
 - Applied to this user only
 - Applied to all users
- 5 Click **OK**.

Change a Password



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

- 1 Click the **Tools** menu, point to **Security**, and then click **Change Password**.
The **Set Password** dialog box appears.
- 2 Type the new password in the **New password** field.
- 3 Type the new password again in the **Confirm password** field.
- 4 Click **OK**.

User Permissions

You can set up user permissions to restrict a user's access to certain software features and functions.



Important: At least one user must have the “Administrator” permission. The “Administrator” permission provides access to all features and functions of the software.

- Administration/Setup permissions (page 71)
- Database permissions (page 72)
- Data permissions (page 72)
- Rules and settings permissions (page 73)
- Labs, lots, tests, and panels permissions (page 73)
- Data handling permissions (page 74)
- Data review permissions (page 74)
- RiliBÄK permissions (page 75)

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.

- **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 Chapter 21, “Configure Unity Real Time” for more information.

- **Operator setup**

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

Database Permissions

- **Archive and Restore**

Users with this permission can archive and restore the Unity Real Time database.

- **Condense data**

Users with this permission can condense data. See “Condense Data” on page 385 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 the Database” on page 386 for more information.



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

Data Permissions

- **Edit all data**

Users with this permission can enter new data and edit any line of data on the data entry dialog boxes.

- **Edit last line**

Users with this permission can enter new data and edit the last line of data on the data entry dialog boxes.



Important: Data is not evaluated against any SPC rule(s) or analytical goal when a user edits data on any line except the last line of data.

- **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 screens but cannot enter, edit, or delete data.

Rules and Settings Permissions

- **Edit test settings/rules**

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.
- Activate an analytical goal.
- Select and apply rules with the optional Westgard Advisor.



Note: Users who do not have the “Edit test settings/rules” permission can access Westgard Advisor but cannot select and apply rules.

- Configure the TE_a.

Labs, Lots, Tests, and Panels Permissions

- **Manage labs**

Users with this permission can:

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

- **Delete labs**

Users with this permission can:

- Delete Bio-Rad lab numbers.



Note: You cannot delete the primary lab number.

- **Manage lots/tests**

Users with this permission can:

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

- **Delete lots/tests**

Users with this permission can:

- Delete lot numbers.
- Delete tests.



Note: The check mark will be set and grayed out if the user already has permissions to delete lab numbers.

- **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.

- **Import data**

Users with this permission can manually import data.



Note: The ability to automatically import data from a laboratory information system (LIS) or middleware is not controlled by permissions in Unity Real Time.

- **Export data**

Users with this permission can manually export data.

- **Graphing Options**

Users with this permission can change the graph options, including the graph against mean/SD/CV for their own charts. Only full Administrators can change options for other users.

- **Actions/Comments by Instrument**

Users with this permission can add actions and comments by instrument and they can manage the Setup Action Filter tool.

- **Manage Data Analysis Grid Templates**

Users with this permission can add, edit, and delete templates in the Data Analysis Grid.

Data Review Permissions

- **Bench Review**

Users with this permission can approve data from the Bench Review. When sending data from the Bench Review to the Unity Interlaboratory Program, the data appears on www.QCNet.com (in an InstantQC Report) after a short processing time.

- **Supervisor Review**

Users with this permission can approve data from the Bench Review or Supervisor Review. When sending data from the Bench Review and Supervisor Review to the Unity Interlaboratory Program, the data appears in the InstantQC Reports on www.QCNet.com after a short processing time.

RiliBÄK Permissions



Note: RiliBÄK permissions only apply to laboratories who use the RiliBÄK protocol based on the “Directive of the German Medical Association on the Quality Assurance Medical Laboratory Tests.” See “RiliBÄK Permissions” on page 75 for more information.

Set Up User Permissions



You must have the “Manage users” permission to perform this function.

- 1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.
- 2 Select the user from the **User ID** list.
- 3 Select the check box or option for each permission you want to apply to the user.

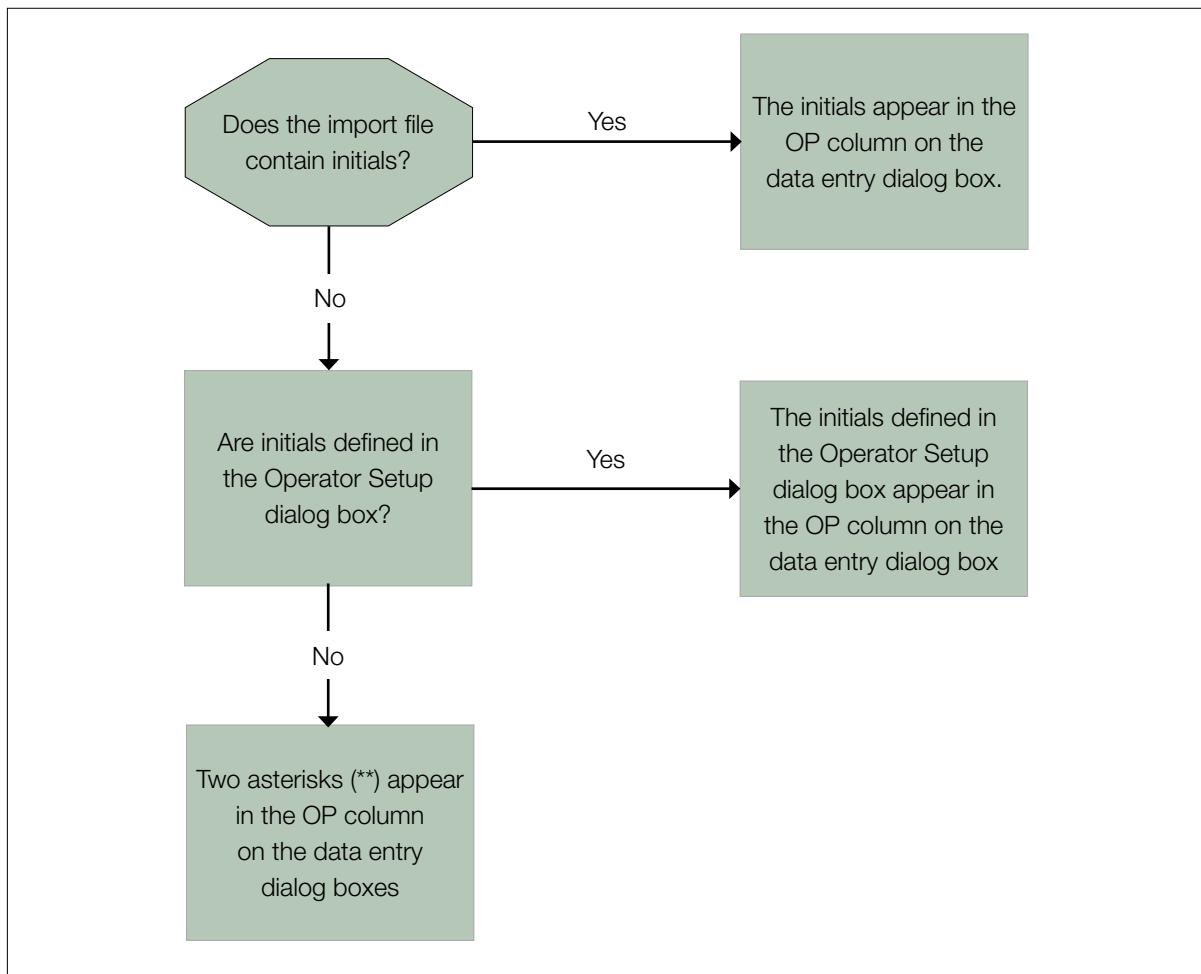


Tip: Select the “Administrator” check box if you want to give the user access to all available software functions. See “User Permissions” on page 71 for a description of permissions.

- 4 Click **OK**.

Operator Setup

You can specify operator initials for data that is imported into Unity Real Time. The software uses the following criteria to determine the initials that appear in the **OP** column of the Single Test Data Entry dialog boxes when data is imported.



Assign Operator Initials and Shifts

You can define up to eight shifts per day and assign a different operator to each shift. The setting for shifts applies to all tests in the database. Unity Real Time divides the 24-hour day evenly among the number of shifts set.

- 1 Click the **Tools** menu, point to **Utilities**, and then click **Operator setup**.

The **Operator Setup** dialog box appears.

2 Select an option for assigning the operator initials:

- All data
- Labs and lots
- Instruments
- Lab and Instrument

3 Enter the number of shifts in the **Number of shifts used per day** field (from one to eight).



Important: Set the number of “Shifts” before you make other selections. The numbers in the “Shift” column list are limited to the number of shifts.

4 Make selections from each of the lists at the top of the dialog box to assign shifts and operator initials.



Note: Different columns appear depending on the option you selected in step 2.

Labs and Lots

In This Chapter

Lab Numbers	78
Lot Numbers	85

Lab Numbers

Unity Real Time uses a six-digit lab number provided by Bio-Rad to uniquely identify your laboratory data. You must have a primary lab number to use Unity Real Time.



Important: If you have two instruments of the identical type, they must each be set up with separate lab numbers. A lab number can only be assigned by Bio-Rad. Contact your Bio-Rad QC Program Representative if you need additional lab numbers.

Types of Lab Numbers

Unity Real Time uses three types of lab numbers:

- Primary lab numbers
- Additional lab numbers
- Affiliated lab numbers

Primary Lab Number

The first lab number set up in Unity Real Time is considered your primary lab number. The primary lab number appears in bold in the **Open labs** list of the Lab dialog box.

You can close the primary lab number but you cannot delete it. See “Close a Lab Number” on page 82 for more information. Contact your Bio-Rad QC Program Representative if you need to change your primary lab number.

Additional Lab Number

You can use more than one lab number in Unity Real Time. For example, you can use a different lab number for each instrument or different lab numbers to identify different departments or shifts.



Important: If you have two instruments of the identical type, they must each be set up with separate lab numbers. A lab number can only be assigned by Bio-Rad. Contact your Bio-Rad QC Program Representative if you need additional lab numbers.

Affiliated Lab Number

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

Add and Update Lab Numbers

Add a Lab Number



You must have the “Manage labs” permission to perform this function.

- 1 Use one of the following methods to open the **Lab** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu and then click **Lab**.
 - Press ALT+F3 on the keyboard.
- 2 Click **Clear** to clear the existing information from the fields.
- 3 Type the six-digit lab number provided by Bio-Rad in the **Lab number** field.
- 4 Type the additional information for the lab number.



Note: An asterisk (*) identifies a required field.

- 5 Click **Add**.
The lab number appears in the **Open labs** list.
- 6 Click **Close** to close the **Lab** dialog box.

Update Lab Number Information



You must have the “Manage labs” permission to perform this function.



Note: You can change and update any information except for the lab number. You cannot update a closed lab number; you must first open it. See “Close a Lab Number” on page 82 for more information.

- 1 Use one of the following methods to open the **Lab** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lab**.
- Press ALT+F3 on the keyboard.

- 2 Select the lab number in the **Open labs** list you want to update.
- 3 Enter the necessary changes.
- 4 Click **Update**.
- 5 Click **Close** to close the **Lab** dialog box.

Duplicate a Lab Number



Important: Duplicating a lab number does not duplicate your QC data.



You must have the “Manage labs” permission to perform this function.

- Duplicating a lab number creates a copy of the lab information and all open lots and tests. The SPC rule and analytical goal settings (if applicable) are duplicated for all open tests. You can choose if you want to duplicate fixed means and fixed SDs.
- You can create the primary lab number and then duplicate it to set up several lab numbers with similar information. You can then edit information for the duplicated lab number as needed. This helps save time when setting up multiple lab numbers.

- 1 Use one of the following methods to open the **Lab** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lab**.
- Press ALT+F3 on the keyboard.

2 Select the lab number in the **Open labs** list or **Closed labs** list you want to duplicate.

3 Click **Duplicate**.

By default, all lots in the current lab number are selected to duplicate to the new lab number.

4 Clear and select the lot numbers you want to duplicate:

- Clear the check box for an individual lot you do not want to duplicate, or
- Click **Clear All** to clear all lots.



Note: Click **Select All** to return to the default settings.

5 Type the new lab number in the **Target lab number** field.

6 Select the appropriate check box for each item you want to duplicate, if applicable:

- **Duplicate fixed mean**
- **Duplicate fixed SD**
- **Target values for Analytical Goals**

7 Click **OK**.

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

8 Edit the duplicated lab information as needed. See “Update Lab Number Information” on page 80 for more information.

Open and Closed Lab Numbers

Lab numbers can be open or closed. Open lab numbers are available for QC data entry and submitting QC data to Bio-Rad. Results for open lot numbers appear on your Unity Interlaboratory Reports. Closed lab numbers are not available for data entry nor submitting QC data to Bio-Rad. However, the data for closed lab numbers remains in the Unity Real Time database. You can re-open a closed lab number at any time.

Close a Lab Number



You must have the “Manage labs” permission to perform this function.

- 1 Use one of the following methods to open the **Lab** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lab**.
- Press ALT+F3 on the keyboard.

- 2 Select the lab number in the **Open labs** list you want to close.

- 3 Click **Close Lab**.

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

- 4 Click **Close** to close the **Lab** dialog box.

Open a Lab Number



You must have the “Manage labs” permission to perform this function.

- 1 Use one of the following methods to open the **Lab** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lab**.
- Press ALT+F3 on the keyboard.

- 2 Select the lab number in the **Closed labs** list you want to open.

- 3 Click **Open Lab**.

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

- 4 Click **Close** to close the **Lab** dialog box.

Arrange the Order of Lab Numbers

You can rearrange the order of lab numbers in the **Open labs** list and **Closed labs** list for convenience.



You must have the “Manage labs” permission to perform this function.

- 1 Use one of the following methods to open the **Lab** dialog box:



- Click  located on the toolbar.
- Click the **Select** menu and then click **Lab**.
- Press ALT+F3 on the keyboard.

- 2 To arrange the lab numbers numerically or alphabetically:
 - a) Click the **Lab** column to arrange the lab numbers numerically from highest to lowest; click again to arrange from lowest to highest.
 - b) Click the **Description** column to arrange alphabetically from z-a; click again to arrange from a-z.
- 3 To custom arrange the lab numbers:
 - a) Select the lab number in the **Open labs** list or **Closed labs** list you want to arrange.
 - b) Drag the lab up or down to the location you want.
- 3 Repeat as needed to arrange other lab numbers.
- 4 You can also drag and drop to rearrange the order of the columns.
- 5 Click **Close** to close the **Lab** dialog box.

Adjust the Column Widths

You can also click the column dividers on the **Lab** dialog box to change the width of the columns as necessary for ease of viewing.

- 1 Position the pointer on a line in the column heading so the pointer changes to a cross arrow .
- 2 Click the left mouse button and drag the line to the width you want.

Delete a Lab Number



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 it. See “Close a Lab Number” on page 82 for more information. You can export the lab data to another file before deleting it. See “Export Data” on page 384 for more information.



You must have the “Delete lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lab** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lab**.
- Press ALT+F3 on the keyboard.

- 2 Select the lab number in the **Closed labs** list you want to delete.

- 3 Click **Delete**.

A message appears asking for confirmation.

- 4 Click **OK**.

- 5 Click **Close** to close the **Lab** dialog box.

Lot Numbers

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

Most Bio-Rad master lot numbers consist of five or six 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

Data can be entered on nine levels of control. However, only four levels can be viewed and selected for test evaluation at a time. See “Test Settings” on page 108 for more information.

Add a Bio-Rad Lot Number



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select the Bio-Rad control from the **Control name** list.



Tip: The magnifying tool is useful when you are not sure of the exact control name. Use the **magnifying glass** button to search for any part of the control name. Click the **magnifying glass** icon on the search window to see the modified/consolidated list of controls. Select the appropriate control and click **OK**.

- 3 Select the master lot number for the control from the **Lot number** list.



Note: If the lot number you want to add is not shown in the **Lot number** list, you need to update your code list. See “View and Update Database Information” on page 380 for more information.

- 4 Click **Add**.

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

- 5 Repeat steps 2–4 to add additional lots as needed.
- 6 Click **Close** to close the **Lot** dialog box.

Add a Non-Bio-Rad Lot Number



You must have the “Manage lots/tests” permission to perform this function.

You can use Unity Real Time for internal performance tracking of non-Bio-Rad control products. All Unity Real Time reports and charts are available. However, Unity Interlaboratory Reports are not available for non-Bio-Rad control products.

Non-Bio-Rad lot numbers can contain up to 15 characters consisting of numbers, letters, and symbols. You cannot assign a Bio-Rad lot number to a non-Bio-Rad control.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select **Other** from the **Control name** list.



Note: The “Other” selection appears last in the **Control name** list rather than in alphanumeric order.

- 3 Click **Add**.

The **Add Non-Bio-Rad Control** dialog box appears.

- 4 Type a name for the control in the **Control name** field.
- 5 Type the lot number in the **Master lot number** field.
- 6 Type the manufacturer name in the **Manufacturer** field.
- 7 Select the matrix from the **Matrix** list.
- 8 Enter the number of levels for the control in the **Levels** field.



Note: Up to nine levels may be defined for the control. However, only four levels can be viewed and used per test. If you have more than 4 levels in use, set up a second test for the analyte using the option for “Other” in the test name field. See “Test Settings” on page 108 for more information regarding assigning the levels to each test.



If your control levels each have their own lot number, then select the total number of levels for each lot you set up. This will allow you to label the levels correctly. Otherwise, all the levels would be labeled as level one and potentially lead to confusion. See “Test Settings” on page 108 for more information regarding level selection.

- 9 Click located in the **Expiration date** field and select an expiration date for the lot from the calendar.
The default expiration date is one year from the last day of the current month.
- 10 Click located in the **Expiration date** field and select an expiration date for the lot from the calendar.
The default expiration date is one year from the last day of the current month.
- 11 Click **OK**.
The lot number appears at the bottom of the **Open lots** list.
- 12 Click **Close** to close the **Lot** dialog box.

Duplicate a Lot Number

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

Items Automatically Duplicated

Unity Real Time automatically duplicates the following when you duplicate a lot:

- Open tests within the lot (closed tests are not duplicated)
- Test settings (levels in use, decimal places, etc.)
- Rule selections for SPC rules and analytical goals
- Tests that are included in Multi-LJ Templates

Optional Items When Duplicating

You can choose to duplicate the following optional items, if applicable:

- Fixed means
- Fixed SDs
- Target values for analytical goals

Duplicate a Bio-Rad Lot Number



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select the lot number in the **Open lots** list you want to duplicate.

- 3 Click **Duplicate**.

The **Duplicate Lot** dialog box appears and shows the current lot number at the top.

- 4 Select the new lot number from the **New lot number** list.



Tip: Only unexpired lot numbers in the same product group appear in the drop down menu.

If a lot number is already displayed in the open or closed list, it will not be included in the drop-down menu.

- 5 All labs using the original lot number are selected by default. Clear the check box for each lab you do not want the lot duplicated to.

- 6 Select the appropriate check box for each item you want to duplicate, if applicable:

- **Fixed means**
- **Fixed SDs**
- **Target values for Analytical Goals**

- 7 Click **OK**.

The new lot number appears below the previous lot number in the **Open lots** list.

- 8 Repeat steps 2–7 as needed to duplicate other lot numbers.

- 9 Click **Close** to close the **Lot** dialog box.

Duplicate a Non-Bio-Rad Lot Number



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select the lot number in the **Open lots** list you want to duplicate.

- 3 Click **Duplicate**.

- 4 Type the new lot number in the **Master lot number** field.

- 5 Click located in the **Expiration date** field and select an expiration date from the calendar.

- 6 Select the appropriate check box for each item to duplicate, if applicable:

- **Fixed means**
- **Fixed SDs**
- **Target values for Analytical Goals**

- 7 Click **OK**.

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

- 8 Repeat steps 2–7 to duplicate the lot number for all lab numbers as needed.

- 9 Click **Close** to close the **Lot** dialog box.

Edit a Bio-Rad Lot Number



Important: You should edit a lot number only if it was defined in error and needs to be corrected. Use the duplicate lot function if you are switching to a new lot number of control. See “Duplicate a Lot Number” on page 87 for more information.



You must have the “Manage lots/tests” permission to perform this function.

You can edit 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 the new lot number you select.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.

- Click the **Select** menu and then click **Lot**.
 - Press CTRL+F3 on the keyboard.
- 2 Select the lot number in the **Open lots** list you want to edit.
- 3 Click **Edit**.
- The **Edit Lot** dialog box appears.
- 4 Select the correct lot number from the **New lot number** list.
- 5 Click **OK**.
- The previous lot number is replaced with the new lot number and appears at the bottom of the **Open lots** list.
- 6 Click **Close** to close the **Lot** dialog box

Edit a Non-Bio-Rad Lot Number



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:
- Click  located on the toolbar.
 - Click the **Select** menu and then click **Lot**.
 - Press CTRL+F3 on the keyboard.
- 2 Select the lot number in the **Open lots** list you want to edit.
- 3 Click **Edit**.
- 4 Type the correct lot number in the **Master Lot Number** field.
- 5 Edit the expiration date if needed.
- 6 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.
- 7 Click **Close** to close the Lot dialog box.

Copy a Lot Number



Important: Use the copy lot function only to copy test information from a selected lab number and lot to another lab number. Use the duplicate lot function if you are switching to a new lot number of control. See “Duplicate a Lot Number” on page 87 for more information.



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Click **Copy**.

The **Copy Lot** dialog box appears.

- 3 All labs not using the original lot number are selected by default. Clear the check box for any lab to which the lot should not be copied to.
- 4 Select the appropriate check box for each item to copy, if applicable:
 - **Fixed means**
 - **Fixed SDs**
 - **Target values for Analytical Goals**
- 5 Click **OK**.
- 6 Repeat steps 2–5 as needed to copy additional lot numbers.
- 7 Click **Close** to close the **Lot** dialog box.

Closed and Open Lot Numbers

Unexpired and expired lot numbers can appear in the Open lots list or the Closed lots list. You can move open lots and closed lots between the two lists.

Open and unexpired lot numbers are available for data entry and submitting to Bio-Rad. Results appear on your Unity Interlaboratory Reports after data is submitted.

Closed lots are not available for data entry nor submitting to Bio-Rad. However, the data for closed lots remains in the Unity Real Time database. You can open a closed lot to view, print, or change data.

Close a Lot Number

You can close a lot if you are no longer running tests on the lot. A closed lot is ignored by the software although the data remains in the Unity Real Time database.



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select the lot in the **Open lots** list you want to close.

- 3 Click **Close Lot**.

- You can choose to close the **Selected Lot** or **Selected Labs** if the same lot is used on other lab numbers.

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

- 4 Click **Close** to close the **Lot** dialog box.

Open a Closed Lot Number



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select the lot in the **Closed lots** list you want to open.

- 3 Click **Open Lot**.

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

- 4 Click **Close** to close the **Lot** dialog box.

Arrange the Order of Lot Numbers

You can rearrange the order of lots in the **Open lots** list and **Closed lots** list for convenience.



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 To arrange the lot numbers numerically or alphabetically:

- a) Click the **Lot** column to arrange the lot numbers numerically from highest to lowest; click again to arrange from lowest to highest.
- b) Click the **Control Name** column to arrange the control names alphabetically from z-a; click again to arrange the lots from a-z.

- 3 To custom arrange the lot numbers:

- a) Select the lot number in the **Open lots** list or **Closed lots** list you want to arrange.
 - To select multiple consecutive lots:
Click the first lot, press the SHIFT key on the keyboard, and then click the last lot.
 - To select multiple non-consecutive lots:
Press the CTRL key on the keyboard, and then click each lot.

- b) Drag the lot up or down to the location you want.
- c) Repeat as needed to arrange other lots.

- 4 You can also drag and drop to rearrange the order of the columns.

- 5 Click **Close** to close the **Lot** dialog box.

Adjust the Column Widths

You can also click the column dividers on the **Lot** dialog box to change the width of the columns as necessary for ease of viewing.

- 1 Position the pointer on a line in the column heading so the pointer changes to a cross arrow
- 2 Click the left mouse button and drag the line to the width you want.

Delete a Lot Number



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 it. See “Close a Lot Number” on page 92 for more information. You can also export the lot data to another file before deleting it. See “Export Data” on page 384 for more information.



You must have the “Delete lots/tests” permission to perform this function.

You cannot delete an open lot number; you must first close it. See “Close a Lot Number” on page 92 for more information.

- 1 Use one of the following methods to open the **Lot** dialog box:



- Click **Lot** located on the toolbar.
- Click the **Select** menu and then click **Lot**.
- Press CTRL+F3 on the keyboard.

- 2 Select the lot in the **Closed lots** list you want to delete.

- 3 Click **Delete**.

A message appears asking for confirmation.

- 4 Click **OK**.

- 5 Click **Close** to close the **Lot** dialog box.

Lot Expiration Notifications

You can configure the software to notify you when a user opens a data entry screen 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** menu and then click **Setup**.
- 2 Select the **Expired lot notification** check box located in the **Notifications** section.
- 3 Click **OK**.

Tests

In This Chapter

Overview	95
Add Tests	97
Update Tests	103
Close and Open Tests	104
Arrange the Order of Tests	105
Delete Tests	106
Test Settings	108
Evaluation Mean and SD	109
VITROS Slide Generation Numbers	115

Overview

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

The six test parameters are:

- **Analyte**
The constituent being measured (for example, albumin, calcium, glucose, etc.).
- **Instrument/Kit**
The instrument or kit used to test the analyte.



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

- **Reagent type**
 - **Dedicated reagent or kit**

Select this option when the reagent manufacturer is the same as the instrument or kit manufacturer. For VITROS instruments using slide generation numbers, select “Dedicated reagent or kit” and type the slide generation number in the **VITROS slide generation number** field.
 - **Alternate formulation/standardization**

Select this option 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. After this occurs, you will be directed by your Bio-Rad QC Program Representative to move your data to the “Dedicated reagent or kit” category.
 - **Alternate calibration**

Select this option when quality control 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 or kit manufacturer. Select “More reagents” and then select the 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. Contact your Bio-Rad QC Program Representative if the method you use does not appear in the list.
- **Unit of measure**

Only units Bio-Rad considers valid for the selected analyte appear in the list. Contact your Bio-Rad QC Program Representative if the unit you use does not appear in the list.
- **Temperature**

Select an available temperature for enzymes. The temperature defaults to “No temperature” and cannot be changed for all other analytes.

Add Tests

You can add tests to Unity Real Time directly and indirectly.

Direct Methods of Adding Tests

- New tests appear in the **Open tests** list of the **Test** dialog box when you manually add a test or use the **Instrument Setup** feature.
- You select the test parameters from lists in the **Test** dialog box when you manually add a test.
- Unity Real Time provides the test codes based on information in the *Unity Method Guide for Selected Instruments* when you use the **Instrument Setup** feature.

Indirect Methods of Adding Tests

The following functions create tests indirectly:

- Duplicate a lab number or lot number
 - Open lots and their open tests are duplicated when you duplicate a lab.
 - Open tests are duplicated when you duplicate a lot. Closed lots and closed tests are not duplicated.
- Change the VITROS slide generation number

Changing the VITROS slide generation number creates a new test with the new slide generation number.
- Transform QC data with Bio-Rad connectivity software

The software can be set up to automatically configure and add tests in Unity Real Time when QC data is transformed with certain Bio-Rad connectivity software.

Add Tests Manually



You must have the “Manage lots/tests” permission to perform this function.

- 1 Select the lot in the **Lab** navigation tree you want to add a test to.
- 2 Use one of the following methods to open the **Test** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Test**.
 - Press F3 on the keyboard.
- 3 Select an option to display the list of valid analytes:
 - **Complete list**
Contains all analytes in the code list.
 - **Filtered list**
Contains a list of the most common analytes for the lot.

- 4 Select the analyte from the **Analyte** list.
- 5 Select the instrument/kit from the **Instrument/Kit** list.
- 6 Select the **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.
 - **More reagents**
Select this option when using a reagent that is not supplied by the instrument manufacturer. Select More reagents and then select the 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.
- 7 **VITROS instruments only:** Enter the VITROS slide generation number in the **VITROS slide generation number** field.
- 8 Select the method for the test from the **Method** list. Select **Qualitative** if the test is qualitative (for example, dipstick urinalysis tests).
- 9 Select the unit of measure from the **Unit of measure** list.
- 10 Select the temperature from the **Temperature** list.

 **Note:** The temperature applies to enzymes only. **No temperature** is automatically selected and cannot be changed for all other analytes.
- 11 Click **Add**.
You can choose to add the test to other lab numbers.
The new test appears at the bottom of the **Open tests** list.

Add Non-Bio-Rad Qualitative Tests with Qualitative Responses



Important: This is the single and only opportunity to create the list of possible responses. You will not be able to change or add to the list at another time. Be sure to have a complete list of all possible responses for the test.

- 1 Select the non-Bio-Rad lot in the **Lab** navigation tree you want to add a test to.
- 2 Use one of the following methods to open the **Test** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Test**.
 - Press F3 on the keyboard.
- 3 Select an option to display the list of valid analytes:
 - **Complete list**
Contains all analytes for the lot available in the code list.
 - **Filtered list**
Contains a list of the most common analytes for the lot.
- 4 Select the analyte from the **Analyte** list.
- 5 Select the instrument/kit from the **Instrument/Kit** list.
- 6 Select the **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 a Bio-Rad QC Program Representative.
 - **More reagents**
Select this option when using a reagent that is not supplied by the instrument manufacturer. Select **More reagents** and then select the 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 the Bio-Rad QC Program Representatives to have codes added to the code list.
- 7 **VITROS instruments only:** Enter the VITROS slide generation number in the **VITROS slide generation number** field.
- 8 Select the method for the test from the **Method** list. Select **Qualitative** if the test is qualitative (for example, dipstick urinalysis tests).
- 9 Select **Qualitative** from the **Unit of measure** list.

10 Click **Add**.

You can choose to add the test to other lab numbers.

The **Set Qualitative Responses** dialog box appears.

11 Click in the first empty row and enter a qualitative response for the test. (For example: Positive, Negative, Trace, etc.)

12 Click **Add Response** to add additional responses as needed.

13 Click the **Remove Response** button to remove a row.



Note: You cannot remove the first or last row. You can drag and drop to rearrange the order of the responses.

14 Click **OK** to save the list of responses.

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 listed in the *Unity Method Guide for Selected Instruments* are available using Instrument Setup. If your 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 on to QCNet, point to **QC Documents**, and then click **Method Guide**.

- You can edit the test and change the reagent type if you use 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 with Instrument Setup



You must have the “Manage lots/tests” permission to perform this function.

1 Select a lot in the **Lab** navigation tree.

2 Use one of the following methods to open the **Test** dialog box:



- Click  located on the toolbar.
- Click the **Select** menu, point to **Test**, and then click **Test**.
- Press F3 on the keyboard.

3 Click **Instrument Setup**.

The **Instrument Setup** dialog box appears.

- 4 Select the instrument in the **Instrument** list.

All available tests for the instrument and lot combination according to the *Unity Method Guide for Selected Instruments* appear.



Tip: The magnifying tool is useful when you are not sure of the exact test name. Use the **magnifying glass** button to search for any part of the test name. Click the **magnifying glass** icon on the search window to see the modified/consolidated list of tests. Select the appropriate test and click **OK**.



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

- 5 All tests are selected by default. Clear the check boxes for any tests you do not want to add.



Tip: Click **Clear All** to clear all check boxes. Click **Select All** to select all check boxes.

- 6 VITROS instruments only: Enter the slide generation number in each of the **SG** fields.
- 7 The Conventional unit is selected by default. Select the **SI** option if you use SI units.
- 8 Click **OK**.

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

Add Tests with a Code of “Other”



You must have the “Manage lots/tests” permission to perform this function.



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 the Bio-Rad QC Program Representatives to have codes added to the code list.

- 1 Use one of the following methods to open the **Test** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Test**.
 - Press F3 on the keyboard.
- 2 Select the test parameter from each of the respective lists in the **Test information** section or select **Other** for any code that does not appear.
- 3 Click **Add**.
The **Other** dialog box appears.
- 4 Enter the information as needed for the description.
- 5 Click **OK**.
You can choose to add the test to other lab numbers.
The new test appears at the bottom of the **Open tests** list.

Duplicate Tests



Note: You cannot duplicate individual tests. However, tests are duplicated when you duplicate a lab or lot number.

Update Tests

You can change any test parameter for an existing test, even if the test contains QC data. This feature is useful if you make a mistake when setting up a test or if a 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 “VITROS Slide Generation Numbers” on page 115 for information about updating tests that use a VITROS slide generation number.

Update a Test



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Test** dialog box:



- Click **Test** located on the toolbar.
- Click the **Select** menu, point to **Test**, and then click **Test**.
- Press F3 on the keyboard.

- 2 Select the test in the **Open tests** list you want to update.

- 3 Update the test parameters as needed from each of the lists:

- **Analyte**
- **Instrument/Kit**
- **Reagent type**
- **Method**
- **Unit of measure**
- **Temperature**

- 4 Click **Update**.

You can choose to update the test for all labs or specified labs.

Based on selections under Tools > Setup > Notifications, you may receive a message reminding you to make the same updates to your test configurations in your connectivity solution.



Note: Data will not import correctly if test settings in Unity Real Time do not match the settings in your connectivity solution. When you update a test in Unity Real Time, make the same updates in connectivity. If not updated to match, results could be sent to the rejection log or imported under an incorrect test configuration.

Close and Open Tests

Closed tests and their data remain in the Unity Real Time database, but they are not available for data entry and do not appear on Unity Interlaboratory Reports. You can re-open a test at any time, if needed.

Close a Test



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Test** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Test**.
 - Press F3 on the keyboard.
- 2 Select the test in the **Open tests** list you want to close.
- 3 Click **Close Test**.

You can choose to close the test for all labs or specified labs.

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

Open a Test



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Test** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Test**.
 - Press F3 on the keyboard.
- 2 Select the test in the **Closed tests** list you want to open.
- 3 Click **Open Test**.

You can choose to open the test for all labs or specified labs.

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

Arrange the Order of Tests

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



You must have the “Manage lots/tests” permission to perform this function.

- 1 Use one of the following methods to open the **Test** dialog box:

- Click  located on the toolbar.
- Click the **Select** menu, point to **Test**, and then click **Test**.
- Press F3 on the keyboard.

- 2 To arrange the tests alphabetically, click the **Analyte** column to arrange the analyte names from z-a; click again to arrange the analytes from a-z.



Note: Tests can be sorted by any column but most people sort by the **Analyte** column.

- 3 To custom arrange the tests:

- a) Select the analyte in the **Open tests** list or **Closed tests** list you want to arrange.
 - To select multiple consecutive tests:
Click the first test, press the SHIFT key on the keyboard, and then click the last test.
 - To select multiple non-consecutive tests:
Press the CTRL key on the keyboard, and then click each test.
 - b) Drag the test(s) up or down to the location you want.
- 4 You can also drag and drop to arrange the order of the columns on the **Test** dialog box.



Tip: This is especially helpful for viewing the VITROS Slide Generation numbers in the **Reagent** column.

- 5 Repeat as needed to arrange other tests.
- 6 Click **Close** to close the **Test** dialog box.

Adjust the Column Widths



Tip: This is especially helpful for viewing the VITROS Slide Generation numbers in the **Reagent** column.

You can also click the column dividers on the **Test** dialog box to change the width of the columns for ease of viewing.

- 1 Position the pointer on a line in the column heading so the pointer changes to a cross arrow .
- 2 Click the left mouse button and drag the line to the width you want.

Delete Tests



Important: Deleting a test permanently deletes all associated data from the Unity Real Time 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 104 for more information. You can also export the data to another file before deleting it. See “Export Data” on page 384 for more information.

You can delete open and closed tests. You can delete tests at these levels:

- Lab level
Deleting a lab also deletes its associated lots, tests, and data. See “Delete a Lab Number” on page 84 for more information.
- Lot level
Deleting a lot deletes its associated tests and data. See “Delete a Lot Number” on page 94 for more information.
- Test level
Deleting a test only deletes the selected analyte. The same test setup identically under another lot number can be deleted as long as it is under the same lot number. All instances of the test must be in the closed list to be deleted. See “Delete Tests” on page 106 for more information.

Delete a Test



You must have the “Delete lots/tests” permission to perform this function.



Note: You cannot delete an open test; you must first close it. See “Close a Test” on page 104 for more information.

- 1 Use one of the following methods to open the **Test** dialog box:



- Click **Test** located on the toolbar.
- Click the **Select** menu, point to **Test**, and then click **Test**.
- Press F3 on the keyboard.

- 2 Select the test you want to delete in the **Closed tests** list.

- 3 Click **Delete**.

A message appears asking for confirmation.

- 4 Click **Yes**.

You can choose to delete the test for specified labs.

- 5 Click **Close** to close the **Test** dialog box.

Test Settings

You can select test settings to specify the following information:

- Levels in use
- Number of decimal places

Select Test Settings



You must have the “Manage lots/tests” permission to perform this function.

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - 2 Use one of the following methods to open the **Test Settings** dialog box:
 - Click  on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Rules/Settings**.
 - 3 Click the **Settings** tab.
 - 4 All available levels in use for the control are selected by default. Clear the appropriate **Levels in use** check box if you do not run a particular level.
-
- Tip:** Any level not in use is omitted from the data entry dialog boxes if no data exists for that level. This simplifies data entry. Any level not in use is also omitted from charts and reports if no data exists for that level.
- 5 The default decimal places for each level is 2. Select the number (0 to 4) for each level. Each level can have a different number of decimal places.
- 6 **Optional:** If you want to apply the settings for a test that is used in multiple lab numbers:
 - a) Click **Apply to all lab numbers**.
 - b) Select all the lab numbers in the list for which you want to apply the settings.
 - c) Click **OK**.
-
- Tip:** This feature can be used to change the settings for a test that is used in multiple lab numbers without the need to change the settings in each lab number.
- 7 Click **OK**.
-
- Unity Real Time 2 • User Guide 108

Evaluation Mean and SD

Overview of Evaluation Mean and SD Options

When determining what mean and SD is used for rule evaluation, Unity Real Time provides four options:

- Use Bio-Rad elInsert data to set a fixed mean and/or fixed SD/CV
- Manually set a fixed mean and/or fixed SD/CV
- Use calculated floating statistics to establish a fixed mean and/or SD/CV
- Use calculated floating statistics to set a fixed mean and/or SD/CV

Fixed vs. Floating

Fixed statistics are more sensitive than floating statistics. However, over time, cumulative statistics stabilize and can simulate a fixed statistic. Therefore, cumulative statistics provide a reasonable degree of sensitivity to shifts and trends.



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

- With Unity Real Time you can specify a fixed mean, fixed SD, or both for a test.
- Unity Real Time allows the use of a fixed CV, if preferred.
- Unity Real Time uses the floating mean and/or floating SD by default when a fixed mean or fixed SD is not specified. Rule evaluation begins after the specified number of points are entered. The default is 20 points.
- Unity Real Time begins SPC rule evaluation immediately if using both a fixed mean and a fixed SD.
- Unity Real Time continues using the fixed statistics until new values are specified or the values are cleared.
- Fixed means and SDs can be manually entered, or for applicable Bio-Rad controls, values can be imported with the Get EI Data selection.
- Fixed means and SDs may be applied to multiple lab numbers for instruments using the same lots and tests.
- You can duplicate the fixed means and/or fixed SDs when duplicating from an existing lot number to a new lot number. See “Duplicate a Lot Number” on page 113 for more information.

Use Bio-Rad elnsert data to set a fixed mean and/or fixed SD/CV



You must have the “Edit test settings/rules” permission to perform this function.



Note:

- This option is only available for Bio-Rad products that have available elnsert data.
- Internet access is required to use this feature.

1 Select a lot or test in the **Lab**, **Panel**, or **Instrument** navigation tree.

2 Click  on the toolbar.

The **Evaluation Mean/SD** dialog box appears.

3 Select the lab number from the **Lab** list.

4 Select the lot number from the **Lot** list.

5 Select each check box for the information you want to appear in the grid:



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

- Method
- Instrument
- Reagent
- Unit
- Temperature

6 Select the **Get EI Data** check box to use the means and SDs/CV from the elnsert.

7 Use the check marks in front of each value to remove any mean, SD or CV that you do not want to set as fixed.



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

8 You can also manually type over any value if you want to modify what the fixed value will be.

9 You can choose to apply fixed means and SDs to multiple lab numbers.

- Click the **M** icon for the appropriate analyte.
- Choose the lab number(s) to which you want to apply the fixed means and/or SDs.
- Check the box for fixed means and/or fixed SDs.
- Click **OK**.
- Click **OK** for the confirmation message.

10 Click **OK**.

Manually Set a Custom Fixed Mean and/or Fixed SD/CV



You must have the “Edit test settings/rules” permission to perform this function.



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

- 1 Select a lot or test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - 2 Click  on the toolbar.
- The **Evaluation Mean/SD** dialog box appears.
- 3 Select the lab number from the **Lab** list.
 - 4 Select the lot number from the **Lot** list.
 - 5 Select each check box for the information you want to appear in the grid:



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

- Method
 - Instrument
 - Reagent
 - Unit
 - Temperature
- 6 Click in the **Mean** field and type the fixed mean for the test you want to set up.
 - 7 If you are using a fixed mean, you can enter a fixed SD or fixed CV and the software will calculate the other value.



Note: If you have entered a fixed mean, you can only fix the SD or the CV. The other value is automatically calculated and displayed, although grayed out.

- To enter a fixed SD:
Click in the **SD** field and enter the fixed SD for the test.
 - To enter a fixed CV:
 - Select the check box located next to the **CV** column.
 - Click in the **CV** field and enter the fixed CV.
- 8 Repeat steps 6 and 7 as needed for each test.
 - 9 You can choose to apply fixed means and SDs to multiple lab numbers.
 - a) Click the **M** icon for the appropriate analyte.

- b) Choose the lab number(s) to which you want to apply the fixed means and/or SDs.
 - c) Check the box for fixed means and/or fixed SDs.
 - d) Click **OK**.
 - e) Click **OK** for the confirmation message.
- 10 Click **OK**.

Use Floating Statistics to Set a Fixed Mean and/or Fixed SD/CV

- 1 Select a lot or test in the **Lab** navigation tree.



- 2 Click **Evaluat...** on the toolbar.

The **Evaluation Mean/SD** dialog box appears.

- 3 Select the lab number from the **Lab** list.
- 4 Select the lot number from the **Lot** list.
- 5 Select each check box for the information you want to appear in the grid:



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

- Method
- Instrument
- Reagent
- Unit
- Temperature

- 6 Select the **Use floating statistics** check box to use your current floating statistics to set the fixed mean and SD.

- 7 Select the range for the floating statistics from the list:

- Last 30 days
- Last 6 months
- Cumulative
- Date range



Note: The **Fixed mean** and **Fixed SD** fields automatically fill in based on the range you select.

- 8 Select the **From date** and the **To date** if you selected the **Date range** option in the previous step.
- 9 Use the check marks to remove any mean, SD or CV that you do not want to set as fixed. The software will keep the current values in place.

- 10 You can choose to apply fixed means and SDs to multiple lab numbers.
 - a) Click the **M** icon for the appropriate analyte.
The **Selected Labs** window appears.
 - b) Choose the lab number(s) to which you want to apply the fixed means and/or SDs.
 - c) Check the box for fixed means and/or fixed SDs, as needed.
 - d) Click **OK**.
 - e) Click **OK** for the confirmation message.
- 11 Click **OK**.

A warning message appears to confirm your selections.

Set a Floating Mean and/or SD



Note: Any fixed mean or SD takes precedence over a floating mean or SD.

If no fixed mean and SD has been set, the test will automatically use a floating mean and SD with a default of 20 points before rule evaluation begins. If you want to change the points before rule evaluation or, if for any reason, you want to restart the floating mean or SD (due to a significant change to a test performance), you can follow these steps.

- 1 Select a lot or test in the **Lab** navigation tree.
 - 2 Click  **Evaluat...** on the toolbar.
- The **Evaluation Mean/SD** dialog box appears.
- 3 Click the **Float Mean and SD** tab.
 - 4 Select the lab number from the **Lab** list.
 - 5 Select the lot number from the **Lot** list.
 - 6 Select each check box for the information you want to appear in the grid:



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

- Method
 - Instrument
 - Reagent
 - Unit
 - Temperature
- 7 To change the number of required points before rule evaluation begins when using floating statistics, click in the **Points** field and type the number of data points desired.



Note: Twenty data points is generally considered the minimum for statistical significance and, therefore, is the default number used in the software.



Note: Based on the number of points entered, the floating mean and SD will populate each level of QC data.

- 8 To reset the start date for the calculated floating mean/SD/CV, select the check box located to the left of the **Set New Start Date and Time** column.
 - The field fills in with the current date and time if no data has been entered for the test.
 - The field fills in with the date and time data was first entered if data has been entered for the test.
- 9 Click in the **Set New Start Date and Time** field. Edit the date and time based on when you want the floating statistics to start calculating from.



Note: The date and time cannot be later than the current date and time.



Tip: An example for why this might be done would be if a reagent lot change occurred and the values have shifted. You may want to adjust the floating statistics based on this change.

- 11 Repeat steps 7–9 for each test as needed.
- 12 Click **OK**.

Set Up an Expected Response



Note: This function is available only for qualitative/semi-quantitative responses.

You can select one or more responses expected for each test and level. The results are marked as “Rejected” if they are not one of the expected responses.

- 1 Select a lot or test in the **Lab** navigation tree.
- 2 Click  **Evaluat...** on the toolbar.
- The **Evaluation Mean/SD** dialog box appears.
- 3 Click the **Expected Response** tab.
- 4 Select the check box for each expected response for each test and level.
- 5 Click **OK**.

VITROS Slide Generation Numbers

Change the VITROS Slide Generation Number



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



You must have the “Manage lots/tests” permission to perform this function.

When you change the VITROS slide generation number for a test, the software creates a new test with the new slide generation number. When you change a VITROS slide generation number, you can 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 “VITROS Slide Generation Numbers” on page 115.

- 1 Select the lot in the **Lab** navigation tree you want to change the slide generation number for.
- 2 Use one of the following methods to open the **Test** dialog box:
 - Click  **Test** located on the toolbar.
 - Click the **Select** menu, point to **Test**, and then click **Test**.
 - Press F3 on the keyboard.

3 Select the test in the **Open tests** list with the slide generation number you want to change.

4 Click **Change Slide Generation**.

The **Change Slide Generation** dialog box appears.

5 Enter the new slide generation in the **VITROS slide generation number** field.

6 Select the **Change to old test** option:

- 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 the test inactive. You can also export the data to another file before deleting it. See “Export Data” on page 384 for more information.

7 Select the **Apply new slide generation 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.

8 Optional: Select the items you want to duplicate to the new slide generation number:

- Fixed means

- Fixed SDs

- Target values for Analytical Goals

9 Click **OK**.

Update the VITROS Slide Generation Number



You must have the “Manage lots/tests” permission to perform this function.

When correcting a slide generation number, you should 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 Unity Real Time. Also, the test is updated in the Unity Interlaboratory Program the next time you submit data.

Follow this procedure to correct a slide generation number.

- 1 Use one of the following methods to open the **Test** dialog box:



- Click **Test** located on the toolbar.
- Click the **Select** menu, point to **Test**, and then click **Test**.
- Press F3 on the keyboard.

- 2 Select the test in the **Open tests** list with the slide generation number you want to update.

- 3 Type the new slide generation number in the **VITROS slide generation number** field.

- 4 Click **Update**.

The **Update Test** dialog box appears.

- 5 Select the **Apply new slide generation to** option:

- All labs

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

- Current lab

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

- Selected test

Select this option to apply the new slide generation number only to the currently selected test. This is the default selection.

- 6 Click **OK**.

- 7 Click **Close** to close the **Test** dialog box.

Panels and Data Groups

In This Chapter

Panels	118
Data Groups	122

Panels

A panel is a user-defined group of tests organized to simplify data entry and data review across lab and lot numbers. Panels are useful 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.

You can create any number of panels. You can add tests to a panel from any lab number and lot number in the software. You can add a single test to any number of panels. However, a test can only appear one time in any one panel.

Create a Panel and Add Tests



You must have the “Manage panels” permission to perform this function.

1 Use one of the following methods to open the **Panel** dialog box:



- Click **Panel** located on the toolbar.
- Click the **Select** menu and then click **Panel**.
- Press SHIFT+F3 on the keyboard.

2 Click **Add**.

The **Panel Tests** dialog box appears.

3 Type the name for the panel in the **Panel** field.

4 Select the lab, lot, or test in the **Available tests** navigation tree you want to add to the panel.

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

5 Click the appropriate button:

- Click **Add** to add the selected test or to add all tests within the selected lab or lot.
- Click **Add All** to add all tests within the navigation tree regardless of what is selected.

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

6 Click **OK**.

7 Click **OK** to close the **Panel** dialog box.

Sort Tests in a Panel



You must have the “Manage panels” permission to perform this function.

1 Use one of the following methods to open the **Panel** dialog box:

- Click  located on the toolbar.
- Click the **Select** menu and then click **Panel**.
- Press SHIFT+F3 on the keyboard.

2 Select the panel name you want to sort.

3 Click **Update/Sort**.

The **Panel Tests** dialog box opens.

4 Select the test to sort in the **Selected tests** list.

- To select multiple consecutive tests:
Click the first test, press the SHIFT key on the keyboard, and then click the last test.
- To select multiple non-consecutive tests:
Press the CTRL key on the keyboard, and then click each test.

5 Use the drag and drop method to move the test(s) up or down in the list.

6 To arrange the tests alphabetically, click the **Analyte** column to arrange the analyte names from z-a; click again to arrange the analytes from a-z.



Note: Tests can be sorted by any column but most people sort by the **Analyte** column.

7 Click **OK**.

8 Click **OK** to close the **Panel** dialog box.

Rename a Panel



You must have the “Manage panels” permission to perform this function.

- 1 Use one of the following methods to open the **Panel** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Panel**.
- Press SHIFT+F3 on the keyboard.

- 2 Select the panel you want to rename.

- 3 Click **Rename**.

- 4 Type the new name for the panel.

- 5 Click **OK**.

Remove Tests from a Panel



You must have the “Manage panels” permission to perform this function.



Note: You can remove a test from a panel at any time. Panels are simply a way of organizing tests for data entry and data review. Therefore, the test configuration and QC data are not deleted from the software when removing a test from a panel.

- 1 Use one of the following methods to open the **Panel** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Panel**.
- Press SHIFT+F3 on the keyboard.

- 2 Select the panel with the tests you want to remove.

- 3 Click **Update/Sort**.

- 4 Select the test to remove from the **Selected tests** list.

- 5 Click **Remove** to remove an individual test or click **Remove All** to remove all tests in the **Selected tests** list.

- 6 Click **OK**.

- 7 Click **OK** to close the **Panel** dialog box.

Sort Panel Names



You must have the “Manage panels” permission to perform this function.

- 1 Use one of the following methods to open the **Panel** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Panel**.
- Press SHIFT+F3 on the keyboard.

- 2 Select the panel you want to sort.

- To select multiple consecutive panels:

Click the first panel, press the SHIFT key on the keyboard, and then click the last panel.

- To select multiple non-consecutive panels:

Press the CTRL key on the keyboard, and then click each panel.

- 3 Use the drag and drop method to move the panel(s) up or down in the list.

- 4 To arrange the panels alphabetically, click the **Panel** heading.

- 5 Repeat as needed to arrange other panels names.

- 6 Click **OK**.

Delete a Panel



You must have the “Manage panels” permission to perform this function.



Note: You can delete a panel at any time. Panels are simply a way of organizing tests for data entry and data review. Therefore, the test configuration and QC data are not deleted from the software when a panel is deleted.

- 1 Use one of the following methods to open the **Panel** dialog box:



- Click located on the toolbar.
- Click the **Select** menu and then click **Panel**.
- Press SHIFT+F3 on the keyboard.

- 2 Select the panel you want to delete.

- 3 Click **Delete**.

A message appears asking for confirmation.

- 4 Click **OK**.

- 5 Click **OK** to close the **Panel** dialog box.

Data Groups

Data groups provide a way to categorize data within a test that have something in common. For example, you could group together data rows that have the same reagent lot number and call the new group Group 1. Later, after you change a reagent lot in use, create a new group called Group 2 that will receive the data from the new lot. This new group indicates where and when in the flow of data a change was made, which could help with troubleshooting later. Data Groups could also be used to group data by calibrator lot or other criteria. When the Data Group feature is enabled for a test, statistics are calculated for the group and shown at the bottom of the Single Test Data Entry page in the Group column.



Note: For other ways to track reagent and calibrator lots see the following:

- “Navigate the Single Test Data Entry Dialog Boxes” on page 161
- “Action Log and Actions” on page 205
- “Comments” on page 210
- Levey-Jennings Chart “Lines Options” on page 242

Overview of Data Groups

- The Month and Group options are available for point data and summary data for both Quantitative and Qualitative/Semi-Quantitative tests.
- You can select or clear the **Group** check box on the Single Test Point Data Entry dialog box and the Single Test Summary Data Entry dialog box to turn the group statistics on or off.
- The Current data selection (Month or Group) in the Data entry configuration section of the **Setup** dialog box applies to all tests. See “Configure Data Entry” on page 431 for more information.
- Unity Real Time assigns all data points to group 0 (zero) until a data group is defined.
- The Group and Cumulative summary statistics are the same if no group is defined for a test.
- The Levey-Jennings chart can be customized under **Options** and the **Lines** tab to indicate the first date of a new Data Group. This can be helpful when trouble shooting the cause or beginning of a shift or trend. See Levey-Jennings Chart “Lines Options” on page 242.



Note: Unity Real Time does not arrange data entry rows into groups.

Month or Group Data Entry Configuration for all Tests



You must have the “Edit setup options” permission to perform this function.



Note: Changing the data entry configuration for all tests to Month or Group is for convenience only and is not required. You can always select or clear the **Group** check box on the **Single Test Data Entry** dialog box to switch between Month and Group.

- 1 Click the **Tools** menu and then click **Setup**.
- 2 Select the **Group** option located in the **Data entry configuration** section.
- 3 Click **OK**.

This will turn on the Data Group option for all tests in the database.

Enable or Disable Data Groups for a Single Test

- 1 Double-click a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
The **Data Entry** dialog box appears.
- 2 Select the **Group** check box.
A new Group column will be enabled in the data entry grid and under the Statistics tab.

Define a Data Group



You must have the “Edit all data” or “Edit last line” permission to perform this function.

- 1 Double-click a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
The **Data Entry** dialog box appears.
- 2 Make sure the **Group** check box is enabled.
- 3 Click in the first row of the **Group** column and type a description for the group. The description can contain up to six alphanumeric characters, but no special characters.



Note: If a description is longer than 6 characters or includes special characters you can use a simple description such as “Group 1”, and use the Comment field to document the exact description.



Note: If some data has already been entered for the group, you will have to enter the description for each row. Unity Real Time assigns successive data entry rows to the same group until you assign another group name in the **Group** column.

- 4 Click **Save**.

Edit a Data Group



You must have the “Edit all data” or “Edit last line” permission to perform this function.

- 1 Double-click a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
The Data Entry dialog box appears.
- 2 Click in the row of the **Group** column you want to edit and type the new description for the Group.

 **Note:** If additional rows have already been entered for the group, you will have to edit the description for each row. Going forward, Unity Real Time assigns successive data entry rows to the same group until you assign another group name in the **Group** column.
- 3 Click **Save**.

Data Group Statistics

There are no reports in Unity Real Time that include Data Group statistics at this time, but you can see summary statistics within the Single Test Data Entry page.

- 1 Double-click a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
The Data Entry dialog box appears.
- 2 Make sure the **Group** check box is enabled.
- 3 Click the **Statistics** tab at the bottom of the page.
- 4 Click in the last row of data for the Data Group you are interested in.
The **Summary Statistics** under the **Group** column will be updated to show the statistics for only the selected data group.

SPC Rules and Analytical Goals

In This Chapter

Overview of SPC Rules	125
Select SPC Rules	130
Summary of SPC Rules	132
Overview of Analytical Goals	134
Imprecision-BV	141
Total Error-BV	142
Medical Relevance	145
State of the Art	147

Overview of SPC Rules

Unity Real Time provides statistical process control (SPC) rules and analytical goals to monitor test performance. Unity Real Time 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 “Summary of SPC Rules” on page 132 for an overview of the SPC rules available.

Many laboratories perform statistical analysis using tools such as OPSpecs Charts, critical-error graphs, and power function curves as described in numerous publications. The optional Westgard Advisor automates statistical analysis and suggests rules based on a selected performance goal, historical data, and Unity Interlaboratory Program consensus group information. See Chapter 18, “Westgard Advisor” for more information about the optional Westgard Advisor.

Notes About Rule Evaluation

- Unity Real Time rejects the entire row if any data within a run violates a SPC rule with a status of “Reject.”
- Unity Real Time excludes rejected data rows when evaluating rules between runs.



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. Unity Real Time assumes subsequent data points reflect these actions.

Below are a few examples of how you may see these specifications play out. For each example, assume the following rules are in use: 1-2s rule set as a warning violation and 1-3s and 2-2s rules set as rejection violations.

Example 1

Row 3:	Level 1 violates the 1-2s rule.
Row 4:	Level 1 also violates the 1-2s rule and therefore becomes a 2-2s rule violation.

Initially, both of the 1-2s violations are acceptable results. Because there are two back-to-back 1-2s violations, this generates the 2-2s violation, which then changes the second point (row four) to a rejection.

Test Information															Action			Comments							
Save			Set Date			Group			Level 1			Level 2			Level 3										
									Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP			
									1 3/30/2017 12:00 AM	228	Y	1-2s[W]	1.13	485	Y	1-2s[W]	1.46	698	Y	1-2s[W]	0.85	sa	I	A	C
									2 3/31/2017 12:00 AM	229	Y	1-2s[W]	1.30	487	Y	1-2s[W]	1.62	692	Y	1-2s[W]	0.55	sa	I	A	C
									3 4/1/2017 12:00 AM	235	Y	1-2s[W]	2.30	485	Y	1-2s[W]	1.46	697	Y	1-2s[W]	0.80	sa	I	A	C
									4 4/2/2017 12:00 AM	235	N	2-2s	2.30	485	N	2-2s	1.46	698	N	2-2s	0.85	sa	I	A	C
									5 4/3/2017 12:00 AM													I	A	C	

Example 2

Row 3:	Level 1 violates the 1-2s rule and level 3 violates the 1-3s rule.
Row 4:	Level 1 violates the 1-2s rule.

In this example, row 4 does not violate the 2-2s rule. Level 1 on row 3 is a rejection due to the rejection on level 3. Unity Real Time rejects the entire row if any data within a run is rejected. Therefore, level 1 on row 4 is the first 1-2s violation against an accepted point, since level 1 on row 3 is automatically rejected.

Test Data Overview																	
		Save			Set Date			Group			I = Test Information		A = Action		C = Comments		
Run ID	Date & Time	Level 1				Level 2				Level 3				OP	I	A	C
		Value	Y/N	Rules	z	Value	Y/N	Rules	z	Value	Y/N	Rules	z				
1	3/30/2017 12:00 AM	228	Y		1.13	485	Y		1.46	698	Y		0.85	sa	I	A	C
2	3/31/2017 12:00 AM	229	Y		1.30	487	Y		1.62	692	Y		0.55	sa	I	A	C
3	4/1/2017 12:00 AM	235	N	1-2S[W]	2.30	485	N		1.46	620	N	1-3S	-3.05	sa	I	A	C
4	4/2/2017 12:00 AM	235	Y	1-2S[W]	2.30	485	Y		1.46	690	Y		0.45	sa	I	A	C
5	4/3/2017 12:00 AM														I	A	C

Example 3

Row 3:	Level 1 violates the 1-3s rule.
Row 4:	Level 1 violates the 1-2s rule.

Row 4 does not violate the 2-2s rule. Level 1 on row 3 is a rejection. Therefore, level 1 on row 4 is the first 1-2s violation against an accepted point.

Test Data Overview																	
		Save			Set Date			Group			I = Test Information		A = Action		C = Comments		
Run ID	Date & Time	Level 1				Level 2				Level 3				OP	I	A	C
		Value	Y/N	Rules	z	Value	Y/N	Rules	z	Value	Y/N	Rules	z				
1	3/30/2017 12:00 AM	228	Y		1.13	485	Y		1.46	698	Y		0.85	sa	I	A	C
2	3/31/2017 12:00 AM	229	Y		1.30	487	Y		1.62	692	Y		0.55	sa	I	A	C
3	4/1/2017 12:00 AM	240	N	1-3S	3.13	485	N		1.46	698	N		0.85	sa	I	A	C
4	4/2/2017 12:00 AM	235	Y	1-2S[W]	2.30	485	Y		1.46	698	Y		0.85	sa	I	A	C
5	4/3/2017 12:00 AM														I	A	C

Rule Status



Note: Only point data is evaluated against SPC rules. Inserted or edited data is not evaluated against SPC rules unless the data is on the last line of the data entry dialog box.

You can set SPC rules to any of the following:



Note: Rules set to “Reject” or “Warn” are the active rules for the test.

- Reject
Unity Real Time rejects data violating the SPC rule and excludes it from the summary statistic calculations. The rule violated appears in the Rules column on the single test data entry dialog boxes and on intralaboratory charts and reports.
- Warn
Unity Real Time accepts data violating the SPC rule. The rule violated appears in the **Rules** column on the single tests data entry dialog boxes and on intralaboratory charts and reports.
- Off
Unity Real Time ignores the rule when evaluating data points.

Unity Real Time 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 **Float mean and SD** tab of the **Evaluation Mean/SD** dialog box. See “Set a Floating Mean and/or SD” on page 113 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. You can specify a fixed mean and SD to have rule evaluation begin immediately. See “Use Bio-Rad elnsert data to set a fixed mean and/or fixed SD/CV” on page 110 for more information.

SPC Rules Precedence When Showing Rule Violations

SPC rules precedence is determined by several factors.

- 1 SPC rules are divided into groups numbered 1 through 7 as shown in the table below.

The lower group numbers indicate a higher severity of violation in comparison to the other groups. This is known as precedence.

For example: A 2-2s (Group 1) violation is more severe than a 1-3s (Group 3) violation.

- 2 Rules are arranged in decreasing order of severity within each group, as shown in the table below. Keep in mind that while a 1-2s rule may be a stricter rule, the 1-5s is the more severe violation since it is further from the mean.

Rule Violation Severity						
Between Groups						
1	2	3	4	5	6	7
2-2s	2 of 3-2s	1-5s	4-1s	R-4s	7-T	12-x
1-2s	1-2s	1-4s	3-1s	-	-	10-x
-	-	1-3.5s	-	-	-	9-x
-	-	1-3s	-	-	-	8-x
-	-	1-2.5s	-	-	-	7-x
-	-	1-2s	-	-	-	-

More Severe
Less Strict
Rule Selections

Less Severe
More Strict
Rule Selections

Rule violations are shown in Point Data Entry pages, Levey-Jennings Charts, Bench and Supervisor Reviews and some intralaboratory reports.

Unity Real Time evaluates the QC data against all active rules as set by the user. If a data point violates more than one rule, Unity Real Time shows only the most severe rule violation. The display of rule violations is sometimes truncated in the Rules column dialog boxes to simplify viewing. Hover the mouse over the dialog box to see a full list of all rules that were violated.

Select SPC Rules

You can select SPC rules at the test level and/or the lot level. However, Bio-Rad strongly recommends selecting SPC rules for each individual test. Using the optional Westgard Advisor is the best method for selecting and applying SPC rules. See Chapter 18, "Westgard Advisor" for more information.



Important: It is a best practice for a laboratory to select rules on a test-by-test basis based on its quality requirements.

Select SPC Rules at the Test Level



You must have the "edit test settings/rules" permission to perform this function.

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
- 2 Click  on the toolbar.
- 3 Select an option (Reject, Warn, or Off) for each SPC rule.



Tip: You can click a rules button (for example ) to view information about the rule. Some rules, based on the type of rule, have the **Within Control Material** and **Across Control Material** options enabled. Use these radio buttons to see examples of rule application Within Control Material (one level) or Across Control Material (all levels of the run). For rule types with this function enabled, both Within and Across evaluations are completed.

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

- Reject
- Warn
- Off



Note: Click **Disable SPC Rules** if you want to set all the rules to "Off." Click **Set as default SPC rules** if you want to set the current rules for all new lots and tests that will be added to Unity Real Time. Click **OK**.

- 4 Click **Apply to all lab numbers** if you want to apply the rules to the same test in other lab number(s).
- 5 Click **OK**.

Select SPC Rules at the Lot Level



You must have the “edit test settings/rules” permission to perform this function.

- 1 Select a lot in the **Lab** navigation tree.
- 2 Click  on the toolbar.
- 3 Select an option (Reject, Warn, or Off) for each SPC rule.

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



Reject



Warn



Off



Tip: You can click a rules button (for example ) to view information about the rule. Some rules, based on the type of rule, have the **Within Control Material** and **Across Control Material** options enabled. Use these radio buttons to see examples of rule application Within Control Material (one level) or Across Control Material (all levels of the run). For rule types with this function enabled, both Within and Across evaluations are completed.

- 4 Click **Apply to all lab numbers** if you want to apply the rules to the same lot in other lab number(s).



Note: Click **Disable SPC Rules** if you want to set all the rules to “Off.” Click **Set as default SPC rules** if you want to set the current rules for all new lots and tests that will be added to Unity Real Time. Click **OK**. **Set as default** will not change or apply rule selections for any test already setup in the software. It is only for new tests going forward.

- 5 Click **OK**.

The following message appears:

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?

- 6 Click **Yes**.

Summary of SPC Rules

The following table summarizes the SPC rules available in Unity Real Time.

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.	This rule is applied within the run only.
1-3s	Random or the beginning of large systematic	A single control observation is outside the $\pm 3\text{SD}$ limit.	This rule is applied within the run only.
1-3.5s	Random and may also indicate systematic	One control value exceeds the mean $\pm 3.5\text{SD}$.	This rule is applied within the run only.
1-4s	Random and may also indicate systematic	One control value exceeds the mean $\pm 4\text{SD}$.	This rule is applied within the run only.
1-5s	Random and may also indicate systematic	One control value exceeds the mean $\pm 5\text{SD}$.	This rule is applied within the run only.
2-2s	Systematic	Two consecutive QC results are outside the $\pm 2\text{SD}$ limit on the same side of the mean.	This rule is applied within and across runs.
2 of 3-2s	Systematic	Two of three levels of control within the same run exceed $\pm 2\text{SD}$ 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 $\pm 4\text{SD}$ difference between control values within a single run.	Bio-Rad software uses the exact within-run difference between control values to determine if R4s is violated.
3-1s	Systematic	Three consecutive results exceed $\pm 1\text{SD}$ on the same side of the mean.	N/A
4-1s	Systematic	Four consecutive results exceed $\pm 1\text{SD}$ on the same side of the mean.	N/A

Summary of SPC Rules (continued)			
Rule	Error type	When violated	Notes
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.
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 7x, 8x, and 9x 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 7x, 8x, 9x, and 10x rules.

Overview of Analytical Goals

Unity Real Time provides analytical goals for ongoing and retrospective review of quality control data. Analytical goals provide statistical feedback and are used in parallel with traditional SPC rules. This creates positive feedback for adjusting SPC rule selections and making control of the analytical process more efficient and effective.



Note: You can configure analytical goals on a test-by-test basis. You can only use one analytical goal at a time.

Analytical goals optimize the QC effort and cost by:

- Reducing false error flags.
- Avoiding unnecessary QC repeats, troubleshooting, and recalibration.
- Fine-tuning the SPC rules applied to laboratory tests.

Unity Real Time provides the following analytical goals:

- Imprecision-BV (page 140)
- Total Error-BV (page 142)
- Medical Relevance (page 145)
- State of the Art (page 147)



Tip: Biological Variation: From Principle to Practice by Dr. Callum Fraser (available from AACC Press) is an excellent biological-variation reference.

Target Values/Data Ranges

The following target value/data range options are available for analytical goals.

Total Error-BV uses a consensus group mean:

- Month
- 6-month
- Cumulative
- A manually entered target value

Imprecision-BV, Medical Relevance, and State of the Art use the MLab (mean value from the lab):

- 30-day rolling
- 6-month rolling
- Cumulative
- A manually entered target value



Tip: You can manually enter a target value/data range to simulate a fixed mean and use the analytical goal when consensus group statistics are not available.

Consensus Groups



Note: In order to view Unity consensus group data, make sure that the “Automatic analytical goals and peer group updates” option is selected in the Setup dialog box in Unity Real Time. With this setting, Unity Real Time prompts you to download the latest updates on a regular basis when logging in. See “Configure Database Updates” on page 433.



Important: Total Error-BV and State of the Art apply statistical information from the Unity Interlaboratory Program consensus groups (Peer, Method, and All Labs). Choose a consensus group carefully. Statistical outcome can be different based on the consensus group.

Unity Real Time uses consensus group data from the Unity Interlaboratory Program to identify the lowest average imprecision practically achievable as the imprecision for a specific consensus group. The following consensus groups are available.

Consensus Group	Description
Peer (most specific)	This 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 for a test.
Method (next specific)	Use 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.

Calculate the Mean

There are two options for calculating the mean when configuring analytical goals:

- Use the software to calculate the mean.
- Manually enter a target value/data range to simulate a fixed mean.



Tip: You can manually enter a target value/data range to simulate a fixed mean and use the analytical goal when consensus group statistics are not available.

Performance Goals

Choose a performance goal based on:

- Overall consensus group performance.
- Capability of your laboratory.



Tip: Consider choosing performance goals based on the capability of your laboratory. Internal process and operational variables unique to your laboratory can affect overall test imprecision or bias.

Unity Real Time provides four performance goals for Imprecision-BV and Total Error-BV.

- **Optimum**

Choose this option when the laboratory can easily attain the desirable performance target.

- **Desirable**

This is the most widely accepted performance target.

- **Minimum**

Choose this option when the laboratory cannot attain desirable performance with current technology.

- **Manual**

Choose this option when the laboratory would like to enter its own established performance target.



Note: Optimum, Desirable, and Minimum performance goals are calculated using biological variation limits recommended by Dr. Carmen Ricos and others and the quality specification formulas of Dr. Callum Fraser. Their works were published in the Scandinavian Journal of Clinical & Laboratory Investigation (1999). 59: 491-500 and in the Annals of Clinical Biochemistry (1997). 34: 8-12. The performance goals are based on suggested correlations between Dr. Fraser's findings and current technology.

The following information provides the suggested initial performance goals based on the laboratory standard deviation index (SDI) and coefficient of variation ratio (CVR). (This information assumes the Bio-Rad consensus group provides an estimate of the capability of existing technology.)

If the laboratory SDI is:	Choose:
SDI < 0.5	Optimum bias
0.5 < SDI < 1.0	Desirable bias
SDI > 1.0	Minimum bias

If the laboratory CVR is:	Choose:
CVR < 1	Optimum imprecision
1 < CVR < 1.5	Desirable imprecision
CVR > 1.5	Minimum Imprecision



Note: These statistics are provided as a service to assess current interlaboratory performance as a means to set initial analytical goal specifications.

Select bias and imprecision goals based on the SDI and CVR. However, you can select the next level of performance as a target for quality improvement.

Rule Status for Analytical Goals

Since analytical goals are intended for retrospective review of QC results, they can be set to “Warn” or “Off” but not to “Reject.”

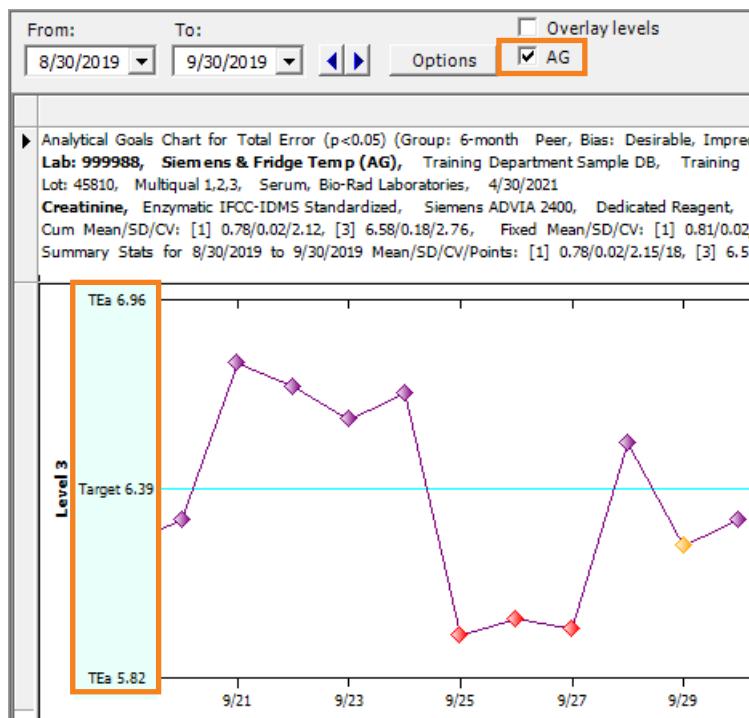
Data is evaluated against the analytical goal during data entry when set to “Warn.” The software displays a violation in the **Rules** column of the data entry dialog boxes when a violation occurs. Violations are also displayed in the Bench Review in the **Rules** column and the row is highlighted in yellow.

Retrospective Evaluation with the Levey-Jennings Chart

By setting up Analytical Goals you can use the Levey-Jennings Chart to assess how your lab is performing in regards to these goals. You can choose to switch the chart view between the standard mean/SD or you can see your daily points plotted against the defined Analytical Goals. There are also options to turn on additional lines so you can see means/SDs and Analytical Goals and limits all at the same time. This can be useful if your QC data performs differently when compared against the two goal methods. This could be an indication that you may need to re-evaluate one goal or the other.

Levey-Jennings with Analytical Goal View Selection

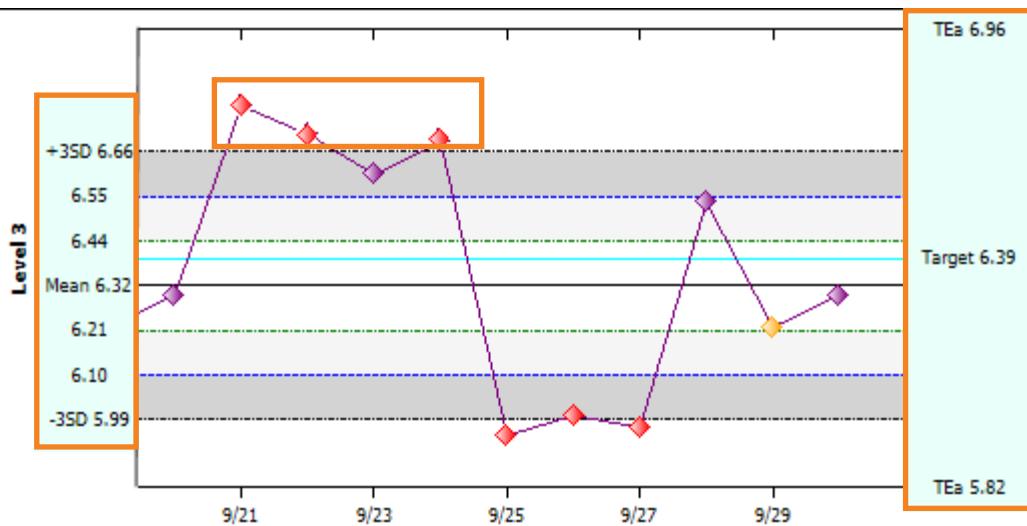
In the example below, note that the check mark for AG is selected. This removed the means and SDs from the Y axis and replaced them with the Analytical Goal and Analytical Goal Limits.



Levey-Jennings with Analytical Goal and Analytical Goal Limits Selections

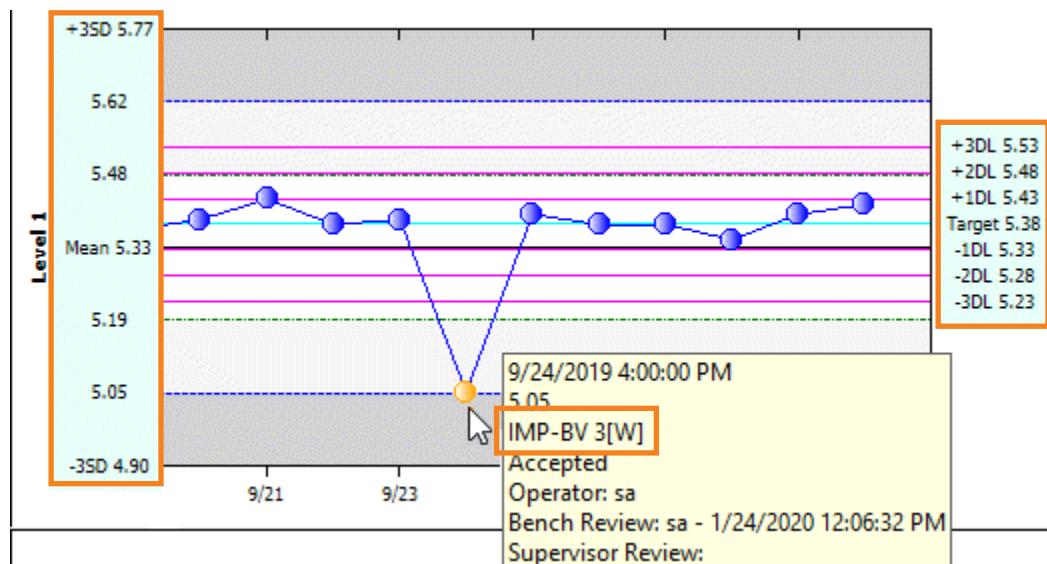
Example 1: In the example below, we see two sets of statistics for the Y axis. On the left is the standard mean and SD and on the right is the Analytical Goal and Analytical Goal Limits. This allows the user to see their points plotted against both sets of statistics at the same time. See “Lines Options” on page 242 for more information about customizing chart lines.

Notice the data points for 9/21, 9/22, and 9/25. These points exceeded the 1-3s rule and were rejected. If you look at the TE_a you see they are still well within the defined Analytical Goal Limits. This could be an indication that the lab needs to re-evaluate their SD for the analyte.



Example 2: In the example below we see an example of a data point that violated the Analytical Goal Limit. Note that it is only a warning and the point is still accepted.

In this example we see a significant discrepancy between the SD ranges and the Analytical Goal ranges. This prompts the question of which is more accurate. Further investigation is needed to determine which set of goals may need to be adjusted.



Imprecision-BV

Imprecision-BV targets the test imprecision based on selected biological variation data and performance goals. Imprecision-BV is based on published “within-subject” biological variation data rather than consensus group performance. As such, Imprecision-BV is a tool to specify acceptable limits of imprecision. Use Imprecision-BV for any analyte with published limits.

Unity Real Time uses the percent (%) biological variation specific for the performance goal. The software plots the ranges (decision limits) on a Levey-Jennings type chart based on the selected performance goal and target value/data range.



Note: Only the most severe Imprecision-BV violation (Bias Goal, Imprecision Goal, TE_a Goal) appears on the charts, reports, and the data entry dialog boxes.

Configure Imprecision-BV



You must have the “Edit test settings/rules” permission to perform this function.

- 1 Select a lot or test in the Lab navigation tree.
- 2 Click  on the toolbar.
- 3 Select a lab number from the **Lab** list.
- 4 Select a lot number from the **Lot** list.
- 5 Click the **Imprecision-BV** tab.
- 6 Select the test(s) for which you want to apply the analytical goal.
- 7 Select the Imprecision Goal (Imp. Goal) for each test.
 - Minimum
 - Desirable
 - Optimum
- 8 Select the Data Range for each test.
 - 30-day rolling
 - 6-month rolling
 - Cumulative
 - Manual
- 9 Select the **W** check box for each decision limit to set “Warning” rule violations. Otherwise, leave the **W** check box deselected to use the analytical goal as a retrospective review of quality control data in a Levey-Jennings chart.
- 10 Click **OK**.
- 11 Select the test(s) to update.
- 12 Click **OK**.

Total Error-BV

Total Error-BV is the most powerful of the analytical goals available in Unity Real Time. Total Error-BV provides useful information about laboratory imprecision and bias using a total error (TE) plot based on biological variation.

Use Total Error-BV as a quality appraisal tool. Total Error-BV sets the upper and lower limits of performance for each test based on the TE_a using “within-subject” and “between subject” biological variation data and the performance goals selected.

When used to its fullest extent, Total Error-BV reveals which SPC rules and specifications are not test-appropriate. Total Error-BV decreases laboratory costs by reducing unnecessary repeat testing, troubleshooting, and recalibration.



Note: The Total Error goal (%) is based on a 95% ($p < 0.05$) confidence interval.

View Consensus Information

- 1 Select a lot or test in the Lab navigation tree.
- 2 Click  on the toolbar.
- 3 Select a lab number from the **Lab** list.
- 4 Select a lot number from the **Lot** list.
- 5 Click the **Total Error-BV** tab.
- 6 Click **Consensus Information**.
- 7 Select the test(s) for which you want to display the consensus information.
- 8 Click **OK**.
The Analytical Goals Report opens in a new window.
- 9 Click  (red x) in the upper right corner to close the report.

Configure Total Error-BV



You must have the “Edit test settings/rules” permission to perform this function.

- 1 Select a lot or test in the Lab navigation tree.
- 2 Click  on the toolbar.
- 3 Select a lab number from the **Lab** list.
- 4 Select a lot number from the **Lot** list.
- 5 Click the **Total Error-BV** tab.



Note: The message “Imprecision and Bias values for biological variation are not available at this time” appears if there are no values available in the Biological Variation table. Select “Manual” for all goals on the test, and then manually enter the goal percentages and data range. The last step is to select the test(s) for which to apply the analytical goal.

- 6 Select the test(s) for which you want to apply the analytical goal.
- 7 Select the Imprecision Goal (Imp. Goal) for each test.
 - Minimum
 - Desirable
 - Optimum
 - Manual
- 8 **Manual option only:** Enter the Imprecision Goal percent for each test.
- 9 Select the **W** check box for each decision limit to set “Warning” rule violations. Otherwise, leave the **W** check box deselected to use the analytical goal as a retrospective review of quality control data in a Levey-Jennings chart.
- 10 Select the Bias Goal for each test.
 - Minimum
 - Desirable
 - Optimum
 - Manual
- 11 **Manual option only:** Enter the Bias Goal percent for each test.
- 12 Select the **W** check box for Bias Goal to set “Warning” rule violations. Otherwise, leave the **W** check box deselected to use the analytical goal as a retrospective review of quality control data in a Levey-Jennings chart.
- 13 The TE_a field(s) are populated based on Bias goal % and Imprecision goal % values entered. Select the **W** check box for TE_a to set “Warning” rule violations. Otherwise, leave the **W** check box deselected to use the analytical goal as a retrospective review of quality control data in a Levey-Jennings chart.

14 Select the Group for each test.

- Peer
- Method
- All Labs

15 Select the Data Range for each test.

- Month
- 6-month
- Cumulative
- Manual

16 Click **OK**.

17 Select the test(s) to update.

18 Click **OK**.

Apply to TE_a

The Total Error-BV Analytical Goal feature is just one way that the TE_a can be defined in the Unity Real Time software. The TE_a can also be set up under the Data Analysis Grid, Westgard Advisor, and Measurement Uncertainty. When changes are made to the TE_a in the Data Analysis Grid, Westgard Advisor, or Measurement Uncertainty, these changes are NOT reflected in the TE_a for Analytical Goals. However, the TE_a selections defined within Analytical Goals can be used to overwrite the TE_a in the Data Analysis Grid, Westgard Advisor, and Measurement Uncertainty. This can be helpful so that the same statistics are used consistently with all features in the software.

- 1 Use the steps listed above under “Configure Total Error-BV” on page 143.
- 2 Click **Apply to TEa**.
- 3 Select the tests to update.
- 4 Click **OK**.

Medical Relevance

Medical Relevance is the amount of total error that would cause a clinician to change a patient's diagnosis, prognosis, or treatment plan. Medical Relevance is based on confirming test imprecision within specified limits.

You can use the Medical Relevance analytical goal to distinguish statistical error from medically important changes. Medical Relevance emphasizes clinical importance rather than statistical significance.



Important: Use Medical Relevance with caution and only with the specific approval of the Laboratory Pathologist or Laboratory Director. Unity Real Time does not define Medical Relevance limits. Each laboratory must define its decision limits based on local standards that define the degree of error that might cause the clinician to change the patient's diagnosis, prognosis, or treatment. The Laboratory Director or Pathologist should determine the laboratory's decision limits.

Medical Relevance limits are expressed as a percent or absolute value and are applied to a target mean. Unity Real Time creates a chart with a single upper and lower limit of acceptability. The software plots the quality control data on a chart for retrospective evaluation.

Use this information to achieve the following:

- Alert the laboratory when a medically important error may have occurred.
- Identify the frequency of runs rejected by traditional single or multiple SPC rules.
- Distinguish statistical error from medically important error.
- Adjust the SPC rules used, thereby possibly reducing the frequency of recalibration, unnecessary troubleshooting, and retesting of patient samples.

Configure Medical Relevance



You must have the "Edit test settings/rules" permission to perform this function.

- 1 Select a lot or test in the Lab navigation tree.
- 2 Click  on the toolbar.
- 3 Select a lab number from the **Lab** list.
- 4 Select a lot number from the **Lot** list.
- 5 Click the **Medical Relevance** tab.
- 6 Select the test(s) for which you want to apply the analytical goal.
- 7 Select the Data Range for each test.
 - 30-day rolling
 - 6-month rolling
 - Cumulative
 - Manual

8 **Manual Data Range only:**

- a) Enter the value in the **Mlab** field.
- 2 Enter the Decision Limit and select the **%** check box, if needed.
- 3 Select the **W** check box for each decision limit to set “Warning” rule violations. Otherwise, leave the **W** check box unselected to use the analytical goal as a retrospective review of quality control data in a Levey-Jennings chart.
- 4 Click **OK**.
- 5 Select the test(s) you want to update.
- 6 Click **OK**.

Apply to TE_a

The Total Error-BV Analytical Goal feature is just one way that the TE_a can be defined in the Unity Real Time software. The TE_a can also be set up under the Data Analysis Grid, Westgard Advisor, and Measurement Uncertainty. When changes are made to the TE_a in the Data Analysis Grid, Westgard Advisor, or Measurement Uncertainty, these changes are NOT reflected in the TE_a for Analytical Goals. However, the TE_a selections defined within Analytical Goals can be used to overwrite the TE_a in the Data Analysis Grid, Westgard Advisor, and Measurement Uncertainty. This can be helpful so that the same statistics are used consistently with all features in the software.

- 1 Use the steps listed above under “Configure Total Error-BV” on page 143.
- 2 Click the tab for **Total Error-BV**.
- 3 Click **Apply to TEa**.
- 4 Select the tests to update.
Make note of which tests were setup using the Total Medical Relevance method.
- 5 Click **OK**.

State of the Art



Note: State of the Art is provided to set performance limits according to the most reasonably achievable imprecision on a particular platform or with a particular test kit or method. You can obtain other State of the Art statistics from the quarterly Unity Statistical Profile Report. Contact your Bio-Rad QC Program Representative to request this report.

State of the Art confines test imprecision within specified limits and is a tool to specify acceptable limits of imprecision. The concept that the imprecision for each test should be equal to or less than the best imprecision achievable by technology is the basis for State of the Art.

Unity Real Time defines the “best imprecision achievable” as the imprecision calculated for a specific consensus group (Peer, Method, or All Labs).

Unity Real Time uses the average level-specific imprecision of the consensus group to create a chart for the corresponding level of control material.



Note: Only the most severe State of the Art violation appears on charts, reports, and the data entry dialog boxes.

View Consensus Information

- 1 Select a lot or test in the Lab navigation tree.
- 2 Click  on the toolbar.
- 3 Select a lab from the **Lab** list.
- 4 Select a lot from the **Lot** list.
- 5 Click the **Total Error-BV** tab.
- 6 Click **Consensus Information**.
- 7 Select the test(s) for which you want to display the consensus information.
- 8 Click **OK**.
The Analytical Goals Report appears in a new window.
- 9 Click  (red x) in the upper right corner to close the report.

Configure State of the Art



You must have the “Edit test settings/rules” permission to perform this function.

- 1 Select a lot or test in the Lab navigation tree.
- 2 Click  on the toolbar.
- 3 Select a lab number from the **Lab** list.
- 4 Select a lot number from the **Lot** list.
- 5 Click the **State of the Art** tab.
- 6 Select the test(s) for which you want to apply the analytical goal.
- 7 Select the Imprecision Goal (Imp. Goal) for each test.
 - Peer
 - Method
 - All Labs
- 8 Select the Data Range option for each test.
 - 30-day rolling
 - 6-month rolling
 - Cumulative
 - Manual
- 9 Select the **W** check box for each decision limit to set “Warning” rule violations. Otherwise, leave the **W** check box unselected to use the analytical goal as a retrospective review of quality control data in a Levey-Jennings chart.
- 10 Click **OK**.
- 11 Select the test(s) you want to update.
- 12 Click **OK**.

Enter Data

In This Chapter

Overview	149
Overview of the Single Test Data Entry Dialog Boxes	150
Set and Change the Date for Data Entry	158
Navigate the Single Test Data Entry Dialog Boxes.....	161
Overview of Single Test Point Data Entry.....	162
Enter Single Test Point Data.....	164
Overview of Single Test Summary Data Entry.....	165
Enter Single Test Summary Data.....	166
Overview of Qualitative Data Entry	167
Enter Qualitative Data	167
Overview of Multi Test Data Entry.....	168
Enter Multi Test Data.....	170

Overview

Manual data entry is a basic feature of Unity Real Time. Alternatively, you can use one of the Bio-Rad Connectivity Solutions to automatically import data from an instrument, middleware, or Laboratory Information System (LIS) for which Bio-Rad has an interface.



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

Unity Real Time provides data entry for the following:

- Single Test Point Data Entry (page 164)
- Single Test Summary Data Entry (page 166)
- Qualitative Data Entry (page 167)
- Multi Test Data Entry (page 169)

Overview of the Single Test Data Entry Dialog Boxes

The Unity Real Time Single Test Point Data Entry dialog box and the Single Test Summary Data Entry dialog box share a common look and consist of the following areas.

Lab: 999991 Primary lab number (999991) Lot: 55930 Unassayed Chemistry Matrix: Serum															
Test: Creatinine, Enzymatic IFCC-IDMS Standardized, Roche cobas 8000, Dedicated Reagent, µmol/L, No Temperature Expires: 2/29/2024 Rules: 1-3s 2-3s R-4s[W]															
Save		Set Date		<input checked="" type="checkbox"/> Group		<input checked="" type="checkbox"/> Reagent Lot		<input checked="" type="checkbox"/> Reagent Bottle		<input checked="" type="checkbox"/> In Use/Standby		<input checked="" type="checkbox"/> Calibrator Lot		<input checked="" type="checkbox"/> Calibration Date	
Level 1				Level 2											
	Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	Reagent Lot	Reagent Bottle No	In Use/Standby	Calibrator Lot	Calibration Date/Tim	
92	9/6/2021 6:03 PM	84.00	Y		0.06	480.00	Y		-1.41	10051	2120	In Use	410090		
93	9/7/2021 6:18 PM	80.00	Y		-1.23	498.00	Y		0.51	10051	2120	In Use	410090		
94	9/8/2021 6:00 PM	84.00	Y		0.06	493.00	Y		-0.02	10051	1710	In Use	410090		
95	9/9/2021 6:11 PM	74.00	N	1-3S	-3.17	489.00	N		-0.45	10051	1710	In Use	410090	9/8/2021 6:22 PM	
96	9/9/2021 6:21 PM	77.00	Y		-2.20	494.00	Y		0.09	10051	1710	In Use	410090		
97	9/10/2021 6:10 PM	78.00	Y		-1.88	489.00	Y		-0.45	21007	1901	In Use	410090		
98	9/10/2021 6:10 PM	77.00	Y		-2.20	492.00	Y		-0.13	21007	1851	Standby	410090	9/10/2021 6:10 PM	
99	9/11/2021 6:10 PM	82.00	Y		-0.59	495.00	Y		0.19	21007	1955	In Use	410090		
100	9/12/2021 6:10 PM	85.00	Y		0.38	480.00	Y		-1.41	21007	1955	Standby	410290	9/12/2021 6:10 PM	
101	9/12/2021 6:10 PM									21007	1955	In Use	410290		

1 Lab, Lot, and Test Information

- Lab number and name
 - Lot number and control product description
 - Matrix
 - Test information including the analyte name, method, instrument, VITROS slide generation number (if applicable), reagent, unit, and temperature
 - Control product expiration date
 - Current SPC rules, if applicable



Note: SPC rules apply to point data only.

2 Data Entry Grid

The data entry grid consists of rows and columns where you manually enter data. Imported data also appears here. The Single Test Point Data Entry dialog box and Single Test Summary Data Entry dialog box each have their own data entry grid. See the following sections for more information:

- Overview of Single Test Point Data Entry (page 162)
 - Overview of Single Test Summary Data Entry (page 165)

Overview of the Single Test Data Entry Dialog Boxes (continued)

Lab: 999991 Primary lab number (999991) Lot: 55930 Unassayed Chemistry Matrix: Serum Test: Creatinine, Enzymatic IFCC-IDMS Standardized, Roche cobas 8000, Dedicated Reagent, $\mu\text{mol/L}$, No Temperature Expires: 2/29/2024 Rules: 1-3s 2-2s R-4s[W]																	
		Save		Set Date		<input checked="" type="checkbox"/> Group		<input checked="" type="checkbox"/> Reagent Lot		<input checked="" type="checkbox"/> Reagent Bottle		<input checked="" type="checkbox"/> In Use/Standby		<input checked="" type="checkbox"/> Calibrator Lot		<input checked="" type="checkbox"/> Calibration Date	
		Level 1				Level 2				3		4		5			
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	Reagent Lot	Reagent Bottle No	In Use/Standby	Calibrator Lot	Calibration Date/Time		
92	9/6/2021 6:03 PM	▼	84.00	Y	▼	0.06	480.00	Y	▼	-1.41	10051	2120	In Use	410090			
93	9/7/2021 6:18 PM	▼	80.00	Y	▼	-1.23	498.00	Y	▼	0.51	10051	2120	In Use	410090			
94	9/8/2021 6:00 PM	▼	84.00	Y	▼	0.06	493.00	Y	▼	-0.02	10051	1710	In Use	410090			
95	9/9/2021 6:11 PM	▼	74.00	N	▼	1-3S	-3.17	489.00	N	▼	-0.45	10051	1710	In Use	410090	9/8/2021 6:22 PM	
96	9/9/2021 6:21 PM	▼	77.00	Y	▼	-2.20	494.00	Y	▼	0.09	10051	1710	In Use	410090			
97	9/10/2021 6:10 PM	▼	78.00	Y	▼	-1.88	489.00	Y	▼	-0.45	21007	1901	In Use	410090			
98	9/10/2021 6:10 PM	▼	77.00	Y	▼	-2.20	492.00	Y	▼	-0.13	21007	1851	Standby	410090	9/10/2021 6:10 PM		
99	9/11/2021 6:10 PM	▼	82.00	Y	▼	-0.59	495.00	Y	▼	0.19	21007	1955	In Use	410090			
100	9/12/2021 6:10 PM	▼	85.00	Y	▼	0.38	480.00	Y	▼	-1.41	21007	1955	Standby	410290	9/12/2021 6:34 PM		
101	9/12/2021 6:10 PM	▼									21007	1955	In Use	410290			

Point Data Summary Data

3 Reagent Lot

- Enter manually or import through some connectivity solutions.
- Available only on the Single Test Point Data Entry dialog box.
- Use check-box to select or clear, unique to each test.
- Useful for internal review.
- Not submitted to the Unity Interlaboratory Program.

4 Reagent Bottle No

- Sometimes referred to as the bottle serial number.
- Enter manually or import through some connectivity solutions.
- Available only on the Single Test Point Data Entry dialog box.
- Use check-box to select or clear, unique to each test.
- Useful for internal review.
- Not submitted to the Unity Interlaboratory Program.
- The **Reagent Lot** column must be enabled to use this column.

5 In Use/Standby

- Refers to the Reagent Lot number's status on the instrument.
- Available options are **In Use**, **StandBy**, and **blank**.
- Enter manually or import through some connectivity solutions.
- Available only on the Single Test Point Data Entry dialog box.
- Use check-box to select or clear, unique to each test.
- Useful for internal review.
- Not submitted to the Unity Interlaboratory Program.
- The **Reagent Lot** column must be enabled to use this column.



Note: The **Reagent Lot**, **Reagent Bottle No** and **In Use/Standby** columns can contain up to 15 characters consisting of numbers and letters.

Overview of the Single Test Data Entry Dialog Boxes (continued)



Note: Reagent Lot, Reagent Bottle No and In Use/Standy columns are not available for GOST and RiliBÄK Unity Real Time user licenses.



Note: When manually entering QC data, the Reagent Lot, Reagent Bottle No and In Use/Standy columns will auto-fill from the row above until new values are entered for the column. If a connectivity solution is used for data import, these fields will only be populated from the data file. Auto-fill from a previous row is not used when a row of data is imported.

Single Test Data Entry Dialog Box																			
		Save		Set Date		<input checked="" type="checkbox"/> Group		<input checked="" type="checkbox"/> Reagent Lot		<input checked="" type="checkbox"/> Reagent Bottle		<input checked="" type="checkbox"/> In Use/Standy		<input checked="" type="checkbox"/> CalibratorLot		<input checked="" type="checkbox"/> Calibration Date		<small>I = Test Information</small>	
		Level 1		Level 2															
Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	Reagent Lot	Reagent Bottle No	In Use/Standy	Calibrator Lot	Calibration Date/Time						
92 9/6/2021 6:03 PM	84.00	Y		0.06	480.00	Y		-1.41	10051	2120	In Use	410090							
93 9/7/2021 6:18 PM	80.00	Y		-1.23	498.00	Y		0.51	10051	2120	In Use	410090							
94 9/8/2021 6:00 PM	84.00	Y		0.06	493.00	Y		-0.02	10051	1710	In Use	410090							
95 9/9/2021 6:11 PM	74.00	N	1-3S	-3.17	489.00	N		-0.45	10051	1710	In Use	410090							
96 9/9/2021 6:21 PM	77.00	Y		-2.20	494.00	Y		0.09	10051	1710	In Use	410090	9/8/2021 6:22 PM						
97 9/10/2021 6:10 PM	78.00	Y		-1.88	489.00	Y		-0.45	21007	1901	In Use	410090							
98 9/10/2021 6:10 PM	77.00	Y		-2.20	492.00	Y		-0.13	21007	1851	Standby	410090	9/10/2021 6:10 PM						
99 9/11/2021 6:10 PM	82.00	Y		-0.59	495.00	Y		0.19	21007	1955	In Use	410090							
100 9/12/2021 6:10 PM	85.00	Y		0.38	480.00	Y		-1.41	21007	1955	Standby	410290							
101 9/12/2021 6:10 PM									21007	1955	In Use	410290	9/12/2021 6:34 PM						

6 Calibrator Lot

- Enter manually or import through some connectivity solutions.
- Available only on the Single Test Point Data Entry dialog box.
- Use check-box to select or clear, unique to each test.
- Useful for internal review.
- Not submitted to the Unity Interlaboratory Program.

7 Calibration Date/Time

- The date and time that instrument calibration was performed.
- Enter manually or import through some connectivity solutions.
- Available only on the Single Test Point Data Entry dialog box.
- Use check-box to select or clear, unique to each test.
- Useful for internal review.
- Not submitted to the Unity Interlaboratory Program.
- The **Calibrator Lot** column must be enabled to use this column.



Note: The Calibrator Lot and Calibration Date/Time columns are not available for GOST and RiliBÄK Unity Real Time user licenses.

Overview of the Single Test Data Entry Dialog Boxes (continued)



Note: When manually entering QC data, the **Calibrator Lot** and **Calibration Date/Time** columns will auto-fill from the row above until new values are entered for the column. If a connectivity solution is used for data import, these fields will not auto-fill and will only be populated from the data file. Auto-fill from a previous row is not used when a row of data is imported.

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) **Lot:** 45810 Multiquad 1,2,3 **Matrix:** Serum
Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature
Expires: 4/30/2024 **Rules:** 1-2s[W] 1-3s

	Date & Time	Level 1			Level 3						
		Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group
101	1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0
102	1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0
103	1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0
104	1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0
105	1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0
106	1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0
107	1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1
108	1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1
109	1/28/2021 2:53 PM	28.00	Y		0.21	75.00	Y		0.38	sa	1

Point Data **Summary Data**

Statistics **Chart**

Summary Statistics	Group	Month	Cumulative	Group	Month	Cumulative
1/17/2021 2:06:00 PM						
Mean	28.68	28.71	28.68	76.37	76.25	76.37
SD	0.58	0.54	0.58	1.34	0.43	1.34
CV	2.03	1.87	2.03	1.76	0.57	1.76
Points	97	11	97	97	11	97

Current Fixed Mean/SD/CV	28.50/1.60/(5.61)	73.50/3.90/(5.31)
--------------------------	-------------------	-------------------

8

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.



Note: This column shows two asterisks (**) if initials are not defined in the Operator Setup. See “Operator Setup” on page 76 for more information.

9

Group

The group designation, if specified. See “Data Groups” on page 122 for more information.

Overview of the Single Test Data Entry Dialog Boxes (continued)

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) **Lot:** 45810 Multiquel 1,2,3 **Matrix:** Serum
Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature
Expires: 4/30/2024 **Rules:** 1-2s[W] 1-3s

		Save		Set Date														
<input checked="" type="checkbox"/> Group		<input type="checkbox"/> Reagent Lot		<input type="checkbox"/> Reagent Bottle		<input type="checkbox"/> In Use/Standby		<input type="checkbox"/> Calibrator Lot		<input type="checkbox"/> Calibration Date		I = Test Information		A = Action		C = Comments		
		Level 1				Level 3												
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group	10					
		101 1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0	I	A	C			
		102 1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0	I	A	C			
		103 1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0	I	A*	C*			
		104 1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0	I	A	C			
		105 1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0	I	A	C			
		106 1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0	I	A*	C			
		107 1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1	I	A	C			
		108 1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1	I	A	C			
		109 1/28/2021 2:53 PM	28.80	Y		0.71	75.00	Y		0.38	sa	1	I	A	C			
		110 1/28/2021 2:53 PM	28.80	Y		0.71	75.00	Y		0.38	sa	1	I	A	C			
Point Data		Summary Data																
Statistics		Chart																
Summary Statistics		Group	Month	Cumulative	Group	Month	Cumulative											
1/17/2021 2:06:00 PM																		
Mean		28.68	28.71	28.68	76.37	76.25	76.37											
SD		0.58	0.54	0.58	1.34	0.43	1.34											
CV		2.03	1.87	2.03	1.76	0.57	1.76											
Points		97	11	97	97	11	97											
Current Fixed Mean/SD/CV		28.50/1.60/(5.61)				73.50/3.90/(5.31)												

10 Information

Click or hover over the Information button  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 if SPC rules are used.
- Bench Review
The date, time, and the initials of the person who reviewed the row of data in the Bench Review, if applicable.
- Supervisor Review
The date, time, and the initials of the person who reviewed the row of data in the Supervisor Review, if applicable.

Overview of the Single Test Data Entry Dialog Boxes (continued)

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) Lot: 45810 Multiqual 1,2,3 Matrix: Serum
 Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature
 Expires: 4/30/2024 Rules: 1-2s[W] 1-3s

Save		Set Date													
<input checked="" type="checkbox"/> Group	<input type="checkbox"/> Reagent Lot	<input type="checkbox"/> Reagent Bottle	<input type="checkbox"/> In Use/Standby	<input type="checkbox"/> Calibrator Lot	<input type="checkbox"/> Calibration Date	I	=Test Information	A	Action	C	Comments				
		Level 1				Level 3									
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group			
101	1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0	I	A	C	11
102	1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0	I	A	C	
103	1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0	I	A	C	
104	1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0	I	A	C	
105	1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0	I	A	C	
106	1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0	I	A	C	
107	1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1	I	A	C	
108	1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1	I	A	C	

Point Data Summary Data 12

Statistics Chart

Summary Statistics		Group	Month	Cumulative	Group	Month	Cumulative
1/17/2021 2:06:00 PM							
Mean	28.68	28.71	28.68	76.37	76.25	76.37	
SD	0.58	0.54	0.58	1.34	0.43	1.34	
CV	2.03	1.87	2.03	1.76	0.57	1.76	
Points	97	11	97	97	11	97	

Current Fixed Mean/SD/CV 28.50/1.60/(5.61) 73.50/3.90/(5.31)

11 Actions and Comments

- Click the Action button  to add an action to the row of data or to view existing actions. A green arrow  appears when an action has been added.



Note: Actions apply to point data only and, therefore, appear only on the Single Test Point Data Entry and Multi Test Point Data Entry dialog boxes.

- Click the Comment button  to add a comment to the row of data or to view existing comments. A green arrow appears when a comment has been added.

12 Tabs

- Click the **Point Data** tab to enter single point data.
 - Click the **Summary Data** tab to enter summary data.
 - Click the **Chart** tab to view a Levey-Jennings Chart for the test (Single Test Point Data Entry dialog box only). See “Levey-Jennings Chart” on page 217 for more information about this chart.



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

- Click the **Statistics** tab to view the Summary Statistics based on group, monthly and cumulative statistics

Overview of the Single Test Data Entry Dialog Boxes (continued)

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) **Lot:** 45810 Multiqual 1,2,3 **Matrix:** Serum
Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature
Expires: 4/30/2024 **Rules:** 1-2s[W] 1-3s

												Save	Set Date	
<input checked="" type="checkbox"/> Group <input type="checkbox"/> Reagent Lot <input type="checkbox"/> Reagent Bottle <input type="checkbox"/> In Use/Standby <input type="checkbox"/> Calibrator Lot <input type="checkbox"/> Calibration Date I =Test Information A =Action C =Comments														
		Level 1				Level 3								
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group		
101		1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0	I A C	
102		1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0	I A C	
103		1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0	I A C*	
104		1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0	I A C	
105		1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0	I A C	
106		1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0	I A C*	
107		1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1	I A C	
108		1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1	I A C	
109		1/28/2021 2:53 PM	28.80	Y		0.21	75.00	Y		0.38	sa	1	I A C	

Point Data **Summary Data**

Statistics **Chart**

Summary Statistics	Group	Month	Cumulative	Group	Month	Cumulative
1/17/2021 2:06:00 PM						
Mean	28.68	28.71	28.68	76.37	76.25	76.37
SD	0.58	0.54	0.58	1.34	0.43	1.34
CV	2.03	1.87	2.03	1.76	0.57	1.76
Points	97	11	97	97	11	97
Current Fixed Mean/SD/CV		28.50/1.60/(5.61)		73.50/3.90/(5.31)		

13 Summary and Group Statistics

The Summary Statistics shows the following information:

- Mean (month and cumulative)
- Standard deviation (SD) (month and cumulative)
- Coefficient of variation (CV) (month and cumulative)
- Number of points (month and cumulative)
- Select the **Group** check box above the data entry grid to view group and cumulative statistics. See “Data Groups” on page 122 for more information about groups. The Group Statistics shows the following information:
 - Mean (group and cumulative)
 - Standard deviation (SD) (group and cumulative)
 - Coefficient of variation (CV) (group and cumulative)
 - Number of points (group and cumulative)



Note: You can set the default statistics to Month or Group for convenience. See “Configure Data Entry” on page 431 for more information.

Overview of the Single Test Data Entry Dialog Boxes (continued)

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) **Lot:** 45810 Multiqual 1,2,3 **Matrix:** Serum
Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature
Expires: 4/30/2024 **Rules:** 1-2s[W] 1-3s

		Save		Set Date															
<input checked="" type="checkbox"/> Group		<input type="checkbox"/> Reagent Lot		<input type="checkbox"/> Reagent Bottle		<input type="checkbox"/> In Use/Standby		<input type="checkbox"/> Calibrator Lot		<input type="checkbox"/> Calibration Date									
		Level 1				Level 3													
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group							
101		1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0	I	A	C				
102		1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0	I	A	C				
103		1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0	I	A*	C*				
104		1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0	I	A	C				
105		1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0	I	A	C				
106		1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0	I	A*	C				
107		1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1	I	A	C				
108		1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1	I	A	C				
...			
Point Data		Summary Data																	
Statistics		Chart																	
Summary Statistics		Group	Month	Cumulative	Group	Month	Cumulative												
1/17/2021 2:06:00 PM																			
Mean		28.68	28.71	28.68	76.37	76.25	76.37												
SD		0.58	0.54	0.58	1.34	0.43	1.34												
CV		2.03	1.87	2.03	1.76	0.57	1.76												
Points		97	11	97	97	11	97												
Current Fixed Mean/SD/CV		28.50/1.60/(5.61)				73.50/3.90/(5.31)				14									

14 Fixed Mean and SD



Note: The fixed mean and SD apply to point data only and, therefore, appear only on the Single Test Point Data Entry dialog box.

The fixed mean and SD appear below the Summary Statistics, if specified. These statistics do not change as you select different rows of data. See “Overview of the Single Test Data Entry Dialog Boxes” on page 150 for more information.

- The evaluation mean and SD appear for each control level.
- SPC rule evaluation begins with the first data point if both statistics are fixed.

Floating Mean/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

- Rule evaluation begins after the specified number of points are entered.

Set and Change the Date for Data Entry

Set Date Feature

- The Set Date feature is slightly different for qualitative data. See “Overview of Qualitative Data Entry” on page 167 for more information.
- Increment

The Increment option is useful when you manually enter several days of data. After you set the date, the software increments the date by one day each time a new row of data is added. The software continues to increment the date by one day until you exit the software. This can be helpful when manually entering data for the last several days at one time.

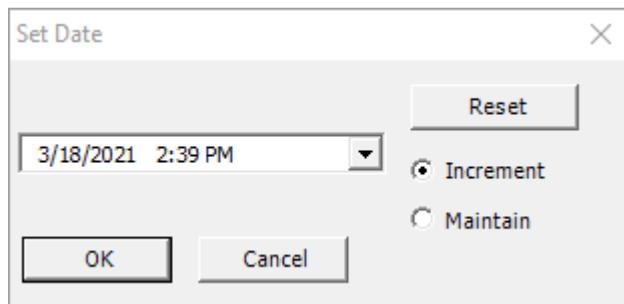
- Maintain

After you set the date, the software keeps the same date for the next row of data. This can be useful if only one day is being entered for multiple tests and/or data is being entered for several runs of data at once. For example, someone enters both the morning run and the afternoon run of QC at the end of the day.

Use the Set Date Feature

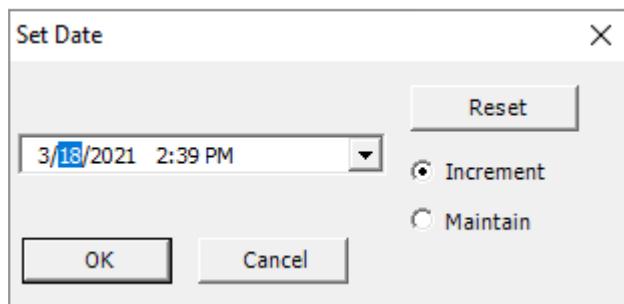
- 1 Click **Set Date**.

The **Set Date** dialog box appears.

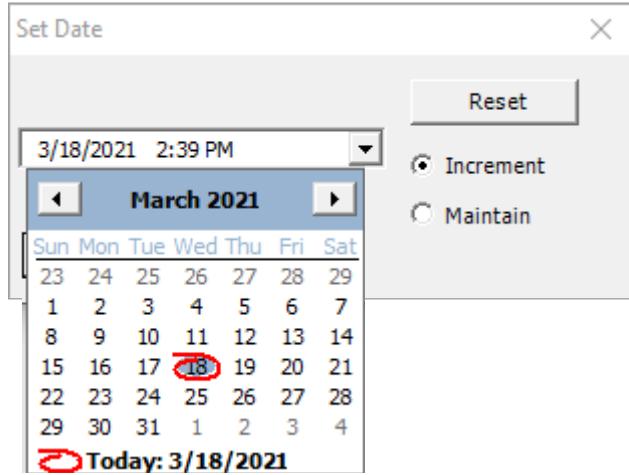


- 2 Use one of the following methods to select the date for the first day of data entry.

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



- Click the arrow located to the right of the date and select the date from the calendar.



- Click at the top of the calendar to go to the previous month.
- Click at the top of the calendar to go to the next month.
- Click to select the current date.

3 Select the option you want:

- Increment
The date increments for each new row of data.
- Maintain
The date remains the same for each new row of data.

4 Click **OK**.

5 Enter your data.

6 Make sure you click **Save** when you are finished entering your data.

Change the Date and Time for a Row of Data

You can only change the date and time for the current data entry row. For example, after you edit the date and time of the last data entry row, the next row you add contains the current date and time.



Note: You must enter all data in chronological order. If you see the message “Invalid date range” when editing a date, you may need to insert a new row of data in the correct order. See “Insert Data” on page 177 for more information.

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

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) Lot: 45810 Multiqual 1,2,3 Matrix: Serum Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature Expires: 4/30/2024 Rules: 1-2s[W] 1-3s												
		Level 1				Level 3						
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group
101	1/19/2021 3:48 PM	29.00	Y	▼		0.31	77.60	Y	▼		1.05	sa 0
102	1/22/2021 3:48 PM	28.00	Y	▼		-0.31	76.00	Y	▼		0.64	sa 0
103	1/23/2021 9:54 AM	28.30	Y	▼		-0.13	75.00	Y	▼		0.38	sa 0
104	1/24/2021 1:53 PM	28.50	Y	▼		0.00	77.90	Y	▼		1.13	sa 0
105	1/25/2021 1:53 PM	28.90	Y	▼		0.25	76.90	Y	▼		0.87	sa 0
106	1/26/2021 1:53 PM	28.60	N	▼		0.06	26.30	N	▼	1-3S	-12.10	sa 0
107	1/26/2021 2:53 PM	28.60	Y	▼		0.06	76.30	Y	▼		0.72	sa 1
108	1/27/2021 2:53 PM	28.80	Y	▼		0.19	75.00	Y	▼		0.38	sa 1

- Click the arrow located to the right of the date and select the date from the calendar.

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) Lot: 45810 Multiqual 1,2,3 Matrix: Serum Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature Expires: 4/30/2024 Rules: 1-2s[W] 1-3s												
		Level 1				Level 3						
		Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group
101	1/19/2021 3:48 PM	29.00	Y	▼		0.31	77.60	Y	▼		1.05	sa 0
102	1/22/2021 3:48 PM	28.00	Y	▼		-0.31	76.00	Y	▼		0.64	sa 0
103	1/23/2021 9:54 AM	28.30	Y	▼		-0.13	75.00	Y	▼		0.38	sa 0
104	1/24/2021 1:53 PM	28.50	Y	▼		0.00	77.90	Y	▼		1.13	sa 0
105	1/25/2021 1:53 PM	28.90	Y	▼		0.25	76.90	Y	▼		0.87	sa 0
106	1/26/2021 1:53 PM	28.60	N	▼		0.06	26.30	N	▼	1-3S	-12.10	sa 0
107	1/26/2021 2:53 PM	28.60	Y	▼		0.06	76.30	Y	▼		0.72	sa 1
108	1/27/2021 2:53 PM	28.80	Y	▼		0.19	75.00	Y	▼		0.38	sa 1

- Click at the top of the calendar to go the previous month.
- Click at the top of the calendar to go to the next month.

Navigate the Single Test Data Entry Dialog Boxes

You can use the keyboard shortcuts described below to navigate the Single Test Point Data Entry and Single Test Summary Data Entry dialog boxes.

To...	Keyboard Shortcut
Go to the next test	F5
Go to the previous test	SHIFT+F5
Go to the next lot (available only in the Lab navigation tree)	F6
Go to the previous lot (available only in the Lab navigation tree)	SHIFT+F6
Go to the next lab (available only in the Lab navigation tree)	F7
Go to the previous lab (available only in the Lab navigation tree)	SHIFT+F7
Go to the next panel (available only in the Panel navigation tree)	F8
Go to the previous panel (available only in the Panel navigation tree)	SHIFT+F8

Overview of Single Test Point Data Entry

The Single Test Point Data Entry grid consists of rows and columns where you manually enter a result (value) for each level. Imported data also appears here. The data is evaluated against any SPC rules or analytical goal, if specified.

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) Lot: 45810 Multiquel 1,2,3 Matrix: Serum Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature Expires: 4/30/2024 Rules: 1-2s[W] 1-3s														
<input type="button" value="Save"/> <input type="button" value="Set Date"/>		<input checked="" type="checkbox"/> Group <input type="checkbox"/> Reagent Lot <input type="checkbox"/> Reagent Bottle <input type="checkbox"/> In Use/Standby <input type="checkbox"/> Calibrator Lot <input type="checkbox"/> Calibration Date I = Test Information A = Action C = Comments												
1	2	3	Level 1			4	Level 3			OP	Group			
	Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group			
101	1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0	I	A	C
102	1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0	I	A	C
103	1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0	I	A*	C*
104	1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0	I	A	C
105	1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0	I	A	C
106	1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0	I	A*	C
107	1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1	I	A	C
108	1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1	I	A	C

1 Row Numbers

Rows are numbered consecutively. The software rennumbers the rows to maintain a consecutive order if you insert or delete a row of data. (Unity Real Time does not number runs within a day).

2 Date & Time

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

3 Value (per Level)

The fields where you type the QC values for each level when you manually enter data. The values for imported data also appear in these fields.

4 Levels

Indicates the levels of control for the test.



Tip: The levels that appear depend on the levels in use selected on the **Test Settings** dialog box. See “Test Settings” on page 108 for more information.

5 Y/N (per Level)

If you are using SPC rules, this column indicates if the data point was accepted (Y) or rejected (N) according to one or more active SPC rules. The software automatically rejects a row of data if a data point within the row violates a SPC rule with a status of “Reject.”



Note: Users with the “Edit data permission” can manually change the accept/reject (Y or N) status of a data point in this column. See “Labs, Lots, Tests, and Panels Permissions” on page 73 for more information.

Overview of Single Test Point Data Entry (continued)

Lab: 999913 D-10 #2 and Arch #2 (Like Inst) Lot: 45810 Multiquant 1,2,3 Matrix: Serum Test: Cholesterol, HDL, Direct measure, polymer-polyanion, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature Expires: 4/30/2024 Rules: 1-2s[W] 1-3s															
				Save		Set Date									
<input checked="" type="checkbox"/> Group		<input type="checkbox"/> Reagent Lot		<input type="checkbox"/> Reagent Bottle		<input type="checkbox"/> In Use/Standby		<input type="checkbox"/> CalibratorLot		<input type="checkbox"/> Calibration Date		I=Test Information	A=Action	C=Comments	
Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	OP	Group					
101 1/19/2021 3:48 PM	29.00	Y		0.31	77.60	Y		1.05	sa	0	I	A	C		
102 1/22/2021 3:48 PM	28.00	Y		-0.31	76.00	Y		0.64	sa	0	I	A	C		
103 1/23/2021 9:54 AM	28.30	Y		-0.13	75.00	Y		0.38	sa	0	I	A*	C*		
104 1/24/2021 1:53 PM	28.50	Y		0.00	77.90	Y		1.13	sa	0	I	A	C		
105 1/25/2021 1:53 PM	28.90	Y		0.25	76.90	Y		0.87	sa	0	I	A	C		
106 1/26/2021 1:53 PM	28.60	N		0.06	26.30	N	1-3S	-12.10	sa	0	I	A*	C		
107 1/26/2021 2:53 PM	28.60	Y		0.06	76.30	Y		0.72	sa	1	I	A	C		
108 1/27/2021 2:53 PM	28.80	Y		0.19	75.00	Y		0.38	sa	1	I	A	C		

6 Rules

Shows any active SPC rules the data point violated. The software shows the most serious rule violation first if you are using multiple rules.



Note: See “SPC Rules Precedence When Showing Rule Violations” on page 129 for more information.

7 z

The z-score indicates the number of standard deviations between a result and the expected mean.



Note: The z-score calculation begins after the specified number of data points have been entered. See “Test Settings” on page 108 for more information.

Enter Single Test Point Data

1 Double-click a test in the Lab, Panel, or Instrument navigation tree.

The data entry dialog box appears.

2 If entering data for a date other than the current date, click **Set Date**.

- Use the calendar or click any part of the date and type over the date and/or time.
- Select the **Increment** or **Maintain** option for the additional rows of data.

3 Click in the first **Level** field and type the value for the level.

4 Press the TAB or ENTER key on the keyboard to go to the next **Level** field.

5 Repeat as needed to enter data for all levels.

When you press the TAB or ENTER key in the last level of the row, the software:

- 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.

6 Continue entering data for all tests.

7 Use one of the following methods to save the data:

- Click **Save**.
- Press CTRL+S on the keyboard to save the changes and close the data entry window.
- Press F5 on the keyboard to save changes and go to the next test to continue entering data.



Note: If the setting for Automatic or Require Action Logs are enabled, you may receive a message after clicking Save to enter an Action to document rejection violations. See “Configure Actions and Comments” on page 432 for more information on Automatic and Require Action Logs.

Overview of Single Test Summary Data Entry

The Single Test Summary Data Entry grid consists of rows and columns where you manually enter the mean, SD, and number of points for each level for a calendar month. Imported data also appears here. Summary data is not evaluated against any SPC rules or analytical goal. Entering summary data is a good option if you use your instrument or LIS to perform quality control evaluation.



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

Lab: 999901 Vitros 5600 (Cum/Peer only) Lot: 57570 Lipids Matrix: Serum Test: Cholesterol, HDL, Direct measure, polymer-polyanion, VITROS 5600 (Wet), Dedicated Reagent, mg/dl, No Temperature Expires: 8/31/2021 Rules:									
<input type="button" value="Save"/> <input type="button" value="Set Date"/>		<input type="checkbox"/> Group <input type="checkbox"/> Reagent Lot <input type="checkbox"/> Reagent Bottle <input type="checkbox"/> In Use/Standby <input type="checkbox"/> Calibrator Lot <input type="checkbox"/> Calibration Date = Test Information = Action = Comments							
1	2	Level 1			Level 2			OP	
		Date & Time	Mean	SD	Point	Mean	SD		
1	1/1/2021 5:00 PM	30.80	1.00	35	59.00	0.80	35	sa	
2	2/1/2021 8:05 AM	32.20	0.50	30	59.70	1.02	30	sa	
3	3/1/2021 5:00 PM	35.00	0.90	35	59.70	1.50	35	sa	
4	4/1/2021 5:00 PM	40.50	1.50	33	61.00	1.20	33	sa	
5	5/1/2021 5:00 PM	45.00	0.75	34	61.40	1.00	34	sa	
6	6/1/2021 8:05 AM	45.90	0.50	30	62.00	1.02	30	sa	
7	7/1/2021 5:00 PM	32.50	1.00	35	59.00	0.80	35	sa	
8	8/1/2021 5:00 PM	37.00	0.80	35	58.90	1.00	35	sa	
9	9/1/2021 8:05 AM	37.50	0.50	30	58.70	1.02	30	sa	
10	10/1/2021 5:00 PM	40.00	0.90	35	59.00	1.50	35	sa	
11	11/1/2021 12:00 AM								

1 Row Number

Rows are numbered consecutively. The software rennumbers the rows to maintain a consecutive order if you insert or delete a row of data. (Unity Real Time does not number runs within a day).

2 Date & Time

The 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, and Number of Points

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

Enter Single Test Summary Data



Important: When submitting summary data to the peer group, it is important to make sure the selected date is in the month when the data was collected. For example, If the current date is February 2nd, but the collected results that you are entering are from January, be sure to change the date to a time in January.

- 1 Double-click a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Summary Data** tab.
- 3 If entering data for a date other than the current date, click **Set Date**.
 - Use the calendar or click any part of the date and type over the date and/or time.
- 4 Click in the first **Mean** field and type the value for the mean.
- 5 Press the TAB or ENTER key on the keyboard to go to the **SD** field.
- 6 Type the value for the SD.
- 7 Press the TAB or ENTER key on the keyboard to go to the **Points** field.
- 8 Type the number of points.
- 9 Repeat steps as needed to enter data for all levels.
- 10 Click **Save**.
- 11 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 161 for information about navigation buttons.

Overview of Qualitative Data Entry



Note: This guide uses the term qualitative to refer to both qualitative and semi-quantitative results. You can enter qualitative data manually or import it in the same way as quantitative data.

Unity Real Time provides the capability to enter qualitative and semi-quantitative data from both the Single Test and Multi Test Point data entry pages.

Qualitative data entry and peer group submission 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

- 1 Double-click a qualitative test in the Lab, Panel, or Instrument navigation tree.
- 2 If entering data for a date other than the current date, click **Set Date**.
 - Use the calendar or click any part of the date and type over the date and/or time.
 - Select the **Increment** or **Maintain** option for the additional rows of data.
- 3 Select the result for the qualitative data from the appropriate **Level** list.
- 4 Press the TAB or ENTER key on the keyboard to go to the next level.
- 5 Repeat steps as needed until all results are entered.
- 6 Click **Save**.
- 7 Click the appropriate navigation button to continue entering data. Make sure to click **Save** before navigating to ensure the data is saved.



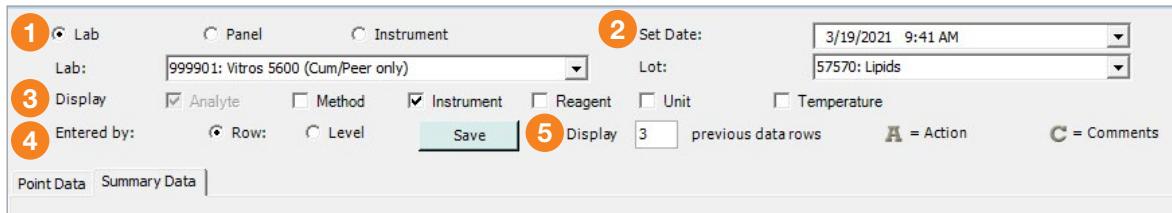
Note: From the Single Test Point Data entry page you can click the **View Expected Response** button to see the expected responses for each test. All users can view this page but cannot make edits regardless of permissions. See “Set Up an Expected Response” on page 115 for more information.



Note: See “Navigate the Single Test Data Entry Dialog Boxes” on page 161 for information about navigation buttons.

Overview of 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, panel or instrument. You can use Multi Test data entry for point and summary data.



1 Filter Data

Click the appropriate button according to how you want to enter data: Lab, Panel or Instrument. Additional filters will become available based on your selection: Lab, Lot, Panel, or Instrument.

2 Set Date

The date and time the QC data was run. The default will be the current date and time. Use the drop-down arrow next to the field to use the calendar tool or click on the text in the field to type over it.

3 Display

Click the appropriate button for any additional information you wish to see along with the analyte name.

4 Entered by

Click the appropriate button to determine if you will enter data by row or by level. This will determine if the cursor moves across the row entering results for each level of an analyte. Or it will determine if the cursor moves down from one test to the next for one level at a time. This will depend on how the information is organized on the printout you work from.

5 Display previous data rows

Enter the number of previous data rows for Unity Real Time to display in the grid below. This can be helpful when manually entering data to easily notice if typo is made where there is something to see for comparison.

Overview of Multi Test Point Data Entry

		Test information	Date & Time	Level 1	Level 2	Level 3		
86		AFP, Abbott ARCHITECT i2000/i2000SR	9/28/2021 9:57:00 A	33.00	123.00	233.00	A	C
87			9/29/2021 9:57:00 A	35.30	120.00	230.00	A	C*
88			9/30/2021 9:57:00 A	38.00	123.00	233.00	A*	C
89			10/1/2021 10:38:35 A				A	C
91		Amikacin, Abbott ARCHITECT i2000/i2000SR	9/28/2021 9:57:00 A	4.30	14.50	27.60	A	C*
92			9/29/2021 9:57:00 A	4.30	15.00	28.00	A	C
93			9/30/2021 9:57:00 A	3.25	14.50	27.60	A	C
94			10/1/2021 10:38:35 A				A	C
90		CEA (Carcinoembryonic Antigen), Abbott ARCHIT	9/28/2021 10:00:00 A	2.88	21.60	37.50	A	C
91			9/29/2021 10:00:00 A	2.67	21.60	38.90	A	C
92			9/30/2021 10:00:00 A	2.88	21.60	37.50	A	C

1 Point Data Tab

Select the appropriate tab to access the point or summary data entry tab.

2 Value

The fields where you type the QC values for each level when you manually enter data.

3 Action and Comments

Actions and comments may be used to enter documentation for the QC data run.

4 Rule violations

Rule evaluation occurs when TAB or ENTER on the keyboard is clicked to move from cell to cell.

Rejection violations are highlighted in red. Warning violations are highlighted in yellow. Hover the mouse over the cell to see what rule was violated and the status of the point.

5 Levey-Jennings chart

Click the chart icon to open another window with the Levey-Jennings chart for the test.

Overview of Multi Test Summary Data Entry

		Point Data	Summary Data								
Row	Test	Test information		Date & Time	Level 1		Level 2		SD	Points	Comments
		Mean	SD	Mean	SD	Mean	SD	Mean			
6	Cholesterol, HDL, VITROS 5600 (Wet)	7/1/2021 5:00:00 PM	28.90	0.75	34	61.75	1.00	34	C		
		8/1/2021 5:00:00 PM	27.50	1.00	35	58.70	0.80	35	C*		
		9/1/2021 8:05:00 AM	27.20	0.50	30	58.70	1.02	30	C		
		9/19/2021 9:41:06 A							C		
		Mean	SD	Points	Mean	SD	Points	Comments			
6	Cholesterol, LDL, VITROS 5600 (Dry Slide)	7/1/2021 5:00:00 PM	71.90	0.75	28	127.00	1.25	29	C		
		8/1/2021 5:00:00 PM	67.50	0.24	31	117.00	0.84	31	C*		
		9/1/2021 8:05:00 AM	67.00	0.50	30	115.00	1.00	30	C		
		9/19/2021 9:41:06 A							C		
		Mean	SD	Points	Mean	SD	Points	Comments			
6	Triglycerides, VITROS 5600 (Dry Slide)	7/1/2021 5:00:00 PM	132.00	0.85	28	418.50	1.20	28	C		
		8/1/2021 5:00:00 PM	132.00	0.70	30	419.00	0.64	30	C		

1 Mean, SD, and Number of Points

The fields where the values for the mean, SD, and number of points are typed for each level when you manually enter data.

2 Comment

Comments may be used to enter documentation for monthly summary statistics.

Enter Multi Test Data

- Click the **Select** menu, point to **Test**, and then click **Multi Test Data Entry**.
Or select a test in the navigation tree and then click the **Multi Test Data Entry** button on the toolbar.
- Click **Set Date** and use one of the following methods to select the date you want for data entry:
 - Click any part of the date and type over to edit the date for the first day of data entry.
 - Click the arrow located to the right of the date and select the date from the calendar for the first day of data entry.
- Select each **Display** check box for the test information you want to show.



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

- Method
- Instrument
- Reagent
- Unit
- Temperature

- 4 Select an **Enter by** option:
 - Row
 - Level
- 5 Click the **Point Data** tab or **Summary Data** tab according to the type of data you are entering.
- 6 Enter your data.
- 7 Click **Save**.



Note: If the setting for Automatic or Require Action Logs are enabled, you may receive a message after clicking Save to enter an Action to document rejection violations. See “Configure Actions and Comments” on page 432 for more information on Automatic and Require Action Logs.

Manage Data

In This Chapter

Overview	172
Data Entry Permissions.....	173
Edit Data, Date, and Time.....	173
Change a Data Point's Accepted/Rejected Status	175
Insert Data.....	177
Delete Data	178

Overview

It is sometimes necessary to make edits to previously entered or imported data. However, Unity Real Time does not re-evaluate edited data against any statistical process control (SPC) rules unless the edited data is on the last line of the data entry dialog box. In this case, Unity Real Time sends the edited data to the Unity Interlaboratory Program the next time you submit data. The following list summarizes the edits you can make:

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



Note: All changes to data are tracked in the audit-trail. If you are using the “Require audit-trail comments” feature, the software requires the user to enter a comment when edits are made.



Note: See “Data Handling Permissions” on page 74 for more information about these permissions.

Edit Data, Date, and Time

You can edit data results and the date and times associated with the results. Unity Real Time automatically adds a comment to the row stating “Inserted data is not evaluated against QC rules” when you edit point data.



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

Unity Real Time assigns manually entered data to the current date and time based on the computer clock unless you use the Set Date feature. You can edit the date and time. However, data points must be in chronological date and time order. Unity Real Time displays the message “Invalid date range” if an edited date and time is not in ascending order.

Edit Data



You must have the “Edit all data” permission to perform this function.

- 1 Double-click the test in the **Lab**, **Panel**, or **Instrument** navigation tree you want to edit.



Note: Data previously entered and saved in the Multi Test Data Entry dialog boxes must be edited in the Single Test Data Entry dialog boxes.

- 2 Click in the field of the data you want to edit.
- 3 Highlight the existing data and enter the new data.



Note: Unity Real Time automatically adds the comment “Inserted/edited data is not evaluated against QC rules” to the row for point data only. A green arrow appears for the row indicating the comment has been added.

- 4 Click **Save**.

Edit the Date and Time



You must have the “Edit all data” permission to perform this function.



Note: You can edit the date and time. However, data points must be in chronological date and time order. Unity Real Time displays the message “Invalid date range” if an edited date and time is not in ascending order.

- 1 Double-click the test in the **Lab**, **Panel**, or **Instrument** navigation tree you want to edit.

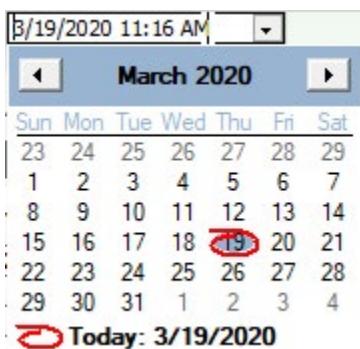


Note: Data previously entered and saved in the Multi Test Data Entry dialog boxes must be edited in the Single Test Data Entry dialog boxes.

2 To edit the date:

- Click the part of the date to edit and type over the date, or

- Click the arrow in the date field and select the date from the calendar.



3 To edit the time, click the part of the time to edit and type over the time.

4 Click **Save**.

Change a Data Point's Accepted/Rejected Status

Unity Real Time automatically accepts or rejects point data based on the active SPC rules. An “N” appears in the **Y/N** column of the Single Test Data Entry dialog boxes when data violates a SPC rule set to “Reject.”

Y	Data point accepted and is included in monthly and cumulative statistics. Data is included in monthly submission statistics for Unity Interlaboratory Reports.
N	Data point is rejected and is not included in monthly or cumulative statistics. Data is not included in monthly submission for Unity Interlaboratory Reports.



Note: SPC rule evaluation is by run rather than level. Unity Real Time rejects the entire row of data if any data point in a run violates a rejection rule.

Unity Real Time updates the summary statistics if you manually change an “N” to a “Y.” Conversely, Unity Real Time updates the summary statistics to exclude the value if you manually change a “Y” to an “N.”

Change the Accepted/Rejected Status of a Data Point

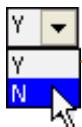


You must have the “Edit all data” permission to perform this function.



Note: Only point data is evaluated by SPC rules. The Single Test Summary Data Entry dialog box does not have a **Y/N** column.

- 1 Double-click the test in the **Lab**, **Panel**, or **Instrument** navigation tree for which you want to change the status.
- 2 Click the arrow located to the right of the **Y** or **N** and change the status.



		Level 1			Level 2			
	Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules
1	04/22/2017 9:36 AM	123.00	Y			123.00	Y	
2	04/22/2017 9:37 AM	123.00	Y			123.00	Y	
3	04/22/2017 9:37 AM	123.00	Y			123.00	Y	
4	04/22/2017 9:37 AM	121.00	Y			123.00	Y	
5	04/22/2017 9:37 AM	123.00	Y			123.00	Y	
6	04/22/2017 9:37 AM	123.00	N			123.00	Y	

- 3 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. Unity Real Time automatically adds the comment “Inserted/edited data is not evaluated against QC rules” to the row for point data only. A green arrow  appears for the row indicating the comment has been added.
- Unity Real Time inserts the row above the row you have selected 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. Unity Real Time displays the message “Invalid date range” if an edited date and time is not in ascending order.

Insert a Data Row



You must have the “Edit all data” permission to perform this function.

- 1 Double-click the test in the Lab, Panel, or Instrument navigation tree you want to insert a row of data for.
- 2 Select the row you want to insert a row above.



Tip: The row is inserted above the line you select.

- 3 Press the INSERT key on the keyboard.
A message appears asking for confirmation.
- 4 Click **Yes**.
A new row appears.
- 5 Edit the date and time of the row to maintain the sequential date and time order, if necessary.
- 6 Enter the data for the new row.



Note: For point data only, Unity Real Time automatically adds a comment to the row stating the inserted data is not evaluated against SPC rules. A green arrow  appears for the row indicating the comment has been added.

- 7 Click **Save**.

Delete Data

Unity Real Time provides two ways to delete data:

- By row in the data entry dialog boxes
- A range of data

See “Delete a Range of Data” on page 387.

Delete a Row of Data from the Data Entry Dialog Boxes



You must have the “Edit all data” permission to perform this function.

- 1 Double-click the test in the Lab, Panel, or Instrument navigation tree for which you want to delete a row of data.

			Level 1			Level 2		
	Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules
1	04/22/2017 9:36 AM	123.00	Y	▼		123.00	Y	▼
2	04/22/2017 9:37 AM	123.00	Y	▼		123.00	Y	▼
3	04/22/2017 9:37 AM	123.00	Y	▼		123.00	Y	▼
4	04/22/2017 9:37 AM	121.00	Y	▼		123.00	Y	▼
5	04/22/2017 9:37 AM	123.00	Y	▼		123.00	Y	▼
6	04/22/2017 9:37 AM	123.00	Y	▼		123.00	Y	▼

- 2 Select the row you want to delete.
 - 3 Press the DELETE key on the keyboard.
- A message appears asking for confirmation.
- 4 Click **Yes**.
 - 5 Click **Save**.

Review and Annotate Data

In This Chapter

Overview	179
About the Bench Review and Supervisor Review.....	180
Overview of the Bench Review and Supervisor Review Process	181
Perform a Bench Review or Supervisor Review	182
Data Analysis Grid	192
Action Log and Actions	205
Comments	210
Actions and Comments by Instrument.....	212
Require Audit Trail Comments.....	213

Overview

Unity Real Time provides the following features to simplify documenting your review of QC data:

- Bench Review and Supervisor Review (page 182)
- InstantQC (page 192)
- Data Analysis Grid (page 192)
- Action Log and Actions (page 204)
- Comments (page 210)
- Actions and Comments by Instrument (page 211)
- Require Audit Trail Comments (page 213)

About the Bench Review and Supervisor Review



Note: The Bench Review and Supervisor Review are for point data only. Summary data does not appear in the Bench Review or Supervisor Review.

Regulatory agencies frequently require the documentation of QC data review. The Bench Review and Supervisor Review simplify this process and provide an electronic trail of the review at two levels:

- Bench Review
The laboratory personnel performing the testing reviews QC results before verifying patient results.
- Supervisor Review
Supervisory personnel retrospectively evaluate QC results and monitor bench performance.

Unity Real Time documents the Bench Review and Supervisor Review using the Data Review Report, which you can print or save to a file. See “Overview of the Data Review Report” on page 190 for more information.

In addition, you can send data to Bio-Rad from the Bench Review and Supervisor Review for inclusion in InstantQC Reports on www.QCNet.com for prospective data review.



Note: Data transmission from the Bench Review and Supervisor Review for InstantQC Reports is activated by default. See “Configure Transmission” on page 435 for more information.

Analytical Goal and Rule Violations Displayed

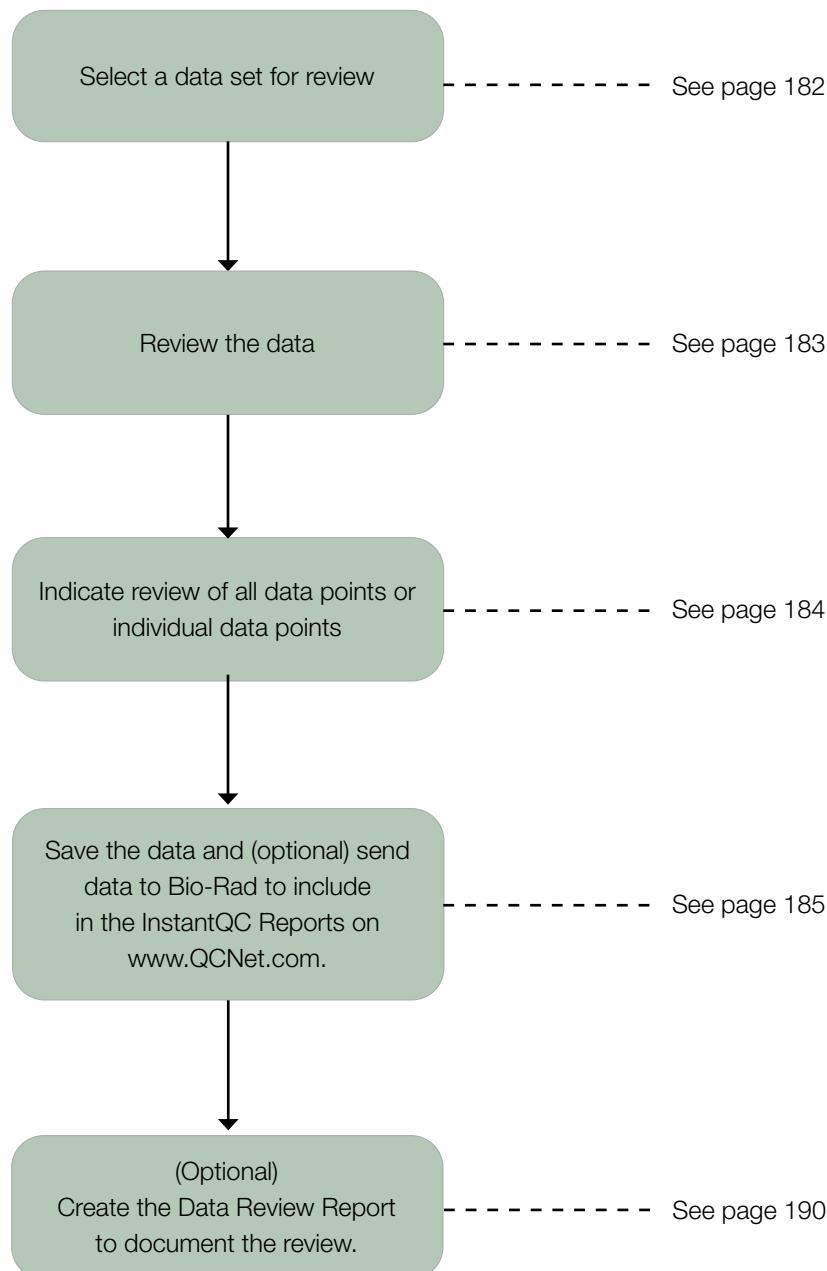
- Analytical goal violations are highlighted in yellow.
- Data points violating a SPC rule with a status of “Reject” are highlighted in red.
- Data points violating a SPC rule with a status of “Warn” are highlighted in yellow.
- Qualitative/semi-quantitative data points violating an expected response setting are highlighted in orange.
- The following message appears on the lower left of the screen if any data point violates an active SPC rule.

 One or more data points violate an evaluation rule.

Summary of the Bench Review and Supervisor Review

- The Bench Review and Supervisor Review are independent. You can use one or both reviews.
- The Bench Review is cleared only if a Bench Review is performed.
- The Supervisor Review is cleared only if the Supervisor Review is performed.
- The Supervisor Review contains all un-reviewed data for the selected data set, including data that has not been reviewed from the Bench Review.

Overview of the Bench Review and Supervisor Review Process



Perform a Bench Review or Supervisor Review

Select a Data Set for Review



You must have the “Bench Review” permission to perform a Bench Review. You must have the “Supervisor Review” permission to perform a Supervisor Review.

- 1 To access the Bench Review or Supervisor Review use one of the following options:
 - Click the **Review** menu and then click **Bench Review** or **Supervisor Review**.
 - Press **F2** or **Shift-F2** on the keyboard.
 - Select a lab, lot, or test from the navigation tree and then click the shortcut button on the Toolbar.
(Refer to “Toolbar” on page 47 for how to add buttons to the toolbar.)
- 2 Click the **Review** menu and then click **Bench Review** or **Supervisor Review**.
- 3 Click the appropriate button according to how you want to perform the review and use the lists located to the right to filter the results.
 - **Lab**
 - Select the lab number from the **Lab number** list or select **All**.
 - Select the lot number from the **Lot number** list or select **All**.
 - Select the instrument from the **Instrument** list or select **All**.
 - **Panel**
 - Select the panel from the **Panel** list or select **All**.
 - **Instrument**
 - Select the instrument from the **Instrument** list or select **All**.
- 4 Select an option for the data to review:
 - **All data**

This option is selected by default. The Bench Review and Supervisor Review shows all data, regardless if the data violated any active SPC rules.
 - **Include rule violations or data with Actions or Comments**
 - The Bench Review and Supervisor Review shows data points violating a SPC rule with a Reject or Warn status with associated actions or comments, or
 - The Bench Review and Supervisor Review shows data points with no SPC rule violations but with an associated action or comment.
 - **Include only rule violations**
 - 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 violating an Analytical Goal violation with a status of “Warn” is highlighted in yellow.
- Data violating an expected response selection for Qualitative/Semi-Quantitative is highlighted in orange.
- Data points that do not violate a SPC or Analytical Goal violation remain as white (non-highlighted) rows.



Note: 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 included so you can see the full run with all of the levels. See “Manually Accept or Reject Data in the Review” on page 184 for more information.



Note: You can click the **Analyte** column and select **Sort Ascending** or **Sort Descending** to sort the order of the analytes.

- 5 Continue with the next section, “Review Data.”

Review Data

Besides reviewing the data from the Bench Review and Supervisor Review grid display, you can also choose to view the data using the Levey-Jennings Chart and the data entry page.

View a Levey-Jennings Chart

- 1 Click **Go to Chart** to view a Levey-Jennings Chart for the test.
- 2 Click a data point on the chart to be prompted to change the status (accept/reject) of the point.
- 3 Click  (gray X) in the upper right corner to close the chart.

View the Data Entry Dialog Box

- 1 Click **Go to Data Entry** to open the data entry dialog box for the test.
- 2 Click an arrow in the **Y/N** column to manually change the accept/reject (Y or N) status of a data point.
- 3 Click the Action button  to add an action to the row of data or to view existing actions.
- 4 Click the Comment button  to add a comment to the row of data or to view existing comments.
- 5 Click **Save** to save changes, if needed.

Add Documentation

See “Add an Action in the Bench Review and Supervisor Review” on page 210 for information about adding actions.

See “Add a Comment in the Bench Review and Supervisor Review” on page 211 for information about adding comments.

Manually Accept or Reject Data in the Review

You can manually accept or reject data in the Bench Review and Supervisor Review. Select and clear the check box in the **Status** column to switch between accepting and rejecting the data.



Important: Unity Real Time rejects the entire row if any data within a run is rejected. Based on best practice principles in the lab, Unity Real Time assumes you will repeat all levels in the QC data run. If your lab only repeats the level that violated the SPC rejection rule and considers the other levels acceptable, then you will need to use this feature to change the status of levels without the violation.

Document the Review

A date and time stamp and the user's initials will be entered for each data point. The reviewed data will be removed from the review tool being used. To see documentation of the completed review in the future, refer to the Data Review Report, the Single Test Point Data Entry page, and the Levey-Jennings Chart.

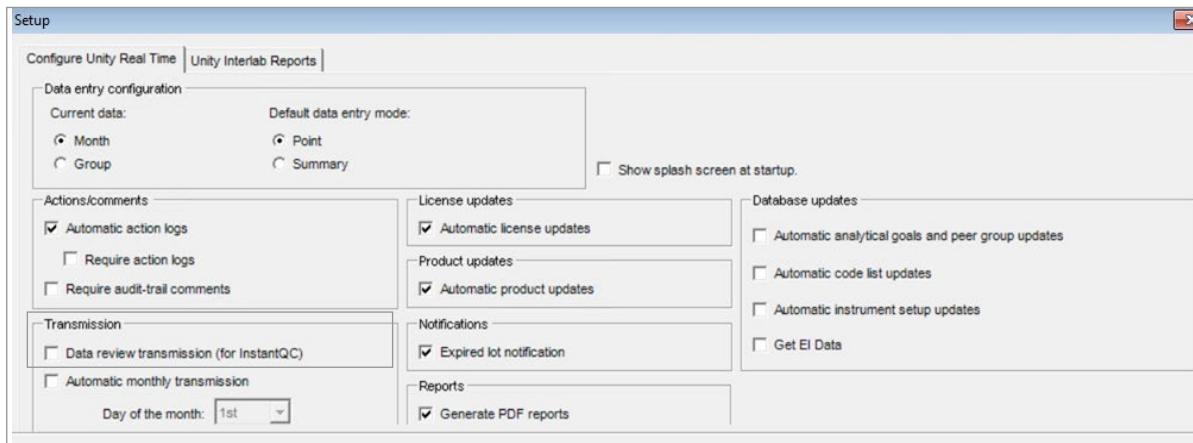
- 1 Select the **All data** option.
- 2 Use one of the following methods to indicate review of the data:
 - Select the **Reviewed** check box to indicate review of all data points on the page.
 - Click the individual check box in the **Reviewed** column to the left of the test to indicate review of the data in the row.
- 3 Click **Save** or **Save and Transmit** depending on the transmission option selected for InstantQC. See the next section "Save and Transmit" for more information.

Note: The save button will be grayed out until at least one data run is selected for review.
- 4 Data may be marked as reviewed while still on one of the filters besides "All Data." The software will go ahead and mark all accepted and rejected data as reviewed regardless of the filter selection.
The only thing you cannot do from the other filters is use the check mark to select individual rows as reviewed. You must be on the "All Data" filter to do this.
- 5 The only thing you cannot do from the individual filter is use the check mark to select individual rows as reviewed. You must be on the "All Data" filter to do this.

Save and Transmit

When each page of the Bench Review or Supervisor Review is complete, click **Save** or **Save and Transmit**.

The **Data review transmission** check box selection in the **Setup** dialog box determines which button appears. By default, the **Data review transmission** check box is selected. See “Configure Transmission” on page 435 for more information.



- 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 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 on www.QCNet.com.

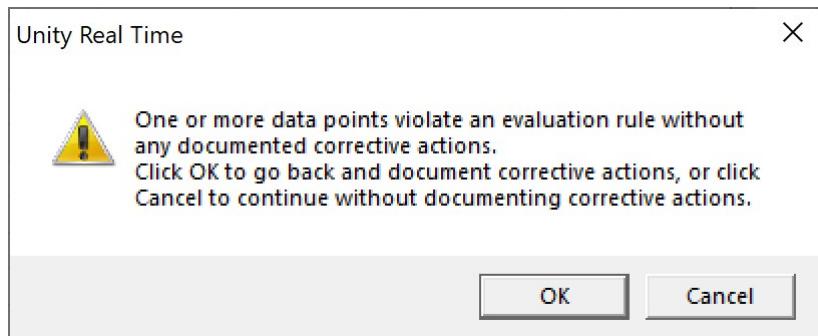
Warning Messages

Automatic or Require Action

If the setting for Automatic or Require Action Logs are enabled you will receive one of two popup messages if you have any rejection violations that do not have an action entered to document how the issue was addressed. See “Configure Actions and Comments” on page 432 for more information on Automatic and Require Action Logs.

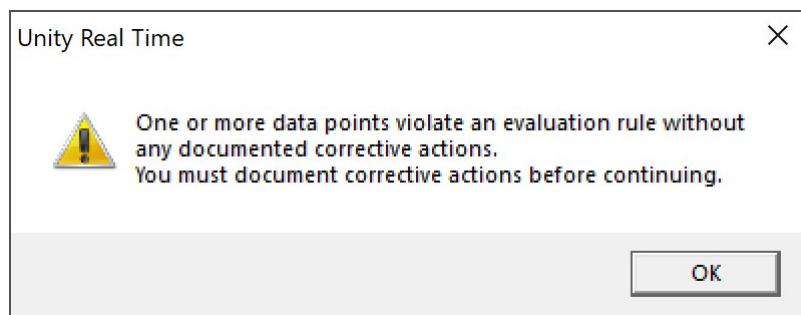
- **Automatic Action Message:**

You have the option to go back and enter an action or you can proceed with marking the data as reviewed.



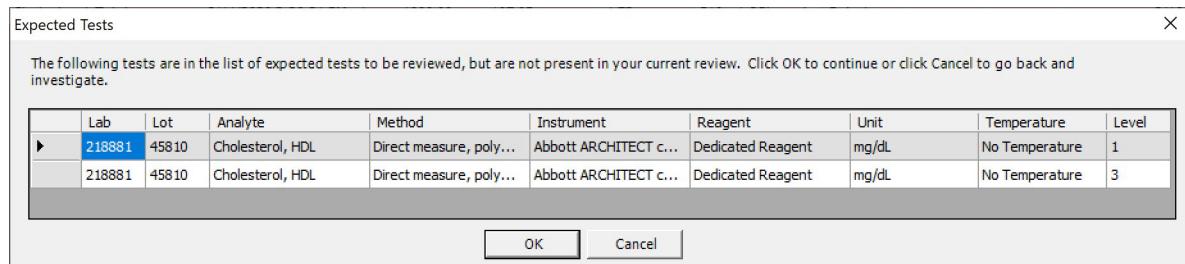
- **Require Action Message:**

You must go back to enter an action for the violation. The software will not allow you to mark data as reviewed without an action.



Expected Tests Message

If the settings for Manage Expected Tests are in use, you will receive a message indicating if any test/test level is missing from the review. This is an excellent tool to ensure users do not overlook a missing test from their review. See “Manage Expected Tests” on page 189 for more information on Expected Tests.



InstantQC

You can use InstantQC Reports to compare your results to the results of other laboratories at any time without deadlines for data submission. Accessed from www.QCNet.com, InstantQC Reports provide easy access to peer group comparison statistics.

Due to the fast report turnaround times, InstantQC is particularly useful for troubleshooting problems with test system performance as they occur. InstantQC Reports are available on www.QCNet.com after a short processing time.



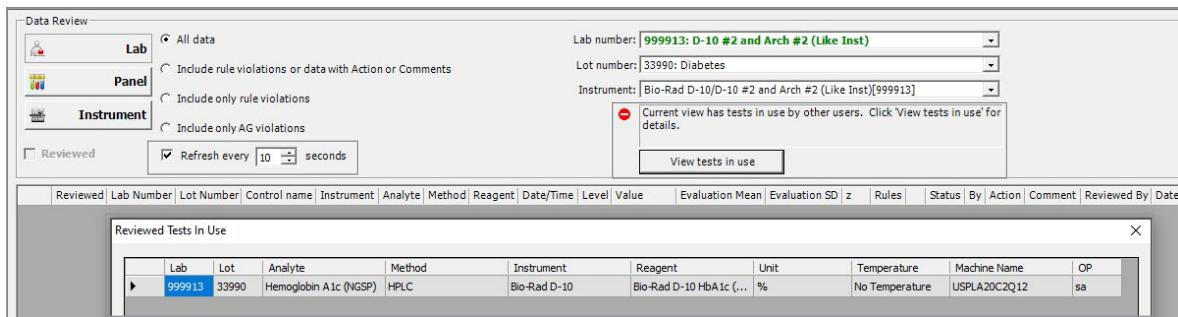
Note: See “InstantQC Reports” on page 305 for more information.

Refresh the Review Window

Because other users may enter or import data while you are working in the Bench or Supervisor Review, you want to make sure you are seeing the most recent information.



Note: By default, the Bench Review is set to refresh every 10 seconds.



- Use the check box in front of the **Refresh every __ seconds** option to turn off or turn on the refresh feature. You can change the refresh rate to any number between 10-99 seconds.
- If another user has already filtered for some or all of the information you are filtering for, you will receive a message at the top of the window.
- Click the **View tests in use** button to see more information such as the operator and the computer name that has tied up the filtered information.

Manage Columns

You can customize the data shown on the Bench Review and Supervisor Review.

- 1 Click **Manage Columns** on the Bench Review or Supervisor Review dialog box.
The **Show Data Review Columns** dialog box appears.
- 2 Select a check box to display the corresponding column in the Supervisor Review or Bench Review. Clear a check box if you want to hide a column.
- 3 Select the option to apply the settings:
 - Apply to all users
 - Apply to current user
- 4 Click **OK**.

Manage Expected Tests

You can define tests that are expected to be present in the Bench Review or Supervisor Review. By default, a notification appears stating a test is not present if it is missing after a Bench Review or Supervisor Review is saved.

The Expected Tests feature looks to see if any test name or level is missing from the Bench Review.

To turn on or off the entire manage expected tests feature, select the **Use the Expected Tests feature** check box located at the top of the page. Select the check mark to turn the feature on or clear the check mark to turn it off. Remember that this will turn off the feature for the entire database.

Sometimes one department wants to use this feature and another doesn't or data is not run every day for certain tests/lots/instruments. For these situations, use the steps below to select which labs, lots, and instruments will receive the notifications for missing tests.

Refer to "Expected Tests Message" on page 187 for more information about the Expected Tests messages.

- 1 Click **Manage Expected Tests** on the Bench Review or Supervisor Review dialog box.

The **Expected Tests** dialog box appears.

- 2 Click the appropriate button according to how you want to manage the expected tests and use the lists located to the right to filter the results.

- **Lab**

- Select the lab number from the **Lab number** list or select **All**.
- Select the lot number from the **Lot number** list.
- Select the instrument from the **Instrument** list.

- **Panel**

- Select the panel from the **Panel** list.

- **Instrument**

- Select the instrument from the **Instrument** list.

Select the **Check analyte by level** check box to receive notifications of tests with missing levels in the Bench or Supervisor Reviews.

- 3 The check boxes for all tests/levels are selected by default. Clear the check box to remove a test/level from the selections.
- 4 Select the option to apply the settings:
 - Apply to all users
 - Apply to current user
- 5 Click **OK**.

Overview of the Data Review Report

The Data Review Report documents the review of point data from the Bench Review and Supervisor Review. The Data Review Report contains the following information for each data point:

- Date and time the QC was run
- Operator initials
- Value for each level
- Associated actions and comments, if any
- Accept/reject status
- Initials of the person performing the Bench Review or Supervisor Review, when available
- Date and time of the Bench Review or Supervisor Review

Unity Real Time						
Data Review Report						
Printed	7/10/2020	Range	7/1/2020 12:00 AM	through	7/10/2020 11:59 PM	Page
Lab number:	358619	Description:	Beckman Coulter/Roche #2 (Ch/Rpt)			
Lab name:	Training Department Sample DB	Department:	Training			
Contact:		Address:	9600 Jeronimo Rd			
City:	Irvine	Postal/ZIP code:	92618			
State:	CA	Lot name:	Multiqual 1,2,3 Unassayed			
Lot number:	47990	Matrix:	Serum			
Manufacturer:	Bio-Rad Laboratories					
Expires:	2/28/2021					
Date	Op	Supervisor Review	Date	Bench Review	Date	
Albumin,Bromcresol Green (BCG),Beckman Coulter AU480,Dedicated Reagent,g/dL,No Temperature						
7/8/2020 12:00:00AM	sa	LT	12/2/2020 2:40:58PM	sa	12/2/2020 2:37:41PM	
Level	1 Value	2.63 Accepted				
Level	2 Value	3.32 Accepted				
Level	3 Value	4.50 Accepted				
Action(s)	Calibration: weekly cal performed due to expiration; patient study within acceptable range (sa - 12/2/2020 2:36:29 PM)					
ALT (ALAT/GPT),UV without PSP,Beckman Coulter AU480,Dedicated Reagent,UL,37° C						
7/8/2020 3:59:00AM	sa	LT	12/2/2020 2:40:58PM	sa	12/2/2020 2:37:41PM	
Level	1 Value	21.87 Accepted				
Action(s)	Calibration: weekly cal performed due to QC open date expiration; patient study within acceptable range (sa - 12/2/2020 2:37:07 PM) Control: All levels reran (sa - 12/2/2020 2:37:41PM)					

Create the Data Review Report

- 1 Perform a Bench Review or Supervisor Review.
- 2 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
- 3 Click the **Reports** menu and then click **Data Review**.
- 4 Click the arrow in the **From** field and select the beginning date for the report.
- 5 Click the arrow in the **To** field and select an ending date for the report.
- 6 **For Panels only:** Select the panel name from the **Panel** list or select **All Panels**.

7 For **Instrument** only:

- Select the instrument name from the **Instrument** list or select **All Instruments**.

8 For **Lab** only:

- Select the lab number(s) from the **Lab** list or select **All Labs**.
- Select the lot number(s) from the **Lot** list or select **All**.
- Select the instrument(s) from the **Instrument** list or select **All Instruments**.

9 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

10 See “Print and Export Reports” on page 277 if you want to print or save the report.

11 Click  in the upper right corner to close the report.

Data Analysis Grid

The Data Analysis Grid allows you to perform a side-by-side comparison of statistics of selected data. It allows multiple data sets to be compared in a single display, with the ability to compare results from multiple instruments against each other, as well as to the results of the Unity consensus group. The Data Analysis Grid also visually distinguishes data points exceeding the specified alert limits.

Each Data Analysis Grid search can be set up and saved as a template to be used again in the future. This is ideal for laboratories or departments that share a Unity Real Time database allowing users to maintain templates specific to their department.

Examples of Comparisons with the Data Analysis Grid

- Compare your instrument(s) against a Unity consensus group.
- Compare the QC results of like instruments running the same QC.
- Compare your QC results against the fixed mean and SD.
- Compare each instrument's results to the mean of all instruments.
- Compare each month's QC results against the Unity consensus group or to your lab's cumulative QC results.
- If assistance is needed with setting up other comparisons that would be helpful, contact Bio-Rad Software Support.



Note: You can set up more than one Data Analysis Grid template to perform various comparisons.

View the Data Analysis Grid

- 1 Select a lab number and lot number in the **Lab** navigation tree for which you want to review data.
- 2 Click the **Analysis** menu and then click **Data Analysis Grid**.
Or create and use a shortcut button from the toolbar.
See “Toolbar” on page 47 for more information on how to customize the toolbar.

Select a Data Analysis Grid Template

On the Data Analysis Grid page, click the down arrow  located in the **Template** field and select the template you want to view.



Note: See “Create a New Data Analysis Grid Template” on page 199 for information about creating a new template.

Select Levels

Click the appropriate **Level** tab located at the top of the Data Analysis Grid to view data for a specific level or for all levels.

Configuration Detail Preview

Position the mouse pointer over one of the cells in the **Data Set** column of the Data Analysis Grid (for example "A") to view configuration details.

Details include:

- Data reference set
- Test Selection (Current Lot or Current Test)
- Data Set A selections
- Data Set B selections
- Alert thresholds

Data Set	Analyte	Lab	Lab description	Method	Instrument	Reagent	Unit	Temper
A	Albumin	2188...	D-10 #1 and ...	Bromcresol Gr...	Abbott ARCHI...	Dedicated Rea...	g/dL	No Temper
B1		9999...	D-10 #2 and ...	Bromcresol Gr...	Abbott ARCHI...	Dedicated Rea...	g/dL	No Temper
A	Alkaline Phosp...	2188...	D-10 #1 and ...	PNPP, AMP Bu...	Abbott ARCHI...	Dedicated Rea...	U/L	37° C
B1	Data reference set: Data Set A Test Selection: Current Lot							
A	Data Set A: Your laboratory, Another Instrument Abbott ARCHITECT c16000/D-10 #1 and Arch #1 (DAG BR)[218881], Cumulative							
B1	Data Set B1: Your laboratory, Another Instrument Abbott ARCHITECT c16000/D-10 #2 and Arch #2 (Like Inst)[999913], Cumulative							
A	Alert thresholds: SDI: ± 2.00, CVR: 2.00, Sigma: 3.00							
B1		9999...	D-10 #2 and ...	UV without P5P	Abbott ARCHI...	Dedicated Rea...	U/L	37° C
A	Calcium	2188...	D-10 #1 and ...	Arsenazo III	Abbott ARCHI...	Dedicated Rea...	mg/dL	No Temper

Column Colors

The Data Analysis Grid uses different colors in the columns to help differentiate selections and comparisons.

- Gray columns indicate information based on the instrument and consensus group selections made when setting up the Data Analysis Grid template.
- Green columns indicate calculations and statistics based on comparisons set up in the Data Analysis Grid template.

Data Analysis Grid Columns

Columns shown on the Data Analysis Grid may be customized for each individual template. See “Data Analysis Grid Formulas” on page 204.

Data Analysis Grid Column	Description
Data Set	Defined group of data points based on instrument, time period, evaluation mean/SD, consensus group, etc.
Analyte	The analyte or test name.
Lab	The lab number.
Lab description	The lab description.
Method	The defined method for the analyte.
Instrument	The instrument the analyte is run on.
Reagent	The defined reagent for the analyte.
Unit	The defined Unit of Measure.
Temperature	The defined temperature.
Mean	The arithmetic average of a set of data points.
SD (Standard Deviation)	Measures a test's precision. “Repeatability.”
CV (Coefficient of Variation)	The observed imprecision or random error of the method, expressed as a percentage of the mean. CV = standard deviation / mean.
CV Threshold	The defined maximum level of CV set up as an alert. See “Configure Alerts” on page 199.
Pts	The number of data points.
Labs	The number of labs reporting.
QC Rules	The SPC and/or Analytical Goal rules defined for the analyte.
SDI (Standard Deviation Index)	Measures your bias relative to the consensus group. SDI = (your lab's mean – mean of the consensus group) / SD of the consensus group
CVR (Coefficient of Variation Ratio)	Measures your imprecision relative to the consensus group. CVR = your lab's CV / CV of the consensus group
Bias%	How far an observed value is from a target value, expressed as a percentage. Laboratory Bias % = [(your mean – consensus group mean) / consensus group mean] * 100
±Bias % Threshold	The defined maximum level of ± Bias set up as an alert. See “Configure Alerts” on page 199.

Data Analysis Grid Column	Description
TE p<0.05 (Total Error)	The overall error in a test result due to the imprecision and bias present in the testing procedure. TE = 1.65 * (imprecision + bias)
TEB% (Total Error Budget)	A quantity that relates the laboratory's test system process capability (TE) to the laboratory's quality requirement (TE _a). TEB = TE/TE _a * 100
TEB% Threshold	The defined maximum level of TEB % set up as an alert. See "Configure Alerts" on page 199.
Sigma	A numeric value that characterizes method performance in terms of the number of standard deviations or sigmas that fit within the tolerance limit or quality requirement of a test. Sigma = (TE _a % -bias %) / CV
TE _a (Allowable Total Error)	A quality requirement that sets limits for the bias and imprecision allowable in a test result.
TE _a Selection	The selection the defined TE _a is based on. See "Configure the TE _a (Allowable Total Error)" on page 196.
RCV (Reference Change Values)	Provide objective tools for assessment of the significance of differences in serial results from an individual. RCV = $2^{1/2} * Z * [CV_A^2 + CV_I^2]^{1/2}$ <ul style="list-style-type: none"> • CV_A: Analytical imprecision. • CV_I: Within subject biological variation estimate

Data Set Configuration



You must have the "Manage Data Analysis Grid Template" permission to manage this function.

All users can access and make changes to the Data Set Configuration, but only users with the permission can save their changes.

Clicking the **Data Set Configuration** button opens the **Data Set Configuration** dialog box where you can configure templates. See the following sections for more information: "Create a New Data Analysis Grid Template" on page 199, "Create a New Template Based on an Existing Template" on page 200, and "Update an Existing Data Analysis Grid Template" on page 200.

Configure the TE_a (Allowable Total Error)



You must have the “Configure TE_a” permission to perform this function.



Note: The TE_a option in the Data Analysis Grid is synchronized with the TE_a selected in the Measurement Uncertainty Report and the optional Westgard Advisor tool. The TE_a selections in the Data Analysis Grid, Measurement Uncertainty Report, and Westgard Advisor will not overwrite the TE_a selections in the Analytical Goals tool. However, the TE_a selections made in analytical goals can be set to overwrite the selections in the Data Analysis Grid, Measurement Uncertainty Report, and Westgard Advisor.

- 1 Click **Configure TE_a** located on the **Data Analysis Grid**.

The **Configure TE_a** dialog box appears.



Note: The Configure TE_a button is grayed out until you select a template.

- 2 Select the analyte on the left side of the dialog box for which you want to configure.
- 3 Click the down arrow located in the **TE_a** field to view the available TE_a options for the test.



Note: The following list does not include all possible options.

- 3SD
 - If CLIA does not have a published value and there are no published Biological Variation values, this will be the default selection.
- BV Des bias / Desirable imprecision
 - If CLIA does not have a published value, this will be the default selection.
- BV Des bias / Min imprecision
- BV Des bias / Op imprecision
- BV Min bias / Des imprecision
- BV Min bias / Min imprecision
- BV Min bias / Opt imprecision
- BV Opt bias / Des imprecision
- BV Opt bias / Min imprecision
- BV Opt bias / Op imprecision



Note: The $\pm 3SD$ limits are based upon the group selected in the Consensus Group section. If the user intends to use actual data from your lab, select “This lab” as the Group.



Note: See “Performance Goals” on page 136 for more information regarding Biological Variation.

BV = Biological Variation

Min = Minimum

Op = Optimum

Des = Desirable

- CLIA
 - Typically, if CLIA has a published value, this will be the default selection.
- CLIA (2019)



Note: If CLIA is the default TE_a selection for a test, it will use the CLIA option. You will have to select CLIA 2019 if you want to use the latest published values.

- EMC (Especificaciones Minimas Consenso)
- GOST
- IPH Belgium
- IQMH
- Loosest
- QUALAB (no bias)
- RCPA
- RiliBÄK
- SEKK
- SKML uses two tolerance ranges:
 - SKML-SA is based on State of the Art.
 - SKML-TE is based on total error allowable defined by either clinical outcome or biological variation.



Note: The settings for individual determinators can be found on <https://www.skml.nl/en/home/schemes/reportings/skml-tolerance-ranges>



Note: For more information on SKML tolerance ranges and their relationship to SKML score, see <https://www.skml.nl/en/home/schemes/reportings/muse>

- State of the Art - no bias
- Tightest
- Turkey TE_a
- User Defined

- The default applies to all matrices
- Select the **Apply by Matrix** check box to enter a different TE_a% for each matrix (serum, urine, blood gas, etc.).
- WS/T (China)



Note: Only published values that are available for the selected analyte appear in the **TE_a** list.
Not all options are available for all tests.

- 4 Select the TE_a option from the **TE_a** list.
- 5 Click **For All Analytes** if you want to apply the selected TE_a to all tests.



Tip: Click **Set Current Analyte to Default** if you want to return the analyte to the default TE_a selection. Click **Set All Analytes to Default** if you want to return all analytes to the default TE_a selections.

- 6 Select the consensus group from the **Group** list.



Note: Only the 3SD and State of the Art options utilize the Consensus Group section. If the listed result for CLIA or RCPA is an absolute value, they will also be calculated based on the Consensus Group section. “This lab” (your own target) is the best option for these options in particular.

- 7 Select the range from the **Group Data Range** list.
- 8 Click **For All Analytes** if you want to apply the consensus group settings to all tests.
- 9 Click **Save** when you are finished making your selections.
- 10 Click **Close** to close the **Configure TE_a** dialog box.

Configure Alerts

The Data Analysis Grid identifies any data exceeding the specified alert limits by highlighting the data in color. You can specify alert limits for the following criteria.

- | |
|---|
| <ul style="list-style-type: none"> • SDI • CVR These alert limits apply to all analytes. • Sigma |
| <ul style="list-style-type: none"> • CV • Bias % These alert limits can be set by analyte and by level. • TEB % |

- 1 Click **Configure Alert**.
- 2 Enter the alert thresholds for each item.
- 3 Click **Set Color** and select the color for each of the alerts to appear on the Data Analysis Grid.
- 4 Click **OK**.

Export the Data Analysis Grid

Click **Export** located on the Data Analysis Grid.

The Data Analysis Grid opens as a Microsoft Excel file.



Note: The Data Analysis Grid cannot be exported to Microsoft 2013 format.

Print the Data Analysis Grid

- 1 Click **Print** located on the Data Analysis Grid.
The **Print Preview** page appears.
- 2 Select the appropriate options for your printer and click **OK**.

Create a New Data Analysis Grid Template

- 1 Use one of the following methods to access the **Data Set Configuration** dialog box:
 - Click the **Analysis** menu and then click **Data Set Configuration**.
 - Click the **Data Set Configuration** button located above the grid.
- 2 Select the **Add** option.
- 3 Enter a name for the template.
- 4 Continue with the section “Configure Data Set A” on page 200.

Create a New Template Based on an Existing Template

- 1 Use one of the following methods to access the **Data Set Configuration** dialog box:
 - Click the **Analysis** menu and then click **Data Set Configuration**.
 - Click the **Data Set Configuration** button located above the grid.
- 2 Select the **Update** option.
- 3 Click the down arrow  and select the template you want to base the new template on.
- 4 Click **Save As** and enter a name for the new template.
- 5 Click **OK**.
- 6 Continue with the section “Configure Data Set A” on page 200.

Update an Existing Data Analysis Grid Template

- 1 Use one of the following methods to access the **Data Set Configuration** dialog box:
 - Click the **Analysis** menu and then click **Data Set Configuration**.
 - Click the **Data Set Configuration** button located above the grid.
- 2 Select the **Update** option.
- 3 Click the down arrow  and select the template you want to update.
- 4 Continue with the next section, “Configure Data Set A.”

Configure Data Set A

- 1 Click the **Data Set A** tab and select one of the following for the data:
 - **Your laboratory**
(Allows you to use your own data collected from within Unity Real Time.)
 - **Consensus group**
(Allows you to use consensus group data collected from the Unity Interlaboratory Program.)



Note: In order to view Unity consensus group data, make sure that the “Automatic analytical goals and peer group updates” option is selected in the **Setup** dialog box in Unity Real Time. With this setting, Unity Real Time prompts you to download the latest updates on a regular basis when logging in. See “Update the Database Automatically” on page 382.

- 2 Continue with the appropriate steps according to your selection in step 1.
 - If you selected “Your laboratory,” go to step 3.
 - If you selected “Consensus group,” go to step 4.
- 3 **Your Laboratory configuration options:**
 - a) Select an option for the laboratory data:

- **Current instrument**
When using the Data Analysis Grid in the future, this will be determined by the lot number or test you select in the navigation tree.
 - **Another instrument**
Select one or more instruments or select the check box at the top of the column to select all.
 - Select the evaluation data:
 - **Evaluation mean/SD**
Fixed mean and SD setup in Unity Real Time, if applicable. Otherwise, the software uses the floating mean and SD.
 - **Cumulative**
Includes all QC data for the selected lot and analyte.
 - **Date range**
Select the desired date range.
- b) Continue with the section, “Configure Data Set B” on page 201.

3 Consensus Group configuration options:



Note: In order to view Unity consensus group data, make sure that the “Automatic analytical goals and peer group updates” option is selected in the Setup dialog box in Unity Real Time. With this setting, Unity Real Time prompts you to download the latest updates on a regular basis when logging in. See “Configure Database Updates” on page 433.

- a) Select an option for the consensus group:
 - Peer
 - Method
 - All Labs
- b) Select the time period for the evaluation data:
 - 1 month
 - 6 months
 - Cumulative
- c) Continue with the next section, “Configure Data Set B” on page 201.

Configure Data Set B

- 1 Click the **Data Set B** tab.
- 2 **Select the number of data sets to compare to Data Set A**
You can compare up to 500 data sets, if needed. Enter the number of data sets. (For example: You have three Siemens EXL instruments and you want to see each instrument compared to Data Set A.)
- 3 **Configure Data Set B1:**
Select an option for the data set:

- **Your laboratory**

Allows you to use your own data collected from Unity Real Time.

- **Consensus Group**

Allows you to use consensus group data collected from the Unity Interlaboratory Program.



Note: In order to view Unity consensus group data, make sure that the “Automatic analytical goals and peer group updates” option is selected in the **Setup** dialog box in Unity Real Time. With this setting, Unity Real Time prompts you to download the latest updates on a regular basis when logging in. See “Update the Database Automatically” on page 382.

4 Continue with the appropriate steps according to your selection in step 3.

- If you selected “Your laboratory,” go to step 5.
- If you selected “Consensus group,” go to step 6.

5 **Your Laboratory configuration options:**

a) Select an option for the laboratory data:

- **Current lab number**

When using the Data Analysis Grid in the future, this will be determined by the lot number or test you select in the navigation tree.

- **Another lab number**

Select one or more lab numbers or select the **Select all** check box.

b) Select the evaluation data:

- **Evaluation mean/SD**

Fixed mean and SD setup in Unity Real Time, if applicable. Otherwise, the software uses the floating mean and SD.

- **Cumulative**

Includes all QC data for the selected lot and analyte.

- **Date range**

Select the desired date range.

c) Click **Save**.

d) Go to the next section, “Configure Data Set B2” on page 203.

5 **Consensus group configuration options:**

a) Select an option for the consensus group:

- Peer
- Method
- All Labs

b) Select the time period for the evaluation data:

- 1 month

- 6 months
 - Cumulative
- c) Go to the next section, “Configure Data Set B2” on page 203.

Configure Data Set B2

Data Set B allows for multiple data sets. For example, you can set Data Set A as the consensus group and set up each instrument running the same QC data in Data Set B for easy comparison of all instruments against the consensus group.

- 1 Repeat steps 3–6 as described in “Configure Data Set B” on page 201 as needed for any additional Data Set for B. (B2, B3, B4...).
- 2 If you do not want to configure additional data sets, go to the next section, “Configure the General tab” on page 203.

Configure the General tab

- 1 Add or remove check marks based on the columns you want displayed on the Data Analysis Grid. Clear the check box for any item you do not want to display or select the information you want included as columns in the grid.
- 2 Select the font size for the text on the Data Analysis Grid.
- 3 Select the data reference set for comparison.
The reference set is the standard for comparison or what you are comparing against between your data sets. Example: If data set A is set as the Peer Group and B is set as your instrument, you would want to select A as your reference set since, typically, you compare your data to the peer group.
- 4 Instrument Scope
This feature is only used if you are comparing different instrument models or models that are not in the same instrument *tier. If this check box is selected, you cannot use the consensus group setting for group A or B.



Note: *Tiered instruments are groups of similar instruments you can compare. For example, you can compare a Dimension Xpand to a Dimension RxL because both are part of the same tiered group.

- 5 Test Selection:
 - **Current Lot**
The Data Analysis Grid will include all tests that are a part of the current lot selected in the navigation tree.
 - **Current Test**
The Data Analysis Grid will only include the one test that is currently selected in the navigation tree.
- 6 Click **Save**.

Data Analysis Grid Formulas

With Data Set A as the reference (this is the default)

CVR = CV_b / CV_a

SDI = (Mean b - Mean a) / SD a

Bias = ((Mean b - Mean a) / Mean a) * 100

TE = Bias(as above) + 1.65 CV_b

Sigma = (Allowable Total Error - Bias(as above)) / CV_b

TEB = (TE (as above) / allowable total error) * 100

With Data Set B as the reference

CVR = CV_a / CV_b

SDI = (Mean a - Mean b) / SD b

Bias = ((Mean a - Mean b) / Mean b) * 100

TE = Bias(as above) + 1.65 CV_a

Sigma = (Allowable Total Error - Bias(as above)) / CV_a

TEB = (TE(as above) / allowable total error) * 100

Action Log and Actions

Unity Real Time includes a library of commonly used actions. These pre-defined messages help standardize documenting the steps taken to correct an error situation. All actions include a date and time stamp and the user initials. This helps you determine if the action was added at the time the data was entered or at a later time.

A red check mark  next to an action in the Action Log indicates the action is in use and cannot be edited or deleted. Therefore, Bio-Rad recommends reviewing the list of pre-defined actions prior to using them. See “Action Log Messages” on page 439 for a list of action log messages. You can also add custom actions for optimal use in your laboratory. See “Add a Custom Action” on page 205 for more information.

When added, actions are shown in the following:

- Bench Review
- Supervisor Review
- Single Point Data Entry dialog box and Multi Test Data Entry dialog box
- Point Data Report
- Data Review Report
- Supervisor Report
- Levey-Jennings Chart



Note: The Levey-Jennings Chart must be configured to show actions. See “Customize the Levey-Jennings Chart” on page 219 for more information.

Add a Custom Action



You must have the “Edit action log” permission to use this function.



Note: 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** menu, point to **Action and Comments**, and then click **Configure Action Logs**.
The **Action Log** dialog box appears.
- 2 Clear the existing text in the **Action(s)** field and type the text for the custom action.
- 3 Click **Add**.
The action is added in alphabetical order. The software assigns a code number to the action based on the next available number.
- 4 Click **Close**.

Edit an Action



You must have the “Edit action log” permission to use this function.



Note: A red check mark next to an action in the Action Log indicates the action is in use and cannot be edited.

- 1 Click the **Tools** menu, point to **Action and Comments**, and then click **Configure Action Logs**.
The **Action Log** dialog box appears.
- 2 Select the action in the **Action(s)** list you want to edit.
- 3 Edit the existing text in the **Action(s)** field.
- 4 Click **Update**.
The edited action appears in the **Action(s)** list.
- 5 Click **Close**.

Sort the Action Log

Some actions are used more frequently than others. You can sort the Action Log list so the most frequently used or important appear at the top or alphabetical order.

- 1 Click the **Tools** menu, point to **Action and Comments**, and then click **Configure Action Logs**.
The **Action Log** dialog box appears.
- 2 Use the drag-and-drop method to sort the actions and code columns or click the Action(s) or Code columns.
- 3 Click **Close**.

Suppress an Action



You must have the “Edit action log” permission to use this function.

- Suppressed actions do not appear in the Action Log but remain in the software for the Audit Trail.
- 1 Click the **Tools** menu, point to **Action and Comments**, and then click **Configure Action Logs**.
The **Action Log** dialog box appears.
 - 2 Select the action in the **Action(s)** list you want to suppress.
 - 3 Click **Suppress**.
The action moves to the **Suppressed Action(s)** list.
 - 4 Click **Close**.

Unsuppress an Action



You must have the “Edit action log” permission to use this function.

- 1 Click the **Tools** menu, point to **Action and Comments**, and then click **Configure Action Logs**.
The **Action Log** dialog box appears.
- 2 Select the action in the **Suppressed Action(s)** list you want to unsuppress.
- 3 Click **Unsuppress**.
The action moves to the **Action(s)** list.
- 4 Click **Close**.

Delete an Action



You must have the “Edit action log” permission to use this function.



Note: A red check mark next to an action in the Action Log indicates the action is in use and cannot be deleted. You can suppress the action if you want. See “Suppress an Action” on page 206 for more information.

- 1 Click the **Tools** menu, point to **Action and Comments**, and then click **Configure Action Logs**.
The **Action Log** dialog box appears.
- 2 Select the action in the **Action(s)** list you want to delete.
- 3 Click **Delete**.
The action is removed from the Action(s) list.
- 4 Click **Close**.

Setup Action Filter

You can use the Setup Action Filter to narrow down the list of actions in the Action Log. The Action Log can accommodate approximately 250 actions. This can potentially be an overwhelming list to sort through. This feature allows you to set up filtered lists based on each instrument model set up in Unity Real Time.

- 1 Click the **Tools** menu, point to **Action and Comments**, and then click **Setup Action Filter**.

The **Setup Action Filter** dialog box appears.

- 2 Select the check box for **Use Action Filter by Instrument**.



Note: The full Action Log list and the filtered lists are shared by the entire database. If you have a shared database with another department or location, you may need to communicate with them before making changes.

- 3 From the **Instrument list** click on the instrument name you want to create a filter for.



Note: By default all actions are included in the Selected Action(s) list.

- 4 From the **Selected Action(s)** list on the right select an **action**.

- To select multiple consecutive actions:
Click the **first action**, press the **SHIFT key on the keyboard**, and then click the **last action**.
- To select multiple non-consecutive action:
Press the **CTRL key** on the keyboard, and then click each **action**.

- 5 Click **Remove**.

- 6 To custom arrange the actions within the Selection Action(s) list, drag the actions(s) up or down to the location you want or click the header bar to sort the list alphabetically.

- 7 To add actions from the **Available Action(s)** list, select the action(s) and click **Add**.

- 8 Click **Apply**.

- 9 Repeat as needed for each instrument model.

- 10 Click **OK**.

Automatic Action Logs



Note: Automatic action logs are available for point data that is manually entered. Automatic actions also are shown on the Bench and Supervisor Review screens.

You can use the automatic action log function to automatically display the **Action Log** dialog box whenever a user enters a data point violating a SPC rule set to “Reject.” Users can apply an action or close the dialog box without adding an action.

You can also use the require action log function to automatically display the **Action Log** dialog box whenever a user enters a data point violating a SPC rule set to “Reject.” Users cannot close, cancel, or exit the **Action** dialog box until an action is added.

When and where the messages will appear

- For Single test point data entry, the message will appear after entering a row of data with a rejection violation.
- For Multi-Test data entry, the message will appear when the save button is clicked.
- For data imported through connectivity, the message will appear in the Bench or Supervisor Review when a user attempts to mark the data as reviewed.

Set Up Automatic Action Logs



You must have the “Edit setup options” permission to use this function.

- 1 Click the **Tools** menu and then click **Setup**.
- 2 If just the Automatic action logs check box is selected, a user will have the option to enter an Action or continue with what they are doing.
- 3 If both the Automatic and Require action logs check box is selected, a user must enter an action for the rejection violation and cannot move forward until this is done.
- 4 Click **OK**.

Turn Off Automatic Action Logs



You must have the “Edit setup options” permission to use this function.

- 1 Click the **Tools** menu and then click **Setup**.
- 2 Clear the **Automatic action logs** check box in the **Actions/comments** section.
- 3 Click **OK**.

View an Action in the Data Entry Dialog Boxes

A green arrow appears next to the Action button  if an action is added to a row of data in the Single Test Point Data Entry, Multi Test Point Data Entry, and Qualitative Data Entry dialog boxes.

Use one of the following methods to view the action:

- Position the mouse over the Action button  to view the comment.
- Click the Action button  to open the Action dialog box.

Add an Action in the Data Entry Dialog Boxes

- 1 Click the Action button  in the row of data you want to add an action to.

The **Action Log** dialog box appears.

- 2 Select the action in the **Action(s) list** you want to add and click **Apply**.

The selected action appears in the **Existing Action** dialog box.

- 3 Repeat step 2 for any additional actions that are needed.

- 4 Click **Close**.

The action is added to the row of data.

Add an Action in the Bench Review and Supervisor Review

- 1 Click in the cross cell for the **Action** column and the row of data you want to add an action to.

The **Action Log** dialog box appears.

- 2 Select the action in the **Action(s) list** you want to add and click **Apply**.

The selected action appears in the **Existing Action** dialog box.

- 3 Repeat step 2 for any additional actions that are needed.

- 4 Click **Close**.

The action is added to the data run.



Important: Actions cannot be edited or deleted once the Apply button is clicked. If an action is applied in error it is usually easiest to add a comment to explain the error.

Comments

A comment is text added to a data run 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.

Comments appear in the following locations:

- Bench Review and Supervisor Review
- Data Entry dialog boxes
- Point Data Report
- Data Review Report
- Supervisor Report

View Comments

A green arrow appears next to the Comment button  if a comment is added to a row of data in any of the data entry dialog boxes.

Use one of the following methods to view the comment:

- Position the mouse over the Comment button  to view the comment.
- Click the Comment button  to open the **Comment** dialog box.



Note: You cannot edit or delete a comment after it is added.

Add a Comment to a Row of Data

- 1 Click the Comment button  for the row in the data entry dialog box you want to add a comment to.

The **Comment** dialog box appears.



Note: Existing comments for the row appear in the **Existing Comment** area in the upper portion of the dialog box.

- 2 Type the comment in the **New comment** field and click **OK**.

The action is added to the data row.

Add a Comment in the Bench Review and Supervisor Review

- 1 Click in the cross cell for the **Comment** column and the row of data you want to add an action to.

The **Comment** dialog box appears.



Note: Existing comments for the row appear in the **Existing Comment** area in the upper portion of the dialog box.

- 2 Type the comment in the **New comment** field and click **OK**.

The comment is added to the data run.



Important: Comments cannot be edited or deleted once the OK button is clicked. If a comment is applied in error, it is usually easiest to add another comment to explain the error.

Actions and Comments by Instrument

You can simplify the documentation procedure 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.

You can apply actions and comments by instrument 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 and/or Comment by Instrument



You must have the “Action and Comment by Instrument” permission to use this function.

- 1 Click the **Tools** menu, point to **Actions and Comments**, and then click **Actions/Comments by Instrument**.
- 2 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.
- 3 If applicable, select the **Action** check box.
- 4 Click **Add**.
The **Action Log** dialog box appears.
- 5 Select the action in the **Action(s)** list you want to add.
- 6 Click **Apply**.
- 7 Repeat steps 4–5 to add additional actions as needed.
- 8 Click **Close**.
- 9 If applicable, click in the blank comment field and type the free text comment.

- 10 Click the arrow in the **Start date** field and select the beginning date for the action.
- 11 Click the arrow in the **End date** field to select an ending date for the action.



Note: The Action and Comments by Instrument feature adds actions and comments to all data points within the date range. Therefore, this could be a lot of actions and comments if you have a wide range of data. If no data is found within the date range, a new blank line is added with the date and time.

- 12 Click **OK**.



Important: Actions and Comments cannot be edited or deleted once the OK button is clicked.

Require Audit Trail Comments



You must have the “Edit setup options” permission to manage this function.

The Audit Trail keeps track of settings for labs, lots, tests and other changes that can affect how data is evaluated. Audit Trail Events are automatically applied by the software. For example, the software applies the “Data inserted” Audit Trail Event when a user inserts a row of data in a data entry dialog box.

If the “Require audit trail comments” feature is selected, the user will be prompted to add a comment every time an audit trail entry is generated. Unity Real Time includes pre-defined Audit Trail Events. See “Audit Trail Events” on page 440 for a list of events that are recorded in the Audit Trail.



Note: You cannot edit Audit Trail Events.

Turn on Require Audit Trail Comments

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Select the **Require audit-trail comments** check box.
- 3 Click **OK**.



Note: See “Audit Trail Report” on page 265 for information about creating an Audit Trail Report.

Turn Off the Require Audit Trail Comments Function

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Clear the **Require audit trail comments** check box.
- 3 Click **OK**.



Important: Audit Trail Comments cannot be edited or deleted once applied.

Unity Real Time Charts

In This Chapter

Overview	215
Keyboard Shortcuts.....	216
Levey-Jennings Chart.....	217
Multi-LJ Chart.....	224
Bar Chart.....	228
Youden Chart	231
Yundt Chart	233
General Chart Options.....	238
Graph Against Options	244
Save and Print Charts.....	246

Overview

Unity Real Time provides a variety of charts for investigating, troubleshooting, and documenting the review of suspect data. The following charts are available:

- Levey-Jennings chart (page 217)
- Multi-LJ chart (page 223)
- Bar chart (page 227)
- Youden chart (page 230)
- Yundt chart (page 233)

Keyboard Shortcuts

You can use the keyboard shortcuts described below when viewing charts.

To...	Keyboard Shortcut
Go to the next test	F5
Go to the previous test	SHIFT+F5
Go to the next lot (available only in the Lab navigation tree)	F6
Go to the previous lot (available only in the Lab navigation tree)	SHIFT+F6
Go to the next lab (available only in the Lab navigation tree)	F7
Go to the previous lab (available only in the Lab navigation tree)	SHIFT+F7
Go to the next panel (available only in the Panel navigation tree)	F8
Go to the previous panel (available only in the Panel navigation tree)	SHIFT+F8
Go to the next instrument (available only in the Instrument navigation tree)	F9
Go to the previous instrument (available only in the Instrument navigation tree)	SHIFT+F9

Levey-Jennings Chart

The Levey-Jennings chart plots laboratory data points for a specified time period against the fixed or cumulative (floating) mean $\pm 3SD$ range for a set of data you define.



Note: Unity Real Time uses fixed statistics if defined, otherwise, the software uses cumulative statistics. See “Use Bio-Rad elInsert data to set a fixed mean and/or fixed SD/CV” on page 110 if you want to use fixed statistics.

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.

Create a Levey-Jennings Chart

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
- 2 Use one of the following methods to create the chart:
 - Click  on the toolbar.
 - Click the **Reports** menu, point to **Charts**, and then click **Levey-Jennings**.
 - Press F9 on the keyboard.
- 3 Use one of the following methods to select the beginning date for the chart:
 - Click the arrow in the **From** field and select the beginning date for the chart.
 - Click  to change the date ahead one month; click  to change the date back one month.
- 4 Use one of the following methods to select the ending date for the chart:
 - Click the arrow in the **To** field and select an ending date for the chart.
 - Click  to change the date ahead one month; click  to change the date back one month.
- 5 Select the **Overlay levels** check box to view all levels on one chart. Clear the **Overlay levels** check box to view each level on a separate chart.
- 6 All levels set up in Unity Real Time are selected for the chart by default. Clear the appropriate **Level** check box to remove a level from the chart. See “Select Test Settings” on page 108 for more information on selecting levels in use.

- 7 Click  in the upper right corner to close the chart.

Change the Status of a Data Point on a Levey-Jennings Chart



You must have the “Edit all data permission” permission to perform this function.

The accept/reject status of a data point indicates if the data point was accepted or rejected according to one or more active SPC rules. The software automatically rejects a row of data if a data point within the row violates an SPC rule with a status of “Reject.” You can manually change the accept/reject status of a data point on the Levey-Jennings chart.

- 1 Position the pointer over a data point on the Levey-Jennings chart.

A small, tooltip window appears and shows the following:

- Date/time
- Value
- Status (Accepted or Rejected)
- Initials of the person who completed the Bench Review
- Initials of the person who completed the Supervisor Review
- Action (if any)
- Comment (if any)
- Reagent lot number (if noted)
- Reagent bottle (if noted)
- Reagent In Use or Standby (if noted)
- Calibrator lot number (if noted)
- Calibration Date/Time (if noted)

Click the data point.

A message appears showing information about the data point and asking if you want to change the status of the data point.

- 2 Click **Yes** to change the accept/reject status of the data point.

Customize the Levey-Jennings Chart



You must have the “Graphing Options” permission to perform this function.



Note: Some Levey-Jennings chart options also apply to the Multi-LJ chart.

- Days on the chart
- Include Action code at the top of the chart
- Display (Symbols, Size, Color, Line Connection)

This does not include the selections for Reagent Lot In Use/Standy options.

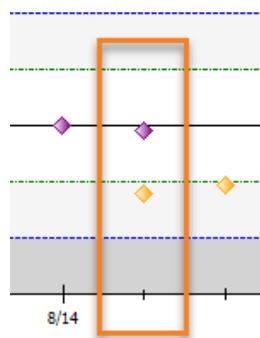


Note: The second tab, where the Levey-Jennings chart options are found, will change based on the chart you are working with.

- 1 Create a Levey-Jennings chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Levey-Jennings** tab.
- 4 Select the **Days on charts** option. The default is 60 days.
- 5 Select the **X-axis type**:

- **Date**

The X-axis shows a vertical mark for each day. Each data point collected that day appears in this column so the individual data points appear to be stacked.

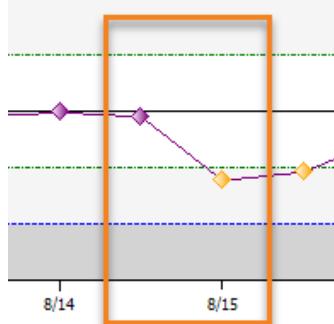


- Select the **Include point representing mean of data points for the day** check box to add a large point representing the daily mean and show the individual data points as smaller points.



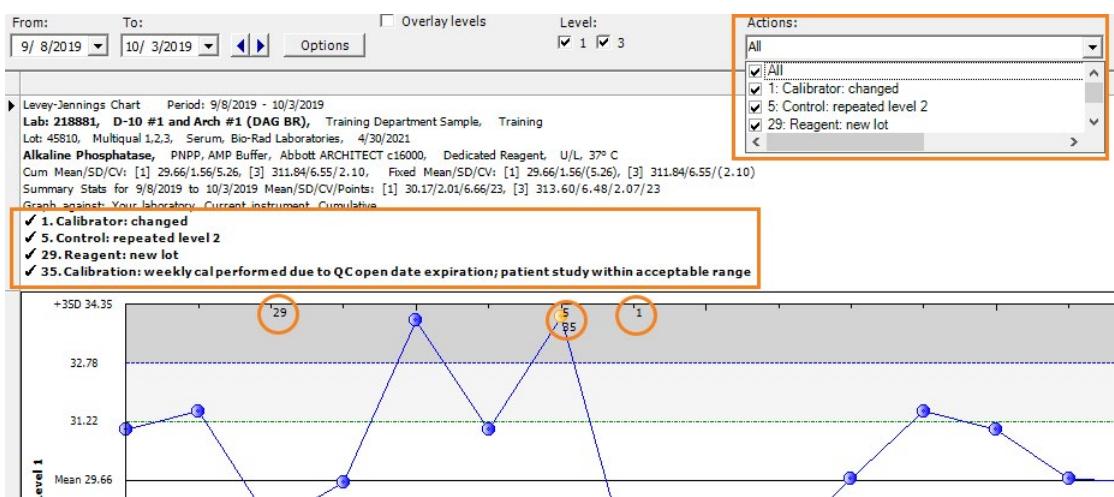
- Sequence**

Each data point appears in its own column.



Note: The **Include point representing mean of data points for the day** check box is unavailable if you select the **Sequence** option.

- 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. If more than one action is included in the time period, an **Actions** drop-down menu will be available to focus on specific action(s) one at a time.



- 7 Each control level has a default symbol to represent each level's data. This is helpful when printing to a black and white printer. To change the default symbol, select the **Symbol** for each Level point from the list.



Tip: The different colors help visually distinguish the levels when viewing the chart on a color monitor. 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 the size from 1 to 10 (pixels).
- 9 Select the **Fill** check box to select the fill color for each level symbol.



Important: Unity Real Time shows data points violating a statistical process control (SPC) rule with a status of "Warn" in yellow and data points violating a SPC rule with a status of "Reject" in red. Therefore, Bio-Rad recommends not using yellow or red for fill colors as it could make these data points difficult to see.

- 10 Select the **Connect line** check box to draw a line connecting the data points on the chart.



Note: The connect lines only appear if the **Include point representing mean of data points for the day** check box is selected or if the **Sequence** option is used (See step 5).

- 11 Repeat steps 7 through 10 as needed for each level.



Note: Click **Default** if you want to return to the default settings.

- 12 **Optional:** If your lab is using reagent lot tracking in Unity Real Time, you can select the check box for **Reagent In Use**, **Reagent Standby**, or both, to overwrite the selections for steps 7 through 10. This will assign unique symbols, size and color fills for applicable data points on the Levey-Jennings chart. This setting may assist with trouble shooting issues by allowing you to see, at a glance, if a data point is from the current reagent in use reagent or from the standby.



Note: Reagent lot numbers can be tracked from the **Single Test Point Data Entry** screen in Unity Real Time. The reagent for each data run can be flagged as either **In Use** or **Standby**.



Note: The **Reagent In Use** and **Reagent Standby** chart settings do not apply to the Multi-LJ chart.



Note: The **Reagent In Use** and **Reagent Standby** chart settings are not available for GOST and RiliBÄK Unity Real Time user licenses.

- 16 Select how to apply the chart options:

- Apply to all users
- Apply to current user

- 17 Click **OK**.
- 18 There are other options that apply to the Levey-Jennings chart. See the following sections for more information:

Option	See ...
General Chart Options	page 238
Header Options	page 241
Lines Options	page 242
Graph Against Options	page 244

Customize the Levey-Jennings Chart for Qualitative Tests

- 1 Create a Levey-Jennings chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Qual. Point Chart** tab.
- 4 Refer to page 219 for information about the **Days on chart** setting.
- 5 Refer to page 219 for information about the **X-axis type** setting
- 6 Refer to page 220 for information about the **Action** Setting.
- 7 Refer to page 221 for information about **Symbols and Sizes**.
- 8 Select the check box for each item you want to appear on the chart:
 - Group
A vertical line is added to chart to indicate when a new group was added. See “Data Groups” on page 122 for more information.
 - (Δf)
A vertical line is added to chart to indicate when an Expected Response for a qualitative test changes. Points to the left of the line are based on the original Expected Response; points to the right of the line are based on the new Expected response. See “Set Up an Expected Response” on page 115 for more information.
- 9 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 10 Click **OK**.



Note: Click **Default** if you want to return the fill colors to the default settings.

Customize the Levey-Jennings Chart Legend



You must have the “Graphing Options” permission to perform this function.



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. The legend appears at the bottom of the chart by default.

- 1 Create a Levey-Jennings chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **General** tab.
- 4 Select the **Show legend** check box.
- 5 Select the option where you want the legend to appear on the chart:
 - Display on top
 - Display on bottom
- 6 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 7 Click **OK**.

Multi-LJ Chart

The Multi-LJ chart provides an easy way to compare multiple tests, such as the same analyte run on two different instruments or on two different lot numbers of control material. You can also view different tests from the same or multiple instruments. The Multi-LJ chart shows a Levey-Jennings chart for up to 500 tests.

Create a Multi-LJ Chart

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
- 2 Use one of the following methods to create the chart:
 - Click  on the toolbar.
 - Click the **Reports** menu, point to **Charts**, and then click **Multi-LJ**.
- 3 Select up to 50 tests to display on the chart.
- 4 All levels set up in Unity Real Time are selected for the chart by default. Clear the appropriate **Level** check box to remove a level from the chart.
- 5 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.
 - Click  to view the charts in three columns.
- 6 Optional: Select a template to apply to the Multi-LJ chart.

 **Note:** See “Create a Multi-LJ Template” on page 226 for more information.
- 7 Optional: Click  if you want to compare the same tests across multiple analyzers.
- 8 See the following sections for more information about the Multi-LJ chart:
 - See “Customize the Multi-LJ Chart” on page 225
 - See “Create a Multi-LJ Template” on page 226
 - See “Update a Multi-LJ Template” on page 227
 - See “Delete a Multi-LJ Template” on page 227
- 9 Click  (gray X) in the upper right corner to close the chart.

Customize the Multi-LJ Chart



You must have the “Graphing Options” permission to perform this function.

- 1 Create a Multi-LJ chart.
- 2 Click **Options** on the chart dialog box.

The **Options** dialog box appears.

- 3 Select a Mode option:
 - Side-by-side test display
Each chart represents a single test. The symbols represent the levels for a single test.
 - Multiple tests on a single chart display
Each chart can include multiple tests. The symbols represent a single level for each test. This feature is used to compare a single level of multiple tests all on one chart.
- 4 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 5 Click **OK**.



Note: All other Multi-LJ options are inherited from the Levey-Jennings chart options.

See the following sections for more information:

Option	See ...
Customize the Levey-Jennings Chart	page 219
Customize the Levey-Jennings Chart Legend	page 222
General Chart Options	page 238
Header Options	page 241
Lines Options	page 242
Graph Against Options	page 244

Create a Multi-LJ Template



Note: When you duplicate a lot that is included in a template, the tests added for the original lot are added to the new lot.

You can create a list of tests and save it as a template for future use.

- 1 Use one of the following methods to access the Multi-LJ Template:
 - Click the **Reports** menu, point to **Charts**, and then click **Set up Multi-LJ Template**.
 - On the Multi LJ window, click  (wrench symbol).
 - 2 Type a name for the template in the **Enter a template name** field.
Examples: “Electrolytes”, “Bilirubens across instruments”, etc.
 - 3 Select the tests in the navigation tree to add to the template.
 - 4 To sort the order of the tests, click the column header to sort alphabetically or drag and drop the tests in the order you want.
 - 5 All levels set up in Unity Real Time are selected for the chart by default. Clear the appropriate **Level** check box to remove a level from the chart.
 - 6 Each control level has a default symbol to represent the level’s data. Select a **Symbol** from the list if you want to change the symbol.
-
- Tip:** The different colors help visually distinguish the levels when viewing the chart on a color monitor. An arrow represents data points that are off the scale, regardless of the level symbol selected.
- 7 Select a Size for each Symbol.
 - The default is 6.
 - Select a size from 1 to 10 (pixels).
 - 8 Select the **Fill** check box to select the fill color for each level symbol.
-
- Important:** Unity Real Time shows data points violating a statistical process control (SPC) rule with a status of “Warn” in yellow and data points violating a SPC rule with a status of “Reject” in red. Therefore, Bio-Rad recommends not using yellow or red for fill colors as it could make these data points difficult to see.
- 9 Select the **Connect line** check box to draw a line connecting the data points on the chart.
-
- Note:** The connect lines only appear if the **Include point representing mean of data points for the day** check box is selected or if the **Sequence** option is selected on the **Options** dialog box. See “Customize the Levey-Jennings Chart” on page 219 for more information.
- 10 Repeat steps 4 through 8 as needed for each level and test.
 - 11 Click **Save**.
 - 12 Click the **Close** button or the  in the upper right corner to close the template.

Update a Multi-LJ Template

- 1 Use one of the following methods to access the Multi-LJ Template:
 - Click the **Reports** menu, point to **Charts**, and then click **Set up Multi-LJ Template**.
 - On the Multi LJ window, click  (wrench symbol).
- 2 Select the **Update** option.
- 3 Select the template you want to update from the **Select a template** list.
- 4 Update the template as needed.
- 5 Click **Save or Save as** to create a new version of the template.

Delete a Multi-LJ Template

- 1 Use one of the following methods to access the Multi-LJ Template:
 - Click the **Reports** menu, point to **Charts**, and then click **Set up Multi-LJ Template**.
 - On the Multi LJ window, click  (wrench symbol).
- 2 Select the **Update** option.
- 3 Select the template you want to delete from the **Select a template** list.
- 4 Click **Delete**.
A message appears asking for confirmation.
- 5 Click **Yes**.

Bar Chart



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.

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 $\pm 3SD$).



Note: The Bar chart also shows the SD, CV, and number of points for each monthly mean.

Create a Bar Chart

- 1 Select the test in the **Lab**, **Panel**, or **Instrument** navigation tree you want to create the chart for.
- 2 Use one of the following methods to create the chart:
 - Click  on the toolbar.
 - Click the **Reports** menu, point to **Charts**, and then click **Bar**.
 - Press SHIFT+F9 on the keyboard.
- 3 Use one of the following methods to select the beginning date for the chart:
 - Click the arrow in the **From** field and select the beginning date for the chart.
 - Click  to change the date ahead one month; click  to change the date back one month.
- 4 Use one of the following methods to select the ending date for the chart:
 - Click the arrow in the **To** field and select an ending date for the chart.
 - Click  to change the date ahead one month; click  to change the date back one month.
- 5 All levels set up in Unity Real Time are selected for the chart by default. Clear the appropriate **Level** check box to remove a level from the chart.
- 6 See the following sections for more information about the Bar chart:
 - See “Customize the Bar Chart” on page 229.
 - See “Customize the Bar Chart for Qualitative Tests” on page 230.
- 7 Click  (gray X) in the upper right corner to close the chart.

Customize the Bar Chart



You must have the “Graphing Options” permission to perform this function.

- 1 Create a Bar chart.
- 2 Click **Options** on the chart dialog box.

The **Options** dialog box appears.

- 3 Click the **Bar** tab.
- 4 Select the **Mode** option:
 - Mean
 - CV
 - The standard error of the mean (SD / square root of N)



Tip: Elect this option if you want to use the standard error of the mean for the Y-axis.

- 5 Select the **Months on charts** option:
 - The default is 13 months.
 - Select the number from 1 to 13.
- 6 Select the fill colors if you want to customize the color:



Tip: The different colors help visually distinguish the levels when viewing the chart on a color monitor.

- Select the fill color for Level 1
- Select the fill color for Level 2
- Select the fill color for Level 3



Note: Click **Default** if you want to return the fill colors to the default settings.

- 7 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 8 Click **OK**.

- 9 There are other options that apply to the Bar chart. See the following sections for more information:

Option	See ...
Customize the Bar Chart for Qualitative Tests	page 230
General Chart Options	page 238
Header Options	page 241
Graph Against Options	page 244

Customize the Bar Chart for Qualitative Tests

- 1 Create a Bar chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Qual. Bar Chart** tab.
- 4 Select the fill colors if you want to customize the color.
 - Select the fill color for Level 1
 - Select the fill color for Level 2
 - Select the fill color for Level 3



Tip: The different colors help visually distinguish the levels when viewing the chart on a color monitor.



Note: Click **Default** if you want to return the fill colors to the default settings.

- 5 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 6 Click **OK**.

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 the points are clustered around the center of the target, the better the precision of the control levels.



Tip: You can place the mouse pointer on an individual data point to view the two associated values, date and time.

Create a Youden Chart

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree for which you want to create the chart.
- 2 Use one of the following methods to create the chart:
 - Click  **Youden** on the toolbar.
 - Click the **Reports** menu, point to **Charts**, and then click **Youden**.
 - Press ALT+F9 on the keyboard.
- 3 Use one of the following methods to select the beginning date for the chart:
 - Click the arrow in the **From** field and select the beginning date for the chart.
 - Click  to change the date ahead one month; click  to change the date back one month.
- 4 Use one of the following methods to select the ending date for the chart:
 - Click the arrow in the **To** field and select the ending date for the chart.
 - Click  to change the date ahead one month; click  to change the date back one month.

- 5 The Youden chart only compares two levels at a time. The first two levels are selected by default. Clear the appropriate **Level** check box(es) so that only two levels are selected.



Tip: If no points show on the Youden chart, try selecting different levels. It may be that the check boxes are set for levels 1 and 2; however, if you only use levels 1 and 3, there would not be a point to plot.

- 7 See the following sections for more information about the Youden chart:
 - See “Customize the Youden Chart” on page 232.
 - See “How to Use the Youden Chart” on page 231.
- 8 Click (gray X) in the upper right corner to close the chart.

Customize the Youden Chart



You must have the “Graphing Options” permission to perform this function.

- 1 Create a Youden chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Youden** tab.
- 4 Select the **Days on charts** option.
 - The default is 60 days.
 - Select the 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 and select the fill color for the point symbol.



Important: Unity Real Time shows data points violating a statistical process control (SPC) rule with a status of “Warn” in yellow and data points violating a SPC rule with a status of “Reject” in red. Therefore, Bio-Rad recommends not using yellow or red for fill colors as it could make these data points difficult to see.



Note: Click **Default** if you want to return to the default settings.



Tip: The different colors help visually distinguish the levels when viewing the chart on a color monitor.

- 8 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 9 Click **OK**.
- 10 There are other options that apply to the Youden chart. See the following sections for more information:

Option	See ...
General Chart Options	page 238
Header Options	page 241
Graph Against Options	page 244

Yundt Chart

The Yundt chart compares the laboratory bias and imprecision to another Graph Against data set. See “Graph Against Options” on page 244 for more information. The Yundt chart contains a circle for each level of control running in the laboratory. Each circle provides information about the standard deviation index (SDI) and coefficient of variation (CV) of the test.

The Yundt chart provides an immediate overview of the laboratory performance without the need to evaluate detailed data. The Yundt chart presents a summary of data that is easily viewed for evaluating laboratory performance compared to the peer group across multiple levels. The Yundt chart is unique in that it combines a graphical format with the SDI so that the effectiveness of the QC system can be easily viewed.

SDI Information

Because the horizontal (X) axis of the chart is the mean $\pm 3\text{SDI}$, the lower a level's SDI, the closer to the center (mean) line it appears. When the SDI is zero, the circle is on the center line.

Interpreting CV with the Yundt Chart

- Lab CV = Graph Against CV

When the CV of a test is equal to the Graph Against CV, the circle appears uniformly gray and does not have a pupil.



When the CV of a test and the CV of a Graph Against data set are not equal, their relative CVs are represented as two concentric circles.

- Lab CV < Graph Against CV

The smaller inner circle (or pupil) represents the group with the smaller CV. The laboratory's pupil is black or colored.



Note: When graphing against the consensus group, this is the ideal shape. This means that your lab's CV (imprecision) is lower than the consensus group's CV.

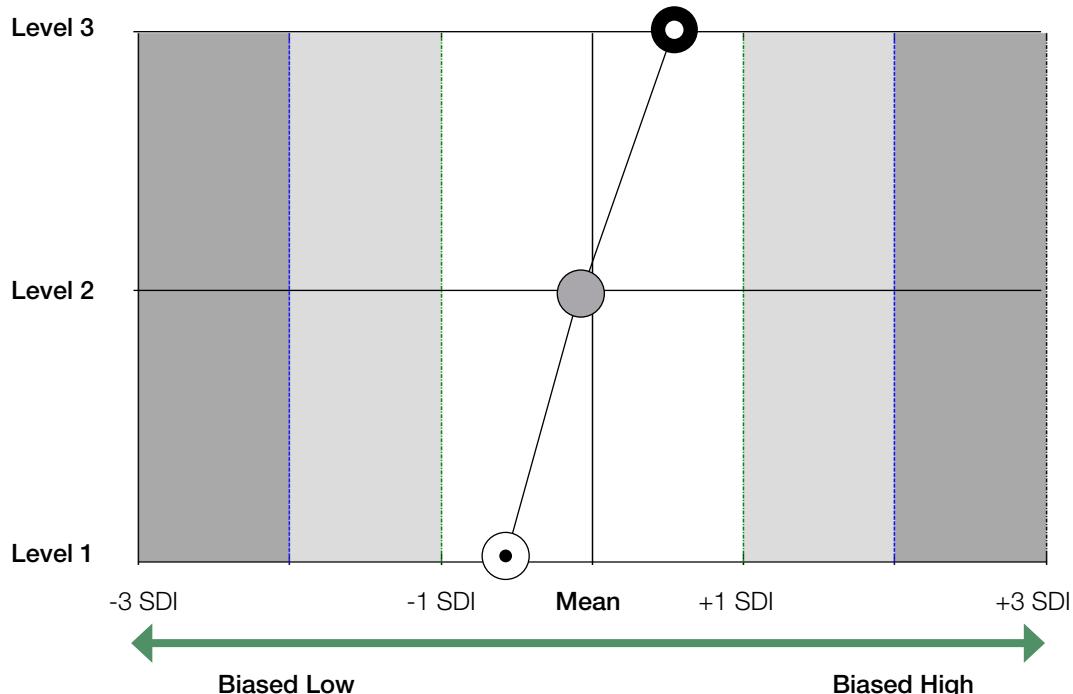
- Lab CV > Graph Against CV

The smaller inner circle (or pupil) represents the group with the smaller CV. The Graph Against pupil is white.



Interpreting Bias and Linearity with the Yundt Chart

The position of the circle relative to the center vertical line represents bias compared to the comparison group mean. Left of the center is biased low. Right of the center is biased high. Linearity considers the position of the circles relative to each other. A straight vertical line indicates perfect linearity. An angle in the line indicates that the levels are not performing the same, signifying a lack of linearity. The less the line is bent, the better your linearity is.



Create a Yundt Chart

- 1 Click the **Reports** menu, point to **Charts**, and then click **Yundt**.
See “Toolbar Buttons” on page 47 for information on adding a shortcut button to the toolbar.
- 2 Use one of the following methods to select the beginning date for the chart:
 - Click the arrow in the **From** field and select the beginning date for the chart.
 - Click to change the date ahead one month; click to change the date back one month.
- 3 Use one of the following methods to select the ending date for the chart:
 - Click the arrow in the **To** field and select the ending date for the chart.
 - Click to change the date ahead one month; click to change the date back one month.
- 4 All levels set up in Unity Real Time are selected for the chart by default. Clear the appropriate **Level** check box to remove a level from the chart.
- 5 See the following sections for more information about the Yundt chart:
 - See “Customize the Yundt Chart” on page 237.
 - See “Interpreting Bias and Linearity with the Yundt Chart” on page 235.
- 6 Click (gray X) in the upper right corner to close the chart.

Customize the Yundt Chart



You must have the “Graphing Options” permission to perform this function.

- 1 Create a Yundt chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Yundt** tab.
- 4 Select the **Days on charts** option.
 - The default is 60 days.
 - Choose a number from 1 to 90.



Note: Click **Default** if you want to return to the default settings.

- 5 Select how to apply the chart options:
 - Apply to all users
 - Apply to current user
- 6 Click **OK**.
- 7 There are other options that apply to the Yundt chart. See the following sections for more information:

Option	See ...
General Chart Options	page 238
Header Options	page 241
Graph Against Options	page 244

General Chart Options



You must have the “Graphing Options” permission to perform this function.

There are three General chart options you can use to customize charts:

- Fill background
- Grid lines and color
- Show legend

Fill Background

Description:	The fill background designates the following: <ul style="list-style-type: none">• $\pm 1\text{SD}$ range• $\pm 2\text{SD}$ range• $\pm 3\text{SD}$ range
Available for:	All charts

Select the Fill Background

- 1 Create a chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **General** tab.
- 4 Select the **Show background** check box.
- 5 Select the fill background: **Options**
 - Select the color for Fill 1
 - Select the color for Fill 2
 - Select the color for Fill 3



Note: Click **Default** if you want to return the fill background colors to the default settings.

6 Select how to apply the fill background:

- Apply to all users
- Apply to current user

7 Click **OK**.

Grid Lines and Color

Description:	The grid lines and color designates the following: <ul style="list-style-type: none"> • $\pm 1SD$ above and below the mean • $\pm 2SD$ above and below the mean • $\pm 3SD$ above and below the mean
Available for:	<ul style="list-style-type: none"> • Levey-Jennings chart • Multi-LJ chart • Youden chart • Yundt chart

Select Grid Lines and Color

1 Create a chart.

2 Click **Options** on the chart dialog box.

The **Options** dialog box appears.

3 Click the **General** tab.

4 Select the dash style:

- Select the Dash style 1
- Select the Dash style 2
- Select the Dash style 3

5 Select the grid line color:

- Select the Color 1
- Select the Color 2
- Select the Color 3



Note: Click **Default** if you want to return the dash styles or the colors to the default settings.

6 Select the option to apply the settings:

- Apply to all users
- Apply to current user

7 Click **OK**.

Show Legend

1 Create a chart.

2 Click **Options** on the chart dialog box.

The **Options** dialog box appears.

3 Click the **General** tab.

4 Click the **Show legend** check box.

5 Select an option where you want the legend to appear on the chart:

- Display on top
- Display on bottom

6 Select the option to apply the settings:

- Apply to all users
- Apply to current user

7 Click **OK**.

Header Options



You must have the “Graphing Options” permission to perform this function.

You can customize the chart header to contain only the information you want to appear at the top of the chart. There are 20 items you can select to appear on the chart header. The header options are available for all charts.

Lab number, Lab description, Lab name, Contact, Department
Lot number, Lot name, Matrix, Product manufacturer, Lot expiration date
Analyte name, Method name, Instrument name, Reagent name, Unit, Temperature name
Cum mean/SD/CV, Fixed mean/SD/CV
Summary stats

Select Chart Header Options

- 1 Create a chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Header** tab.
- 4 Select the check box for each item you want to appear in the chart header; clear the check box to remove an item from the chart header.
- 5 Select the corresponding check box number for one or more items you want to appear in bold.



Note: Click **Default** if you want to return the header to the default settings.

Select an option to apply the header settings:

- Apply to all users
- Apply to current user

- 6 Click **OK**.

Lines Options



You must have the “Graphing Options” permission to perform this function.



Note: Lines are shown in charts only when applicable or otherwise noted.



Note: The Reagent Lot, Reagent Bottle, Calibrator Lot and Calibration Date/Time lines are not available for GOST and RiliBÄK Unity Real Time user licenses.

- 1 Create a chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click the **Lines** tab.
- 4 Select the check box for each item you want to appear on the chart:
 - Group
A vertical line is added to chart to indicate when a new group was added. See “Data Groups” on page 122.
 - Reagent Lot
A vertical line appears on the chart to indicate when a new reagent lot was added to the single test point data entry screen. This line is only available on the standard Levey-Jennings chart.
See “Overview of the Single Test Data Entry Dialog Boxes” on page 150.
 - Reagent Bottle
A vertical line appears on the chart to indicate when a new reagent lot bottle (serial number) was added to the single test point data entry screen. This line is only available on the standard Levey-Jennings chart. See “Overview of the Single Test Data Entry Dialog Boxes” on page 150.
 - Calibrator Lot
A vertical line appears on the chart to indicate when a new calibrator lot was added to the single test point data entry screen. This line is only available on the standard Levey-Jennings chart.
See “Overview of the Single Test Data Entry Dialog Boxes” on page 150.
 - Calibrator Date
A vertical line appears on the chart to indicate when calibration is performed and a date/time was added to the single test point data entry screen. This line is only available on the standard Levey-Jennings chart. See “Overview of the Single Test Data Entry Dialog Boxes” on page 150.
 - Floating Mean
 - Fixed Mean
 - 3SD range based on the floating SD
 - 3SD range based on the fixed SD

- Analytical goal target value See “Retrospective Evaluation with the Levey-Jennings Chart” on page 138.
 - Analytical goal decision limit range See “Retrospective Evaluation with the Levey-Jennings Chart” on page 138.
 - Fixed Mean and/or SD has changed
A vertical line is added. Points to the left of the line are based on the original statistics; points to the right of the line are based on the new statistics.
- 5 Select the dash style for each item.
- 6 Select the color for each item.



Tip: It is a good idea to select a different color for the lines in use. If the fixed mean is a black line and you turn on a cumulative mean that is also a black line, this can become confusing while looking at the charts.



Note: Click **Default** if you want to return to the default settings.

- 7 Select the option to apply the settings:
- Apply to all users
 - Apply to current user
- 8 Click **OK**.



Note: Most lines do not appear on the chart if the **Overlay levels** check box is selected. However, the following lines are exceptions that will display if the overlay levels check box is selected on the Levey-Jennings chart.

- Group
- Reagent Lot
- Reagent Bottle
- Calibrator Lot
- Calibration Date

Graph Against Options



You must have the “Graphing Options” permission to perform this function.

Description:	<ul style="list-style-type: none"> Use the Graph Against options to select the data set to determine the scaling (mean and $\pm 3SD$ range) of the Y-axis. The Graph Against option can be a subset of your laboratory’s data, a consensus group, or tiered instruments.
Available for:	All charts

When viewing a chart, the graph against source will be listed on the last line of the header. Anytime you open a chart, it is important to make note of where the graph against mean/sd/cv are coming from.

```

Levey-Jennings Chart Period: 9/29/2019 - 10/31/2019
Lab: 999913, D-10 #2 and Arch #2 (Like Inst), Training Department Sample DB, Training
Lot: 40980, Immunoassay Plus, Serum, Bio-Rad Laboratories, 9/30/2020
CEA (Carcinoembryonic Antigen), Chemiluminescence, Abbott ARCHITECT i2000/i2000SR, Dedicated Reagent, ng/mL, No Temperature
Cum Mean/SD/CV: [1] 2.79/0.13/4.84, [2] 21.40/0.43/2.02, [3] 39.17/1.10/2.80, Fixed Mean/SD/CV: [1] 2.90/0.20/(6.90), [2] 20.20/1.00/(4.95), [3] 44.70/5.36/(11.99)
Summary Stats for 9/29/2019 to 10/31/2019 Mean/SD/CV/Points: [1] 2.78/0.15/5.35/2, [2] 21.60/0.00/0.00/2, [3] 38.20/0.99/2.59/2
Graph against: Consensus group, Peer, 6 Months, Mean/SD/CV/Labs/Points: [1] 2.88/0.18/6.22/87/9468, [2] 18.93/0.88/4.65/65/7816, [3] 45.08/1.97/4.38/78/8827

```

Graph Against Your Laboratory

- Create a chart.
- Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- Click the **Graph Against** tab.
- Select the **Your laboratory** option.
 - Current instrument**
This is determined by the test you select in the navigation tree.
 - Another instrument**
Select one or more instruments or select the check box at the top of the column to select all.
This can also be used to compare tiered instruments.
Tiered instruments are groups of similar instruments. For example, you can compare a Dimension Xpand to a Dimension RxL because both are part of the same tiered group.
- Select an option for the laboratory data:
 - Evaluation mean/SD**
Fixed mean and SD set up in Unity Real Time, if applicable. Otherwise, the software uses the floating mean and SD.
 - Cumulative**
Includes all QC data for the selected lot and analyte.

- **Date range**
Select the desired date range.
- **Z-Score** (available only if you selected the **Current instrument** option in step 5)
 - Example of possible use: When fixed means and SD's have changed during the life of the lot, the values may display differently in the charts (a value on the mean can now show as a completely different value) graphing against a Z-Score will normalize that difference.

6 **Date range option only:**

- Click the arrow in the **From** field and select the beginning date for the data.
- Click the arrow in the **To** field and select an ending date for the data.

7 Select the option to apply the settings:

- Apply to all users
- Apply to current user

8 Click **OK**.

Graph Against the Consensus Group



Note: In order to view Unity consensus group data, make sure that the “Automatic analytical goals and peer group updates” option is selected in the Setup dialog box in Unity Real Time. With this setting, Unity Real Time prompts you to download the latest updates on a regular basis when logging in. See “Configure Database Updates” on page 433.

- 1 Create a chart.
- 2 Click **Options** on the chart dialog box.
The **Options** dialog box appears.
- 3 Click **Graph Against**.
- 4 Select the **Consensus group** option.
- 5 Select the Consensus group:
 - Peer
 - Method
 - All Labs
- 6 Select the time period for the consensus group data:
 - 1 month
 - 6 months
 - Cumulative
- 7 Select the option to apply the settings:
 - Apply to all users

- Apply to current user
- 8 Click **OK**.

Save and Print Charts

- 1 Create a chart.
- 2 Click the **File** menu and then click **Save/Print Chart**.
The **Save/Print Charts** dialog box appears.
- 3 Select the data for the chart you want to save:
 - If you selected a test in the **Lab** navigation tree, you can choose:
 - Custom Selection
 - Select one or more Lab number, Lot number, Analyte, and/or Instrument.
 - All Data
 - Current Lab
 - Current Lot
 - Current Test
 - If you selected a test in the **Panel** navigation tree, you can choose:
 - Current Test
 - Current Panel
 - If you selected a test in the **Instrument** navigation tree, you can choose:
 - Current Test
 - Current Instrument
- 4 Select the **Save background color** check box to save the chart background as it appears on the screen.



Tip: Clear the **Save background color** check box to conserve toner when you print charts.

- 5 Select the Page break for new analytes, if desired.



Tip: By not selecting this option you can save paper when printing.

- 6 **To Print:** Click the **Print** button.
The chart is created in Adobe PDF format and opens in a new window.
- 7 **To Save:** Click the **Save** button.
- 8 Navigate to the location where you want to save the chart.

9 Type a name for the chart in the **File name** field.

10 Click **Save**.

The chart is created in Adobe PDF format and opens in a new window.

Unity Real Time Intralaboratory Reports

In This Chapter

Overview	248
Configure Report Headers	249
Point Data Report.....	250
Summary Data Report.....	253
Statistical Report	256
Supervisor's Report	258
Operator Report	261
Measurement Uncertainty Report	263
Audit Trail Report	265
Listings Reports.....	267
Transmission Data Summary Report.....	276
Print and Export Reports	277
Add a Signature to Report Reviews	278

Overview

Unity Real Time intralaboratory reports are a valuable addition to the monthly Unity Interlaboratory Reports. You can create the following Unity Real Time reports at any time:

- Data Review Report (See Chapter 12, page 190)
- Point Data Report (page 250)
- Summary Data Report (page 253)
- Statistical Report (page 256)
- Supervisor's Report (page 258)
- Operator Report (page 261)
- Measurement Uncertainty Report (page 263)
- Audit Trail Report (page 265)
- Listings Reports (page 267)
- Transmission Data Summary Report (page 276)

Configure Report Headers

You can customize report headers to contain specific information you want to appear at the top of the report. The header options are arranged by Lab Profile, Lot Profile, and Test Profile. The header options are available for all reports.

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of a lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu and then click **Configure**.
The **Configure** dialog box appears.
- 3 The selected check boxes on the **Lab profile** tab indicate the items that will appear in the report header. Clear the check box(es) if you do not want the item to appear in the report header.
- 4 Click the **Lot Profile** tab.
- 5 The selected check boxes on the **Lot profile** tab indicate the items that will appear in the report header. Clear the check box(es) if you do not want the item to appear in the report header.
- 6 Click the **Test Profile** tab.
- 7 The selected check boxes on the **Test profile** tab indicate the items that will appear in the report header. Clear the check box(es) if you do not want the item to appear in the report header.
- 8 Click **OK**.



Tip: Excluding information that is not necessary from the header can potentially save paper when printing.

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. The Point Data Report shows the following statistics:

- Date/time data was entered
- Operator
- Level
- Value
- Z-Score
- Status of Accept/Reject
- Rule violations
- Actions (when added)
- Comments (when added)
- Summary information for each analyte
 - Calculated Mean, SD, CV, Number of Points
 - Fixed Mean, SD, and CV
 - Active Rules



Note: The fixed SD or CV displayed in parentheses indicates the value that is calculated based on the mean and the other value.

Unity Real Time Point Data Report							BIO-RAD
Printed	3/20/2020	Range	9/17/2019 12:00 AM	through	9/21/2019 11:59 PM	Page	1
Lab number:	999913	Description:	D-10 #2 and Arch #2 (Like Inst)				
Lab name:	Training Department Sample DB	Department:	Training				
Contact:							
Lot number:	33990	Control:	Diabetes				
Expires:	6/30/2021						
Matrix:	Whole Blood	Manufacturer:	Bio-Rad Laboratories				
Analyte:	Hemoglobin A1c (NGSP)	Method:	HPLC				
Instrument/Kit:	Bio-Rad D-10	Reagent:	Bio-Rad D-10 HbA1c (220-0101)/12000949				
Unit:	%	Temperature:	No Temperature				
Entered Date	Op	Level	Value	z	Status	Rules	
9/17/2019	12:00:00AM	sa	1	5.50	0.50	Accepted	
9/17/2019	12:00:00AM	sa	2	9.70	0.25	Accepted	
9/18/2019	12:00:00AM	sa	1	9.50	20.50	Rejected	1-3S R-4S
9/18/2019	12:00:00AM	sa	2	5.50	-10.25	Rejected	1-3S R-4S
Action(s)	Calibration: weekly cal performed due to expiration; (sa - 1/24/2020 12:06:28 PM)						
Comment(s)	patient study within acceptable range (sa - 1/24/2020 12:06:28 PM)						
9/18/2019	12:30:00AM	sa	1	5.40	0.00	Accepted	
9/18/2019	12:30:00AM	sa	2	9.50	-0.25	Accepted	
9/19/2019	12:00:00AM	sa	1	5.60	1.00	Accepted	
9/19/2019	12:00:00AM	sa	2	9.60	0.00	Accepted	
9/20/2019	12:00:00AM	sa	1	5.50	0.50	Accepted	
9/20/2019	12:00:00AM	sa	2	9.60	0.00	Accepted	
9/21/2019	12:00:00AM	sa	1	5.40	0.00	Accepted	
9/21/2019	12:00:00AM	sa	2	9.70	0.25	Accepted	
Summary Statistics	Mean	SD	CV	# Points	Fixed Mean	Fixed SD	Fixed CV
9/17/2019 12:00 AM	9/21/2019 11:59 PM						
Level 1	5.48	0.08	1.53	5	5.40	0.20	(3.70)
Level 2	9.62	0.08	0.87	5	9.60	0.40	(4.17)
Active Rules:	1-2sW,1-3s,2-2s,R-4s,10-XW						

Create a Point Data Report

- Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of a lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- Click the **Reports** menu, point to **General**, and then click **Point Data Report**. Dialog box appears.
 - Click the down arrow in the **From** field and select the beginning date for the report.
 - Click the down arrow in the **To** field and select the ending date for the report.
- Select an option for the report:
 - If you selected a test in the **Lab** navigation tree, you can select one of the following:
 - Custom Selection:
 - Select one or more Lab number, Lot number, Analyte, and/or Instrument.

- All data
- Current lab
- Current lot
- Current test



Tip: Use the Custom Selection to narrow the search by a combination of Labs, Lots, Analytes and Instruments. Click the Show List button to refresh the list based on selections. Use the check marks to narrow the list further.

- If you selected a test in the **Panel** navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the **Instrument** navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 4 Select the **Order report by Level** check box if you want the report arranged by levels.
- 5 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 6 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 7 Click (gray X) in the upper right corner to close the report.

Summary Data Report

The Summary Data Report shows the following monthly and cumulative statistics:

- Summary information for each month within the range
 - Level
 - Mean
 - Standard deviation (SD)
 - Coefficient of variation (CV)
 - Number of data points for each test in the selected data set
- Summary information for the full date range
 - Cumulative Mean, SD and CV
 - Fixed Mean, SD and CV
 - SDI
 - Active rules (if any)



Note: The fixed SD or CV displayed in parentheses indicates the value that is calculated based on the mean and the other value.



Tip: These statistics combine both point and summary data and provide a quick way to review large amounts of data. The fixed mean and fixed SD are included if fixed statistics are used.

Unity Real Time Summary Data Report									BIO-RAD			
Printed 11/19/2020		Range 1/1/2020 12:00 AM		through 3/31/2020 11:59 PM		Page 1						
Lab number:	218881	Description:			D-10 #1 and Arch #1 (DAG BR)							
Lab name:	Training Department Sample	Contact:										
Department:	Training											
Lot number:	456810	Control name:			Multiqual 1,2,3							
Expires:	4/30/2021	Matrix:			Serum							
Month												
Level	Mean	SD	CV	# Points	Mean	SD	CV	# Points				
Glucose, Hexokinase, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature												
2020/01	1	56.49	1.02	1.80	31	56.49	1.02	1.80	31			
2020/01	3	376.32	2.96	0.79	31	376.32	2.96	0.79	31			
2020/02	1	56.45	1.04	1.85	29	56.47	1.02	1.81	60			
2020/02	3	376.24	3.05	0.81	29	376.28	2.98	0.79	60			
2020/03	1	56.30	1.09	1.93	24	56.42	1.04	1.84	84			
2020/03	3	376.58	3.12	0.83	24	376.37	3.00	0.80	84			
Summary Statistics												
1/1/2020 12:00 AM	—	3/31/2020 11:59 PM			Mean	Fixed Mean	Fixed SD	Fixed CV	SDI			
Level	1	56.42	1.04	1.84	84	56.00	1.30	(2.36)	1.09			
Level	3	376.37	3.00	0.80	84	374.00	7.80	(2.09)	0.30			
Active Rules:	1-2sW,1-3s,2-2s,R-4s											
Cholesterol, Total, Cholesterol oxidase, esterase, peroxidase, Abbott ARCHITECT c16000, Dedicated Reagent, mg/dL, No Temperature												
2020/01	1	107.34	1.69	1.57	32	107.34	1.69	1.57	32			

Create a Summary Data Report

- Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- Click the **Reports** menu, point to **General**, and then click **Summary Data Report**.
- Click the down arrow in the **From** field and select the beginning date for the report.
- Click the down arrow in the **To** field and select the ending date for the report.
- Select an option for the report:
 - If you selected a test in the **Lab** navigation tree, you can select one of the following:
 - Custom Selection
 - Select one or more Lab number, Lot number, Analyte, and/or Instrument.
 - All data
 - Current lab

- Current lot
- Current test



Tip: Use the Custom Selection to narrow the search by a combination of Labs, Lots, Analytes and Instruments. Click the Show List button to refresh the list based on selections. Use the check marks to narrow the list further.

- If you selected a test in the **Panel** navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the **Instrument** navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 Select the **Order report by Level** check box if you want the report arranged by levels.
- 7 Click **OK**.
- The report opens in the format configured for your software.
-
- Note:** Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.
- 8 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 9 Click  (gray X) in the upper right corner to close the report.

Statistical Report

The Statistical Report shows the percentage of point data that did not violate any rejection rule. The Statistical Report provides a helpful overview of how well your laboratory is meeting its performance goals. The report shows the laboratory's statistics for each calendar month.

Unity Real Time Statistical Report				
Printed:	4/28/2017	2/1/2017	through	4/24/2017
			Page	1
Lab number:	999913	Description:	Arch2: Fixed Means & SDs Westgard Adv	
Lab name:	Training Department Sample DB	Contact:		
Lot number:	45730	Control:	Multiqual 1,2,3	
Expires:	2/28/2018			
Manufacturer:	Bio-Rad Laboratories			
Albumin ,Bromcresol Green (BCG) ,Abbott ARCHITECT c16000 ,Dedicated Reagent ,g/dL ,No Temperature				
4/2017	Level: 1	100.00%	of data accepted	
4/2017	Level: 3	100.00%	of data accepted	
Alkaline Phosphatase ,PNPP, AMP Buffer ,Abbott ARCHITECT c16000 ,Dedicated Reagent ,U/L ,37° C				
4/2017	Level: 1	91.67%	of data accepted	
4/2017	Level: 3	91.67%	of data accepted	
ALT (ALAT/GPT) ,UV without P5P ,Abbott ARCHITECT c16000 ,Dedicated Reagent ,U/L ,37° C				
4/2017	Level: 1	100.00%	of data accepted	
4/2017	Level: 3	100.00%	of data accepted	
AST (ASAT/GOT) ,UV without P5P ,Abbott ARCHITECT c16000 ,Dedicated Reagent ,U/L ,37° C				
4/2017	Level: 1	100.00%	of data accepted	
4/2017	Level: 3	100.00%	of data accepted	
Calcium ,Arsenazo III ,Abbott ARCHITECT c16000 ,Dedicated Reagent ,mg/dL ,No Temperature				
4/2017	Level: 1	100.00%	of data accepted	
4/2017	Level: 3	100.00%	of data accepted	
Chloride ,ISE indirect ,Abbott ARCHITECT c16000 ,Dedicated Reagent ,mEq/L ,No Temperature				
4/2017	Level: 1	100.00%	of data accepted	
4/2017	Level: 3	100.00%	of data accepted	

Create a Statistical Report

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu, point to **General**, and then click **Statistical Report**.
- 3 Click the down arrow in the **From** field and select the beginning date for the report.
- 4 Click the down arrow in the **To** field and select the ending date for the report.

5 Select an option for the report:

- If you selected a test in the **Lab** navigation tree, you can select one of the following:
 - Custom Selection
 - Select one or more Lab number, Lot number, Analyte, and/or Instrument.
 - All data
 - Current lab
 - Current lot
 - Current test



Tip: Use the Custom Selection to narrow the search by a combination of Labs, Lots, Analytes and Instruments. Click the Show List button to refresh the list based on selections. Use the check marks to narrow the list further.

- If you selected a test in the **Panel** navigation tree, you can select one of the following:
 - Current panel
 - Current test
- If you selected a test in the **Instrument** navigation tree, you can select one of the following:
 - Current instrument
 - Current test

6 Select the **Order report by Level** check box if you want the report arranged by levels.

7 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

8 See “Print and Export Reports” on page 277 if you want to print or save the report.

9 Click  (gray X) in the upper right corner to close the report.

Supervisor's Report

The Supervisor's Report shows data points that:

- Violate a SPC rule set to Reject.
- Violate a SPC rule set to Warn.
- Have an action or comment attached.

The Supervisor's Report shows the following statistics:

- Date and time of QC
- Operator
- Level
- Value
- Z-Score
- Status
- Rule Violations
- Actions
- Comments

Unity Real Time Supervisor's Report						
Data for 11/19/2018 12:00 AM		through 12/8/2018 11:59 PM		Printed 11/13/2018	Page 1	
Lab number:	999913	Description:	D-10 #2 and Arch #2 (Like Inst)			
Lab name:	Training Department Sample DB	Department:	Training			
Contact:		Postal/ZIP code:	92618			
Lot number:	45810	Control name:	Mutiquil 1,2,3			
Expires:	4/30/2021	Manufacturer:	Bio-Rad Laboratories			
Date	Op	Level	Value	Z-score		
Albumin, Bromcresol Green (BCG), Abbott ARCHITECT c16000, Dedicated Reagent, g/dL, No Temperature						
11/23/2018	9:50:00AM	sa	1	2.30	0.50	Accepted
Action(s)	Mean: established new (sa - 11/23/2018 9:50:00 AM)					
Comment(s)	Post QC review mean adjusted made to match april peer group mean on all analytes except the followi (sa - 11/23/2018 09:50:00) Post QC review mean adjusted made to match april peer group mean on all analytes except the followi (sa - 11/23/2018 09:50:00)					
11/23/2018	9:50:00AM	sa	3	4.45	-0.75	Accepted
Action(s)	Mean: established new (sa - 11/23/2018 9:50:00 AM)					
Comment(s)	Post QC review mean adjusted made to match april peer group mean on all analytes except the followi (sa - 11/23/2018 09:50:00) Post QC review mean adjusted made to match april peer group mean on all analytes except the followi (sa - 11/23/2018 09:50:00)					
11/25/2018	1:53:00PM	sa	1	2.29	0.40	Rejected
Action(s)	Control: repeated level 3 (sa - 11/25/2018 1:53:00 PM)					
11/25/2018	1:53:00PM	sa	3	2.40	-11.00	Rejected
Action(s)	Control: repeated level 3 (sa - 11/25/2018 1:53:00 PM)					
Alkaline Phosphatase, PNPP, AMP Buffer, Abbott ARCHITECT c16000, Dedicated Reagent, U/L, 37° C						
11/23/2018	9:50:00AM	sa	1	29.70	0.44	Accepted

Create a Supervisor's Report

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu, point to **Supervisory**, and then click **Supervisor's Report**.
- 3 Click the down arrow in the **From** field and select the beginning date for the report.
- 4 Click the down arrow in the **To** field and select the ending date for the report.
- 5 Select an option for the report:
 - If you selected a test in the **Lab** navigation tree, you can select one of the following:
 - Custom Selection
 - Select one or more Lab number, Lot number, Analyte, and/or Instrument.
 - All data
 - Current lab
 - Current lot
 - Current test



Tip: Use the Custom Selection to narrow the search by a combination of Labs, Lots, Analytes and Instruments. Click the Show List button to refresh the list based on selections. Use the check marks to narrow the list further.

- If you selected a test in the **Panel** navigation tree, you can select one of the following:
 - Current panel
 - Current test
- If you selected a test in the **Instrument** navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 The **Reject** check box is selected by default. Clear the **Reject** check box if you want to exclude data points with a status of "Reject."
- 7 Select the **Warn** check box if you want to include data points with a status of "Warn."
- 8 Select the **Action** check box if you want to include data points with an action attached.
- 9 Select the **Comment** check box if you want to include data points with a comment attached.
- 10 Select an option for rule violations:
 - Display all rule violations
 - Display selected rule violations only

11 Display selected rule violations only: Select the rule violation(s) you want to include in the report.

- To select multiple consecutive rules:
Click the first rule, press the SHIFT key on the keyboard, and then click the last rule.
- To select multiple non-consecutive rules:
Press the CTRL key on the keyboard, and then click each rule.

12 Select an option for actions:

Note: The **Action** check box must be selected in step 8 before you can select an option for actions.

- Display all actions
- Display selected actions only

13 Display selected actions only: Select the actions you want to include in the report.

- To select multiple consecutive actions:
Click the first rule, press the SHIFT key on the keyboard, and then click the last action.
- To select multiple non-consecutive actions:
Press the CTRL key on the keyboard, and then click each action.

14 Select an option for comments:

Note: The **Comment** check box must be selected in step 9 before you can select an option for comments.

- Display all comments
- Filter comments by selected text

15 Filter comments by selected text: Enter the text in the text field to filter the data in the report.**16** Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 or more information.

17 See “Print and Export Reports” on page 277 if you want to print or save the report.**18** Click

(gray X) in the upper right corner to close the report.

Operator Report

The Operator Report shows the following statistics for each test entered by operator:

- Operator
- Mean
- Standard Deviation (SD)
- Coefficient of Variation (CV)
- Number of data points

Unity Real Time Operator Report									
Printed:	4/28/2017	Range	4/1/2017	through	4/28/2017	Page	1		
Lab number:	999913				Description:	Arch2: Fixed Means & SDs Westgard Adv			
Lab name:	Training Department Sample DB				Contact:				
Lot number:	40910				Control:	Immunoassay Plus			
Expires:	2/28/2018				Manufacturer:	Bio-Rad Laboratories			
OP	Mean	SD	CV	Pts					
Acetaminophen, Enzymatic, colorimetric, Abbott ARCHITECT c16000, Dedicated Reagent, µg/mL, No Temperature									
Level 1	sa	9.70	0.65	6.66	60				
Level 2	sa	37.06	1.14	3.08	58				
Level 3	sa	113.49	1.64	1.44	58				
Amikacin, Immunoturbidimetric, Abbott ARCHITECT c16000, Dedicated Reagent, µg/mL, No Temperature									
Level 1	sa	4.44	0.39	8.73	58				
Level 2	sa	14.60	0.71	4.87	58				
Level 3	sa	27.49	0.96	3.51	58				
Digoxin, Chemiluminescence, Abbott ARCHITECT i2000/i2000SR, Dedicated Reagent, ng/mL, No Temperature									
Level 1	sa	0.75	0.04	4.78	60				
Level 2	sa	1.72	0.07	4.15	60				
Level 3	sa	3.09	0.09	2.80	60				
AFP, Chemiluminescence, Abbott ARCHITECT i2000/i2000SR, Abbott ARCHITECT AFP (7K67), ng/mL, No Temperature									
Level 1	sa	31.33	0.90	2.86	60				

Create an Operator Report

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu, point to **Supervisory**, and then click **Operator Report**.
- 3 Click the down arrow in the **From** field and select the beginning date for the report.
- 4 Click the down arrow in the **To** field and select the ending date for the report.
- 5 Select an option for the report:
 - If you selected a test in the **Lab** navigation tree, you can select one of the following:
 - Custom Selection
 - Select one or more Lab number, Lot number, Analyte, and/or Instrument.
 - All data
 - Current lab
 - Current lot
 - Current test



Tip: Use the Custom Selection to narrow the search by a combination of Labs, Lots, Analytes and Instruments. Click the Show List button to refresh the list based on selections. Use the check marks to narrow the list further.

- If you selected a test in the **Panel** navigation tree, you can select one of the following:
 - Current panel
 - Current test
- If you selected a test in the **Instrument** navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 Select the **Order report by Level** check box if you want the report arranged by levels.
- 7 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 8 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 9 Click (gray X) in the upper right corner to close the report.

Measurement Uncertainty Report

The Measurement Uncertainty Report calculates measurement uncertainty to help determine the accuracy of results. The report uses expanded uncertainty (calculated using a Z-Score of 2) to increase the confidence interval of the results.

Unity Real Time Standard Expanded Uncertainty													BIO-RAD	
Printed:	3/22/2020	Range	9/1/2019	through	9/28/2019	Page	1							
Lab:	218881													
Lot:	33990 Diabetes Matrix: Whole Blood Manufacturer: Bio-Rad Laboratories Expires: 6/30/2021 12:00:00 AM													
Analyte	Method	Instrument	Reagent	Unit	Temperature	Level	Mean	SD	CV	Points	U	U(%)	TEa	TEa Selection
Hemoglobin A1c (NGSP)	HPLC	Bio-Rad D-10	Bio-Rad D-10 HbA1c (220-0101)	%	No Temperature	1	5.44	0.07	1.25	28	0.14	2.50	10.00	CLIA 2019
Hemoglobin A1c (NGSP)	HPLC	Bio-Rad D-10	Bio-Rad D-10 HbA1c (220-0101)	%	No Temperature	2	9.59	0.08	0.80	28	0.15	1.60	10.00	CLIA 2019

Create a Measurement Uncertainty Report

- Select a test in the **Lab**, **Panel**, or **Instrument** 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, panel, or instrument to view the tests.
- Click the **Reports** menu, then click **Measurement Uncertainty**.
- Select an option for the report:
 - Standard Expanded Uncertainty

$$U = SD * 2$$

- Click **OK**.
- Select dates for the **Data Range**.
- Select the **Current Lot** or **Current Test**.
- Combined Expanded Uncertainty (+ Interlaboratory Bias)

$$U = 2 * \sqrt{(SD^2 + [Bias / \sqrt{3}]^2 + SDBias^2)}$$

- Click **OK**.
- Select **Last Year** or **Last 6 Months** for the **Data Range**.
- Select **Current Lot** or **Current Test**.
- Select **Peer**, **Method**, or **All Labs** for the bias comparison.

- Combined Expanded Uncertainty (+ Calibration Uncertainty)

$$U = 2 * \sqrt{SD^2 + Cal\ U^2}$$

- a) Click **OK**.
- b) Select dates for the **Data Range**.
- c) Select **Current Lot** or **Current Test**.
- d) Select the appropriate check marks to display additional analyte information.
- e) Enter the **Calibrator Uncertainty** value.



Note: Combined Expanded Uncertainty is disabled for non-Bio-Rad lots.

- 4 Click **OK**.

The table opens.

- 5 Click the appropriate **Level** tab located at the top to view data for a specific level or for all levels.
- 6 Click the check box at the top left to display additional columns.
- 7 Click **Configure TE_a** to make changes to TE_a selections. See “Configure the TE_a (Allowable Total Error)” on page 196 for more information.
- 8 Click **Export** to create a Microsoft Excel file.



Note: The Measurement Uncertainty Report cannot be exported to Microsoft Excel 2013 format.

- 10 Click **Print** to create a PDF file.
- 11 Click  (gray X) in the upper right corner to close the report.

Audit Trail Report

The Audit Trail Report shows events that changed the way data points were evaluated. The Audit Trail Report contains all events for all labs, lots, and tests when first created. You can filter the report by any of the following criteria:

- Date and time
- Level
- Lab number
- Lot number
- Test
- Event

Audit Trail

Audit Trail Information

Start:	End:	Lab number:	Lot number:
2/ 1/2017 11:09 AM	4/26/2017 11:09 AM	999988	66760

Test information:
Creatinine|Alkaline picrate-kinetic, IFCC-IDMS Standardized|Siemens Dimension AR |Dedicated Reagent|mg/dL|No Temperature

Event:
(All)

Data

Date	Level	Lab	Lot	Test	Expires	Event	Initials	Original	Changed to	Comment(s)
4/17/2017 10:13:03 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point edited	sa	4/14/2017 2:3	4/14/2017 2:3	
4/17/2017 10:03:07 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Fixed mean added	sa	158.00	136.53	
4/17/2017 10:03:07 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Fixed mean added	sa	66.60	58.68	
4/17/2017 9:55:24 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	3/13/2017 12:	3/11/2017 2:0	
4/17/2017 9:55:24 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	3/13/2017 12:	3/11/2017 2:0	
4/17/2017 9:55:17 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	3/11/2017 11:	3/11/2017 1:0	
4/17/2017 9:55:17 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	3/11/2017 11:	3/11/2017 1:0	
4/17/2017 9:54:53 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	3/12/2017 12:	3/11/2017 11:	
4/17/2017 9:54:53 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	3/12/2017 12:	3/11/2017 11:	
4/17/2017 9:53:32 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/17/2017 9:5	3/13/2017 12:	
4/17/2017 9:53:32 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/17/2017 9:5	3/13/2017 12:	
4/17/2017 9:53:29 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/17/2017 9:5	3/12/2017 12:	
4/17/2017 9:53:29 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/17/2017 9:5	3/12/2017 12:	
4/17/2017 9:53:23 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/17/2017 9:5	3/11/2017 12:	
4/17/2017 9:53:23 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/17/2017 9:5	3/11/2017 12:	
4/10/2017 11:47:25 AM	1	999988	66760	Creatinine Alkaline	3/31/2018	Data point edited	sa	2/20/2017 12:	2/20/2017 12:	
4/10/2017 11:44:03 AM	2	999988	66760	Creatinine Alkaline	3/31/2018	Data point date/tim	sa	4/9/2017 3:49	2/14/2017 12:	

Buttons: Print | Close

Audit Trail Events



Note: See “Audit Trail Events” on page 440 for more information about the types of Audit Trail events.

The Event list contains auditable events that have been performed in the software. The following information appears for each event:

- Date of the event
- Level
- Lab number
- Lot number
- Test
- Expiration date of the lot
- 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

See “Configure Actions and Comments” on page 432 for more information about Audit Trail Comments.

Create an Audit Trail Report

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu and then click **Audit Trail**.

The **Audit Trail Information** dialog box opens.

- 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 you make.

- 4 Click the down arrow in the **Start** field and select the beginning date for the report.
- 5 Click the down arrow in the **End** field and select the ending date for the report.
- 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 information** list or select **All**.

- 9 Select the event from the **Event** list or select **All**.



Note: See “Audit Trail Events” on page 440 for more information about the types of Audit Trail events.

- 10 Click **Print**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 11 See “Print and Export Reports” on page 277 if you want to print or save the report.

- 12 Click  (gray X) in the upper right corner to close the report.

Listings Reports

The Listings Reports are helpful to view information set up in Unity Real Time.

Labs Listing Report

The Labs Listing Report shows all lab numbers organized by open and closed status.

Unity Real Time Lab Listing		BIO-RAD
Printed	4/28/2017	Page
Open lab numbers:		
Lab: 160193 Training Department Sample DB EXL1, VITROS 1, Clinitek 1: UC2 Demo		
Department:	Training	
Contact:		
Address:	9600 Jeronimo Rd	
City:	Irvine	
State:	CA	
Postal/ZIP code:	92618	
Country:	United States	
Lab: 176358 Training Department Sample DB EXL2, VITROS 2, Clinitek 2: UC2 Practice		
Department:	Training	
Contact:		
Address:	9600 Jeronimo Rd	
City:	Irvine	
State:	CA	
Postal/ZIP code:	92618	
Country:	United States	
Lab: 218881 Training Department Sample Arch1: Instrument Comparison		
Department:	Training	
Contact:		
Address:	9600 Jeronimo Rd	
City:	Irvine	

Create a Labs Listing Report

- 1 Select a test in the **Lab** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.

- 2 Click the **Reports** menu, point to **Listings**, and then click **Labs**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 3 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 4 Click  (gray X) in the upper right corner to close the report.

Lots Listing Report

The Lots Listing Report shows all lot numbers for all lab numbers (open and closed).



Tip: This report is helpful when using the **Expiration Date** option (step 3) to manage your control lot numbers and expiration dates.

Unity Real Time Lot Listing			
Printed	4/28/2017	Page	1
Lab number: 160193 Training Department Sample DB, EXL1, VITROS 1, Clinitek 1: UC2 Demo			
31390	Cardiac Markers LT	Expires 6/30/2018	Open
31830	Unassayed Chemistry	Expires 6/30/2018	Open
55660	Spinal Fluid	Expires 6/30/2018	Open
66780	Urine Chemistry	Expires 9/30/2018	Open
31400	Cardiac Markers LT	Expires 10/31/2018	Open
40920	Immunoassay Plus	Expires 10/31/2018	Open
55670	Spinal Fluid	Expires 12/31/2018	Open
66790	Urine Chemistry	Expires 12/31/2018	Open
67200	Urinalysis	Expires 5/31/2019	Open
Lab number: 176358 Training Department Sample DB, EXL2, VITROS 2, Clinitek 2: UC2 Practice			
40310	Immunoassay Plus	Expires 12/31/2017	Open
31390	Cardiac Markers LT	Expires 6/30/2018	Open
31830	Unassayed Chemistry	Expires 6/30/2018	Open
55660	Spinal Fluid	Expires 6/30/2018	Open
66780	Urine Chemistry	Expires 9/30/2018	Open
31400	Cardiac Markers LT	Expires 10/31/2018	Open
40920	Immunoassay Plus	Expires 10/31/2018	Open
67200	Urinalysis	Expires 5/31/2019	Open
Lab number: 218881 Training Department Sample, Arch1: Instrument Comparison			
21680	Pediatric	Expires 9/30/2019	Open
Lab number: 218881 Training Department Sample, Arch1: Instrument Comparison			
21650	Pediatric	Expires 8/31/2018	Closed
Lab number: 999901 Training Department Sample DB, Vitros: Peer Submission Only			
45730	Multiquel 1,2,3	Expires 2/28/2018	Open
21680	Pediatric	Expires 9/30/2019	Open

Create a Lots Listing Report

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu, point to **Listings**, and then click **Lots**.
- 3 Select an option according to how you want to organize the report:
 - Navigation Tree
 - Expiration Date
- 4 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.

See “Configure the Report Format” on page 436 for more information.

- 5 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 6 Click  (gray X) in the upper right corner to close the report.

Tests Listing Report

The Test Listings Report includes the following information defined for each test at the time the report is created:

- QC Rules (SPC and/or Analytical Goal)
- Cumulative mean, SD, CV, Points
- Fixed mean, SD, CV

Unity Real Time					
Test Listing					
Printed 11/1/2021					Page 1
Lab: 218881 Training Department Sample D-10 #1 and Arch #1 (DAG BR)					
85810	Diabetes				4/30/2022
Hemoglobin A1c (NGSP), HPLC, Bio-Rad D-10, Bio-Rad D-10 HbA1c (220-0101), %, No Temperature					
QC Rules:	1-3s,2-2s,R-4s,10-XW				
Level 1	Mean	SD	CV	Points	
Cumulative	5.45	0.08	1.40	151	
Fixed	5.40	0.20	(3.70)		
Level 2	Mean	SD	CV	Points	
Cumulative	9.56	0.12	1.29	151	
Fixed	9.60	0.40	(4.17)		
45870	Multiqual 1,2,3				4/30/2023
Albumin, Brom cresol Green (BCG), Abbott ARCHITECT c16000, Dedicated Reagent, g/dL, No Temperature					
QC Rules:	1-2sW,1-3s,2-2s,R-4s				
Level 1	Mean	SD	CV	Points	
Cumulative	2.20	0.09	4.11	151	
Fixed	2.25	0.10	(4.44)		
Level 3	Mean	SD	CV	Points	
Cumulative	4.47	0.17	3.78	151	
Fixed	4.60	0.20	(4.35)		

Create a Test Listings Report

- 1 Click the **Reports** menu, point to **Listings**, and then click **Tests**.

The **Test Listing Report** dialog box appears.

- 2 Select an option for the report:

- All data
- Current lab
- Current lot
- Current test

- 3 Select each check box for the information you want to include in the report:

- QC Rules
- Cumulative Statistics
- Fixed Mean and SD
- Only Open Tests

- 4 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 5 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 6 Click

Panels Listing Report

The Panels Listing Report shows all panels and associated tests organized by lab number and lot number.

Unity Real Time		BIO-RAD
Panel Listing		
Printed	4/28/2017	Page
Panel Chloride		
Lab 999901, Vitros: Peer Submission Only	Lot 45730, Multiqual 1,2,3	
Chloride, ISE direct, VITROS 5600 (Dry Slide), Slide generation #05, mEq/L, No Temperature		
Lab 999913, Arch2: Fixed Means & SDs Westgard Adv	Lot 45730, Multiqual 1,2,3	
Chloride, ISE indirect, Abbott ARCHITECT c16000, Dedicated Reagent, mEq/L, No Temperature		
Lab 999988, Siemens: Floating Means & SDs	Lot 45730, Multiqual 1,2,3	
Chloride, ISE indirect, Siemens ADVIA 2400, Dedicated Reagent, mEq/L, No Temperature		

Create a Panels Listing Report

- 1 Select a test in the **Panel** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu, point to **Listings**, and then click **Panels**. The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 3 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 4 Click  (gray X) in the upper right corner to close the report.

See “Panels” section on page 118 for more information.

Test Code Report

The Test Code Report shows the Unity codes for each test based on the specified criteria. This report is typically used by software support for troubleshooting. This report includes the Unity codes for:

- Analyte
- Method
- Instrument/kit
- Reagent
- Unit
- Temperature

Code Listing						BIO-RAD
Lab	999901	Lot	21680			
Bilirubin, Direct/BC (DBIL)	36	Spectrophotometric	933	VITROS 5600 (Dry Slide)	1407	
Slide generation #16	1016	mg/dL	14	No Temperature	6	
Lab	999901	Lot	21680			
Bilirubin, Total/TBIL, Diphylleine, Diazonium Salt-VITROS, VITROS 5600 (Dry Slide), Slide generation #17, mg/dL, No Temperature						
Bilirubin, Total/TBIL	38	Diphylleine, Diazonium Salt-VITROS	121	VITROS 5600 (Dry Slide)	1407	
Slide generation #17	1017	mg/dL	14	No Temperature	6	
Lab	999901	Lot	45730			
Albumin, Brom cresol Green (BCG) - Vitros, VITROS 5600 (Dry Slide), Slide generation #15, g/dL, No Temperature						
Albumin	7	Brom cresol Green (BCG) - Vitros	79	VITROS 5600 (Dry Slide)	1407	
Slide generation #15	1015	g/dL	15	No Temperature	6	
Lab	999901	Lot	45730			
Alkaline Phosphatase, PNPP, AMP Buffer-VITROS, VITROS 5600 (Dry Slide), Slide generation #10, U/L, 37° C						
Alkaline Phosphatase	26	PNPP, AMP Buffer-VITROS	87	VITROS 5600 (Dry Slide)	1407	
Slide generation #10	1010	U/L	56	37° C	5	
Lab	999901	Lot	45730			
ALT (ALAT/GPT), UV with P5P-VITROS, VITROS 5600 (Dry Slide), Slide generation #33, U/L, 37° C						
ALT (ALAT/GPT)	20	UV with P5P-VITROS	91	VITROS 5600 (Dry Slide)	1407	

Create a Test Code Listings Report

- 1 Select a test in the **Lab**, **Panel**, or **Instrument** navigation tree.
 - Click + (plus sign) to the left of the lab number to view the lots.
 - Click + (plus sign) to the left of a lot number, panel, or instrument to view the tests.
- 2 Click the **Reports** menu, point to **Listings**, and then click **Test Code Report**.
- 3 Select an option for the report:
 - If you selected a test in the **Lab** navigation tree, you can select one of the following:
 - All data
 - Current lot
 - Current test
 - If you selected a test in the **Panel** navigation tree, you can select one of the following:
 - Current test
 - Current panel
 - If you selected a test in the **Instrument** navigation tree, you can select one of the following:
 - Current instrument
 - Current test

- 4 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.

See “Configure the Report Format” on page 436 for more information.

- 5 See “Print and Export Reports” on page 277 if you want to print or save the report.
- 6 Click  (gray X) in the upper right corner to close the report.

Transmission Data Summary Report

Prior to submitting results to the Unity Interlaboratory Program, the Transmission Data Summary Report is useful to check the summary QC data results that will be submitted. This is a real time snapshot of data records waiting to be submitted since the last submission. After the QC data is submitted, the report will reset to populate with new and/or edited data records. The Transmission Data Summary Report shows the following statistics:

- Lab numbers included in the transmission
- Level
- Mean
- Standard deviation (SD)
- Number of data points for each test in the selected data set
- Time period

Transmission Data Summary							
<small>Printed 2/18/2021</small>				<small>Page 1</small>			
Lab numbers included in transmission: 999991							
Lab number:	999991	Mean	SD	Points			
Lot number:	45860						
Albumin,Bromcresol Purple (BCP),Roche cobas 6000,Dedicated Reagent,g/dL,No Temperature							
Submitting the following point data for 2021-02:							
Level	1	2.56917	0.022747	18			
Level	2	3.66333	0.0122474	18			
Level	3	4.7875	0.0291548	18			
Lot number:	68600						
Glucose,Dipstick,Siemens CLINITEK 500,Dedicated Reagent,Qualitative,No Temperature							
Submitting the following Qualitative point data for 2021-10:							
Level	1	1					
Lot number:	85210						
Acetaminophen,Enzymatic, colorimetric,Siemens Dimension EXL,Dedicated Reagent,µg/mL,No Temperature							
Submitting the following point data for 2021-01:							
Level	1	17.1064	0.84267	18			
Level	2	39.872	1.17656	18			
Level	3	108.045	25.2984	18			
Submitting the following point data for 2021-04:							
Level	1	16.985	0.766837	32			
Level	2	39.6171	1.1194	31			
Level	3	111.133	1.22099	33			

Create a Transmission Data Summary Report

1 Click the **Tools** menu, point to Unity **Interlab**, and then click **Send/Receive Data**.

2 Click the **View Transmission Data** button.

The report opens in the Crystal Reports format.

If there are no new and/or edited data records waiting to be submitted, a message will appear to indicate “No data to transmit”.

3 See “Print and Export Reports” on this page if you want to print or save the report.

4 Click  (gray X) in the upper right corner to close the report.

Print and Export Reports

By default, Unity Real Time generates reports that can be printed or exported to Crystal Reports (*.rpt format). You can also export reports in Unity Real Time to formats compatible with popular business software such as Microsoft Excel and Microsoft Word. You can export reports to the following formats.

- Adobe Acrobat (*.pdf)
- Microsoft Excel (*.xls)
- Microsoft Word (*.doc)
- Rich Text Format (*.rtf)



Note: You can configure Unity Real Time to always generate reports in PDF format. See “Configure the Report Format” on page 435 for more information.

Export Reports

1 Create a report.

2 Click **Export**.

The **Save As** dialog box appears.

3 Enter a name for the report in the **File name** field.

4 Select the format you want to save the report in from the **Save as type** list.

5 Navigate to the location where you want to save the report.

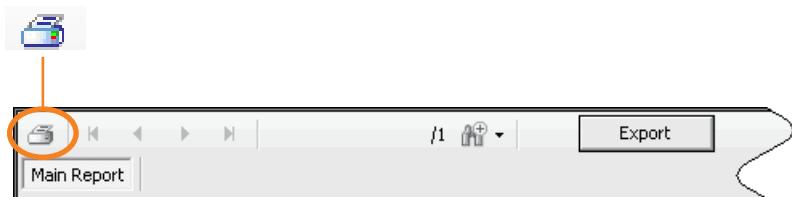
6 Click **Save**.

A message appears when the export is complete.

7 Click **OK**.

Print with SAP Crystal Reports

- 1 Create a report.
- 2 Click the printer button located on the toolbar.



The **Print** dialog box appears.

- 3 Select the appropriate options for your printer and click **OK**.

Add a Signature to Report Reviews

The reports contain a signature line and a section to document corrective actions, if needed.



Note: Unity Real Time does not support electronic signatures. However, you can use a third-party software product such as Adobe Acrobat.

Submit Data to the Unity Interlaboratory Program

In This Chapter

Overview	279
Submit Data Manually.....	280
Activate Automatic Monthly Transmission	281
Submit Data from the Bench Review or Supervisor Review.....	281
Activate Transmission for InstantQC.....	281

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.



Note: See Chapter 16, “Unity Interlaboratory Reports” for more information about the reports.

There are three options for submitting data to the Unity Interlaboratory Program:

- Submit data manually (page 280)
- Submit data with Automatic Monthly Transmission (page 281)
- Submit data from the Bench Review or Supervisor Review (page 281)

You can use a combination of these options to ensure your QC data is submitted on time.



Note: As a general rule, you must send your data to Bio-Rad by the seventh day of the following month. Data received after the 7th is late.



Important: If you have a shared database with other departments or locations, keep in mind that data is submitted for the entire database. This applies for both a manual submission and automatic monthly transmission. You cannot submit data for individual lab numbers.



Important: If data is submitted by another user or by the software before you are ready, you can still make changes to your QC data. When data is resubmitted, only the changes or new data is sent to Bio-Rad. The last submission received before midnight (Pacific Time) is what Bio-Rad will use as your submission.



Important: Any QC data submitted after the 7th is considered late. Reports for late submissions will be available on www.QCNet.com after a short processing time. See “View, Print, and Save Interlaboratory Reports” on page 284 and also Chapter 16, “Unity Interlaboratory Reports” for more information about the reports.

Submit Data Manually



Note: Bio-Rad recommends activating automatic monthly transmission to ensure your data is submitted on time. See “Activate Transmission for InstantQC” on page 281 for more information.



You must have the “Communicate with Unity Interlab” permission to use this function.

You can submit data manually at any time even if you use the automatic monthly transmission feature.

- 1 Click the **Tools** menu, point to **Unity Interlab**, and then click **Send/Receive Data**.
The **Send/Receive Data** dialog box appears.
- 2 **Optional:** Click the **View Transmission Data** button to view the **Transmission Data Summary Report**.
Prior to submission, this report will allow you to double check the summary values that will be sent to the Unity Interlaboratory Program. See “Transmission Data Summary Report” on page 276 for more information.
- 3 Make sure the **Send data to Bio-Rad** check box is selected.
- 4 Click **OK**.
A message appears stating the data was successfully transmitted.
- 5 Click **OK**.

Activate Automatic Monthly Transmission



You must have the “Communicate with Unity Interlab” permission to use this function.



Important: Unity Real Time submits data upon log in when using the automatic monthly transmission feature.



You must have the “Edit setup options” permission to set up this function.

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Select the **Automatic monthly transmission** check box located in the Transmission section.
- 3 Select the day from the **Day of the month** list you want the software to automatically transmit your data to Bio-Rad. The day of the month options are the 1st through 7th.
- 4 Click **OK**.

Submit Data from the Bench Review or Supervisor Review



Note: Only point data can be submitted to the Unity Interlaboratory Program from the Bench Review or Supervisor Review.

You can send point data to the Unity Interlaboratory Program each time a Bench Review or Supervisor Review is approved. The data appears on InstantQC Reports on www.QCNet.com after a short processing time.

You can submit data from the Bench Review or Supervisor Review as a substitute for submitting data monthly. See “Perform a Bench Review or Supervisor Review” on page 182 for more information.

Activate Transmission for InstantQC



You must have the “Edit setup options” permission to set up this function.

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Select the **Data review transmission (for InstantQC)** check box located in the Transmission section.
- 3 Click **OK**.

Unity Interlaboratory Reports

In This Chapter

Overview	282
View, Print, and Save Interlaboratory Reports	284
Monthly Reports	285
Comprehensive Reports	295
Affiliated Reports	297
Qualitative Reports	302
InstantQC Reports.....	305

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.



Important: As a general rule, data must be sent to Bio-Rad by the seventh day of the following month. For late submissions, copies of your monthly reports that will include the QC data submitted after the deadline will be available on www.QCNet.com after a short processing time.

The Unity Interlaboratory Program provides the following types of reports:

- Monthly Reports
- Comprehensive Reports
- Affiliated Reports (optional)
- Qualitative Reports (optional)
- InstantQC Reports (optional)

Monthly Reports



Important: As a general rule, data must be sent to Bio-Rad by the seventh day of the following month. For late submissions, copies of your monthly reports that will include the QC data submitted after the deadline will be available on www.QCNet.com after a short processing time.

- The Unity Interlaboratory Program automatically generates the Monthly Evaluation Report for each month you submit your data. This report compares your laboratory data to the data of your consensus group.
- The Unity Interlaboratory Program also generates the following reports according to the frequency (monthly, quarterly, or never) specified in Unity Real Time.
 - Laboratory Performance Overview Report (page 286)
 - Laboratory Comparison Report (page 288)
 - Laboratory Histogram Report (page 290)
 - Statistical Profile Report (page 291)
 - Bias and Imprecision Histogram Report (page 293)



Note: See “Configure Unity Interlaboratory Report Frequency and Language” on page 437 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 295)
- Manufacturer Report (page 296)

Affiliated Reports

Affiliated Reports allow a group of laboratories to compare results, essentially becoming their own consensus group. See “Affiliated Reports” on page 297 for more information.



Note: Affiliated reports are available by request. Contact the Bio-Rad QC Program Representatives for more information.

Qualitative Reports

See “Qualitative Reports” on page 302 for more information.

InstantQC Reports

When you send data to the Unity Interlaboratory Program, the InstantQC Reports are available on www.QCNet.com after a short processing time. See “InstantQC Reports” on page 305 for more information.

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, Print, and Save 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 Interlab Reports**.
- 4 Point to **Reports**, and then click **My Reports**.
- 5 Click the appropriate tab according to the type of reports you want to view.
 - **My Reports** (Monthly Reports, Affiliated Reports, Urinalysis Reports)
 - **InstantQC Reports**
 - **Worldwide Reports**
 - **Manufacturer Reports**
- 6 Make the appropriate selections from the lists.

The selected report appears in Adobe Reader.

Print Interlaboratory Reports

- 1 Click the printer button located on the Adobe Reader toolbar.



Note: The buttons may look slightly different depending on the version of Adobe Reader installed on your computer.

The **Print** dialog box appears.

- 2 Select the appropriate options for your printer and click **OK**.

Save Interlaboratory Reports

- 1 Click the save button located on the Adobe Reader toolbar.



Note: The buttons may look slightly different depending on the version of Adobe Reader installed on your computer.

The **Save a Copy** dialog box appears.

- 2 Navigate to the location where you want to save the report and click **Save**.

Monthly Reports



Important: As a general rule, data must be sent to Bio-Rad by the seventh day of the following month. For late submissions, copies of your monthly reports that will include the QC data submitted after the deadline will be available on www.QCNet.com after a short processing time.

Monthly Evaluation Report

The Monthly Evaluation Report provides an overview of your laboratory performance for the month.

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 resubmit the data. Unity Interlaboratory Reports will be regenerated automatically after a short processing time. 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.

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.
- 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.
- Identifies data that has been rejected and therefore excluded from the Unity Interlaboratory Program.
- 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.

Rejection 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.

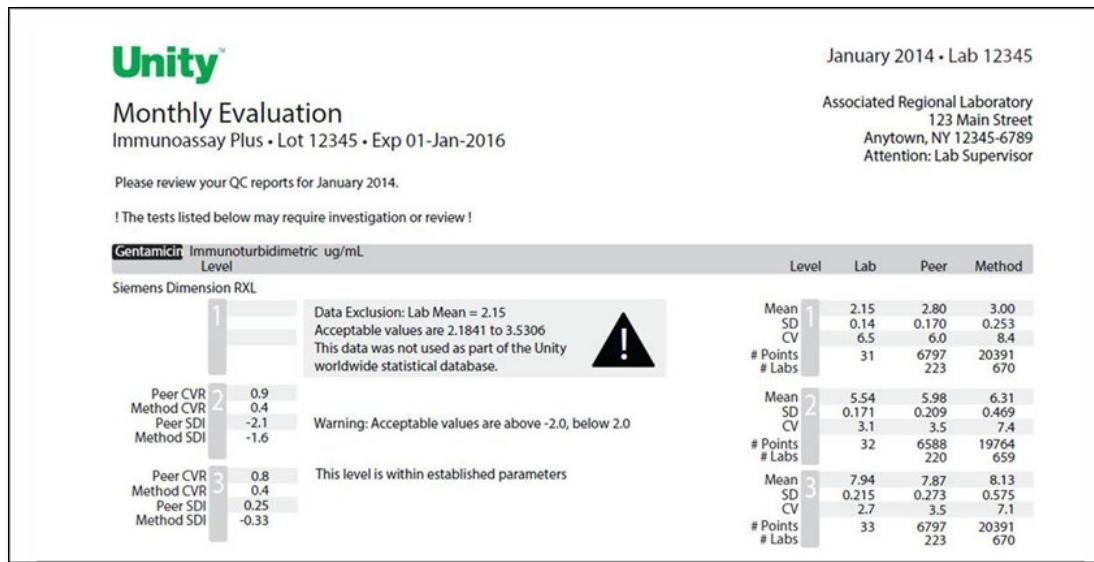
Rejection Limits for the CV

- 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.

Monthly Evaluation Report: Example



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

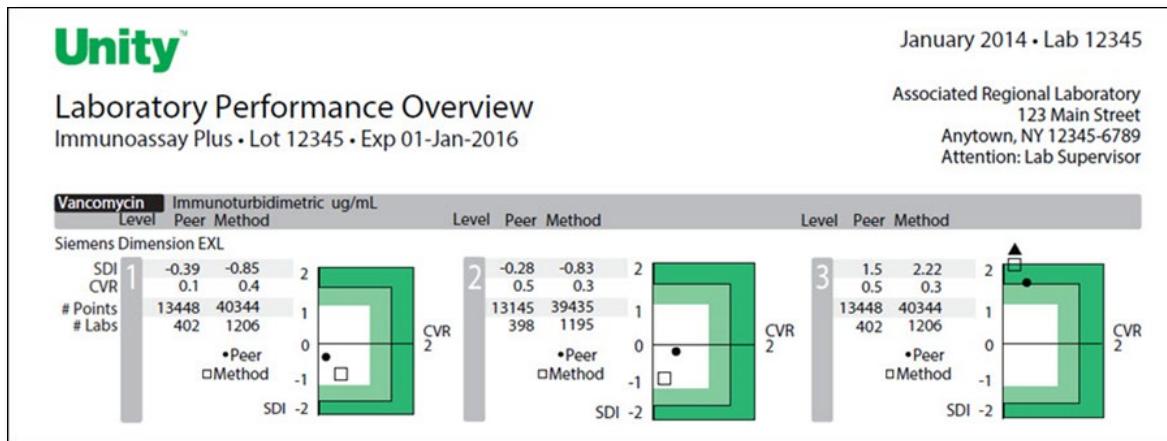
The SDI and CVR are combined as X-Y coordinates located within one of three performance zones shown by increased levels of shading:

Shading	Description
No shading	Acceptable performance.
Slight shading	Acceptable to marginal performance. 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 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.

Laboratory Performance Overview Report: Example



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 some analytes.

How to Use This Report

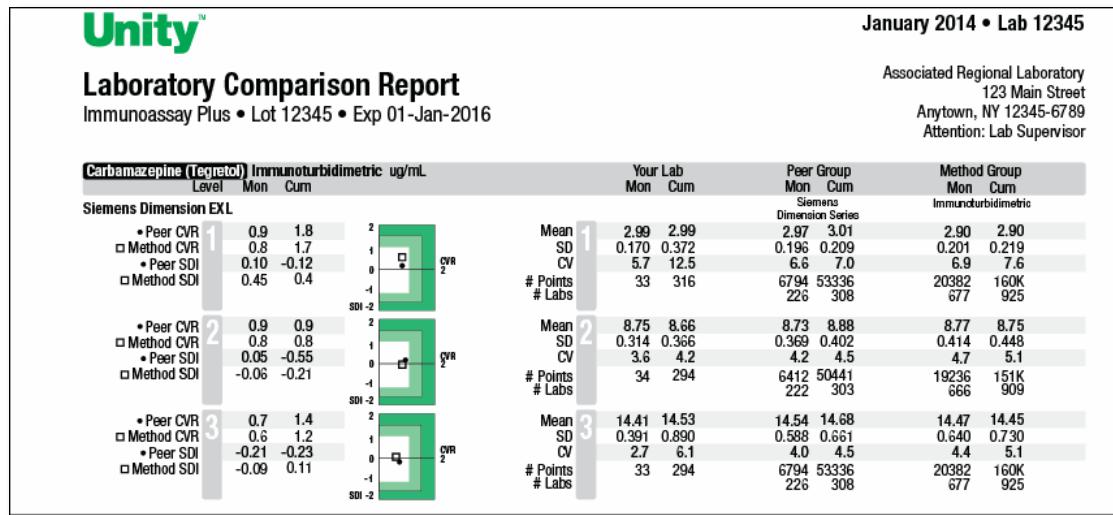
For each test, the report contains the following monthly and cumulative statistics:

- 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 reporting

Laboratory Comparison Report: Example



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

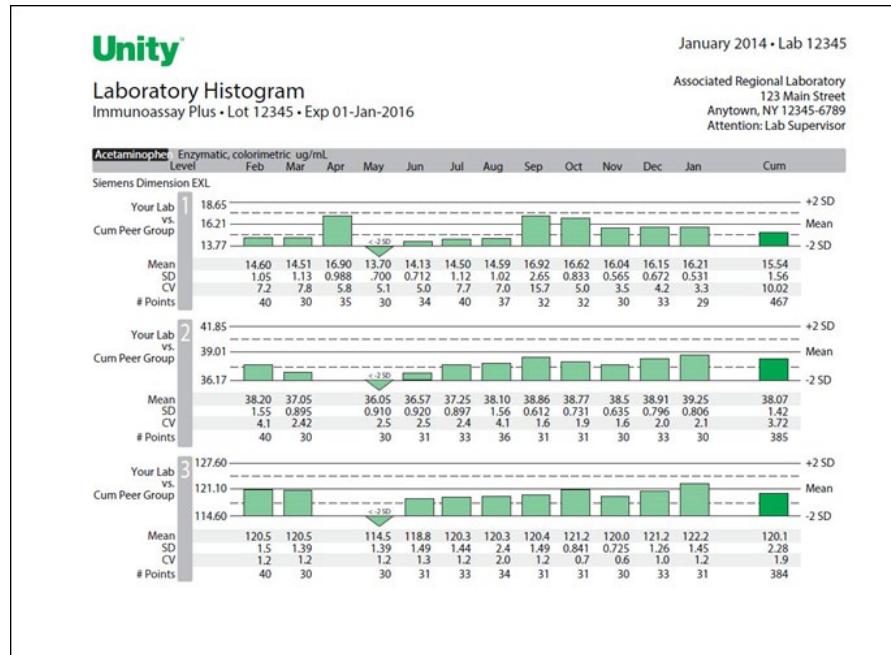
How to Use This Report

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 Monthly Evaluation Report.

Laboratory Histogram Report: Example



Statistical Profile 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.

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.

Summary Statistics—Example

Unity™ Statistical Profile		January 2014 • Lab 12345								Associated Regional Laboratory			
Calcium	Arsenazo III - VITROS	mg/dL	Level	Your Lab	Peer Group	Method Group	All Labs	Qtr	Year	Qtr	Year	Qtr	Year
Unassayed Chemistry • Lot 12345 • Exp 01-Jan-2016													
VITROS 5600 (Dry Slide) mg/dL • Slide generation #19					VITROS Microslide Series	Brom cresol Green (BCG)							
Lab 2s Range	1	7.80 - 8.14	7.79 - 8.16	Median	1	N/A	N/A	7.97	8.05	8.01	8.05	8.07	8.08
Lab 3s Range	1	7.71 - 8.22	7.69 - 8.26	Mean	1	7.97	7.98	7.98	8.04	8.01	8.05	8.10	8.11
				SD	1	0.08	0.09	0.14	0.21	0.16	0.18	0.21	0.22
				CV	1	1.06	1.18	1.71	2.66	2.03	2.19	2.60	2.75
				ILab Bias	1	N/A	N/A	0.16	0.82	0.59	0.88	1.67	1.61
				# Points	1	97	204	356	2096	19260	62940	193K	718K
				# Labs	1			6	20	216	236	859	880

Frequency Histograms

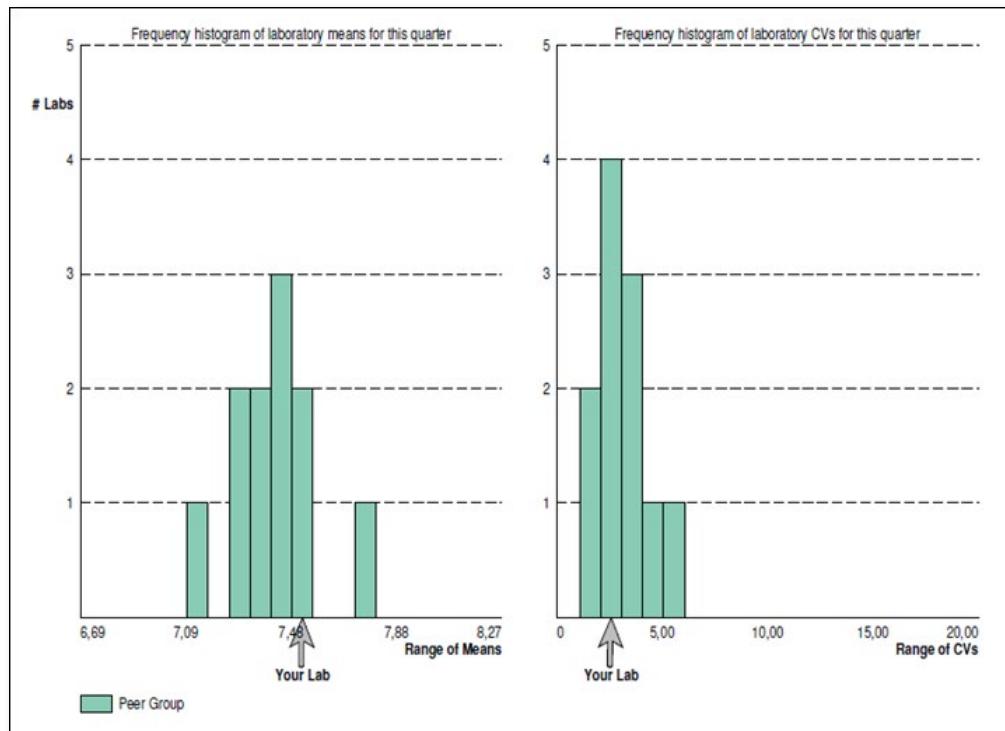
The frequency histogram section of the Statistical Profile Report contains two frequency histograms which show the location of:

- 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.

Frequency Histogram: Example

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. 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.



Percentile Distribution Table



Note: If reporting fewer than six data points during the quarter, your laboratory is not included in the Percentile Distribution Table.

The Percentile Distribution Table shows the laboratory distribution in percentiles for absolute bias, standard deviation (SD), and coefficient of variation (CV) for each consensus group (Peer, Method, and All Labs).

How to Use This Report

Compare the absolute bias, SD, or CV to the table to see your approximate position in the percentile distribution and find out how many laboratories have better or worse performance than your laboratory.

Percentile Distribution Table: Example

Percentile Distribution	10°		20°		30°		40°		Median 50°		60°		70°		80°		90°		95°	
	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year	Qtr	Year
Peer																				
Bias1	0.160	0.174	0.160	0.247	0.160	0.617	0.250	0.987	0.267	1.13	0.267	1.45	1.25	1.55	1.25	2.33	1.63	3.30	1.63	3.54
SD	0.070	0.000	0.070	0.049	0.070	0.062	0.080	0.069	0.082	0.094	0.082	0.100	0.084	0.112	0.084	0.143	0.093	0.148	0.093	0.150
CV	0.866	0.000	0.866	0.617	0.866	0.756	1.00	0.850	1.02	1.16	1.02	1.21	1.06	1.37	1.06	1.80	1.16	1.81	1.16	1.94
Method																				
Bias1	0.184	0.237	0.438	0.510	0.647	0.678	0.827	0.892	1.03	1.20	1.18	1.57	1.56	1.87	2.06	2.23	2.37	2.70	2.80	3.29
SD	0.061	0.066	0.071	0.074	0.077	0.081	0.082	0.087	0.087	0.095	0.093	0.103	0.104	0.113	0.121	0.131	0.149	0.163	0.196	0.187
CV	0.761	0.818	0.888	0.925	0.969	1.00	1.02	1.08	1.08	1.18	1.16	1.29	1.30	1.41	1.51	1.63	1.85	2.03	2.45	2.32
All Labs																				
Bias1	0.283	0.242	0.608	0.620	0.930	0.916	1.22	1.20	1.52	1.51	1.83	1.88	2.24	2.28	2.81	2.80	3.48	3.35	4.19	3.91
SD	0.074	0.078	0.085	0.091	0.094	0.104	0.104	0.115	0.115	0.128	0.126	0.140	0.138	0.153	0.156	0.169	0.190	0.201	0.216	0.244
CV	0.924	0.969	1.06	1.12	1.17	1.29	1.29	1.42	1.42	1.58	1.5	1.74	1.72	1.89	1.93	2.10	2.36	2.46	2.67	3.05

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.

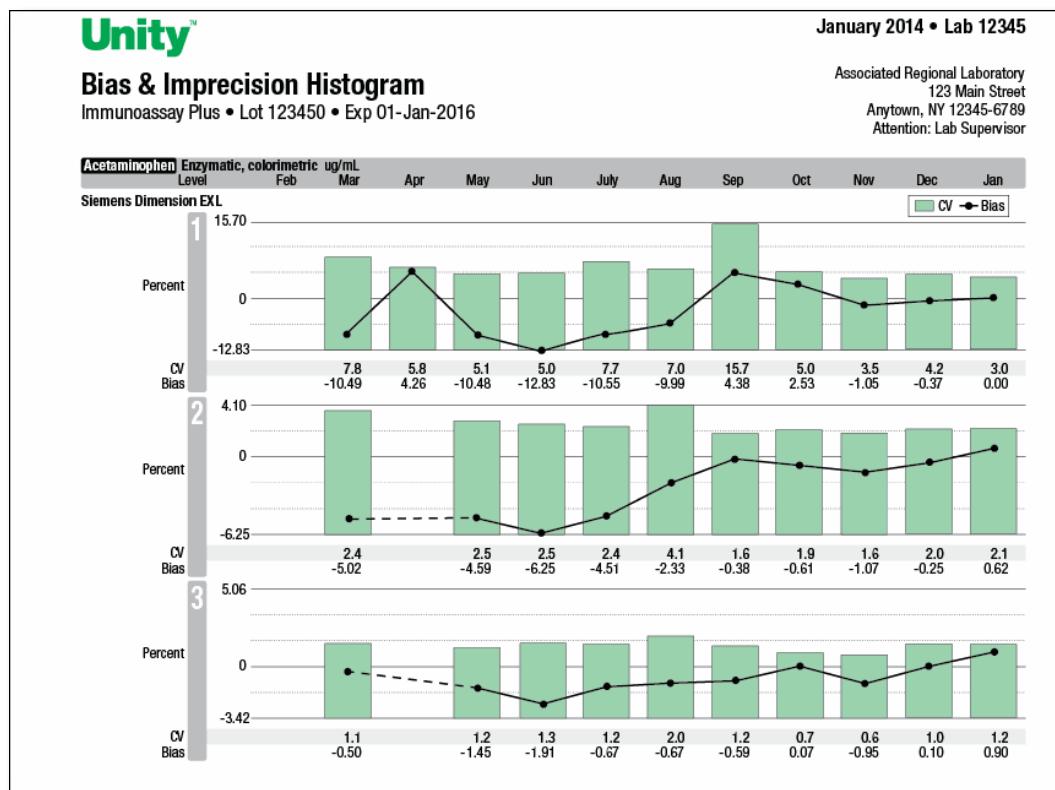
How to Use This Report

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 imprecision, bias, 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.

Bias and Imprecision Histogram Report: Example



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.

Worldwide Report: Example

Unity™											
January 2014											
Conventional Units											
Worldwide Report											
Multiquant 1, 2, 3 Unassayed • Lot 23456 • Exp 01-Jan-2016											
Albumin Brom cresol Purple (BCP) g/dL											
Level			Mon			Cum			Level		
Abbott AEROSET/ARCHITECT (c, i, ci models)			Level			Mon			Level		
Mean			2.40			3.39			3.93		
SD			0.032			0.050			0.169		
CV			1.3			2.1			4.3		
# Points			2346			48958			2270		
# Labs			43			67			42		
Beckman Coulter CX Series											
Mean			2.44			2.44			-		
SD			0.051			0.056			-		
CV			2.1			2.3			-		
# Points			88			7108			-		
# Labs			4			24			-		
Beckman Coulter LX20, LXi725, Chemistry Systems											
Mean			2.44			2.44			3.42		
SD			0.045			0.054			0.059		
CV			1.8			2.2			1.7		
# Points			436			16842			416		
# Labs			10			58			9		
BIO-RAD											

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.

Manufacturer Report: Example

Unity™												February 2014
												Conventional Units
Manufacturer Report for Abbott												
Multiqa 1,2,3 Unassayed • Lot 46520 • Exp 31-Mar-2016												
Acetaminophen Enzymatic, colorimetric µg/mL												
Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Abbott AEROSET/ARCHITECT (c, i, ci models)												
Mean	1	14.18	13.83	2	44.80	44.51	3	131.7	131.6			
SD		0.766	0.957		0.551	0.998		1.72	2.54			
CV		5.4	6.9		1.2	2.2		1.3	1.9			
# Points		65	468		57	335		64	468			
# Labs		3	7		2	5		3	7			
Albumin Bromcresol Green (BCG) g/dL												
Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Abbott AEROSET/ARCHITECT (c, i, ci models)												
Mean	1	2.52	2.54	2	3.95	3.96	3	4.00	4.01			
SD		0.038	0.043		0.035	0.048		0.039	0.054			
CV		1.5	1.7		1.0	1.4		1.0	1.3			
# Points		705	2482		638	2143		712	2484			
# Labs		9	11		7	8		9	11			
Albumin Bromcresol Purple (BCP) g/dL												
Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Abbott AEROSET/ARCHITECT (c, i, ci models)												
Mean	1	2.42	2.47	2	3.20	3.25	3	3.83	3.85			
SD		0.044	0.072		0.036	0.049		0.047	0.070			
CV		1.8	2.9		1.1	1.5		1.2	1.8			
# Points		303	1560		52	339		304	1563			
# Labs		11	16		2	4		11	16			
Alkaline Phosphatase PNPP, AMP Buffer U/L @ 37° C												
Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	Level	Mon	Cum	
Abbott AEROSET/ARCHITECT (c, i, ci models)												
Mean	1	35.88	35.80	2	141.2	142.3	3	324.2	325.2			
SD		2.06	2.01		4.15	4.63		6.45	6.78			
CV		5.7	5.6		2.9	3.3		2.0	2.1			
# Points		846	3567		513	1980		840	3571			
# Labs		20	27		9	12		20	27			

Affiliated Reports



Note: Affiliated Reports are optional. Contact the Bio-Rad QC Program Representatives to request Affiliated Reports.

Affiliated Reports allow a group of laboratories to compare results, essentially becoming their own consensus group. The Unity Interlaboratory Program provides the following Affiliated Reports:

- Affiliated Laboratory Comparison Report (this page)
- Affiliated Laboratory Comparison Report: Abbreviated Summary (page 299)
- Affiliated Data Exception Report (page 300)



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.

Affiliated Laboratory Comparison Report: Example

Unity

January 2014

Affiliated Laboratory Comparison Report

Unassayed Chemistry • Lot 12345 • Exp 01-Jan-2016

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

123456 Reference Laboratory		234567 Western Laboratory		456789 Eastern Laboratory	
123456 R&D Laboratory	345678 Central Laboratory	999999 Southern Laboratory			
* Lab data was not available for processing for the date listed. Consequently no reports were generated for this lab during the reporting cycle.					

Bilirubin, Direct/BC (mg/dL)

Level			Lab	Affiliated Group	Peer Group	Method Group	
Mon	Cum		Mon	Cum	Mon	Cum	
Roche MODULAR (ISE, D, P, E170)			Mean	0.301 0.301	0.302 0.301	0.300 0.306	0.294 0.292
123456 Reference Laboratory • Roche MODULAR			SD	0.010 0.015	0.015 0.012	0.017 0.025	0.065 0.065
○ Affiliated CVR 1 0.7 1.3	+ Peer CVR 0.6 0.7	□ Method CVR 0.2 0.2	CV	3.3 5.0	4.9 3.9	5.7 8.2	22.2 22.4
○ Affiliated SDI -0.08 0.06	+ Peer SDI -0.08 -0.08	□ Method SDI 0.10 0.13	Lab Bias	-0.23 0.00	0.23 -1.63	2.38 3.08	
○ Affiliated CVR 2 0.9 1.1	+ Peer CVR 0.7 0.9	□ Method CVR 0.3 0.3	# Points	99 821	183 1922	2459 35520	63934 447K
○ Affiliated SDI -0.22 -0.25	+ Peer SDI 0.27 -0.10	□ Method SDI 0.06 0.06	# Labs	2 3	32 54	619 1404	
○ Affiliated CVR 1 1.3 0.7	+ Peer CVR 1.1 0.4	□ Method CVR 0.3 0.1	Mean	0.874 0.868	0.884 0.880	0.862 0.884	0.863 0.856
○ Affiliated SDI 0.08 -0.02	+ Peer SDI 0.21 -0.12	□ Method SDI 0.14 0.12	SD	0.044 0.049	0.048 0.047	0.068 0.050	0.172 0.173
○ Affiliated CVR 2 1.0 1.0	+ Peer CVR 0.8 0.9	□ Method CVR 0.3 0.3	CV	5.1 5.6	5.4 5.4	6.8 5.6	19.9 20.2
○ Affiliated SDI 0.25 0.08	+ Peer SDI 0.78 0.18	□ Method SDI 0.19 0.15	Lab Bias	-1.18 1.26	2.58 -1.81	1.27 1.40	
○ Affiliated CVR 1 0.9 0.5	+ Peer CVR 0.2 0.2	□ Method CVR 0.13 -0.20	# Points	84 739	183 1922	2459 35520	63934 447K
○ Affiliated SDI 0.12 0.13	+ Peer SDI 0.55 -0.08	□ Method SDI 0.12 0.14	# Labs	2 3	32 54	619 1404	
○ Affiliated CVR 2 0.8 1.0	+ Peer CVR 0.3 0.3	□ Method CVR 0.12 0.14	Mean	0.896 0.884	0.884 0.880	0.862 0.884	0.863 0.856
○ Affiliated SDI 0.12 0.14	+ Peer SDI 0.55 -0.08	□ Method SDI 0.12 0.14	SD	0.050 0.048	0.048 0.047	0.068 0.050	0.172 0.173
○ Affiliated CVR 1 0.8 1.0	+ Peer CVR 0.3 0.3	□ Method CVR 0.12 0.14	CV	5.6 5.4	5.4 5.4	6.8 5.6	19.9 20.2
○ Affiliated SDI 0.12 0.14	+ Peer SDI 0.55 -0.08	□ Method SDI 0.12 0.14	Lab Bias	1.36 0.46	5.16 0	3.82 3.27	
○ Affiliated CVR 2 0.8 1.0	+ Peer CVR 0.3 0.3	□ Method CVR 0.12 0.14	# Points	85 738	184 1918	2398 33889	62348 436K
○ Affiliated SDI 0.12 0.14	+ Peer SDI 0.55 -0.08	□ Method SDI 0.12 0.14	# Labs	2 3	29 47	760 1209	

Affiliated Group: Roche MODULAR

Level			Lab	
Mon	Cum		Mon	
○ Peer CVR 1 0.9 0.5	+ Peer CVR 0.2 0.2	□ Method CVR 0.13 -0.20	Mean	0.304 0.300
○ Method CVR 0.2 0.2	+ Peer SDI 0.13 -0.20	□ Method SDI 0.12 0.13	SD	0.019 0.008
○ Peer SDI 0.13 -0.20	□ Method CVR 0.3 0.1	○ Method SDI 0.12 0.13	CV	6.2 2.7
○ Method SDI 0.12 0.13	○ Peer CVR 0.2 0.2	○ Peer SDI 0.13 -0.20	Lab Bias	0.68 -0.3
○ Peer CVR 2 0.8 1.0	+ Peer CVR 0.3 0.3	□ Method CVR 0.12 0.14	# Points	84 739
○ Method CVR 0.3 0.3	+ Peer SDI 0.55 -0.08	□ Method SDI 0.12 0.14	# Labs	2 3
○ Peer SDI 0.55 -0.08	○ Peer CVR 0.3 0.3	○ Method CVR 0.12 0.14	Mean	0.896 0.884
○ Method SDI 0.12 0.14	○ Peer SDI 0.55 -0.08	○ Method SDI 0.12 0.14	SD	0.050 0.048
○ Peer CVR 1 0.8 1.0	+ Peer CVR 0.3 0.3	○ Method CVR 0.12 0.14	CV	5.6 5.4
○ Method SDI 0.12 0.14	○ Peer SDI 0.55 -0.08	○ Method SDI 0.12 0.14	Lab Bias	1.36 0.46
○ Peer CVR 2 0.8 1.0	+ Peer CVR 0.3 0.3	○ Method CVR 0.12 0.14	# Points	85 738
○ Method SDI 0.12 0.14	○ Peer SDI 0.55 -0.08	○ Method SDI 0.12 0.14	# Labs	2 3

Univar Regression of Means

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 that 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.

Affiliated Laboratory Comparison Report: Abbreviated Summary: Example

Unity™		January 2014																																																																																																																																																																																																																																																																																																																		
Affiliated Laboratory Comparison Report: Abbreviated Summary																																																																																																																																																																																																																																																																																																																				
Unassayed Chemistry • Lot 12345 • Exp 01-Jan-2016																																																																																																																																																																																																																																																																																																																				
Associated Regional Laboratory 123 Main Street Anytown, NY 12345-6789 Attention: Lab Supervisor																																																																																																																																																																																																																																																																																																																				
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Albumin Brom cresol Green (BCG) g/dL <table border="1"> <thead> <tr> <th>Level</th> <th>Mean</th> <th>SD</th> <th>CV</th> <th># Points</th> <th>Affiliated CVR</th> <th>Peer SDI</th> <th>CVR</th> <th>Peer SDI</th> <th>Method O/R</th> <th>Method SDI</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>2.88</td> <td>0.085</td> <td>3.0</td> <td>1324 (4 Labs)</td> <td></td> <td></td> <td>1.11</td> <td>-0.91</td> <td>0.9</td> <td>-0.42</td> </tr> <tr> <td>Affiliated Group</td> <td>2.95</td> <td>0.078</td> <td>2.7</td> <td>6698 (45 Labs)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Peer Group</td> <td>2.93</td> <td>0.102</td> <td>3.5</td> <td>33164 (435 Labs)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Method Group</td> <td>2.90</td> <td>0.072</td> <td>2.5</td> <td>358</td> <td>0.8</td> <td>0.22</td> <td>0.9</td> <td>-0.67</td> <td>0.7</td> <td>-0.24</td> </tr> <tr> <td>123456 Reference Laboratory • Roche MODULAR</td> 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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.

Affiliated Data Exception Report: Example

Unity

Affiliated Data Exception Report

Unassayed Chemistry • Lot 12345 • Exp 01-Jan-2016

January 2014

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

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

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

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

Level	Mean	SD	CV	# Points	# Labs	Lab	Affiliated	Peer	Method
1	165.7	8.31	5.0	33	3	151.9	148.1	147.8	147.8
2	353.4	11.99	3.4	564	3	325.6	325.6	320.4	320.4
						15.25	15.25	17.48	17.48
						4.7	4.7	5.5	5.5
						5872	5872	10482	10482
						158	158	261	261

Siemens Dimension Series

123456 City Regional Hospital • Siemens Dimension EXL

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

Affiliated CVR 1 Peer CVR 0.8 Method CVR 0.6 Affiliated SDI 1.82 Peer SDI 2.37 Method SDI 1.89

23456789 Reference Lab • Siemens Dimension EXL

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

2 Data Exclusion: Lab Mean = 28.21
Acceptable values are 282.35 - 361.86
This data was not used as part of the Unity worldwide statistical database

!

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

Coding Rejections

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

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

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

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

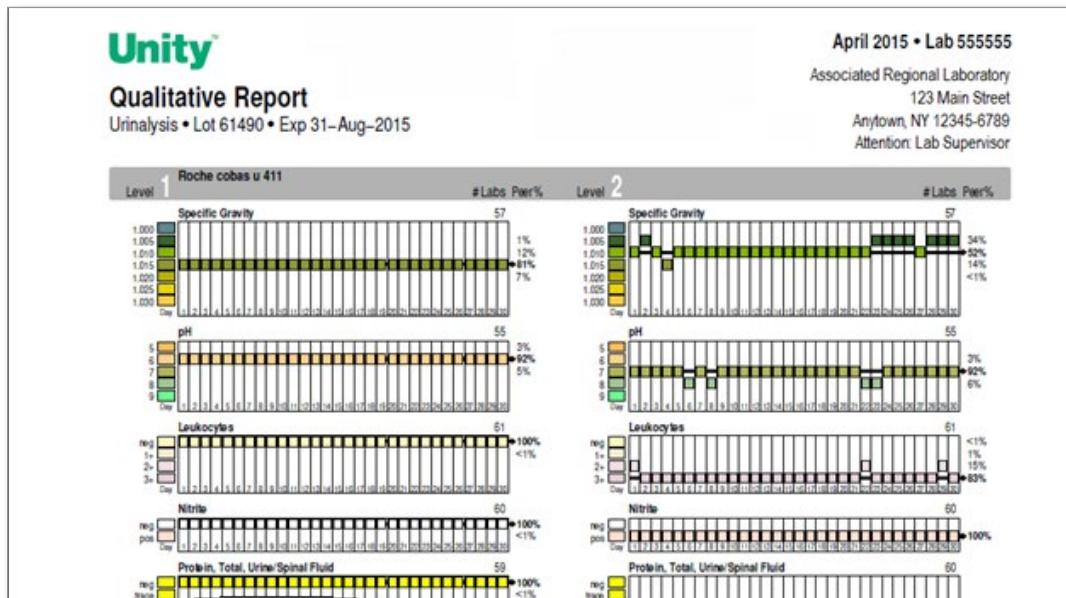
Qualitative Reports

Qualitative Urinalysis Report

Urine Chemistry Report

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

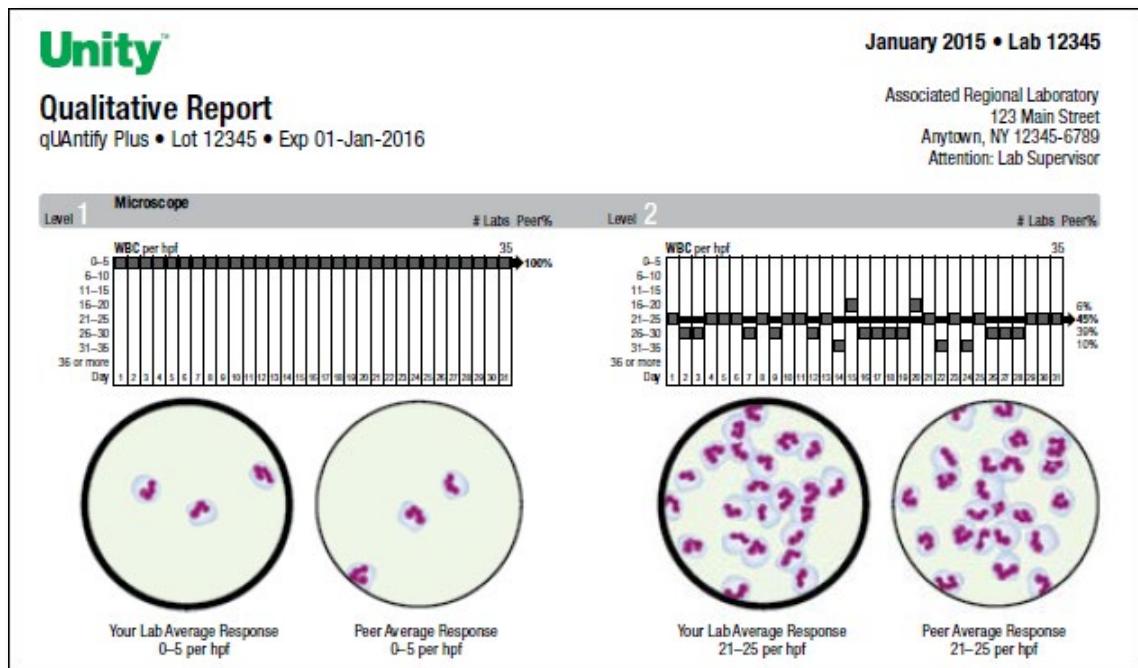
- Arrows identify the majority group response.
- Displays multiple responses per day.



Microscopic Report

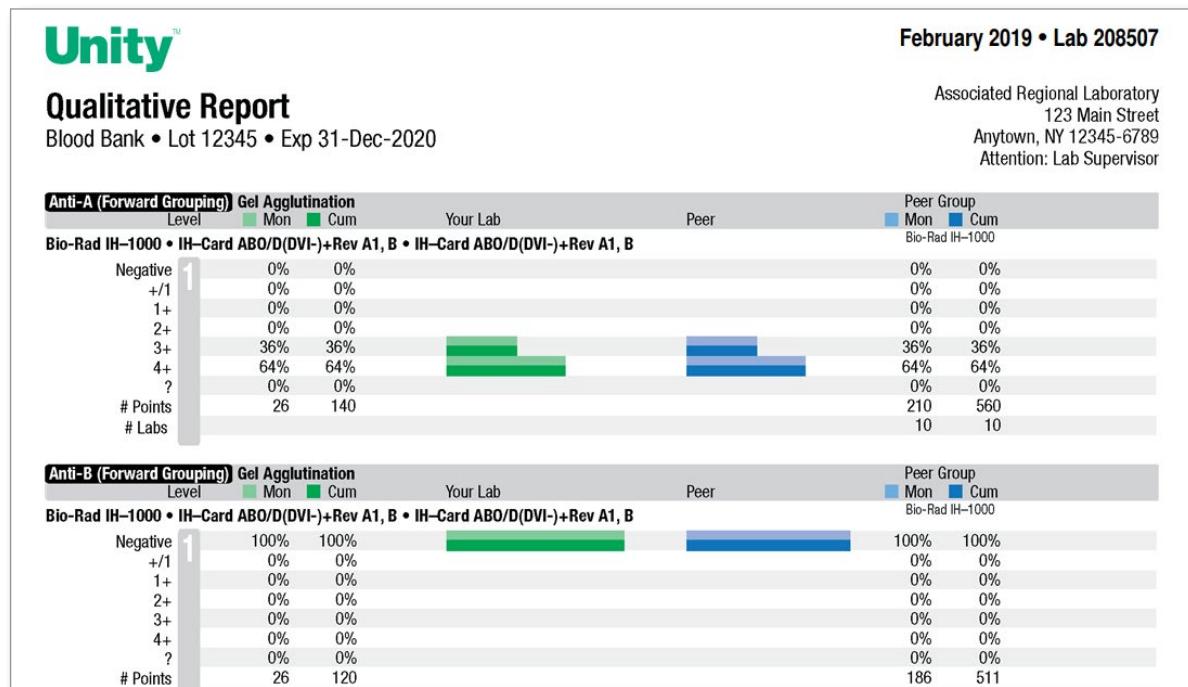
Graphics simulate your average response and the group's average response.

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



Qualitative Blood Typing/Serum Indices Reports

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



Qualitative Worldwide Report

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

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

InstantQC Reports



Note: When sending data to the Unity Interlaboratory Program, the InstantQC Reports are available on www.QCNet.com after a short processing time. See “InstantQC Reports” on page 305 for more information.

InstantQC Reports provide on-demand access to the latest Unity Interlaboratory Program statistics. These reports are particularly useful for troubleshooting issues with test system performance because of the rapid report turnaround times with up-to-the-minute peer group data.

InstantQC Reports are simply an early version of the Monthly Evaluation and Lab Comparison Reports. The only difference in the format of the InstantQC Reports compared to their counterparts is that they include the title “InstantQC Report.”

Advantages of InstantQC Reports

- InstantQC Reports are generated the moment they are requested by a user with the consensus group data available at the moment they are requested.
- InstantQC Reports do not require point data submission to view reports. All Unity Interlaboratory Program participants can generate InstantQC Reports for all open tests at any time, even if you have not yet submitted data for the selected period.
- The InstantQC Report design significantly improves report turnaround time.
- InstantQC Reports are generated in the same language you have defined for monthly Unity Interlab Reports. See “Configure Unity Interlaboratory Report Frequency and Language” on page 437 for more information.
- InstantQC Reports are available as Adobe Acrobat PDF files in a format similar to the monthly reports.

Comparison statistics shown:

- SDI (standard deviation index)
A measurement of your bias compared to your selected consensus group.
- CVR (coefficient of variation ratio)
Compares your laboratory’s precision to that of other laboratories in the consensus group.

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



Since InstantQC Reports are intended primarily for an interim review of test system performance, the reports are only provided for time periods up to the release of the standard monthly Unity Interlaboratory Program Reports. Always refer to your standard monthly reports when they become available (from My Reports). The monthly reports are more comprehensive, and the application of a deadline ensures that peer group sizes are maximized for regular, documented review of your test systems.

- 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 Interlab Reports**.
- 4 Click **InstantQC Reports**.
- 5 Make selections for the lab number, period, and lot number.

Regulatory Requirements and Reports

In This Chapter

Overview	307
CLIA Requirements.....	308
CAP Accreditation Requirements.....	312
ISO 15189 Requirements	322

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.

Unity Real Time also provides a variety of intralaboratory reports and charts to help meet regulatory requirements. See Chapter 13, “Unity Real Time Charts” and Chapter 14, “Unity Real Time 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.

Requirement: Have a record of test system performance.

- 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

Requirement: Monitor the accuracy of the analytical process.

- 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

CLIA Requirements (continued)

Requirement: Detect immediate errors.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Operator Report
 - Data Review Report
- InstantQC Reports

Requirement: Establish or verify the criteria for acceptability of all control materials.

- Intralaboratory Reports and Charts:
 - Levey-Jennings Chart
- Unity Interlaboratory Reports:
 - Monthly Evaluation Report
- InstantQC Reports

Requirement: Establish statistical parameters for each batch and lot number of control materials.

- Intralaboratory Reports and Charts:
 - Summary Data Report
 - Levey-Jennings Chart
- Unity Interlaboratory Reports:
 - Laboratory Comparison Report
 - Statistical Profile Report
- InstantQC Reports

Requirement: Document all control procedures performed.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Supervisor's Report
 - Levey-Jennings Chart

CLIA Requirements (continued)

Requirement: Document that at least once each day patient specimens are assayed or examined, test two control materials of different concentrations.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Summary Data Report
 - Levey-Jennings Chart

Requirement: 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.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report

Requirement: Evaluate and define the relationship between test results for the same analyte using different methodologies, instruments, or testing sites.

- Unity Interlaboratory Reports:
 - Affiliated Data Exception Report
 - Affiliated Laboratory Comparison Report

Requirement: Document all corrective actions taken as a result of QC.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Supervisor's Report
- Unity Interlaboratory Reports:
 - Monthly Evaluation Report

CLIA Requirements (continued)

Requirement: Document all analytic systems assessment activities.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Supervisor's Report
- Unity Interlaboratory Reports:
 - Monthly Evaluation Report
 - Laboratory Performance Overview
 - Laboratory Comparison Report
 - Laboratory Histogram Report
 - Bias and Imprecision Histogram
 - Statistical Profile Report

Requirement: Document that, over time, control material testing is rotated among all operators who perform the test.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Supervisor's Report
 - Levey-Jennings Chart

Requirement: Document that control material testing is performed after a complete change of reagent, major preventive maintenance, or when any critical part is replaced.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Supervisor's Report

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.

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 (continued)

Requirement: Use data to make changes to improve performance and patient safety.

- 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
 - 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

Requirement: For quantitative tests, document use of control materials at more than one concentration (level) at least daily.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Summary Data Report
 - Supervisor's Report
 - Data Review Report
 - Levey-Jennings Chart
- InstantQC Reports

CAP Accreditation Requirements (continued)

Requirement: For numeric QC data, document calculation of QC statistics at specified intervals to define analytic imprecision.

- Intralaboratory Reports and Charts:
 - Summary Data Report
- Unity Interlaboratory Reports:
 - Laboratory Comparison Report
 - Bias and Imprecision Histogram
 - Statistical Profile Report
 - Affiliated Laboratory Comparison Report
- InstantQC Reports

Requirement: Demonstrate that QC and instrument maintenance are performed and evaluated.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report
- Unity Interlaboratory Reports: Monthly Evaluation Report
- InstantQC Reports

Requirement: Document verification results of controls for acceptability before reporting patient test results.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report
 - Levey-Jennings Chart

CAP Accreditation Requirements (continued)

Requirement: For hematology, document testing of two different stabilized control specimens and record results during each 24 hours of analyzer use.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Summary Data Report
 - Supervisor's Report
 - Data Review Report
 - Levey-Jennings Chart
- InstantQC Reports

Requirement: If commercially assayed controls are used for hematology instruments, verify the target values (mean and QC ranges).

- Intralaboratory Reports and Charts:
 - Operator Report
- Unity Interlaboratory Reports:
 - Laboratory Comparison Report
 - Laboratory Histogram Report
 - Statistical Profile Report
- InstantQC Reports

Requirement: If unassayed controls are used in hematology, establish a statistically valid target mean and range for each lot by repetitive analysis.

- Intralaboratory Reports and Charts:
 - Operator Report
- Unity Interlaboratory Reports:
 - Laboratory Comparison Report
 - Laboratory Histogram Report
 - Statistical Profile Report
- InstantQC Reports

CAP Accreditation Requirements (continued)

Requirement: Fully define and document tolerance limits (numeric and nonnumeric) for all hematology and coagulation control procedures.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Summary Data Report
 - Supervisor's Report
 - Operator Report
 - Data Review Report
 - Levey-Jennings Chart
- InstantQC Reports

Requirement: Monitor precision data for significant changes.

- Intralaboratory Reports and Charts:
 - Levey-Jennings Chart
- Unity Interlaboratory Reports:
 - Monthly Evaluation Report
 - Laboratory Performance Overview
 - Laboratory Histogram Report
 - Bias and Imprecision Histogram
 - Affiliated Data Exception Report
 - Affiliated Laboratory Comparison Report
- InstantQC Reports

CAP Accreditation Requirements (continued)

Requirement: Document review and assessment of quality control data at least monthly.

- Intralaboratory Reports and Charts:
 - Summary Data Report
 - Supervisor's Report
 - Levey-Jennings Chart
- Unity Interlaboratory Reports:
 - 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

Requirement: Verify manufacturer's calibrations with control materials appropriate for the system.

- Intralaboratory Reports and Charts:
 - Data Review Report

Requirement: Document that the photo-optical coagulation testing system (for PT, aPTT, etc.) 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.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report

Requirement: 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.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report

CAP Accreditation Requirements (continued)

Requirement: Document ongoing evaluation of (QC) records, instrument maintenance and function, temperature, etc.

- Intralaboratory Reports and Charts:
 - Data Review Report
- Unity Interlaboratory Reports:
 - Monthly Evaluation Report
 - Laboratory Performance Overview
- InstantQC Reports

Requirement: Organize and present QC data so that it can be evaluated daily by the technical staff to detect problems, trends, etc.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Summary Data Report
 - Supervisor's Report
 - Levey-Jennings Chart
- InstantQC Reports

Requirement: 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.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report

Requirement: Document that control materials for pH, pCO₂, and pO₂ represent both high and low values on each day of patient testing.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report
 - Levey-Jennings Chart
- InstantQC Reports

CAP Accreditation Requirements (continued)

Requirement: 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.

- Intralaboratory Reports and Charts:
 - Point Data Report
 - Supervisor's Report
 - Data Review Report

Requirement: Document the review for acceptability of quality control results.

- 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
 - Laboratory Performance Overview
 - Bias and Imprecision Histogram

CAP Accreditation Requirements (continued)

Requirement: Collect and analyze pertinent data to monitor and assess 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
 - 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

CAP Accreditation Requirements (continued)

Requirement: Use data to identify unwanted trends.

- 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
 - 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

ISO 15189 Requirements

Requirement: The laboratory shall design internal quality control procedures that verify the attainment of the intended quality of results.

- 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
 - 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

ISO 15189 Requirements (continued)

Requirement: Provide staff members with clear and easily understood information on which to base technical and medical decisions.

- 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
 - 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

Requirement: The laboratory shall participate in an interlaboratory comparison program(s).

- 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

ISO 15189 Requirements (continued)

Requirement: The laboratory shall have a procedure to prevent the release of patient results in the event of quality control failure.

- Supervisor's Review
- Bench Review
- Supervisor's Report
- Levey-Jennings Chart

Requirement: Quality control data shall be reviewed at regular intervals to detect trends in examination performance.

- Intralaboratory Reports and Charts:
 - Data Review Report
 - Point Data Report
 - Summary Data Report
 - Statistical Report
 - Supervisor's Report
 - Operator Report
 - Levey-Jennings Chart
 - Multi- LJ Chart
 - Bar Chart
 - Youden Chart
 - Yundt Chart

Requirement: When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, the results shall be rejected and relevant patient samples re-examined after the error condition has been corrected.

- Analytical Goals
- Levey-Jennings Chart

Westgard Advisor

In This Chapter

Overview	325
Flowchart of the Westgard Advisor Process.....	327
Allowable Total Error (TE _a)	328
Preferences	331
View Lab Data and Group Statistics	333
Design QC Rules	334
View the Data Grid Tab	340
View OPSpecs Chart.....	341
View Sigma Metrics Chart.....	345
Advanced Tool.....	347
Westgard Advisor Report.....	348
Apply Rules with Westgard Advisor.....	349
Delete Historical Rules Suggestions.....	350

Overview

Westgard Advisor is an optional feature of Unity Real Time that identifies the tests that need improvement and the tests that routinely achieve the required quality. Westgard Advisor uses the following information to recommend statistical process control (SPC) rules and the number of control samples per run:

- A selected TE_a
- Lab data for the test
- A selected consensus group



Note: The consensus group can be a date range of the laboratory's data, a Unity Interlaboratory consensus group (Peer, Method, or All Labs), or a user-defined bias %.



Note: In order to view Unity consensus group data, make sure that the "Automatic analytical goals and peer group updates" option is selected in the Setup dialog box in Unity Real Time. With this setting, Unity Real Time prompts you to download the latest updates on a regular basis when logging in. See "Configure Database Updates" on page 433.

Using Westgard Advisor, it is possible to generate rules based on different combinations of these selections,

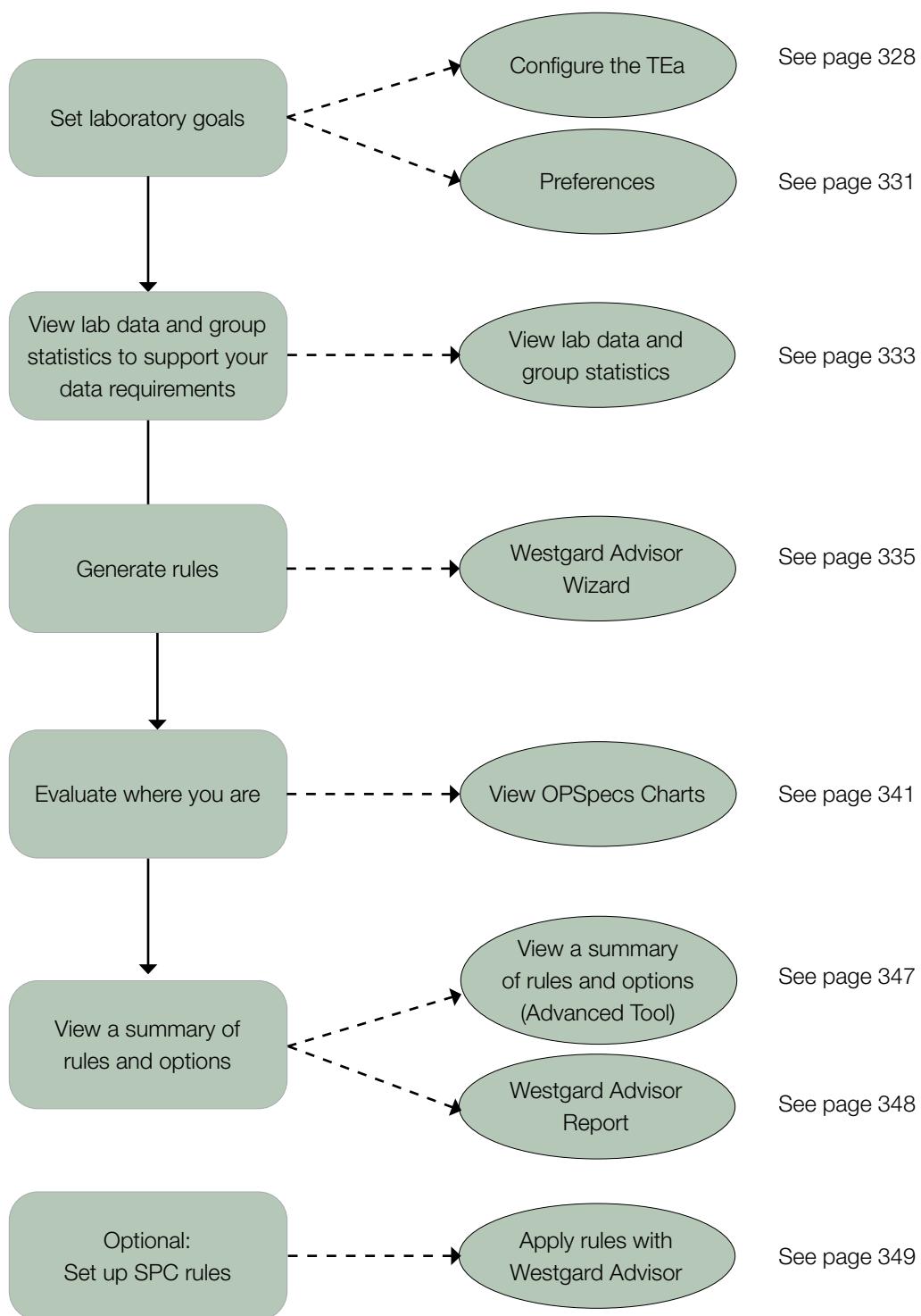
display the OPSpecs and Sigma Metrics charts, and apply the suggested SPC rules.

Westgard Advisor provides suggestions. However, if a method has poor performance, Westgard Advisor is not able to recommend a set of SPC rules that will solve performance problems. When no multi-rule meets the quality specification, Westgard Advisor reports a maximum QC condition and recommends all available multi-rules.



Note: The rules suggested by Westgard Advisor are recommendations only. Conditions in the laboratory may make some rules impossible to use.

Flowchart of the Westgard Advisor Process



Allowable Total Error (TE_a)

Before generating rules for a test, configure the quality requirements (allowable total error) for the test and specify the data requirements.

The TE_a tool in Westgard Advisor is the same as used in the Data Analysis Grid. If changes are made in either place, it affects the other tool.

Analytical goal rules can also be used to define TE_a settings. Be aware that while the Data Analysis Grid, Measurement Uncertainty, and Westgard Advisor cannot change the TE_a settings for analytical goal rules, analytical goal rules can be set up to overwrite the settings in this tool.



Note: Each analyte in the Unity Real Time database can only be assigned one TE_a selection. This is important to note for laboratories that share a database with another group. You will have to remember to verify the TE selections each time or the groups will need to come to an agreement on which settings to use.

Allowable Total Error (TE_a) Options

Westgard Advisor 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.

- 3SD
 - If CLIA does not have a published value and there are no published Biological Variation values, this will be the default selection.
-
- Note:** The ±3SD limits are based upon the group selected in the Consensus Group section. If the user intends to use actual data from your lab, select "This lab" as the Group.
- BV Des bias / Desirable imprecision
 - If CLIA does not have a published value, this will be the default selection.
 - BV Des bias / Min imprecision
 - BV Des bias / Op imprecision
 - BV Min bias / Des imprecision
 - BV Min bias / Min imprecision
 - BV Min bias / Opt imprecision
 - BV Opt bias / Des imprecision
 - BV Opt bias / Min imprecision
 - BV Opt bias / Op imprecision



Note: See “Performance Goals” on page 136 for more information regarding Biological Variation.

BV = Biological Variation

Min = Minimum

Op = Optimum

Des = Desirable

- CLIA
 - Typically, if CLIA has a published value, this will be the default selection.
- CLIA (2019)



Note: If CLIA is the default TE_a selection for a test, it will use the CLIA option. You will have to select CLIA 2019 if you want to use the latest published values.

- EMC (Especificaciones Minimas Consenso)
- GOST
- IPH Belgium
- IQMH
- Loosest
- QUALAB (no bias)
- RCPA
- RiliBÄK
- SEKK
- SKML uses two tolerance ranges:
 - SKML-SA is based on State of the Art.
 - SKML-TE is based on total error allowable defined by either clinical outcome or biological variation.



Note: The settings for individual determinators can be found on <https://www.skml.nl/en/home/schemes/reportings/skml-tolerance-ranges>



Note: For more information on SKML tolerance ranges and their relationship to SKML score, see <https://www.skml.nl/en/home/schemes/reportings/muse>

- State of the Art - no bias
- Tightest
- Turkey TE_a
- User Defined

- The default applies to all matrices
- Select the **Apply by Matrix** check box to enter a different TE_a% for each matrix (serum, urine, blood gas, etc.).
- WS/T (China)



Note: Only published values that are available for the selected analyte appear in the TE_a list.
Not all options are available for all tests.



Note: BV and country-specific options are only available when published.

Configure the Allowable Total Error (TE_a)



Note: The TE_a option in the Westgard Advisor is synchronized with the TE_a selected in the Data Analysis Grid, and the Measurement Uncertainty Report. Be aware that the TE_a selections made in the Analytical Goals tool can be set to overwrite the selections in the Data Analysis Grid, Measurement Uncertainty Report and Westgard Advisor.



You must have the “Configure TEa” permission to perform this function.

- 1 Click the **Advisors** menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

- 2 Click the **Configure TEa** tab.

All quantitative analytes in the Unity Real Time database appear in the list with the current TE_a selection.



Note: The analytes available in the list are only analytes that have been configured for the lot that was chosen. If a particular analyte does not appear in the list, you must select a lot that contains the analyte or add the analyte to the selected lot.

- 3 Select the analyte in the **Analyte** list you want to configure.

- 4 Click the arrow in the **TEa** field to view the available TE_a options for the analyte.



Tip: Only published values that are available for the selected analyte appear in the TE_a list.

- 5 Select the TE_a option from the list.

- 6 **Optional:** Click **For All Analytes** if you want to apply the selected TE_a to all analytes.

- 7 Select the group from the **Consensus Group** list (if applicable).



Note: Only the 3SD and State of the Art options utilize the Consensus Group section. If the listed result for CLIA or RCPA is an absolute value, they will also be calculated based on the Consensus Group section. “This lab” (your own target) is the best option for these options in particular.

- 8 Select the range from the **Group Data Range** list.
- 9 Click **For All Analytes** if you want to apply the consensus group settings to all tests.
- 10 Click **Save** when you are finished making your selections.
- 11 Click  (red x) in the upper right corner to close the **Westgard Advisor** dialog box.



Note: Westgard Advisor uses the TE_a selections when generating rules with the Wizard or the Advanced method.

Preferences

Data Requirements



Important: Westgard Advisor will not generate rules for a test until the minimum data requirements are met.



Tip: You can select the existing rules and then click the **Lab Data** tab on the **Existing QC Rules** dialog box to view the current number of points for a test when configuring the data requirements. The information that appears in the lower pane pertains to the test selected in the upper pane.

Westgard Advisor provides a default set of data requirements to use for suggesting rules; however, you can customize the data requirements as described in this section.

- 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 333 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 a Test” on page 103 for more information.

Customize Data Requirements

- 1 Click the **Advisors** menu and then click **Westgard**.
The **Westgard Advisor** dialog box appears.
- 2 Click the **Preferences** tab.
- 3 Enter the minimum number of points in the **Minimum number of lab data points** field. This is the number of data points that must be entered in the software before Westgard Advisor can begin generating rules for a test.
- 4 Enter the minimum number of consensus group points in the **Minimum number of consensus group data points** field. This is the number of consensus group points that must be entered in the software before Westgard Advisor can begin generating rules for a test.
- 5 Enter the minimum number of labs in the **Minimum number of consensus group labs** field. This is the number of consensus group labs that must participate in the Unity Interlaboratory Program consensus group before Westgard Advisor can begin generating rules for a test.
- 6 Click **Save**.

Grid Display Options

You can use the Grid Display Options to determine the information that appears on the grid on the **Design QC Rules** dialog box and the **Existing QC Rules** dialog box. The software provides a default set of options; however, you can customize the Grid Display options.

- 1 Click the **Advisors** menu and then click **Westgard**.
The **Westgard Advisor** dialog box appears.
- 2 Click the **Preferences** tab.
- 3 Select the check box for each item you want to appear on the **Design QC Rules** grid and the **Existing QC Rules** grid:
 - Method
 - Instrument
 - Reagent
 - Unit
 - Temperature

4 Select the check box for each item you want to appear on the **Design QC Rules** grid:

- TEa selection
- Sigma
- N
- Detection Level
- False Rejections



Tip: Click **Set Defaults** if you want to return to the default settings.

5 Click **Save**.

View Existing QC Rules

1 Click the Advisors menu and then click **Westgard**.

The **Westgard** Advisor dialog box appears.

2 Click the **Existing QC Rules** tab.

The **Existing QC Rules** shows the rules currently applied.

3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to view existing rules.

View Lab Data and Group Statistics

1 Click the Advisors menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

2 Click the **Existing QC Rules** tab.

3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to view lab data and group statistics.

4 Click the **Lab Data** tab.

5 Select a test to view the following information available each calendar month, by level for the selected lab number, lot number, and test.

- Mean
- Coefficient of variation (CV)
- Number of points

- 6 Click the **Group Statistics** tab to view the following information for your laboratory's cumulative data and the available consensus groups:
 - Your laboratory's cumulative data:
 - Mean
 - CV
 - Bias %
 - Number of points
 - Number of labs

Design QC Rules

There are three methods for generating SPC rules with Westgard Advisor:

1 Westgard Advisor Wizard

Westgard Advisor guides you through the process by presenting a series of dialog boxes from which you select options.



Tip: The Westgard Advisor 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.

2 Advanced option

Westgard Advisor displays a single dialog box for selecting all options.



Tip: This advanced option is a good choice when familiar with Westgard Advisor since this option does not provide any explanatory text.

3 Defaults

Westgard Advisor generates rules based on its default options. The default selections are:

- Peer consensus group
- 6-months (date range for data)



Note: You cannot make changes to the options when using the default method.

Consensus Groups

Westgard Advisor uses consensus groups from the Unity Interlaboratory Program to calculate performance estimates.



Note: Westgard Advisor cannot generate rules for a test if there are no 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 the same lot number, level, units, and temperature of a test.

Generate Rules with the Westgard Advisor Wizard

- 1 Click the **Advisors** menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

- 2 Click the **Design QC Rules** tab.

- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to generate rules.

- 4 Click **Generate Rules**.

The **Configure Rule Selection** dialog box appears.

- 5 Select the **Wizard** option and click **OK**.

The **Configure Rule Selection Wizard – Step 1 of 4** dialog box appears with the following message:

How many control measurements (N) would you like to select per run?

You can define the number of control measurements per run using the Automatic Selection or Manual Selection option. Automatic Selection will pick the number of control measurements for you.

6 Select the number of control measurements (N) you want to select per run:

- Automatic Selection

Select this option if you want the software to select the number of control measurements (levels) used per run for you.

- Manual Selection

Select this option if you want to manually enter the number of control measurements used per run.



Tip: This does not define what levels should be used in each run but rather how many measurements per run. For example: If the software suggests six measurements per run, that could be levels 1, 2, and 3 two times or be levels 1 and 3 three times.

7 Click **Next**.

The **Configure Rule Selection Wizard – Step 2 of 4** dialog box appears.



Note: Westgard Advisor will use all available data by default.

8 Click the arrow in the **First Date** field and select the 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 range of laboratory data that reflects the performance you expect to achieve in the future. See “View Lab Data and Group Statistics” on page 333 to review data collected in the software and find an appropriate date range to use.

9 Click the arrow in the **Last Date** field and select the ending date for the range of data.

10 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?

QC Rules are suggested by analyte. If you are testing more than one level of control, a single level must be selected to compute performance estimates for the analyte.

Use by Level if you want to specify a specific level to use. You must specify the level to use.

Use by Performance if you want the Westgard Advisor to evaluate performance statistics from all available levels for each analyte and choose the level with the Highest Total Error (resulting in conservative settings) or Lowest Total Error (resulting in optimistic settings).

11 Select a **Lot Selection** option:

- **By Level**

Select this option to specify a control level to use for the calculations and then select the level from the **By Level** list. The level selected is used for all tests in the selected lot.

- **By Performance**

Select this option for Westgard Advisor to evaluate performance statistics from all available levels for each analyte and select an option for the performance:

- Use level with lowest Total Error (results in optimistic settings)
- Use level with highest Total Error (results in conservative settings)

12 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 you select a consensus group for comparison. If you wish to omit bias from the performance estimates, select This Lab. Otherwise, select either Peer, Method, or All Labs for the appropriate comparison to your consensus group.

The Peer group includes other laboratories using equivalent instruments, methods and reagents to your laboratory. The Method group includes other laboratories using equivalent test methods to your laboratory. The All Labs group includes all laboratories testing the same analyte.

You may also select the Group Data Range. Monthly will use the last month's group data. 6 Months will use the last 6 months' group data. And cumulative will use the cumulative group data.

To help you select the appropriate Group and Group Data Range, you may check the Group Statistics option within Westgard Advisor to verify the integrity of the statistics and the number of participants within your selected option.

13 Select an option for the consensus group.

- This Lab (no bias)

- Peer

- Method

- All Labs

- User Defined

This option can be used to set a specific bias % and it can also be used when working with non-Bio-Rad controls that are set up in Unity Real Time.

- Lab Group Selection

This option can be used to define a customized consensus group based on a combination of the laboratory's lab numbers and a selected date range.

14 User Defined only:

- a) Click **Configure Bias**.
- b) Enter the bias % for each test.
- c) Click **OK**.
- d) Go to step 16.

5 Lab Group Selection only:

- a) Click **Select Lab/Instrument**.
- b) Use the check boxes to select all or specific lab numbers or instruments to include in the statistics.
- c) Select a date range.
- d) Click **OK**.
- e) Go to step 16.

6 Select an option for the Group Data Range.

- Monthly
- 6 Months
- Cumulative

7 Click **Finish**.

The suggested rules and related information appears.

Generate Rules with the Advanced Option

1 Click the **Advisors** menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

2 Click the **Design QC Rules** tab.**3** Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to generate rules.**4** Click **Generate Rules**.

The **Configure Rule Selection** dialog box appears.

5 Select the **Advanced** option and click **OK**.

Measurements Per Run: See page 336.

Lab Data Range: See page 336.

Lot Selection: See page 337.

By Level: See page 337.

Group: See page 337.

Group Data Range: See page 338.

Click **OK**.

Generate Rules with the Westgard Advisor Defaults



Note: You cannot make changes to any options when using the default method.

- 1 Click the **Advisors** menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

- 2 Click the **Design QC Rules** tab.

- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to generate rules.

- 4 Click **Generate Rules**.

The **Configure Rule Selection** dialog box appears.

- 5 Select the **Use Defaults** option and click **OK**.

- Peer Group
- 6 month statistics
- Level with the smallest TEa (optimistic)

The suggested rules and related information appears.



Note: See the following sections to better understand the rules suggestions:

- “View OPSpecs Chart” on page 341
- “View Sigma Metrics Chart” on page 345
- “Advanced Tool” on page 347

View the Data Grid Tab

- 1 Click the **Advisors** menu and then click **Westgard**.
The **Westgard Advisor** dialog box appears.
- 2 Click the **Design QC Rules** tab.
- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to view the Data Grid.
- 4 Select the rule suggestion you want to see from the list at the top of the page.
- 5 Click the **Data Grid** tab.

The following information is provided for each test:

- Level used for comparisons
- TE_a
- Bias
- CV
- Sigma
- Existing rules that are currently in use
- Rules suggested by Westgard Advisor
- N (control sample per run)



Note: N represents how many control samples or measurements should be run in order to meet the quality specification. If you used the Wizard or Advanced option for Westgard Advisor to suggest how many samples to use, it may suggest as many as eight samples per run. You can decide what levels to use. For Example: If the software suggests six samples or measurements per run, that can be levels 1, 2, and 3 two times, or be levels 1 and 3 three times.



Note: The rules and N (control samples per run) are recommendations only. Conditions in the laboratory may make some rules impossible to use.

View OPSpecs Chart

The OPSpecs Chart (operational process specifications) 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.

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 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.

1 Click the **Advisors** menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

2 Click the **Design QC Rules** tab.

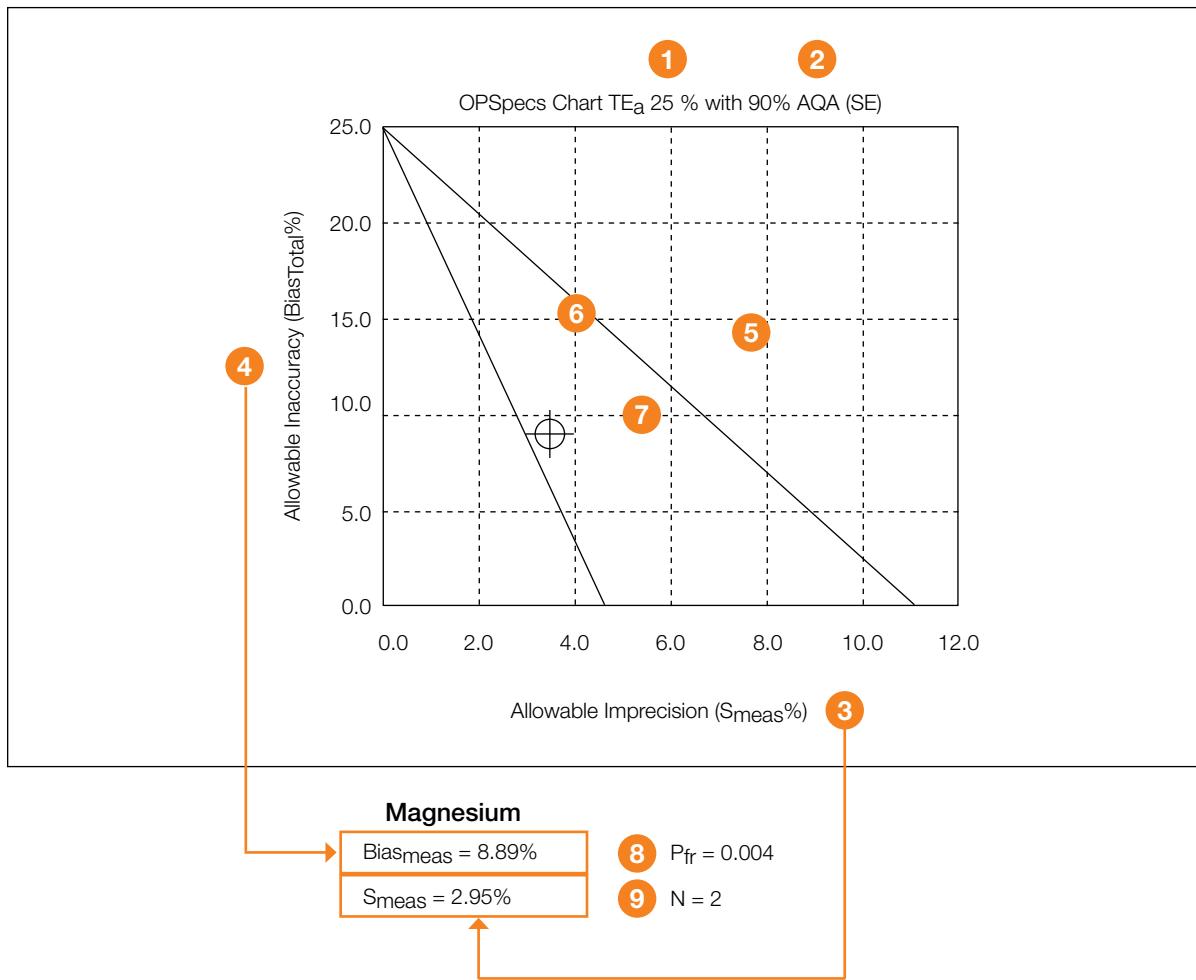
3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want the OPSpecs chart.

4 Select the rules suggestion you want to see from the list located at the top of the window.

5 Click the **Data Charts** tab.

6 Click the **OPSpecs Chart** tab.

OPSpecs Chart Components



1 TE_a

Allowable total error. The quality requirement for the test. The TE_a is 25% in the previous example.

2 AQA (SE)

Analytical quality assurance for systematic error. The percentage of error detection. 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). The goal is always 90%. The AQA is 90% in the previous example.

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. The value for the imprecision is shown in the legend in the lower left corner. The allowable inaccuracy (Biasmeas) is 8.89% in the previous example.

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 previous example). This line and the displayed suggested QC rules are calculated based on the selections you made with the Wizard, Advanced, or Default selection. 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.

8 P_{fr}

The probability of false rejection is the probability of rejecting an analytical run when there are no errors except for the inherent imprecision of the measurement procedure. Inherent imprecision refers to the random error of the method under stable operation. Ideally, the probability of false rejection should be 0.00. The P_{fr} is 0.004 in the previous example.

9 N

The number of control measurements per run that is necessary to monitor and assure the desired test quality.

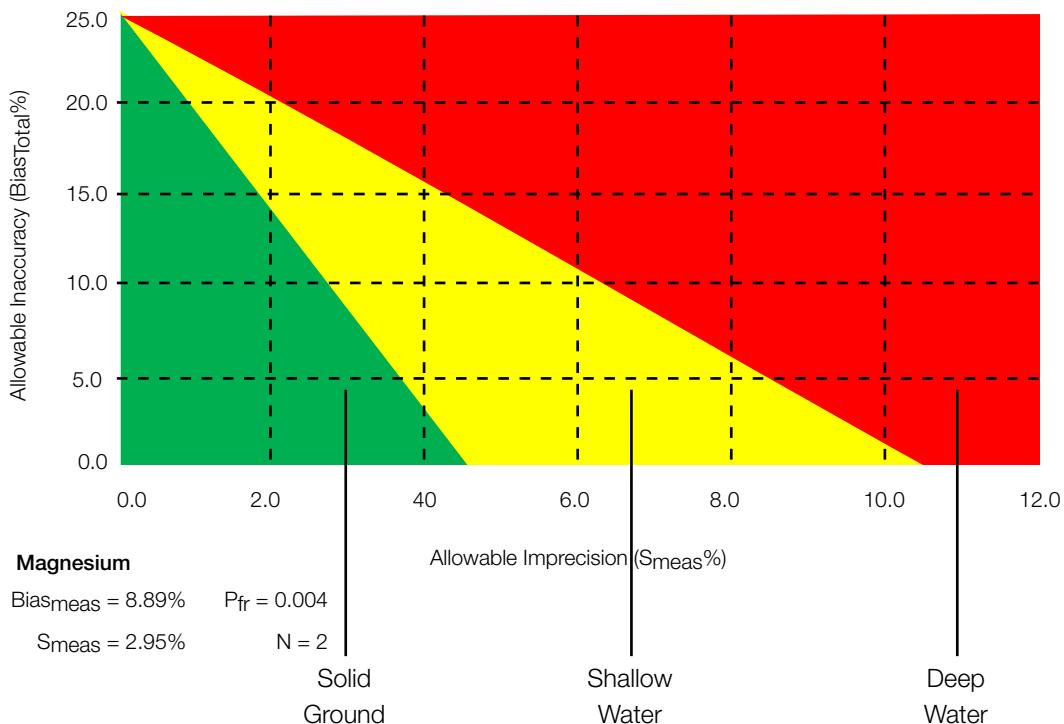
An OPSpecs Chart shows the operational limits for bias and imprecision for the specified candidate QC procedure at either 90%, 50%, or 25% analytical quality assurance (AQA or error detection).

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 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 will most likely recommend a maximum QC procedure.

When Westgard Advisor 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 25% 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.

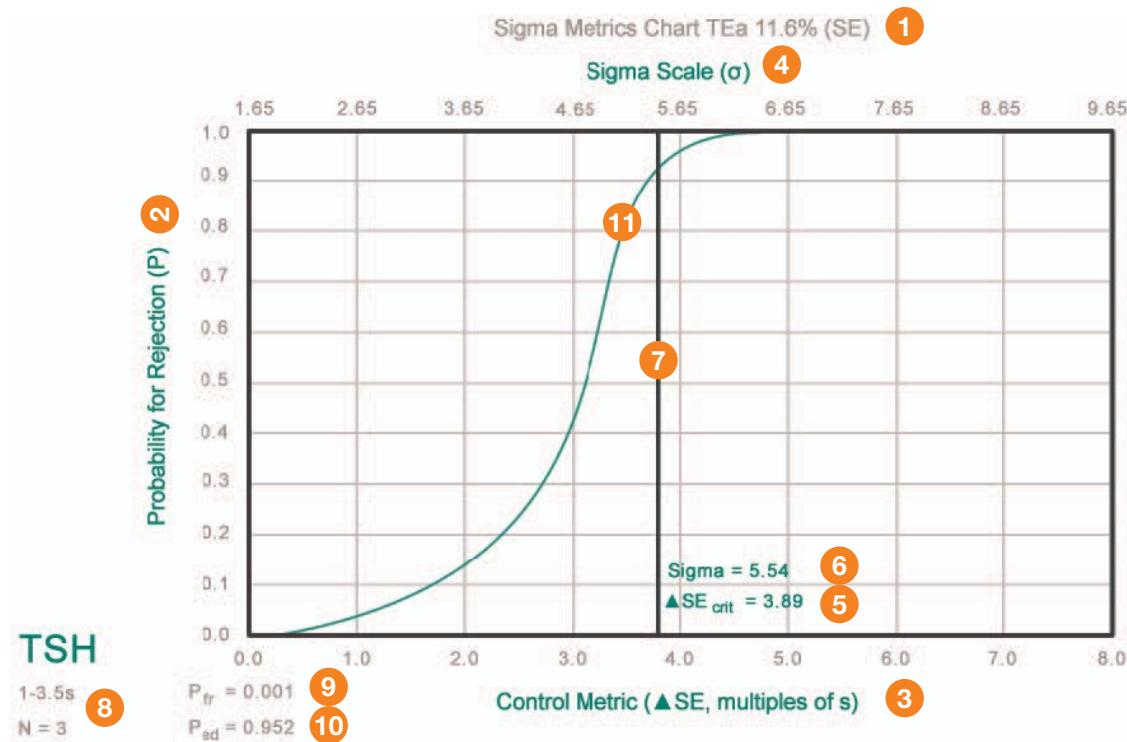
View Sigma Metrics Chart

The Sigma Metrics Graph is an evolution of power function graphs and critical error graphs. The Sigma Metrics Graph shows the potential capability of achieving or satisfying the stated quality requirement. In routine operation, the actual achievement of this quality is assured by applying the proper QC procedure.

Sigma Metrics provide a universal benchmark for process performance. The performance of all processes can be characterized on the Sigma scale. Values typically range from 2 to 6, where the goal for “world class quality” is 6. The bold vertical line displays the Sigma Metric of a test and the key on the right of the graph details the different SPC rules from Westgard Advisor that will detect nearly every critical error. If the Sigma Metric is less than 3, the process is so unreliable it should not be used for routine production. A process with a low Sigma Metric costs time and effort to maintain.

- 1 Click the **Advisors** menu and then click **Westgard**.
The **Westgard Advisor** dialog box appears.
- 2 Click the **Design QC Rules** tab.
- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to view Sigma Metrics.
- 4 Select the rule suggestion you want to view from the list at the top of the page.
- 5 Click the **Charts** tab.
- 6 Click the **Sigma Metrics** tab.

Components of a Sigma Metrics Chart



- 1** TEa
Allowable total error. In the example above, the TE_a is 11.6%.
- 2** (P)
Probability for rejection.
- 3** Control Metric
The critical systematic error (the minimum size of systematic errors that can be detected with 90% accuracy). This is determined by Sigma - 1.65.
- 4** Sigma Scale
The upper horizontal axis (x-axis) is the Sigma scale.
- 5** Critical Systematic Error (SE_{crit})
The SE_{crit} is 3.89 in the example above.
- 6** Sigma (σ)
The Sigma is 5.54 in the example above.
- 7** Sigma metric line
The vertical line drawn from the control metric (critical systematic error) to the Sigma.
- 8** Recommended rules and number of control (samples [levels]) per run.
The recommended rules are 1-3.5s and the number of control runs is 3 in the example above.

- 9** Probability of false rejection (P_{fr})
Ideally, the lower this value is the better. The P_{fr} is 0.001 in the previous example.
- 10** Probability of error detection (P_{ed})
Ideally this should be above 90%. The P_{ed} is 0.952 in the previous example.
- 11** Power curve
A power curve is selected using the recommended rules, the recommended number of control runs, the calculated probability of false rejections, and the calculated probability of error detection.
The power curve begins at the P_{fr} value on the y-axis, then crosses the Sigma metric line at the P_{ed} value.

Advanced Tool

The Advanced tool generates an OPSpecs chart side-by-side with a Sigma Metrics chart for rules that have previously been generated. This is very helpful for evaluating a set of rules. You can also select other tests, change the TE_a , Bias%, and/or the CV.

- 1 Click the **Advisors** menu and then click **Westgard**.
The **Westgard Advisor** dialog box appears.
- 2 Click the **Design QC Rules** tab.
- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you have previously generated rules and for which you want to view the OPSpecs chart and Sigma Metrics chart side-by-side.
- 4 Click **Advanced**.
The Advanced window opens.
- 5 To select another test, use the drop-down feature or the **Previous** and **Next** buttons to move from one test to another.
- 6 To change N, check or uncheck the check boxes and select the number of samples per run that you would like the calculations to be based on. Click **Recalculate** to update the page.
- 7 To change TE_a , Bias%, or CV, type over the current values with the ones you would like to use. Click **Recalculate** to update the page.
- 8 View charts based on selected rules: The first Rule Suggestion in the list is based on calculations from the displayed values. Click the row for a different Rule Suggestion to see how the charts, N, Ped, P_{fr} , and Detection levels are affected. This can help you determine the amount of risk you are willing to accept based on the rules you decide to use.
- 9 Apply rule selections: Confirm that the N, TE_a , Bias%, and CV are the desired values. Click the row for the Suggested Rule that you want to use. Click **Apply Rules**. A confirmation window will appear. Click **OK**.
- 10 Print: Select the appropriate test. Click the row for the Suggested Rule that you want to use. Click **Print**. Remove the check mark from any of the following that you do not want to include:

- Data Grid
- OPSpecs Chart
- Sigma Metrics

Click **Save/Print**. Select where to save the file and click **Save** or print the report.

Westgard Advisor Report

The Westgard Advisor Report summarizes the options used each time SPC rules are generated with Westgard Advisor. The Westgard Advisor Report shows the information from the **Grid** and **Chart** options of the **Design QC Rules** dialog box. You can print the report to document the selected rules.

- 1 Click the **Advisors** menu and then click **Westgard**.
The **Westgard Advisor** dialog box appears.
- 2 Click the **Design QC Rules** tab.
- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to generate the report.
- 4 Click **Print**.
The **Print Report** dialog box appears.
- 5 Select an option for the range of tests to print:
 - **Current Test**
Select this option to print the report for the selected test.
 - **Current Lot**
Select this option to print the report for all tests in the lot number.
- 6 Select each check box for the information you want to include in the report:
 - Data Grid
 - OPSpecs Chart
 - Sigma Metrics
- 7 Click **Save/Print**.
The **Save As** dialog box appears.
- 8 Navigate to the location where you want to save the report and click **Save** or print the report.
The Westgard Advisor Report is saved in PDF format.

Apply Rules with Westgard Advisor

After Westgard Advisor generates rules, the recommendations appear in the **Suggested Rules** column on the **Design QC Rules** dialog box.

WA generates only rejection rule suggestions. It does not suggest any rules for warnings. If applied, any existing rules will be overwritten or removed based on the suggest rules.

Apply Rules

- 1 Click the **Advisors** menu and then click **Westgard**.

The **Westgard Advisor** dialog box appears.

- 2 Click the **Design QC Rules** tab.

- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot to which you want to apply rules.

- 4 Make sure the **Data Grid** tab is selected.

- 5 Select the rule suggestion at the top of the dialog box you want to apply.

The **Data Grid** tab updates with the statistics, existing rules, suggested rules, and performance information for each analyte.

- 6 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.

Clear the check box or click **Select None** (located at the bottom of the page) to clear all check boxes. A cleared check box indicates there will not be any rules applied.



Note: If Westgard Advisor 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. The check box cannot be selected if no rules are available.

- 7 Click **Apply Rules**.

The **Apply Rules** dialog box appears.

- 8 Select an option to apply the rules:

- Selected Analytes for Highlighted Lot Number
- Highlighted and Selected Analyte Only

- 9 Click **OK**.

- 10 Repeat steps 4–8 to make additional changes based on other rule suggestions, as needed.



Note: You may decide to set rules for some analytes based on one set of rule suggestions and other tests off of other rule suggestions.

- 12 The new rule selection(s) appear on the **Rules** tab of the **Rules/Settings** dialog box and Unity Real Time evaluates new data points against the rules. See “Chapter 9: SPC Rules and Analytical Goals” on page 125 for more information about the Rules tab.

Delete Historical Rules Suggestions

Rules suggestions are saved each time SPC rules are generated using Westgard Advisor. You can delete the suggestions if they are no longer needed.



Note: Deleting rules suggestions does not delete any applied rules.

- 1 Click the **Advisors** menu and then click **Westgard**.
The Westgard Advisor dialog box appears.
- 2 Click the **Design QC Rules** tab.
- 3 Use the navigation tree in the **Westgard Advisor** dialog box to select the lab and lot for which you want to delete rules suggestions.
- 4 Select the rule suggestions you want to delete.
- 5 Click the right mouse button and then click **Delete Rules**.
A message appears asking for confirmation.
- 6 Click **OK**.

Using RiliBÄK

In This Chapter

Overview	351
RiliBÄK Permissions	355
Getting Started with RiliBÄK	356
Add RiliBÄK Tests.....	356
RiliBÄK Settings.....	358
Enter Data	361
Charts	363
RiliBÄK Reports.....	365

Overview

The Unity Real Time RiliBÄK protocol is based on the “Directive of the German Medical Association on the Quality Assurance Medical Laboratory Tests.” This guideline became effective December 23, 2019 and replaces the version from 2014.

The RiliBÄK directive regulates the quality assurance of medical laboratory tests as part of medical care for laboratories within Germany. The guideline consists of Part A and Part B. Part A consists of general requirements and is mandatory for all medical laboratory tests. Part B consists of additional specific requirements that apply to stipulated tests.



Important: The requirements for quality management according to Part A and Part B of the new directive must be in place within 24 months after the directive went into effect on December 23, 2019.

Part A

Part A contains general requirements for all medical laboratory tests and consists of the following sections:

- Scope
- Objective
- Terminology (including control cycle, root mean square of the error of measurement, etc.)
- Structure (legal identification of the institution and organization)
- Resources (management, personnel, accommodations, and environmental conditions and equipment)
- Medical laboratory examinations (pre-analytic, medical laboratory test procedures, and post analytic)
- Quality management system (quality management manual, document control, resolution of complaints, examinations by referral laboratories, and non-conformities)
- Internal and external quality assurance

Part B

Part B consists of internal and external quality control requirements for medical laboratory tests.

Part B1 defines the minimum requirements for quality assurance of quantitative results. If a test is performed on multiple instruments, internal quality assurance must be performed for each instrument. All analytes (except new Table B1a analytes from version 2019) listed in Table B1 a-d must also follow external quality control requirements (not covered in this guide).



Note: Erythrocyte sedimentation rate testing, cell counting chamber, and pH-dipsticks are not included in this guideline.

Analytes Listed in Table B1

There are 84 analytes listed in Table B1. The table consists of three parts:

- Part B1a
Consists of plasma, serum, and whole blood analytes.
- Part B1b
Consists of ten urinalysis analytes.
- Part B1c
Consists of seven cerebral spinal fluid (CSF) analytes.
- Part B1d
Consists of 4 dry blood analytes.

The table consists of six columns.

- Columns 1 and 2
Indicates the analyte and sequence number.
- Columns 3 and 4
Used for internal quality assurance.
 - Column 3 describes the deviation of the data point respective to the root mean square of the error of measurement.
 - Column 4 contains the validity range, which affects the use of column 3.
- Columns 5 and 6
Pertain to external quality assurance which describes the allowed relative deviation and the target value for the test.

Although there are only 114 analytes currently listed in Table B1, all analytes are covered under the guideline. Therefore, there are two modes of testing:

- 1 Analytes that are part of Table B1.
- 2 Analytes that are not part of Table B1.

Internal Quality Control Requirements

All analytes must follow internal quality control requirements. The internal quality control requirements consist of the standard evaluation of individual control results and retrospective evaluation after completing a control cycle.

The RiliBÄK directive dictates that control samples must be:

- Run at least twice every 24 hours (and within 16 hours for the latest sample) on days that patient samples are analyzed. Also, a control sample must be run after each instrument intervention such as a restart, recalibration, repair, maintenance, lot change, etc.
- As similar as possible to the patient sample to be measured.
- Different from the calibrator material.
- In the relevant medical decision limit ranges.
- Used alternately and in a minimum of two different concentrations (depending on availability).

Part B dictates that the evaluation of individual control results be based on one of the following:

- The limits of permissible error as listed in Table B1, column 3.
- The laboratory's internal limits of permissible error.
- The ranges published by the control manufacturer.

If an individual result exceeds the limits of permissible error, patient results cannot be released while the cause of the error is being investigated. Based on an assessment of the medical relevance, an administrator must decide:

- If the patient value will be released.
- If a rerun of previous tests (including the control) is required.
- If the result recipients must be informed in reference to results that have already been released.



Important: The complete process must be documented.

Part B requires a retrospective evaluation after the completion of a control cycle. A control cycle is generally defined as one calendar month. If less than 15 values are available within this period, the cycle can be extended for an additional month until 15 values are available.



Important: A control cycle cannot exceed three months.

Based upon the control results constituting a control cycle, the relative root mean square of the error of measurement must be calculated immediately upon the completion of a control cycle. For analytes listed in Table B1, this value must not exceed the limits of permissible error as listed in Table B1, column 3.



Note: The relative root mean square of the error of measurement is shown as "Delta Rel" on the Data Entry dialog box in Unity Real Time.

Analytes Not Listed on Table B1

For analytes not listed in Table B1, the laboratory must calculate its own limits of permissible error using the root mean square of the error of measurement calculation stipulated in requirement 2.1.4 in Part B. The internal limits of permissible error calculated must be within the manufacturer ranges. For lots used fewer than 12 weeks, the control manufacturer ranges can be used.



Note: Unity Real Time calculates the internal limits of permissible error automatically for analytes not listed in Table B1, column 3. The permissible error is shown as "Delta Max Rel" on the Data Entry dialog box in Unity Real Time.

If a control cycle exceeds the limits of permissible error, patient results cannot be released while the cause of the error is investigated. If the subsequent control cycle exceeds permissible error limits, the responsible federal authorities must be informed according to MPSV §2.



Important: The complete process must be documented.

Laboratories must follow the manufacturer's instructions on quality control for point-of-care testing.

For infrequently run tests with fewer than 15 control values in three months, it is necessary to analyze two control samples of different concentrations (when available) every day patient test results are analyzed. For Table B1 analytes, the allowed deviation of column 3 needs to be used. For Non Table B1 analytes, the manufacturer control limits are valid. There is no need to retrospectively assess the cycle.

RiliBÄK Permissions

Unity Real Time uses three permissions to control access to RiliBÄK functions:

- Start LIME/Release data
Users with this permission can manually start a LIME cycle at any time and can release data entry for a test that has been locked following two consecutive failed control cycles.
- Disable LIME and cycles (POCT)
Users with this permission can select and clear the following check boxes on the Settings tab of the RiliBÄK Settings dialog box:
 - Disable LIME
 - Disable cyclic accuracy and precision
 - Point-of-care testing (disable both LIME and control cycles)
- Close cycles manually
Users with this permission can manually close a control cycle that contains at least 15 accepted, first-in-series data points.

Set Up RiliBÄK Permissions



You must have the “Manage users” permission to perform this function.

- 1 Click the **Tools** menu, point to **Security**, and then click **Administrator**.
- 2 Select the user from the **User ID** list.
- 3 Select the check box or option for each RiliBÄK permission you want to apply to the user.

 **Tip:** Select the **Administrator** check box if you want to give the user access to all available software functions. See “User Permissions” on page 71 for a description of permissions.
- 4 Click **OK**.

Getting Started with RiliBÄK

Perform the following tasks before you enter data:

- 1 Add a lab number—see Chapter 6, “Labs and Lots” for more information.
- 2 Add lot numbers—see Chapter 6, “Labs and Lots” for more information.
- 3 Add tests—see “Add RiliBÄK Tests” (this page) for more information.

Add RiliBÄK Tests



Important: You must select all parameters for a test (analyte, instrument reagent, method, unit, temperature) for the test to be evaluated according to the RiliBÄK guidelines. The standard settings for the test appear if all parameters are not selected.

- 1 Select the lot in the Lab navigation tree you want to add a test to.
- 2 Use one of the following methods to open the **Test** dialog box:
 - Click  located on the toolbar.
 - Click the **Select** menu and then click **Test**.
 - Press F3 on the keyboard.
- 3 Select an option to display the list of valid analytes for the lot:
 - Complete list
Contains all analytes for the lot available in the code list.
 - Filtered list
Contains a list of the most common analytes for the lot.
- 4 Select the analyte from the **Analyte** list.
- 5 Select the instrument/kit from the **Instrument/Kit** list.
- 6 Select the 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 a Bio-Rad QC Program Representative.
 - Alternate calibration
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 the 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 the Bio-Rad QC Program Representatives to have codes added to the code list.

- 7 **VITROS instruments only:** Enter the VITROS slide generation number in the **VITROS slide generation number** field.
- 8 Select the method for the test from the **Method** list. Select “Qualitative” if the test is qualitative (for example, dipstick urinalysis tests).
- 9 Select the unit of measure from the **Unit of measure** list.
- 10 Select the temperature from the **Temperature** list.



Note: The temperature applies to enzymes only. No temperature is automatically selected and cannot be changed for all other analytes.

- The message “Analyte is on the RiliBÄK table” appears on the upper right side of the dialog box.
- The **Apply RiliBÄK schema to this test?** Check box is automatically selected.



Important: Do not clear the check box. The test will not be set up and evaluated according to RiliBÄK guidelines.

- 11 Click **Add**.

The test is added and appears in the **Open test** list.

The **RiliBÄK Settings** dialog box appears.

- 12 Enter the necessary information in the **RiliBÄK Settings** dialog box.



Note: The RiliBÄK settings are described below.

- 13 Click **OK**.



Note: For analytes not listed in Table B1 of the RiliBÄK guideline, the examination of the laboratory internal error limits automatically begins when you enter the first value.

RiliBÄK Settings

The RiliBÄK Settings dialog box automatically appears when you add a new test and apply the RiliBÄK guidelines to a test.



Tip: You can also click  on the toolbar to open the RiliBÄK Settings dialog box.

Use the RiliBÄK Settings dialog box to configure the following:

- RiliBÄK Target Value and Deviation (page 358)
- Settings (page 358)

Unity Real Time contains all information from Table B1, including the maximum allowed deviation converted into all current units. Therefore, you only need to enter target values to begin evaluation of measurement values based on the RiliBÄK guidelines.

All other quantitative analytes will be evaluated against the lowest and highest allowed deviation. These values are located on the data sheet of the control manufacturer.

RiliBÄK Target Value and Deviation



Important: Make sure all data entry dialog boxes are closed. You cannot make any changes in the RiliBÄK Settings dialog box if a data entry dialog box is open.

The RiliBÄK Settings dialog box automatically appears when you add a new test and apply the RiliBÄK guidelines to a test.

Analyte Listed on Table B1

Unity Real Time automatically determines if the analyte is listed on Table B1 and the matrix (serum, urine, etc.).



Note: The message “Analyte is not on the RiliBÄK table” appears on the upper right side of the Test dialog box if the analyte is not on the RiliBÄK table. See “Analytes Not Listed on Table B1” on page 354 for more information.

Enter the target value from the insert of the control material in the **Target value** field.

Unity Real Time verifies if the concentration of the analyte is in range according to Table B1, column 4. You are not required to enter any additional information.

The following information is shown:

- The acceptable relative deviation (calculated from the control manufacturer limits in %).
- The lower limit of the control (from the data sheet of the control manufacturer).
- The upper limit of the control (from the data sheet of the control manufacturer).
- The examination criteria (single value examination follows regarding the laboratory internal error limits).



Note: The single value examination with the control manufacturer ranges continues until the finish of the examination of the laboratory internal error limits.

Analytes Not Listed on Table B1

If the analyte is not listed on Table B1 or the concentration (target value) is outside of the range according to Table B1, column 4, you are prompted to do one of the following. This allows you to evaluate a test with the RiliBÄK guidelines even though the limits are not defined by the German Medical Association.

- Use Table B1, column 3 (if available)
- Enter the following values of the control from the manufacturer's control insert:
 - Target value
 - Lower limit of the control
 - Upper limit of the control



Important: You must enter the target value. You cannot close the RiliBÄK Settings dialog box until you enter the target value and, if required, the lower limit of the control and the upper limit of the control.



Note: Bio-Rad recommends recalculating the values in absolute figures if the percentage details of the maximum allowed deviation are available.

Perform the following steps if an analyte/matrix combination does not appear on Table B1.

- 1 Enter the target value from the insert of the control material in the **Target value** field.
- 2 Enter the lower limit of the control from the data sheet of the control manufacturer in the **Lower limit of the control** field.
- 3 Enter the upper limit of the control from the data sheet of the control manufacturer in the **Upper limit of the control** field.
- 4 Repeat steps 1–3 as needed for all levels.

The control cycle is automatically calculated and validated.



Note: Bio-Rad recommends using the values from the control manufacturer to recalculate the lower and upper limits even if only the percentage of maximum allowed deviation is provided.

The following information is shown:

- The acceptable relative deviation (calculated from the control manufacturer limits in %).



Note: If the maximum allowed deviation value is a percentage, Bio-Rad recommends using the values from the control manufacturer to recalculate to absolute value.



Note: The single value examination follows until the finish of the examination of the laboratory internal error limits regarding the details of the control manufacturer (upper and lower limits).

- The lower limit of the control (from the data sheet of the control manufacturer).
- The upper limit of the control (from the data sheet of the control manufacturer).
- The examination criteria (single value examination regarding the laboratory internal error limits).



Note: You can change a target value only with the actual date. A retrospective change of the date and examination of the measurement value is not possible.

Settings



Important: Make sure all data entry dialog boxes are closed. You cannot make any changes in the **RiliBÄK Settings** dialog box if a data entry dialog box is open.

You can select test settings to specify the following information:

- Levels in use

All available levels in use for the control are selected by default. Clear the appropriate Levels in use check box if you do not run a particular level.



Tip: Any level not in use is omitted from the Data Entry dialog boxes. This simplifies data entry.

- Number of decimal places

The default decimal places for each level is 2. Select the number (0 to 4) for each level.



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

- Disabled functions

- Disable LIME

You can disable the laboratory internal error limits calculation (LIME) and the cycle calculation. This is intended for infrequently run tests (fewer than 15 values in three months) or tests within 12 weeks of expiration.

- Disable cyclus

You can disable the laboratory internal error limits calculation (LIME) and the cycle calculation. This is intended for infrequently run tests (fewer than 15 values in three months) or tests within 12 weeks of expiration.

- Point-of-care test (disable LIME and cyclus)

Enter Data

The Data Entry dialog box consists of two areas:

- Data entry grid
- Control cycle screen

Data Entry Grid

The data entry grid shows the following:

- The information at the top of the screen shows the lab number, lot number and name, system (matrix), analyte information, and the lot expiration date.
- The data entry grid consists of rows and columns where you manually enter data. Imported data also appears here. The data entry grid also shows the run numbers, the accepted/rejected status (Y/N), the percent deviation, and other information such as actions and comments, if any.
- Statistics section that displays the LIME, target value, and cycle details.

Control Cycle Screen

Click the **Control Cycle** tab to view the statistical calculation and examination of control cycles. You can also type comments. The screen includes the number of points, mean, SD, and CV for the cycles and the relative Delta (Delta Rel %) and relative Delta Max (Delta Max %) calculated values.

RiliBÄK Evaluation of Individual Results

Unity Real Time calculates the maximum allowed range for the assessment of individual results based upon any of the following:

- Published value in Table B1, column 3
- The calculation of laboratory error limits
- The specifications of the control manufacturer

Regardless of the limits used, Unity Real Time shows the allowed range, the deviation (%), and the target value on the Data Entry dialog box.

- If the analyte is listed on Table B1 for the appropriate matrix and the target value is within the range listed in column 4, the data is evaluated per the specifications in column 3.
- If the analyte is listed on Table B1 for the appropriate matrix, but the target value is outside of the range listed in column 4, the data is either evaluated per the specifications in column 3 or per the internal laboratory error limits. This option is determined on the RiliBÄK Settings dialog box when the test is set up.
- If the analyte is not listed on Table B1, the data is evaluated per the internal laboratory error limits.



Note: During the period which the laboratory internal error limits are being established, the control manufacturer limits will be used. These limits are entered in the RiliBÄK Settings dialog box when you set up a test if you are not using the values in Table B1, column 3.

If an individual result is outside of acceptable limits, the value is flagged and an action must be added. You can select a predefined action or you can type a custom action. You can also add a comment in the C (Comment) column.

Calculation of Internal Laboratory Error Limits

In the case where the laboratory elects to calculate internal laboratory error limits (LIME), Unity Real Time automatically calculates these limits using the first data point from each day for 15 days. The 15 day period can be extended up to the end of the control cycle in the case where the value exceeds the manufacturer's published limits.

The LIME status field on the Data Entry dialog box indicates the progress of the internal laboratory error limits calculation. Pass indicates that the calculation is currently within the manufacturer control limits and fail means it is not. The LIME pass/fail status is provided after there are seven accepted measurement values on seven different days. The LIME status is updated with the addition of each value until the LIME calculation is complete. The LIME status provides an early indication that the LIME may not pass.

If a completed LIME fails, a new LIME is automatically started. If a completed LIME passes, the value is used for subsequent evaluation of individual results as well as for the cycle assessment. After a LIME passes, Unity Real Time updates the Judgement field on the Data Entry dialog box to indicate that the individual result evaluation switches from using the control manufacturer ranges to the laboratory internal error limits (LIME).



Note: There are two Unity Real Time reports available to view the laboratory internal error limits. See “Create a Cyclus Report” on page 367 and “Create a LIME Report” on page 370.

Assessment of Control Cycles

The Status field on the Data Entry dialog box indicates the progress of the current cycle.

- Pass = the relative Delta (Delta Rel %) is currently less than or equal to the relative Delta Max (Delta Max %).
- Fail = exceeds the relative Delta Max (Delta Max %).

The pass/fail status is provided after there are 10 accepted measurement values. The cycle status is updated with the addition of each value until the cycle is complete. The cycle status provides an early indication that a cycle may not pass. A failed status indicates a potential problem with RiliBÄK regulation compliance.



Important: If a control cycle exceeds the limits of permissible error, patient results cannot be released while the cause of the error is being investigated. If the subsequent control cycle exceeds permissible error limits, the responsible federal authorities must be informed according to MPSV 2, and Unity Real Time blocks further data entry for the test.

Administrative Buttons

The data entry dialog box contains five administrative buttons. These buttons are:

- **Save**
Click the **Save** button to save your data and close the data entry dialog box after you enter data.
- **Set Date**
Click the **Set Date** button to set the date when you manually enter several days of data. After you set the date, the software increments the date by one day each time a new row of data is added. The software continues to increment the date by one day until you exit the software.
- **LIME**
Click the **LIME** button to initiate the calculation of new laboratory internal error limits and close the current LIME.
- **Start Cycles**
Click the **Start Cycles** button to close the current cycle with the current status as the judgement and start a new cycle.
- **Release Data**
Click the **Release Data** button to release a test after two consecutive failed cycles. The RiliBÄK regulation requires an extensive inspection of the cause of the failed cycles and a correction of the error before a test can be released for patient testing.



You must have the “Start LIME/release data” permission to perform this function.

Charts

Unity Real Time provides a variety of charts. See the following sections for more information:

- Levey-Jennings Chart (page 217 and page 365)
- Multi-LJ Chart (page 223)
- Bar Chart (page 228)
- Youden Chart (page 231)
- Yundt Chart (page 233)

Accuracy and Precision

You can select accuracy and precision options for RiliBÄK tests on the following charts:

- Multi-LJ Chart
- Bar Chart
- Youden Chart
- Yundt Chart



Tip: Press the F5 key while viewing a chart to view the chart in the accuracy mode.

Accuracy

The following is shown for an analyte in the accuracy mode:

- Analyte is listed in Table B1 and judged with column 3:
 - Target value provided by the manufacturer of the control.
 - The maximum allowed deviations +/- mzA from Table B1, column 3 (left side of the chart).
- Analyte is not listed in Table B1:
 - The target value provided by the manufacturer of the control during the calculation of the lab internal margins of error.
 - The maximum permissible deviations +/- mzA provided by the manufacturer of the control (left side of the chart).
 - The maximum permissible deviations +/- mzA from the determination of the lab internal margins of error (right side of the chart).

Precision

- Analyte is listed in the Table B1 and judged with column 3:
 - Nothing is shown.
- The following is shown if the **Cumulative** check box is selected:
 - The cumulative mean.
 - The cumulative 1SD, 2SD, and 3SD ranges from the statistics of all measurements during the complete time period.
 - The calculation of the lab internal margins of error.
- Analyte is not listed in Table B1:
 - The mean from the calculation of the laboratory internal margins of error.
 - The 3SD range from the calculation of the laboratory internal margins of error (left side of the chart).
- The start and end of the laboratory internal margins of error are marked with a red line and shown with the text "Calculation of the laboratory internal margins of error."

Accuracy + Precision

The accuracy and precision charts are overlaid. The following information is shown:

- Analyte is listed in Table B1 and judged with column 3:
 - The target value provided by the manufacturer of the control.
 - The maximum allowed deviations +/- mzA from Table B1, column 3 (shown on the left side of the chart).
 - No information shown on the right side of the chart unless the **Cumulative** check box is selected.
- Analyte is not listed in Table B1:
 - The target value provided by the manufacturer of the control.
 - The maximum permitted deviations +/- mzA from Table B1, column 3 (shown on the left side of the chart).
 - The mean from the calculation of the laboratory internal margins of error.
 - The 3S range from the calculation of the laboratory internal margins of error (shown on the right side of the chart).

Levey-Jennings Chart

Select the **Cyclic** check box to view additional purple lines which show the cycles. You can position the mouse on one of the lines to view comment with detailed information about the cycle.

RiliBÄK Reports

Unity Real Time provides a variety of RiliBÄK reports. See the following sections for more information:

- Cyclus Report (page 366)
- Negative Cyclus Report (page 367)
- LIME Report (page 367)
- Graphic LIME Report (page 370)
- Point Data Report (page 372)
- Graphic Point Data Report (page 373)
- Supervisor's Report (page 373)
- Summary Data Report (page 374)
- Target Report (page 376)
- Test Overview Report (page 376)

Cyclus Report

This report shows the following information:

- Basic information
 - Lab number
 - Description
 - Lab name and information
 - Test
 - Instrument/Kit
 - Unit
 - Lot number
 - Control name
 - Expiration date
 - Matrix
 - Manufacturer
 - Method
 - Reagent
 - Temperature
- Control cycle
- Level information
 - Level
 - Number of judged values
 - Mean
 - Standard deviation (SD)
 - Coefficient of variation (CV%)
- Target value
- Delta Rel % (relative square deviation)
- Delta Max Rel % (maximum permissible relative square deviation)
- Judgement (judgement of the control cycle)
 - Positive judged cycles appear with the message “The max. permitted rel. square deviation was not exceeded.”
 - Negative judged cycles appear with the message “The max. permitted rel. square deviation was exceeded.”

Create a Cyclus Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Cyclus Report**.
- 3 Click the arrow in the **From** field and select the beginning date for the report.
- 4 Click the arrow in the **To** field and select the ending date for the report.
- 5 Select an option for the report:
 - If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
 - If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 Select the **Order report by Level** check box if you want the report arranged by levels.
- 7 Click OK.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 8 See “Print and Export Reports” on page 277 for more information.
- 9 Click  (gray x) the upper right corner to close the report.

Negative Cyclus Report

Only negative cycles where the max. permitted rel. square deviation was exceeded will appear on this report.

This report shows the following information:

- Basic information
 - Lab number
 - Description
 - Lab name and information
 - Test
 - Instrument/Kit
 - Unit
 - Lot number
 - Control name
 - Expiration date
 - Matrix
 - Manufacturer
 - Method
 - Reagent
 - Temperature
- Negative Control cycle
- Level information
 - Level
 - Number of judged values
 - Mean
 - Standard deviation (SD)
 - Coefficient of variation (CV%)
- Target value
- Delta Rel % (relative square deviation)
- Delta Max Rel % (maximum permissible relative square deviation)
- Judgement (judgement of the negative control cycle)
 - “The max. permitted rel. square deviation was exceeded.”

Create a Negative Cyclus Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Negative Cyclus Report**.
- 3 Click the arrow in the **From** field and select the beginning date for the report.
- 4 Click the arrow in the **To** field and select the ending date for the report.
- 5 Select **All Data** for the report.
- 6 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 7 See “Print and Export Reports” on page 277 for more information.
- 8 Click  (gray x) the upper right corner to close the report.

LIME Report

This report provides a convenient way to review your LIME cycles for a test. The report includes the following information for completed and ongoing LIME cycles:

- Cycle start and end date/times
- Control level
- Mean, SD, and CV determined during the LIME cycle
- Target value in effect at the time of the cycle
- Difference between the LIME mean and the target value, expressed as both an absolute value and a percent
- Maximum allowable inaccuracy and imprecision limits from the RiliBÄK table
- Status of the cycle

Create a LIME Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **LIME Report**.
- 3 Click the arrow in the **From** field and select the beginning date for the report.
- 4 Click the arrow in the **To** field and select the ending date for the report.
- 5 Select an option for the report:
 - If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
 - If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 Select the **Order report by Level** check box if you want the report arranged by levels.
- 7 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 8 See “Print and Export Reports” on page 277 for more information.
- 9 Click  (gray x) the upper right corner to close the report.

Graphic LIME Report

This report shows information for a single LIME cycle you select. The report includes the following:

- A Levey-Jennings Chart plotting the data points used to calculate the LIME graphed against a $\pm 3SD$ range
- Cycle start and end date/times
- Control level
- Mean, SD, and CV determined during the LIME cycle
- Target value in effect at the time of the cycle
- Difference between the LIME mean and the target value, expressed as both an absolute value and a percent
- Maximum allowable inaccuracy and imprecision limits from the RiliBÄK table
- Status of the cycle
- Information for each data point used to calculate the LIME and includes the:
 - Date/time
 - Series number
 - Run number
 - Operator's initials
 - Value (result)

Create a Graphic LIME Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Graphic LIME Report**.

The **Graphic LIME Report** dialog box appears.

- 3 Select the control level from the **Level** list you want to show on the report.
- 4 Click **Show List**.

A list of LIME cycles with the start and end date/times appears.

- 5 Select the LIME cycle you want to view and click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See "Configure the Report Format" on page 436 for more information.

- 6 See "Print and Export Reports" on page 277 for more information.
- 7 Click (gray x) the upper right corner to close the report.

Point Data Report

This report shows the following information:

- Date and time the value was measured
- Run
- Initials of the operator who measured the value
- Value
- Accepted status
 - Y = value is accepted
 - N = value is not accepted because it is outside the permitted ranges.

Actions and comments are shown on the next line.

Create a Point Data Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Point data**.
- 3 Click the arrow in the **From** field and select the beginning date for the report.
- 4 Click the arrow in the **To** field and select the ending date for the report.
- 5 Select an option for the report:
 - If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
 - If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 Select the **Order report by Level** check box if you want the report arranged by levels.
- 7 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 8 See “Print and Export Reports” on page 277 for more information to print or save the report.
- 9 Click  (gray x) the upper right corner to close the report.

Graphic Point Data Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Graphic Point data**.
- 3 Select the control level from the **Level** list you want to show on the report.
- 4 Click the arrow in the **From** field and select the beginning date for the report.
- 5 Click the arrow in the **To** field and select the ending date for the report.
- 6 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 7 See “Print and Export Reports” on page 277 for more information.
- 8 Click  (gray x) the upper right corner to close the report.

Supervisor’s Report

This report shows any rule violations, actions, and/or comments, if added. The message “No values for the selected time period” indicates there are no rule violations for the selected time period.

Create a Supervisor’s Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Supervisor**.
- 3 Click the arrow in the **From** field and select the beginning date for the report.
- 4 Click the arrow in the **To** field and select the ending date for the report.

5 Select an option for the report:

- If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
- If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
- If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test

6 Select the **Order report by Level** check box if you want the report arranged by levels.

7 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

8 See “Print and Export Reports” on page 277 for more information.

9 Click  (gray x) the upper right corner to close the report.

Summary Data Report

This report shows your monthly statistics and contains the following information:

- Mean
- CV (coefficient of variation)
- SD (standard deviation)
- Number of measurements

Create a Summary Data Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Summary Data**.
- 3 Click the arrow in the **From** field and select the beginning date for the report.
- 4 Click the arrow in the **To** field and select the ending date for the report.
- 5 Select an option for the report:
 - If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
 - If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 6 Select the **Order report by Level** check box if you want the report arranged by levels.
- 7 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 8 See “Print and Export Reports” on page 277 for more information.
- 9 Click  (gray x) the upper right corner to close the report.

Target Report

This report shows following information:

- Target value
- Lab internal margins of error (if calculated)
- Maximum accepted range

Create a Target Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Test Overview**.
- 3 Select an option for the report:
 - If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
 - If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test
- 4 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.
See “Configure the Report Format” on page 436 for more information.

- 5 See “Print and Export Reports” on page 277 for more information.
- 6 Click (gray x) the upper right corner to close the report.

Test Overview Report

This report shows following information:

- Target value
- Lab internal margins of error (if calculated)
- Maximum accepted range

Create a Test Overview Report

- 1 Select a test in the Lab, Panel, or Instrument navigation tree.
- 2 Click the **Reports** menu, point to **RiliBÄK Reports**, and then click **Test Overview**.
- 3 Select an option for the report:
 - If you selected a test in the Lab navigation tree, you can select one of the following:
 - All data
 - Current lab
 - Current lot
 - Current test
 - If you selected a test in the Panel navigation tree, you can select one of the following:
 - Current panel
 - Current test
 - If you selected a test in the Instrument navigation tree, you can select one of the following:
 - Current instrument
 - Current test

- 4 Click **OK**.

The report opens in the format configured for your software.



Note: Unity Real Time generates reports in Crystal Reports format or Adobe Reader format.

See “Configure the Report Format” on page 436 for more information.

- 5 See “Print and Export Reports” on page 277 for more information.
- 6 Click  (gray x) the upper right corner to close the report.

Unity Real Time Database

In This Chapter

Log On To the Database.....	378
View and Update Database Information.....	380
Database Utilities.....	383
Backup and Restore the Database	390

Log On To the Database

Default Database Log On

Unity Real Time creates a default database user ID and password during installation. You can use the default user ID and password if you do not have a separate server log on set up.



Note: You must contact the Database Administrator from your local IT department if they have changed the default user ID and password.

Default User ID and Password

User ID:	sa
Password:	biorad



Note: Admin permission is needed to access certain folders within Unity Real Time. Therefore, it is best practice to use SQL authentication instead of Windows login.

Change the Database at Log On

- 1 Click **Start** on the taskbar, point to **All Programs**, point to **Bio-Rad Laboratories**, and then click **Unity Real Time**.

The **Login** dialog box appears.

- 2 Click **Change** located to the right of the **Server** field.
- 3 The **Server Login** dialog box appears.
- 4 Select the server from the **SQL Server** list where the database resides.



Note: You can also type the computer name or IP address.

- 5 Select the database from the **Database** list.
- 6 Type your SQL server ID and SQL Server password in the respective fields.



Note: The SQL server ID and password may or may not be the same as your Unity Real Time user ID and password. Use the default if you do not have a SQL server ID and password. See the previous section “Default Database Log On” for more information.

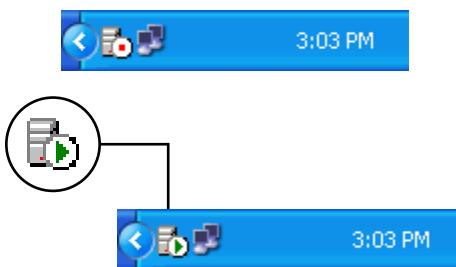
- 7 Click **OK**.



Log On To a Different Database

The installation creates a single database named QCDAO in the location specified when the software was installed. This database can be on the same computer as the client software or on a different computer in a client server environment. Your database administrator can create additional databases as necessary.

If you already have a user ID and password on the SQL server where the database resides, you can use them to log on to the Unity Real Time database. If there is no existing user/password, the installation creates a user "sa" with the password "biorad".



If you have more than one database, you can choose which one to attach to when you log on to Unity Real Time.



Note: Bio-Rad requires that you create this database using the standard naming format "BIORAD_" (Example: BIORAD_Lab1).

View and Update Database Information

Bio-Rad continually updates the Unity Real Time database information. This information includes:

- Code list
Contains the latest lot numbers, analytes, instruments/kits, reagents, methods, units, and temperature. Bio-Rad updates the code list at least monthly. Update the code list on a regular basis and especially before adding lots or tests.
- Analytical goal information
Contains various statistical data and consensus group data for the different types of analytical goals.
- Instrument setup information
Contains the typical methodology for analytes for selected instruments using dedicated reagents and reporting QC data to the Unity Interlaboratory Program. Instrument setup information is based on information in the *Unity Method Guide for Selected Instruments* when using the Instrument Setup function.



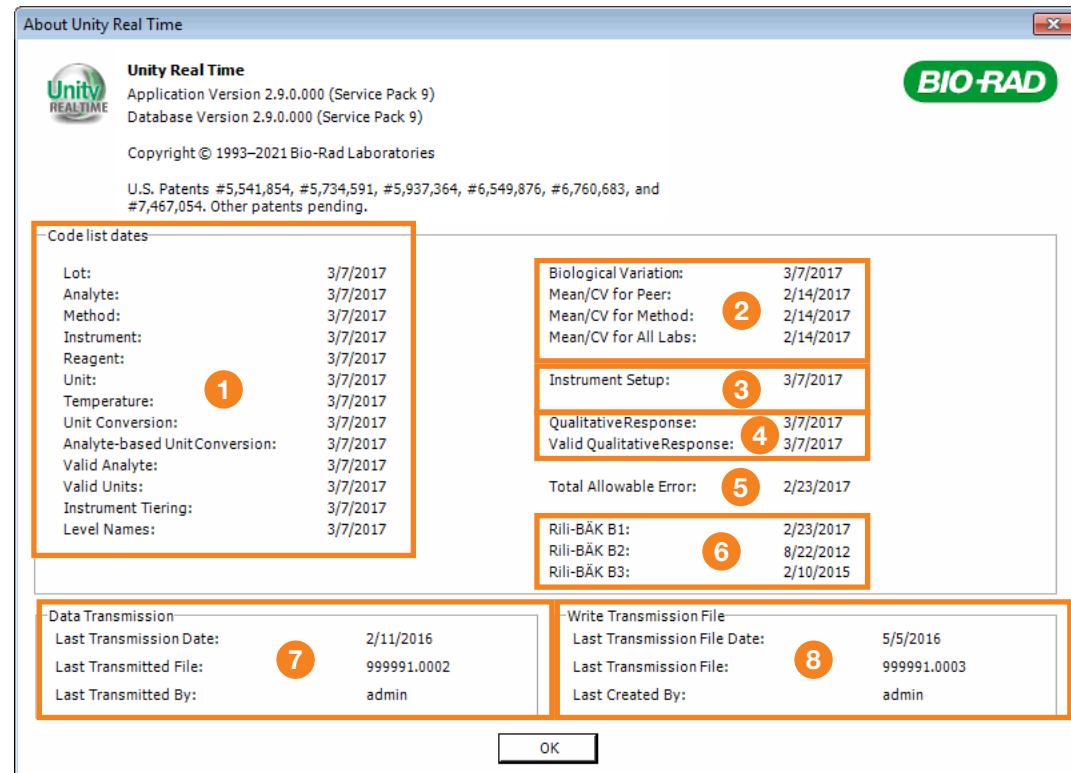
Note: elnsert data is not included with the other database updates because the data is not saved to the code list. elnsert data is retrieved from Bio-Rad each time a user selects the "Get EI Data" check mark on the Evaluation Mean/SD window.

View Database Information

Click the **Help** menu and then click **About** Unity Real Time.

The **About** Unity Real Time dialog box appears and shows the latest database updates.

 **Note:** To ensure that the database information in your software is always up to date, click **Tools**, then **Setup** and make sure that the **Database updates** check boxes are selected. Refer to “Configure Database Updates” on page 433 for more information.



- 1 Code list dates
- 2 Analytical goal dates
- 3 Instrument setup date
- 4 Qualitative dates
- 5 Allowable Total Error date
- 6 RiliBÄK date
- 7 Last data transmission details (date, file name, and user)
- 8 Last manual write transmission file (Date, file name and user)



Note: The RiliBÄK module is for German laboratories only.

Update the Database Automatically



You must have the “Communicate with Unity Interlaboratory Program” permission to perform this function.



Note: You must have Internet access to update the database automatically. See the next topic, “Update the Database from a CD-ROM” if you do not have Internet access.

- 1 Go to the computer where the database is installed.
- 2 Log on to Unity Real Time as a user with the “Communicate with Unity Interlaboratory Program” permission.
- 3 Close any open data entry dialog boxes.
- 4 Click the **Tools** menu, point to **Unity Interlab**, and then click **Send/Receive Data**.
- 5 Select the **Receive data** option.
- 6 Select each check box for the information you want to download. You can select any combination of the check boxes.



Note: Selecting all check boxes ensures your software always has the most up-to-date information. All laboratories should regularly update the code list. It is not necessary to update analytical goals or instrument setup if you do not use those functions.

- Receive code list
- Receive Analytical Goals information
- Receive instrument setup

Unity Real Time checks for any available updates and installs them. This may take several minutes depending on your network speed. You can download each update separately to help decrease download time.

A message appears when the update is complete.

Click **OK**.



Note: Bio-Rad recommends that you configure Automated Database updates in the Tools Setup menu. Automated Database updates will check for updates at every login.

Update the Database from QCNet.com

- 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 **QC Documents**, point to **Code Lists**, and then click **Unity**.
- 4 Locate the code list for your version and language of Unity Real Time.
- 5 Click the link in the **Download** column for your version.

The download information appears.
- 6 Click **OK**.
- 7 Click **Save** to save the download to the local computer where Unity Real Time is installed.
- 8 Select **Tools**, then **Unity Interlab**, then **Update Database**.
- 9 Select the location where you saved the code list.
- 10 Select the code lists and click **OK** to update the code lists.
- 11 Repeat the steps for Analytical Goals information and instrument setup.

Database Utilities

Unity Real Time provides the following database utilities:

- Export data (page 384)
- Condense data (page 385)
- Reconcile data (page 386)
- Delete a range of data (page 387)
- Move Data (page 389)

Export Data



You must have the “Export data” permission to perform this function.

- 1 Click the **Tools** menu, point to **Utilities**, and then click **Export**.

The **Export** dialog box appears.

- 2 Select an option for the data you want to export:

- If you selected an item in the Lab navigation tree, you can select one of the following:
 - All data
 - Current Lab
 - Current Lot
 - Current Test
- If you selected an item in the Panel navigation tree, you can select one of the following:
 - Current Test
 - Current Panel
- If you selected an item in the Instrument navigation tree, you can select one of the following:
 - Current Test
 - Current Instrument

- 3 Select the option for the type of file to export:

- Text file

This option creates a file for use with word processing software. Unity Real Time 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 standard Unity Real Time import file.

- 4 Type the name in the **File name** field for the file you want to export.



Note: Unity Real Time saves the file to the last location where you previously saved an export file. You can create a folder to store these types of files if you want. Also, you can click the ellipsis button and browse to a folder.

- 5 Click the arrow in the **From** field and select the beginning date for the data.

- 6 Click the arrow in the **To** field and select the ending date for the data.

7 Select the type of data you want to export:

- Point Data
- Summarized Data



Note: Data entered as summary data cannot be exported as point data.

8 Click **OK**.



Note: Comments will not be included in the data export file.

Condense Data



Important: You cannot reverse condensed data. Bio-Rad recommends backing up the database before you condense data. See “Perform a Manual Backup” on page 391 for more information.



You must have the “Condense data” permission to perform this function.

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.



Tip: Condensing data does not change the monthly summarized data values. Therefore, you do not need to resubmit condensed data to Bio-Rad.

1 Click the **Tools** menu, point to **Utilities**, and then click **Condense**.

2 Select an option for the data you want to condense:

- If you selected an item in the Lab navigation tree, you can select one of the following:
 - All data
 - Current Lab
 - Current Lot
 - Current Test
- If you selected an item in the Panel navigation tree, you can select one of the following:
 - Current Test
 - Current Panel
- If you selected an item in the Instrument navigation tree, you can select one of the following:
 - Current Test

- Current Instrument
- 3 Click the arrow in the **From** field and select the beginning date for the data.
 - 4 Click the arrow in the **To** field and select the ending date for the data.
 - 5 Click **OK**.
A message appears asking for confirmation.
 - 6 Click **Yes**.
A message appears when complete.
 - 7 Click **OK**.

Reconcile the Database



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

The Reconcile Data function creates a file of all data in the software. This is used in rare circumstances to send QC data to Bio-Rad.

The reconciled file replaces any existing data in the Unity Interlaboratory Program. Data can be reconciled for a lab number, lot number, or all lab numbers in the database.

Delete a Range of Data

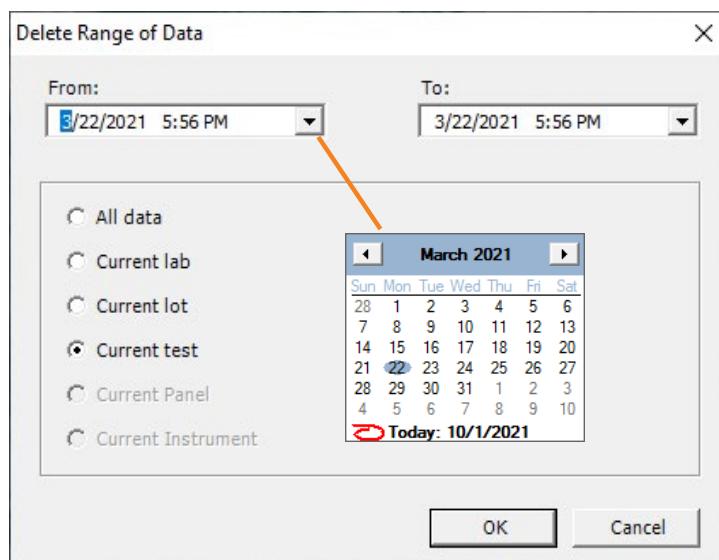


Important: Deleting a range of data permanently removes the data from the software. Bio-Rad recommends backing up the database before you delete data. See “Perform a Manual Backup” on page 391 for more information.



You must have the “Edit all data” permission to perform this function.

- 1 Click the **Tools** menu, point to **Utilities**, and then click **Delete range of data**.
- 2 Click the arrow in the **From** field and select the beginning date for the range of data.



- 3 The **From** field also shows the current time so you can selectively delete a portion of data points for a day. Click any part of the time and type over if you want to edit the time.
Click the arrow in the **To** field and select an ending date for the data.
- 4 The **To** field also shows the current time so you can selectively delete a portion of data points for a day. Click any part of the time and type over if you want to edit the time.
- 5 Select an option for the data you want to delete:

If you selected an item in the Lab navigation tree, you can select one of the following:

- All data
- Current Lab
- Current Lot
- Current Test
- If you selected an item in the Panel navigation tree, you can select one of the following:
 - Current Test

- Current Panel
- If you selected an item in the Instrument navigation tree, you can select one of the following:
 - Current Test
 - Current Instrument
- 6 Click **OK**.
- A message appears asking for confirmation.
- 7 Click **Yes**.
- A message appears when complete.
- 8 Click **OK**.

Move Data

With the Move Data utility, you can select a range of data for a test and move it to another test that is within the same lab number and lot number. For example, if QC data was imported or manually entered under the wrong test in Unity Real Time, you could correct the data by moving it to the correct test.

- Only quantitative tests can be updated with this utility. Qualitative and semi-quantitative tests are not supported.
- The inserted data is evaluated against the current rules and evaluation mean/SD defined for the destination test.
- All existing data runs for the destination test are re-evaluated from the insertion point forward against the current rules and evaluation mean/SD.
- Actions and comments from the source test will be inserted with the QC results.
- Actions and comments associated with the existing data runs for the destination test are not removed or updated based on the re-evaluation.
- Documentation of the moved data is recorded in the Audit Trail. Use an Action or Comment if you want to have a record of the change with the data itself.

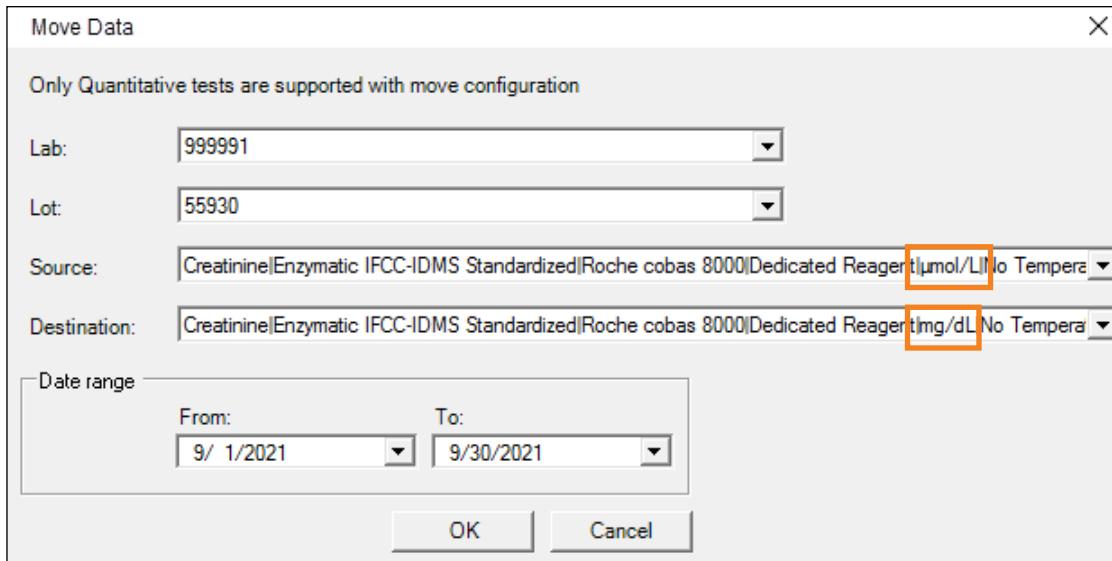


Important: Before you begin, you may want to save a copy of the Point Data Report for both the source and destination tests. See “Point Data Report” on page 250 for more information.



You must have the “Edit all data” permission to perform this function.

- 1 Click the **Tools** menu, point to **Utilities**, and then click **Move Data**.
- 2 Select an option from the **Lab** list.



- 3 Select an option from the **Lot** list.
- 4 Select a test from the **Source** list.
- 5 Select a test from the **Destination** list.
- 6 Click the arrow in the **From** field and select the beginning date for the range of data you want to move.
- 7 Click the arrow in the **To** field and select an ending date for the range of data.
- 8 Click **OK**.

Backup and Restore the Database

Overview

The Unity Backup/Restore Utility functions with the Unity Real Time database and allows you to:

- Perform a manual backup of the database.
- Restore the database from a backup file.
- Schedule backups on a one-time, daily, weekly, or monthly basis.

The Unity Backup/Restore Utility also includes a feature that records backup events to an Activity Log.

Before You Start



Important: You must have full read/write permissions to the source and destination folders to perform any of the tasks described in this document.

Start the Utility

The Unity Backup/Restore Utility is packaged and installed with the Unity Real Time Database Utilities installation.

On the taskbar, click **Start**, point to **All Programs > Bio-Rad Laboratories > Unity Real Time - Database Utilities**, and then click **Backup - Restore Database**.



You can also navigate through Microsoft Windows Explorer directly to the installation path and double-click **UnityDBTool.exe**. (C:\MSSQL\Utils\UnityDBTool.exe).

Perform a Manual Backup

- 1 Start the Unity Backup/Restore Utility.
- 2 Click the **Backup** tab.
- 3 The database server should automatically be entered in the **Database Server** field as (LOCAL). If not, select the database server from the **Database Server** drop-down list.
 - If you are using multiple instances of SQL Server, you must specify the instance running the Unity Real Time database. For example: (LOCAL)\SQLEXPRESS.
 - You can also select other database servers on your network from the **Database Server** drop-down list.



- Type the SQL Server credentials in the respective fields.

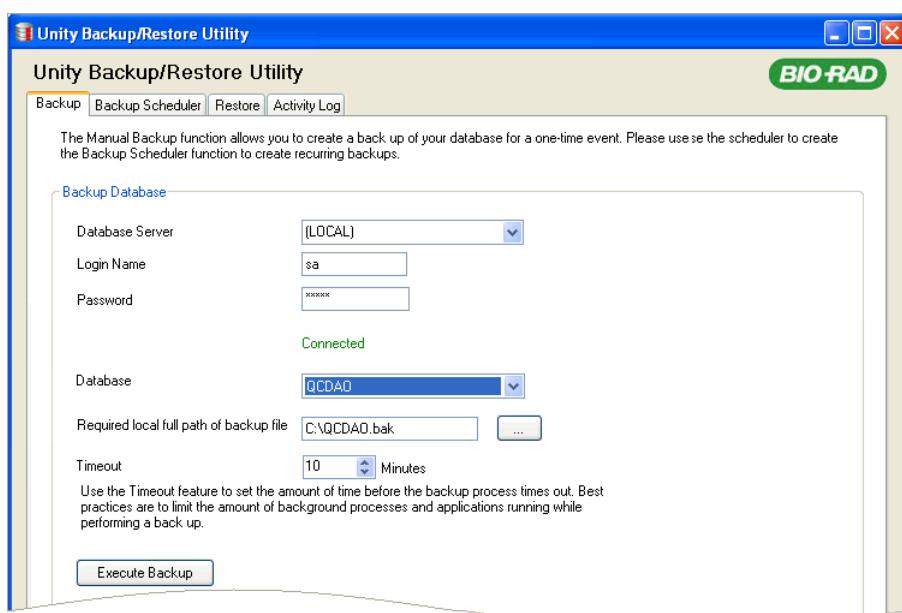
The Unity Real Time database uses the following SQL Server credentials by default:

- Login Name: sa
- Password: biorad

- Select the database from the **Database** drop-down list you want to back up.



Note: The default Unity Real Time database is named “QCDAO.”



The word “Connected” appears in green above the database name when you are connected to the

database.

- The default location where the backup file will be saved is C:\
- The default name of the backup file is the name of the database. For example: **QCDAO.bak**

You can change the name of the backup file with the following restrictions:

- The file name must have the .bak extension.
- The file must have a contiguous name. You can use the underscore character to space out the name as shown in the example below.

 Correct example: Backup_07_22_2011.bak

 Incorrect example: Backup 07 22 2011.bak

- 6 Use the **Timeout** field to select the amount of time before the backup process will “time out.”



Note: It is best to limit background processes and applications that are running while performing a backup.

- 7 Click **Execute Backup** when you are ready to back up the database.

A message appears when the backup is complete.

Set Up a Scheduled Backup

Use the Backup Scheduler function to set up recurring backups on a one-time, daily, weekly, or monthly schedule.

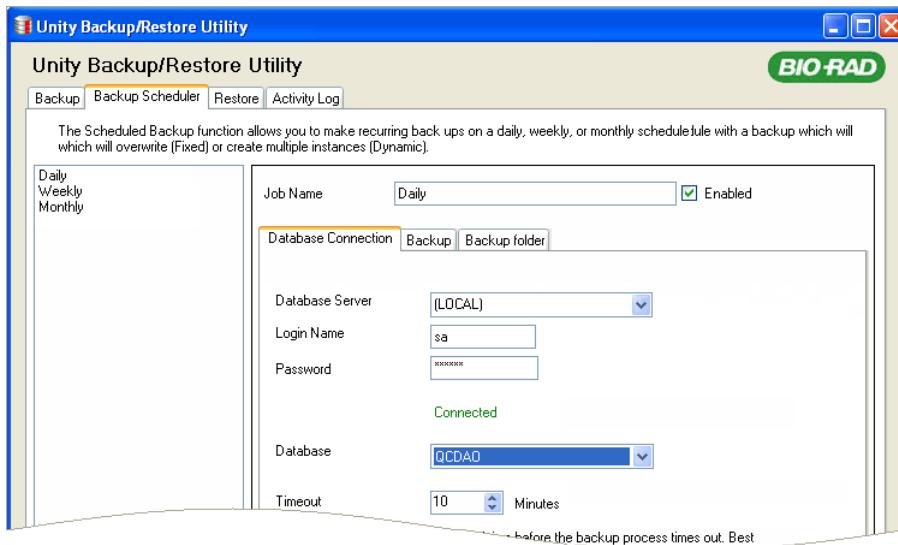
You can select to perform either of the following types of backups when using the Backup Scheduler:

- **Dynamic**
 - Each new backup file has a unique name based on the date and time.
 - Use the Dynamic option to create multiple copies of your database at different dates.
 - The Dynamic option allows you to back up the database to a specific date according to when the original backup file was created.
- **Fixed**
 - The newest backup file overwrites the oldest backup file.

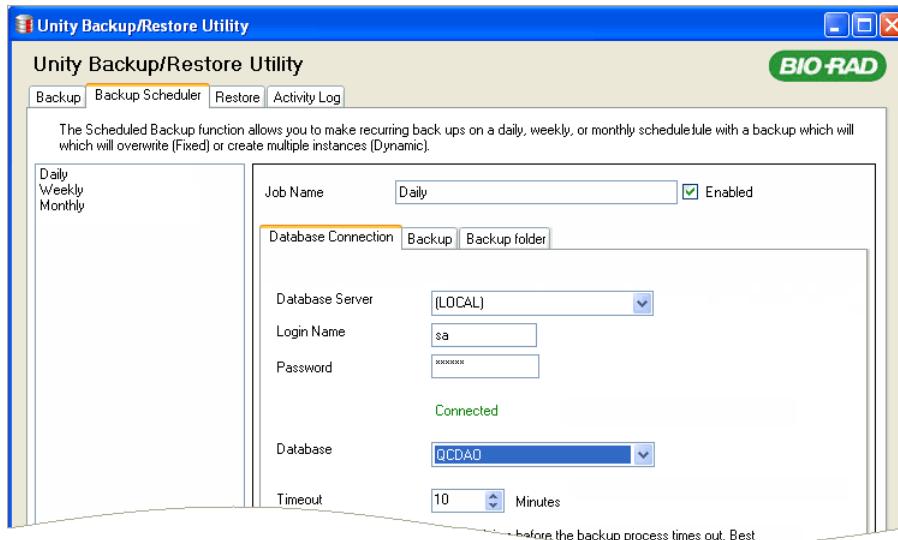
- 1 Start the Unity Backup/Restore Utility.
- 2 Click the **Backup Scheduler** tab.
- 3 Click the **Database Connection** tab if it is not already selected.
- 4 Type a name for the backup in the **Job Name** field.



Clear the **Enabled** check box to stop the job.



- 5 The database server should automatically be entered in the **Database Server** field as (LOCAL). If not, select the database server from the **Database Server** drop-down list.
- If you are using multiple instances of SQL Server, you must specify the instance running the Unity Real Time database. For example: (LOCAL)\SQLEXPRESS.
 - You can also select other database servers on your network from the **Database Server** drop-down list.



- 6 Type the SQL Server credentials in the respective fields.

The Unity Real Time database uses the following SQL Server credentials by default:

- Login Name: sa
- Password: biorad

- 7 Select the database from the **Database** drop-down list you want to back up.



Note: The default Unity Real Time database is named “QCDAO.”

The word “Connected” appears in green above the database name when you are connected to the database.

- The default location to where the backup file will be saved is C:\
 - The default name of the backup file is the name of the database. For example: QCDAO.bak
- 8 Continue with the next section “Select the Frequency of the Backup.”

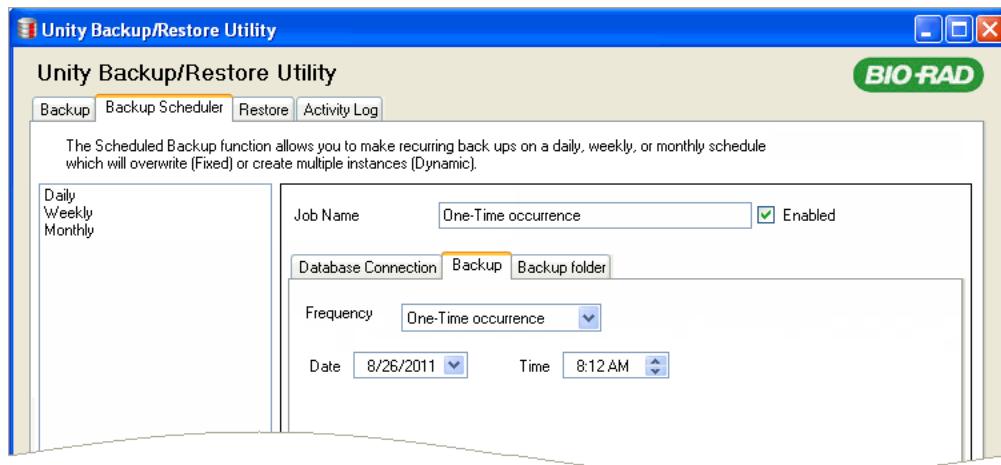
Select the Frequency of the Backup

You can select one of the following for the frequency of the scheduled backup:

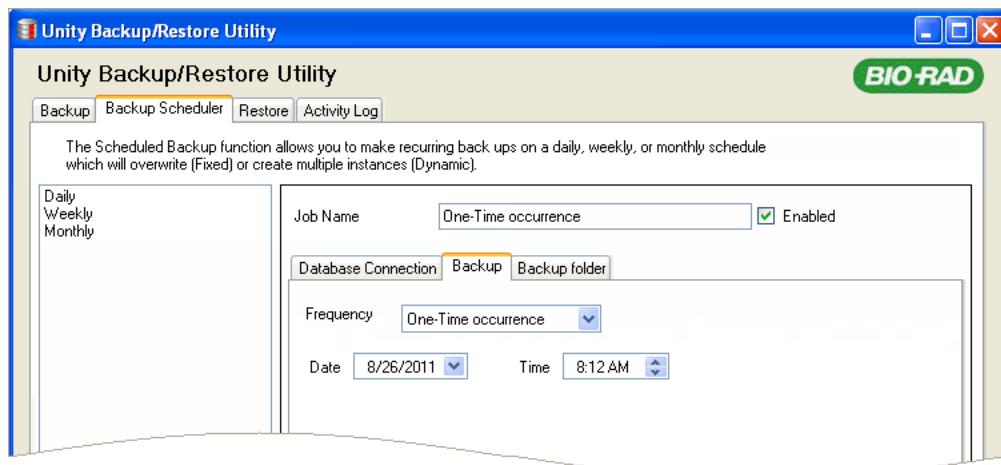
- One-time occurrence (this page)
- Daily (page 397)
- Weekly (page 398)
- Monthly (page 399)

One-Time Occurrence

- 1 Click the **Backup** tab.



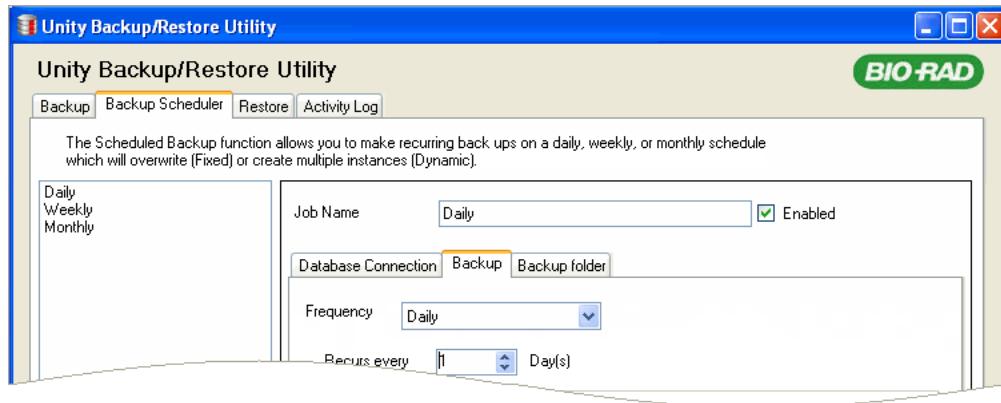
- 2 Select **One-Time occurrence** from the **Frequency** drop-down list.
- 3 Select the date and time for the backup.



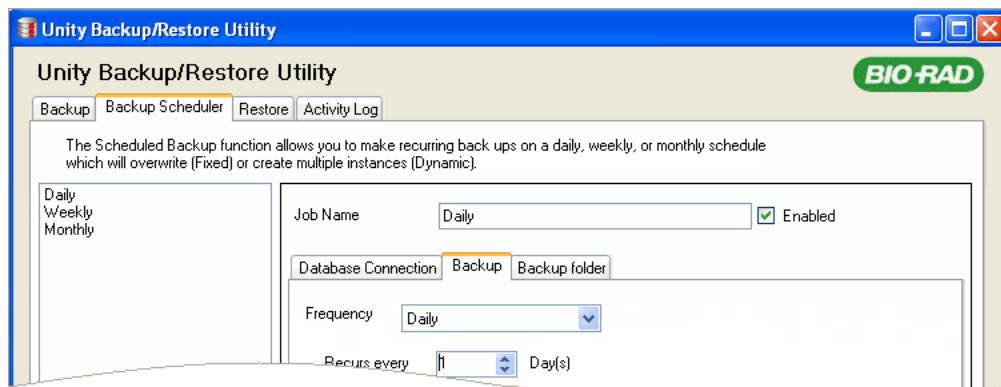
- 4 Click **Apply**.
- 5 Go to “Select the Backup Folder” on page 401.

Daily Backup

- 1 Click the **Backup** tab.



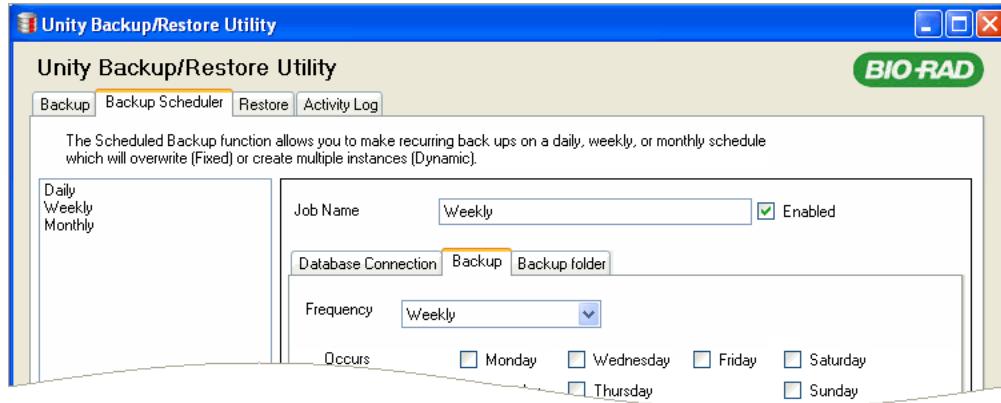
- 2 Select **Daily** from the **Frequency** drop-down list.
- 3 Select the options for the backup:
 - **Recur every:** Select the number of days if you want the backup to occur at an interval other than every day.
 - **Daily frequency:**
 - Occurs once at
 - Occurs every
 - **Duration:**
 - Start date and End date
 - No end date



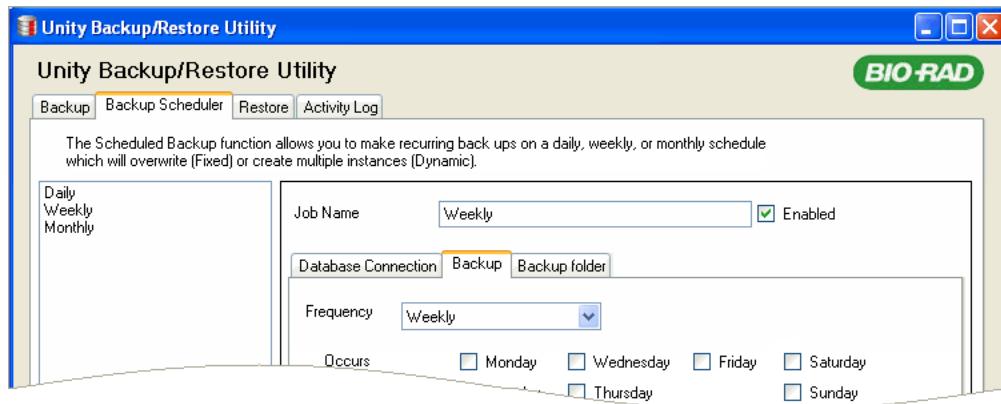
- 4 Click **Apply**.
- 5 Go to “Select the Backup Folder” on page 401.

Weekly Backup

- 1 Click the **Backup** tab.



- 2 Select **Weekly** from the **Frequency** drop-down list.
- 3 Select the options for the backup:
 - **Occurs:** Select the check box for each day of the week you want the backup to occur.



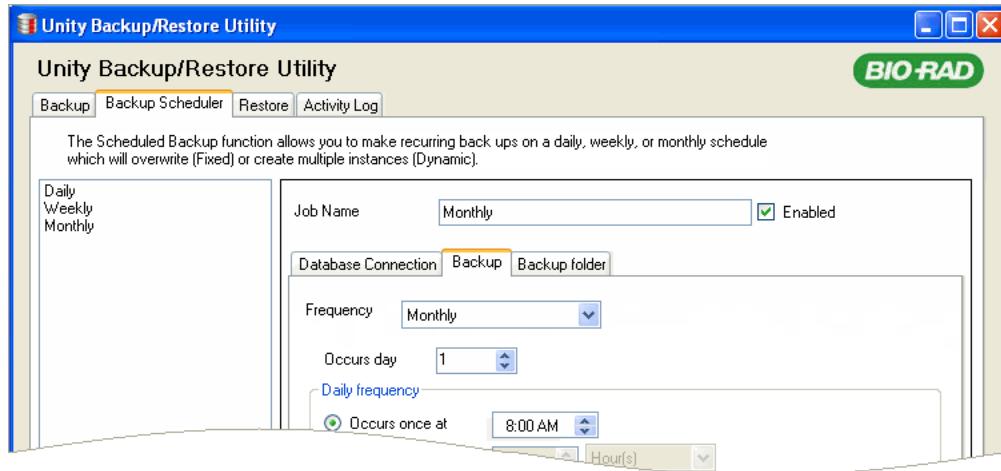
- **Daily frequency:**
 - Occurs once at
 - Occurs every
- **Duration:**
 - Start date and End date
 - No end date

- 4 Click **Apply**.

- 5 Go to “Select the Backup Folder” on page 401.

Monthly Backup

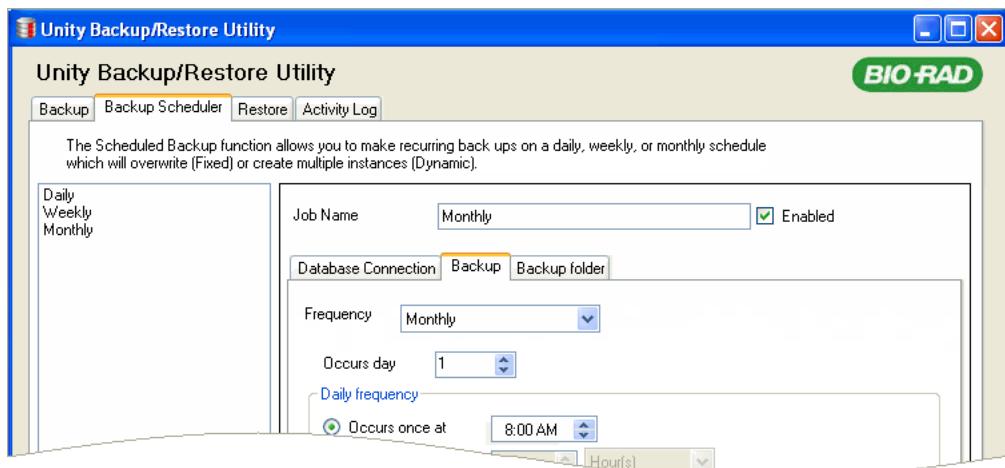
- 1 Click the **Backup** tab.



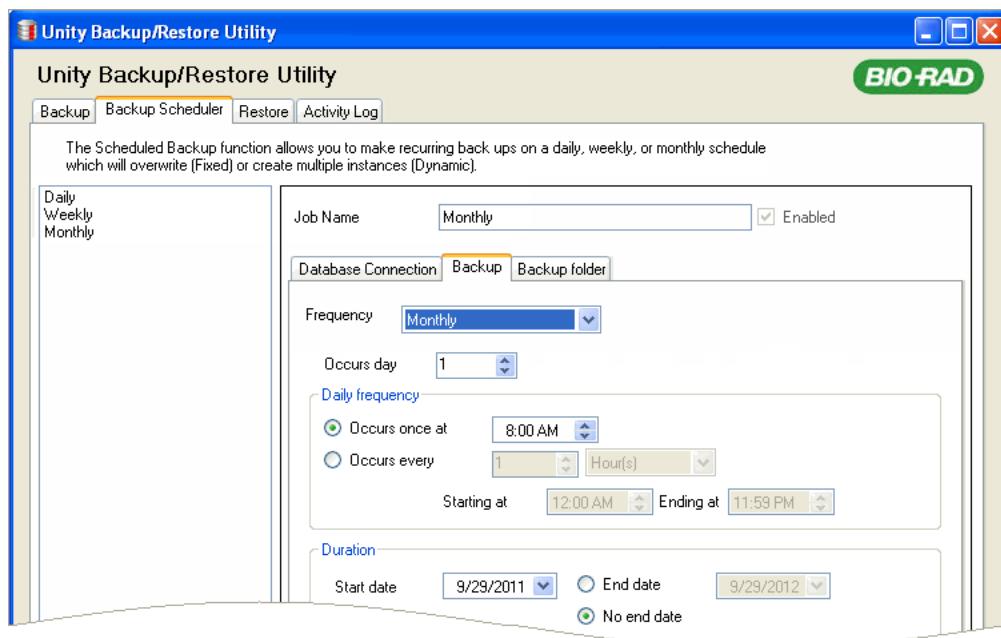
- 2 Select **Monthly** from the **Frequency** drop-down list.
 3 Select the options for the backup:
 - Occurs day:** Select the day of the month you want the backup to occur.



Note: It is best to not select the last one or two days of a month. This helps to prevent missing a monthly backup where a month such as June does not have a 31st day.



- **Daily Frequency:**
 - Occurs once at
 - Occurs every
- **Duration:**
 - Select a Start date and End date
 - No end date



- 4 Click **Apply**.
- 5 Continue with the next section “Select the Backup Folder.”

Select the Backup Folder



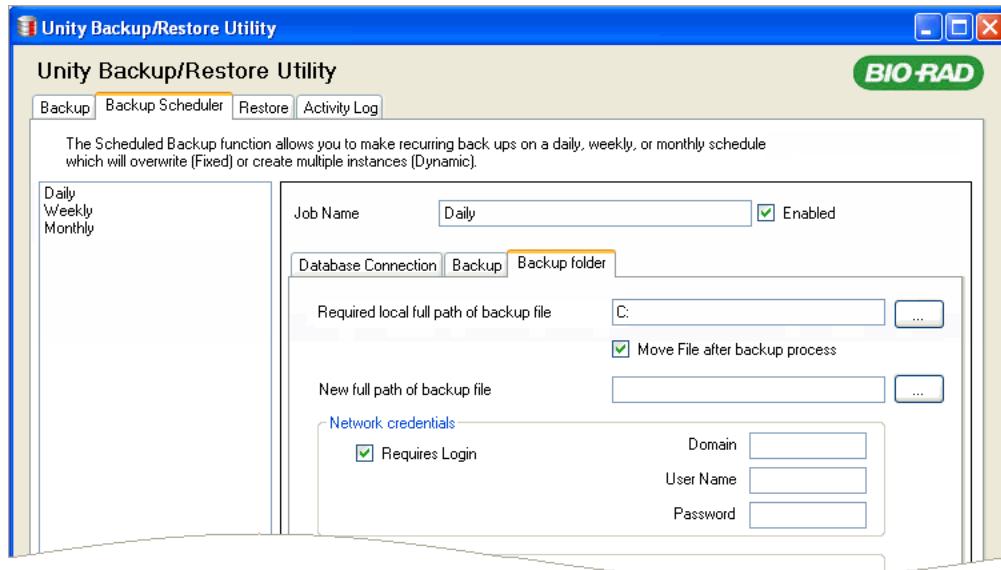
Note: When backing up multiple databases, Bio-Rad Support recommends separating each job into its own folder.

- 1 Click the **Backup** tab.
- 2 Select the full path where the backup file is located:



Note: The path must be on the local computer.

- Manually type the full path in the field, or
- Click and navigate to the path where the backup file is located.



Note: The following steps 3-5 are optional. However, Bio-Rad recommends following these steps to move the backup file to a network location for optimum redundancy.

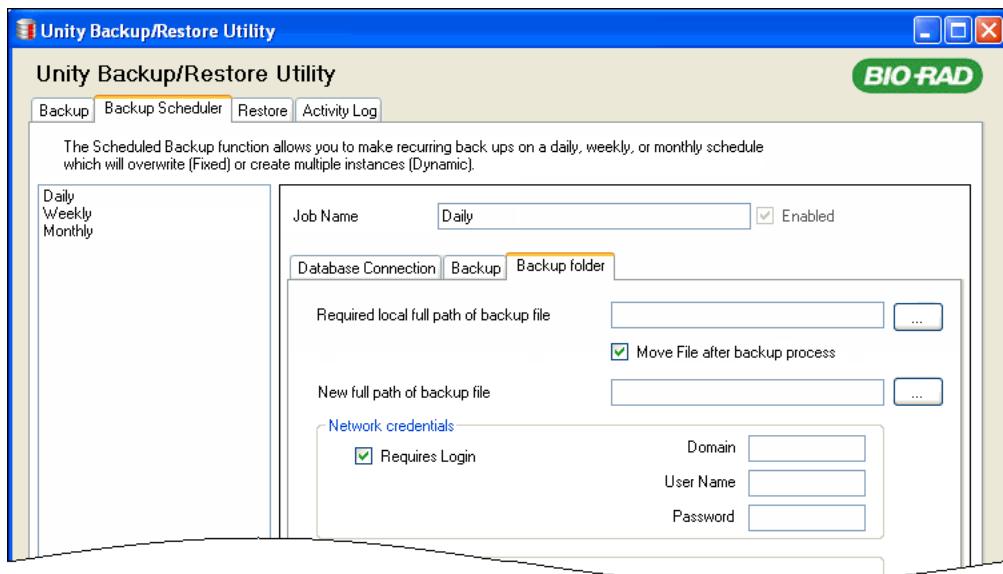
- 3 Select the **Move File after backup process** check box.

- 4 Select the full path where you want to move the backup file:

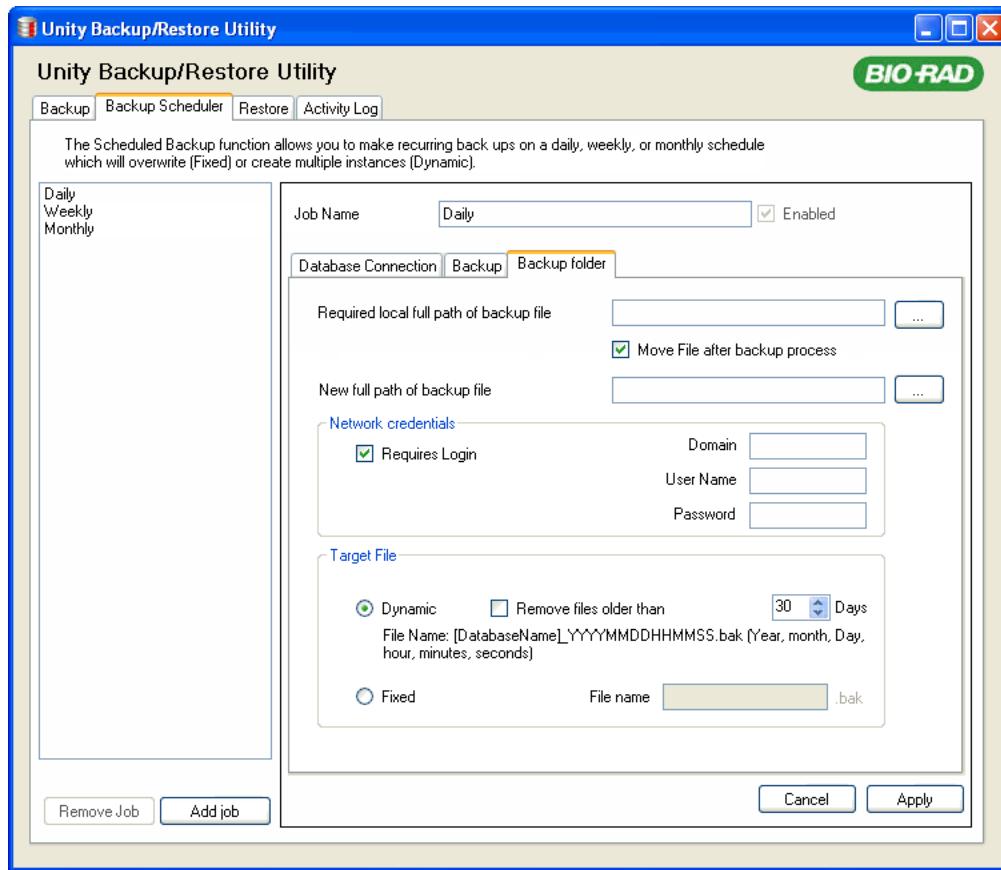


Note: Bio-Rad Support recommends using the absolute path. For example, [\\server name\\folder name] rather than a network share [S:\\folder name].

- Manually type the full path of the network location you want to move the file to (for example \\server name\\share),
or
- Click and navigate to the path where you want to move the file.



- 5 Select the **Requires Login** check box if the network location requires credentials for access and enter the following information:
- Domain name
 - User name
 - Password
- 6 Select an option for the type of target backup file you want:
- Dynamic**
 - Each new backup file has a unique name based on the date and time.
 - Use the Dynamic option to create multiple copies of your database at different dates.
 - The Dynamic option allows you to back up the database to a specific date according to when the original backup file was created.
 - Fixed**
 - The newest backup file overwrites the oldest backup file.



- 7 You can select the **Remove files older than** check box to purge older dynamic backup files. Then select the number of days you want to wait before the files are removed.

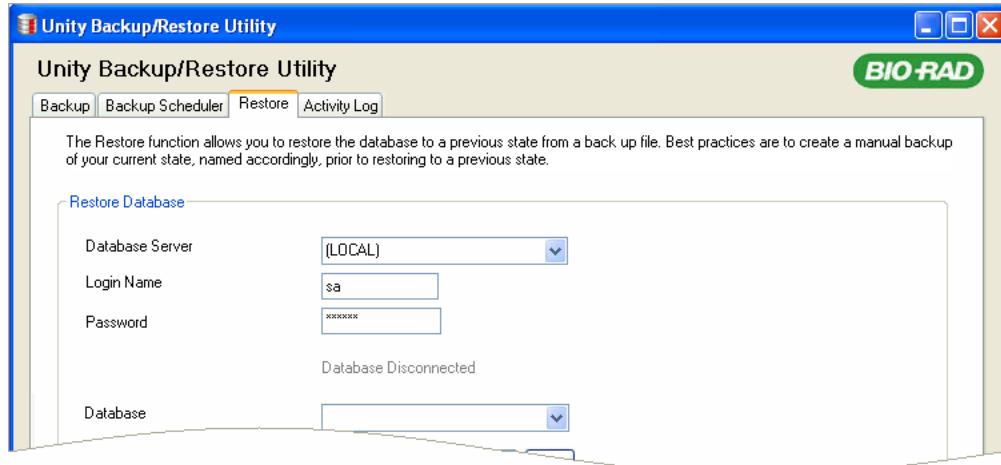


Note: All files with a .BAK extension will be removed. Bio-Rad Support recommends separating each job into its own folder.

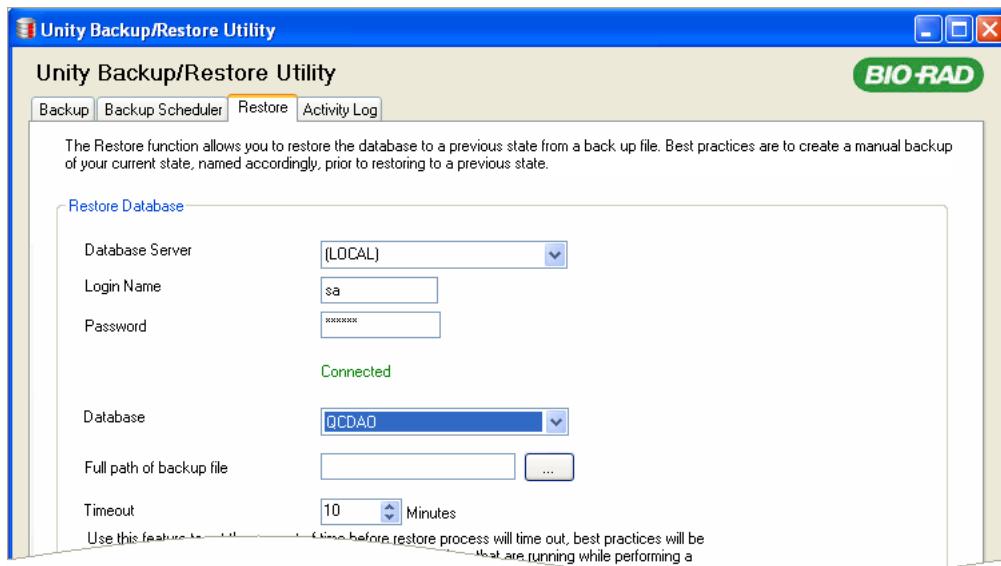
- 8 Click **Apply**.

Restore the Database

- 1 Click the **Restore** tab.



- 2 Your database server should automatically be entered in the **Database Server** field as (LOCAL). If not, select the database server from the **Database Server** drop-down list.
 - If you are using multiple instances of SQL Server, you must specify the instance running the Unity Real Time database. For example: (LOCAL)\SQLEXPRESS.
 - You can also select other database servers on your network from the **Database Server** drop-down list.



- Type the SQL Server credentials in the respective fields.

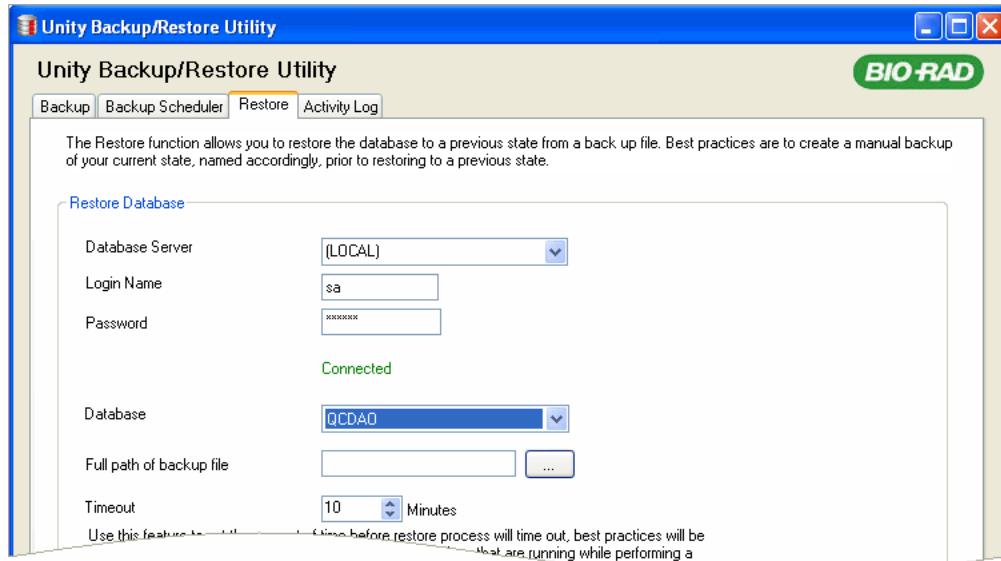
The Unity Real Time database uses the following SQL Server credentials by default:

- Login Name: sa
- Password: biorad

- Click the **Database** drop-down list and select the database you want to restore.



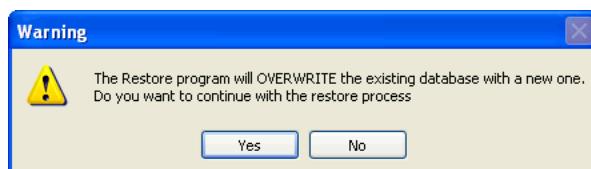
Note: The default Unity Real Time database is named “QCDAO.”



The word “Connected” appears in green above the database name when you are connected to the database server.

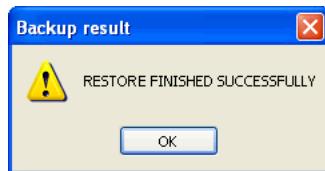
- Click
- Use the **Open** dialog box to navigate to the backup file you want to restore and then click **Open**.
- Click **Execute Restore**.

A warning message appears stating the restore process will overwrite the existing database.



- Click **Yes** to continue.

The following message appears when the restore is complete.



Manually Back Up or Restore the Database Remotely

You can use this feature to back up or restore the database from a remote location within the local network.

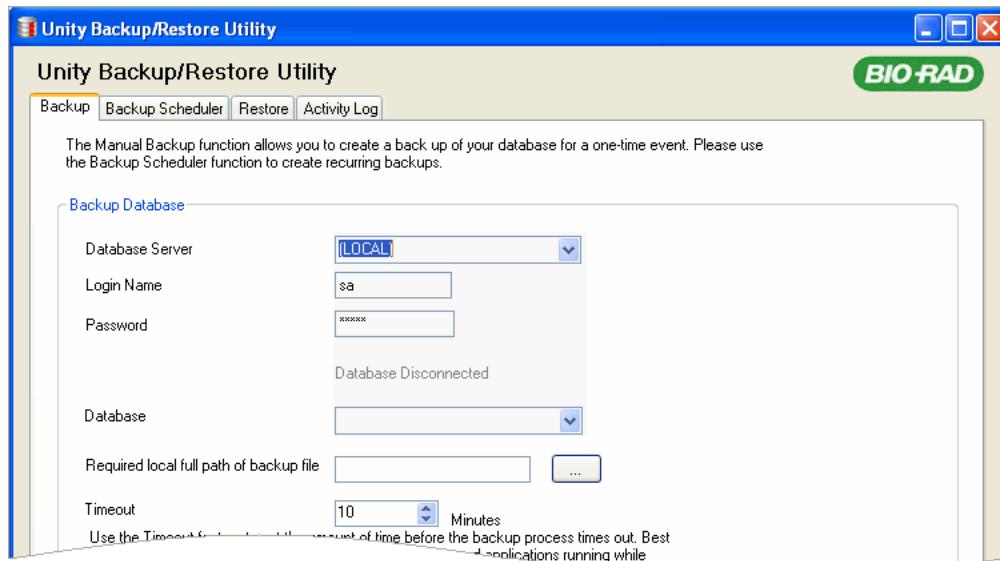


Note: Bio-Rad Support recommends running the Unity Backup/Restore Utility locally to the SQL Server instance to reduce network traffic collisions or unforeseen events. However, the Unity Backup/Restore Utility also accommodates remote backup and restore functionality.

Manually Back Up the Database Remotely

- 1 Click the **Backup** tab.
- 2 Select the database server from the **Database Server** drop-down list. If the server does not appear in the list, you can manually enter the name or IP address.

If you are using multiple instances of SQL Server, you must specify the instance running the Unity Real Time database. For example: ServerName\SQLEXPRESS.



- 3 Type the SQL Server credentials in the respective fields.

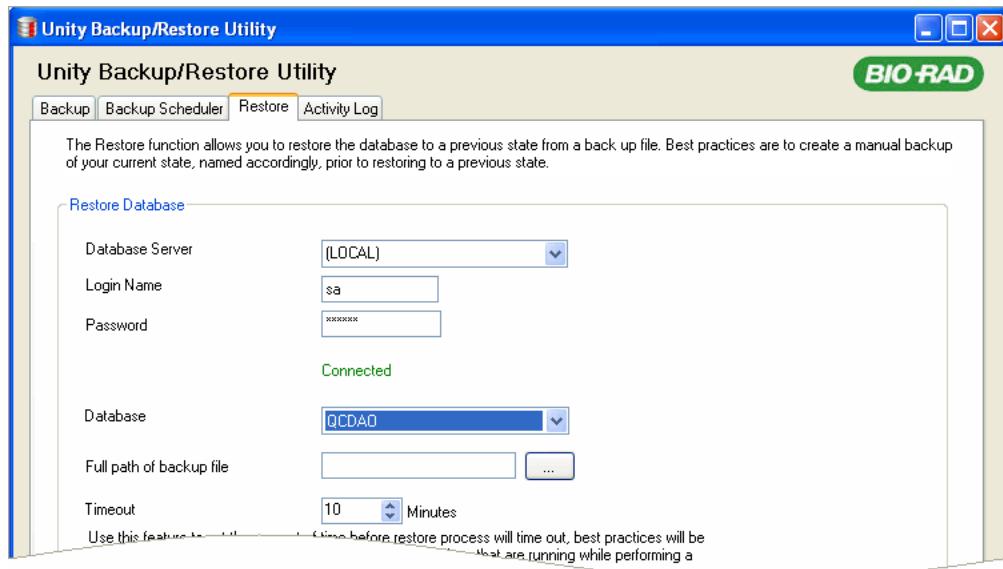
The Unity Real Time database uses the following SQL Server credentials by default:

- Login Name: sa
- Password: biorad

- 4 Select the database from the **Database** drop-down list you want to back up.



Note: The default Unity Real Time database is named “QCDAO.”



The word “Connected” appears in green above the database name when you are connected to the database server.

- The default location where the backup file will be saved is **C:**
- The default name of the backup file is the name of the database. For example: **QCDAO.bak**

You can change the name of the backup file with the following restrictions:

- The file name must have the .bak extension.
- The file must have a contiguous name. You can use the underscore character to space out the name as shown in the example below.



Correct example:

Backup_07_22_2021.bak



Incorrect example:

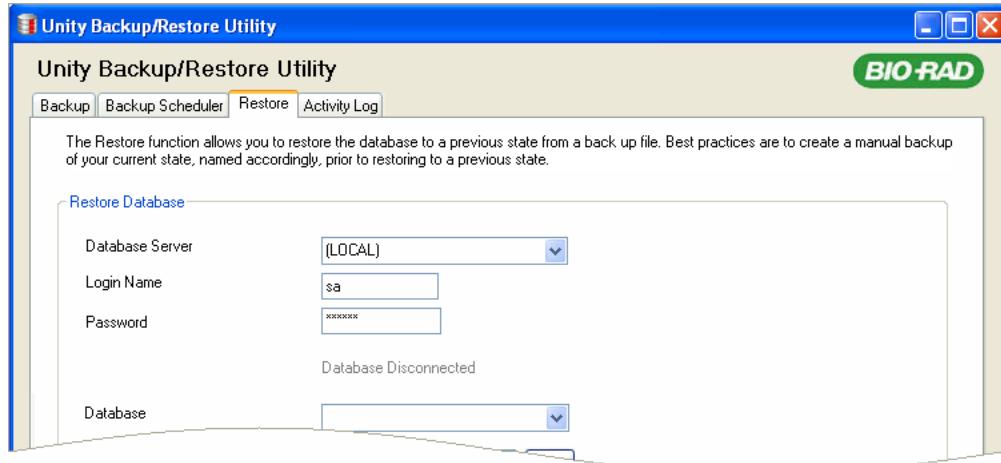
Backup 07 22 2021.bak

- 5 Click **Execute Backup** when you are ready to back up the database.

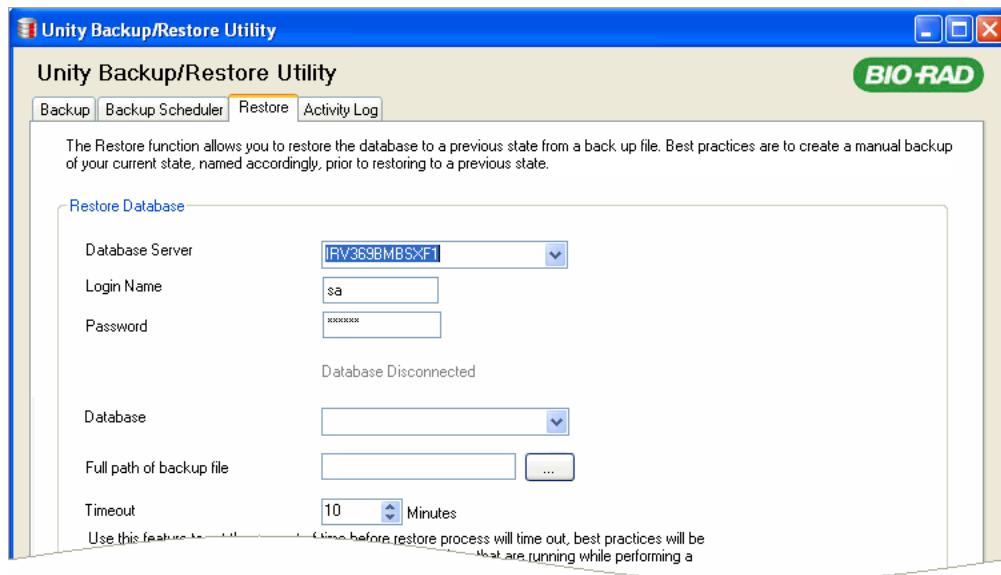
A message appears when the backup is complete.

Manually Restore the Database Remotely

- 1 Click the **Restore** tab.



- 2 Select the database server from the **Database Server** drop-down list.



- 3 Enter your login name and password.

The Unity Real Time database uses the following SQL Server credentials by default:

- Login Name: sa
- Password: biorad

- Select the database from the **Database** drop-down list you want to restore.



Note: The default Unity Real Time database is named “QCDAO.”

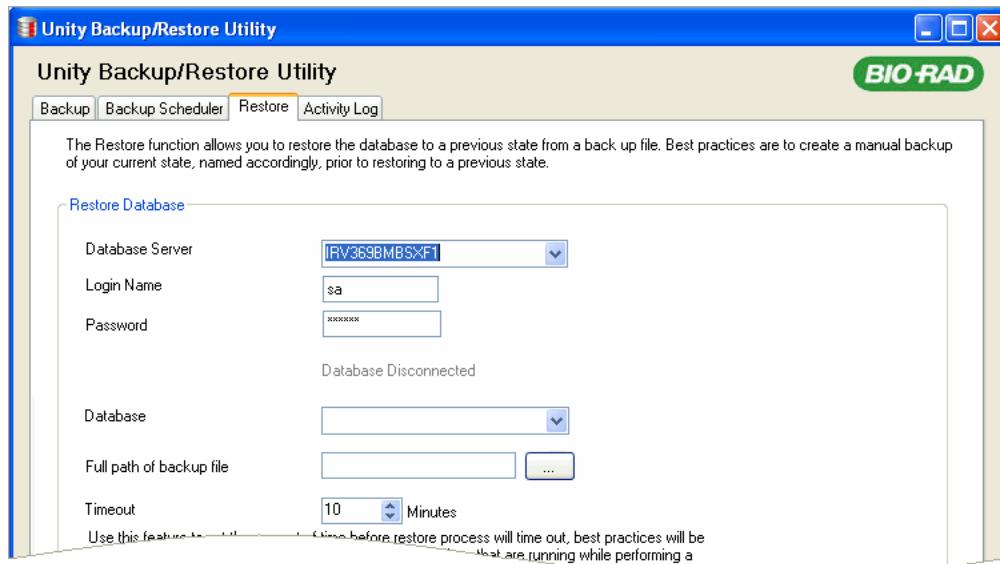
The word “Connected” appears in green above the database name when you are connected to the database server.

- Select the path where the backup file is located:



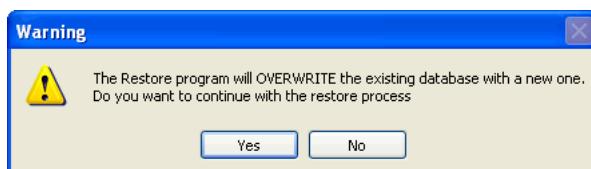
Note: You can access the restore path using the local (C:\local) or the absolute path (\server name\folder name).

- Manually type the path in the field,
- or
- Click and navigate to the path where the backup file is located.



- Click **Execute Restore**.

A warning message appears stating the restore process will overwrite the existing database.



- Click **Yes** to continue.

A message appears when the restore is complete.

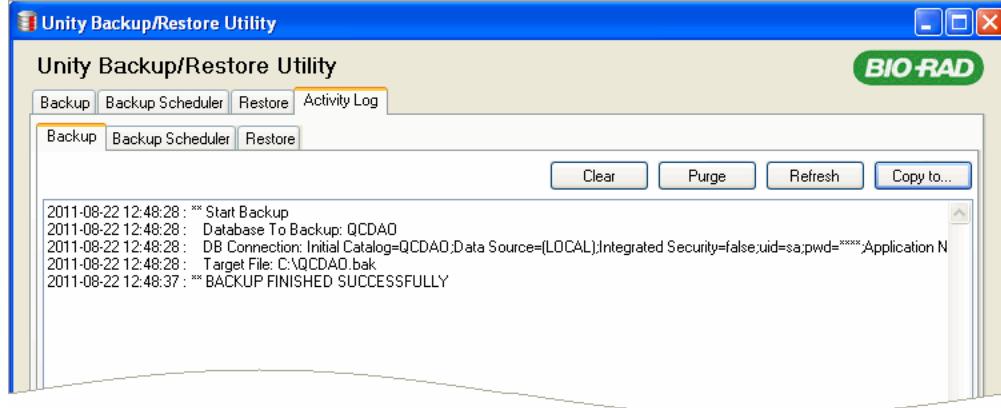


View the Activity Log

Use the Activity Log to perform the following functions:

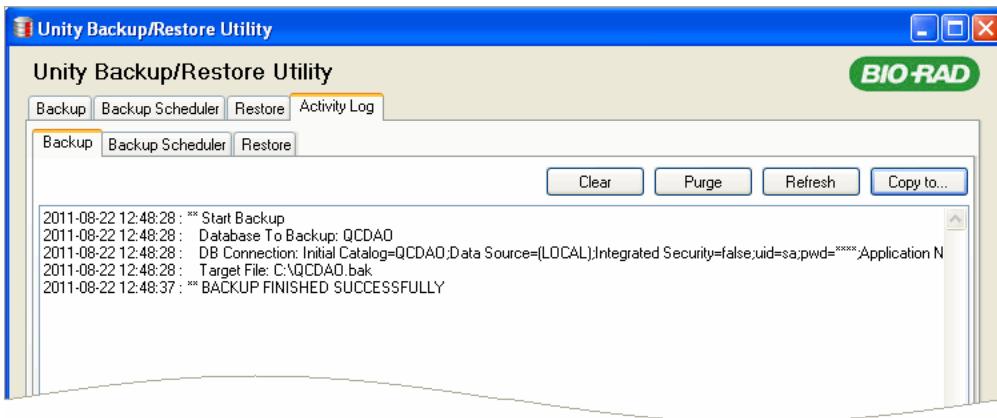
- **Clear**
Clears the information that currently appears in the Activity Log.
- **Purge**
Permanently deletes the log file for the selected type and/or job.
- **Refresh**
Refreshes what is happening with the backup scheduler on a selected type and/or job.
- **Copy to**
Copies the log file information in text (.txt) format.

1 Click the **Activity Log** tab.



2 Click the tab according to the **Activity Log** you want to view.

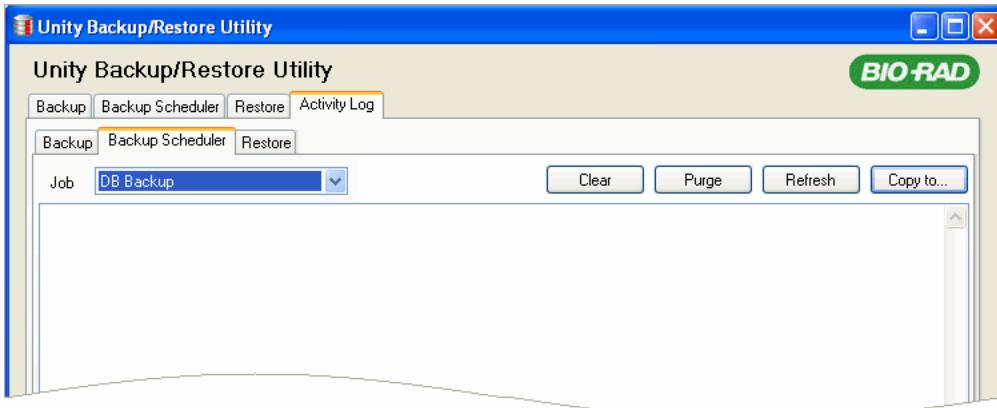
- Backup
- Backup Scheduler
- Restore



- Click the button according to the action you want to take:



Note: Select the job from the **Job** drop-down list if you selected the **Backup Scheduler** tab.



- Clear**
Clears the information that currently appears in the **Activity Log**.
- Purge**
Permanently deletes the log file for the selected type and/or job.
- Refresh**
Refreshes what is happening with the backup scheduler on a selected type and/or job.
- Copy to**
Copies the log file information in text (.txt) format.



Note: For customers using Microsoft SQL Version 2008 or higher, Bio-Rad recommends using SQL Server Management Studio. To create or restore a backup, open Studio, right click on the database, select **Tasks**, then select backup.

Install Unity Real Time

In This Chapter

Introduction	412
Overview	412
Users' access to these functions and other features are controlled by Unity Real Time administrators.	412
Unity Real Time Client System Requirements.....	414
Getting Started with Installation	415
Unity Real Time Database Compatibility and Settings	416
Unity Real Time Disaster Recovery and Backups.....	423
Unity Real Time HIPAA Compliancy	424
Unity Real Time Certifications and Regulations	425
Unity Real Time Development Life Cycle.....	425
Unity Real Time Support.....	426
Updating and Upgrading the Software.....	428

Introduction

This document describes the technical and operational components of Unity Real Time. A technical review is a necessary step in evaluating any proposed technology solution.

Overview

Unity Real Time is a client server application for laboratory QC data management. Unity Real Time has four primary functions:

- Provide high quality run validation with comprehensive QC related audit trails
- Facilitate routine bench-level and supervisory QC data review
- Provide advanced data analysis charts and reports
- Submit QC data for peer group comparison

Users' access to these functions and other features are controlled by Unity Real Time administrators.

Functional Components of Unity Real Time

Software Components

Each of the functional components of Unity Real Time depends upon read/write access to the database, making the entire application a client that connects to a database.

Application Environment

Unity Real Time uses the Microsoft.NET run-time environment for the application and database. Microsoft.NET requires Dynamic Link Library (DLL) components for performing tasks as well as Open Database Connectivity (ODBC) and ActiveX Data Objects (ADO) connections to the database.

Unity Real Time Client System Requirements

Supported operating systems :	<ul style="list-style-type: none"> Microsoft Windows 7 32/64-bit Microsoft Windows Server 2008 R2 64-bit Microsoft Windows 8.1 32/64-bit Microsoft Windows Server 2008 and 2008 R2 Microsoft Windows Server 2012 R2 Microsoft Windows 10 32/64-bit Microsoft Windows Server 2016 Microsoft Windows Server 2019 Note: Microsoft Windows 7 users cannot use Microsoft SQL Server Express 2017
Prerequisite software:	<ul style="list-style-type: none"> Microsoft Internet Explorer 11.0 (prerequisite for Microsoft .NET Framework) Microsoft Data Access Components (MDAC) 2.8 SP1 or later (required for Microsoft SQL Server setup).
Software bundled with Unity Real Time:	<ul style="list-style-type: none"> Crystal Reports runtime SP25 (for all reporting tools) Microsoft .NET Framework 3.5 Adobe Acrobat 11 or higher Microsoft SQL Server Express 2017 64-bit
RAM:	<ul style="list-style-type: none"> 2 GB (minimum) 4 GB or more (recommended)
CPU:	<ul style="list-style-type: none"> Intel Core 2 Duo or faster processor 2.8 GHz and above
Storage:	20 GB free space (minimum)
Network requirements:	See “Users’ access to these functions and other features are controlled by Unity Real Time administrators.” on page 412.

Getting Started with Installation

The core component of the Unity Real Time software is the database. In cases where enterprise-wide deployment is required, Bio-Rad recommends hosting the Unity Real Time database on a fully licensed Microsoft SQL Server Standard or Microsoft SQL Server Enterprise in a redundant environment.

Client computers on the same network can access the Unity Real Time database. The typical and minimum recommended installation environment for Unity Real Time (application and database) is a desktop personal computer. The maximum installation configuration depends on licensing and hardware resources.

Bio-Rad encourages facilities seeking enterprise level configurations to consult with a Bio-Rad Quality Systems Specialist for expert recommendations and planning.

Application Deployment

The Unity Real Time .MSI file does not support unattended installations or answer files. However, Bio-Rad has provided a method for system administrators to deploy the application unattended over the network using the setup.exe file. Please consult with your Bio-Rad Field Application or Support Specialist for updated information regarding this type of application deployment.

Virtual Environments

Due to numerous virtual environments such as Citrix, VMware, and Microsoft Windows Virtual PC, Bio-Rad does not directly support the use of Unity Real Time in such environments. This does not mean Unity Real Time will not work in a virtual environment and it does not void any specific warranty. It simply means that the bulk of support and troubleshooting for virtual system related issues may be the burden of the end user. However, if an issue is reproducible on the application server hosting Unity Real Time, Bio-Rad will provide full support of the application if all system compatibility profiles have been met (i.e., operating systems compatibility list, etc.).

Unity Real Time Database Compatibility and Settings

Database Platforms				
Microsoft SQL Server	URT Supporting SQL Server Environments			
	SQL Server Environments	Express	Standard	Enterprise
	SQL Server 2005 *	✓	✓	✗
	SQL Server 2008 & 2008 R2	✓	✓	✓
	SQL Server 2012 & 2012 R2	✓	✓	✓
	SQL Server 2014	✓	✓	✓
	SQL Server 2016	✓	✓	✓
	SQL Server 2017	✓	✗	✗
*SQL Server 2005 is applied to existing URT users only.				
These database platforms provide the most optimal host for the database to reside (i.e., robust server specifications, database maintenance plans, access controls, etc.). Please refer to the Microsoft website for minimum system requirements for these database platforms.				
Bio-Rad Installation Package	<p>Microsoft SQL Server 2017 Express is licensed, packaged and deployed by Bio-Rad during installation of the Unity Real Time database setup. SQL Server 2017 Express has limitations which must be considered in environments requiring superior performance and database size. These limitations include:</p> <ul style="list-style-type: none"> • Maximum database size is 10GB, the same as a SQL Server 2016, SQL Server 2014, SQL Server 2012, SQL Server R2 Express • 1.5 GB of available system RAM is used • Only allows the lesser of one CPU socket or four cores 			

Unity Real Time Database Compatibility and Settings (continued)

Supported O/S:	New Users		
		Installation	
Supported Windows Environments	URT Application	SQL Server 2017 Express	
Windows 7 (32-bit)	✓	✗	
Windows 8.1 (64-bit)	✓	✓	
Windows 10 (32-bit)	✓	✗	
Windows 10 (64-bit)	✓	✓	
Windows Server 2008 and 2008 R2	✓	✗	
Windows Server 2012 R2	✓	✓	
Windows Server 2016	✓	✓	
Windows Server 2019	✓	✓	
Existing Users			
Supported Windows Environments	Installation		
	URT Application	SQL Server 2017 Express	
Windows 7 (32-bit)	✓	✗	
Windows 7 (64-bit)	✓	✓	
Windows 8.1 (32-bit)	✓	✗	
Windows 8.1 (64-bit)	✓	✓	
Windows 10 (32-bit)	✓	✗	
Windows 10 (64-bit)	✓	✓	
Windows Server 2008 and 2008 R2	✓	✓	
Windows Server 2012 R2	✓	✓	
Windows Server 2016	✓	✓	
Windows Server 2019	✓	✓	

Unity Real Time Database Compatibility and Settings (continued)

All Versions	The use of various cluster/disaster recovery/high availability (HA) utilities can be used. However, the bulk of support is on the end user. Bio-Rad will provide support on a limited best-effort basis.
Additional Requirements and Settings	
RAM:	
CPU:	See “Unity Real Time Database Sizing Recommendations” on page 419.
Storage:	
Communication protocols:	See “Unity Real Time Network and Interface Requirements” on page 421.
Non-standard SQL configurations, collations, settings required:	<ul style="list-style-type: none"> • Login account to SQL server must be granted db_owner rights to the database • The collation is [SQL_Latin1_General_CI_AS] • Transaction log growth size is set to 10% unrestricted by default. Unity Real Time uses a stored procedure to truncate down to 1 MB when detected • Recovery model needs to be set to “Simple”
I/O transactions:	<ul style="list-style-type: none"> • Each Unity Real Time import string, equivalent to a data point, generates 23 SQL requests from the Unity Real Time application. Any further SQL transactions are not identified. The scope to identify the amount of I/O requests would be to calculate the total number of expected QC results processed daily. • 1 data point result equals ~1 KB within the database • Volume is dependent on usage • Application transaction type is OLTP
License scheme:	<ul style="list-style-type: none"> • The default Unity Real Time license allows for three concurrent users and can be expanded in increments of five. For example: 3, 8, 13, 18, 23, etc. • Multiple databases can be licensed as well as multiple clients

Unity Real Time Database Sizing Recommendations

Small Scale Implementation Specifications

Number of instruments resulting QC:	1–6
Number of concurrent users:	1–10
RAM:	2–4 GB
CPU:	Intel Core 2 Duo, 2.8 GHz and above
Storage:	40–60 GB
Microsoft SQL Server platform:	Microsoft SQL Server Express 2017 (no multi-core > 2 Core Duo support)

Medium Scale Implementation Specifications

Number of instruments resulting QC:	7–15
Number of concurrent users:	10–20
RAM:	4–8 GB
CPU:	Intel Core 2 Duo, 2.8 GHz and above
Storage:	60–80 GB
Microsoft SQL Server platform:	<ul style="list-style-type: none"> Microsoft SQL Server Express 2019 (no multi-core > 2 Core Duo support) Microsoft SQL Server Standard 2008 R2, 2012 R2, 2014, and 2016 (multi-core support)

Enterprise Level Implementation Specifications

Number of instruments resulting QC:	16+
Number of concurrent users:	20+
RAM:	8+ GB
CPU:	Intel Xeon CPU (Dedicated VM/Server/etc.)
Storage:	100+ GB
Microsoft SQL Server platform:	<ul style="list-style-type: none"> Microsoft SQL Server Standard 2008 R2, 2012 R2, 2014, and 2016 (multi-core support) Microsoft SQL Server Enterprise 2008 R2, 2012 R2, 2014, and 2016 (multi-core support with enhanced options)

Scalability

Unity Real Time is very scalable even when installed with the default configuration. The need for more concurrent users, multiple sites, large data pushes, long-term storage of results, and bandwidth limitations can be addressed by hardware or non-default installations of the software. Bio-Rad personnel are available to assist in scalability planning.

Reliability

Microsoft SQL Server Relational Database Management Systems (RDBMS) are considered world-class database hosting solutions. Reliability is generally limited by hardware quality and performance rather than software.

Unity Real Time Network and Interface Requirements

Ports, Protocols and Services (PPS):	Internet Information Services (IIS) 5.0 or later is required for Microsoft SQL Server 2005 Reporting Services (SSRS) installations.
Initial login: (check for product updates) (check for license updates)	
Peer data submission:	www.qconcall.com
Receive code lists:	
Receive analytical goals:	
Receive instrument setup:	
www.QCNet.com:	157.238.195.219
Ports:	<ul style="list-style-type: none"> • http port for monthly peer group submission and product downloads (default port 80) • 1433 for ODBC SQL connection • 443 for remote sessions during support (if necessary) • 443 for viewing InstantQC Reports on QCNet using the following URL: http://www.qcnet.com:443/Login.aspx
Client to database connection:	<ul style="list-style-type: none"> • TCP/IP for connectivity with the SQL database • Named pipes for connectivity with the SQL database • ADO.Net for import string functionality to the database • Open Database Connectivity (ODBC) • Multi-protocol
Proxy:	Proxy server aware, including multiple proxy types, DNS with NT authentication
Bandwidth requirements:	Optimal performance requires a minimum 100BASE-TX
Bandwidth utilization:	Based upon large database queries (40,000 QC files processed), which are not constant, the end-user can experience up to 2 Mbps (2%) utilization and an average of 285 packets per second on a 1 Gbps LAN environment
Supported network environments:	Unity Real Time provides QC data management and reporting functions across multiple facilities, time zones, and regions
Size of files transmitted/received from Bio-Rad:	<ul style="list-style-type: none"> • Code list download ~756 KB on disk • Analytical Goals download ~24 MB on disk • Instrument Setup ~460 KB on disk • QC data transmission files depend on the amount of data being transmitted (average ~200 KB)
HL7 or ADT compliant:	Not compatible with Unity Real Time

Security and Access Control Information

Database Security

- Data authentication is passed through using ADO.Net SQL authentication.
- SQL authentication password complexities must conform to local IT policy.
- SQL authentication password expiration is dependent on the security login account created on the server.

Application Security

- Passwords must be at least 2 characters long for the application.
- Passwords for the application can be set to expire in 3, 6, or 9 months. By default, password expiration periods are set to never, a time period must be selected to activate them. The Administrator can enforce password expirations at a configurable interval.
- There are no password complexity requirements for the application.
- Unity Real Time does not allow for credentials to be saved locally (bypassing future authentication).
- Unity Real Time users must manually log out during periods of inactivity.

Encryption

Unity Real Time encrypts the following values within the UnityRealTime.exe.config file using a lateral-bit rotation scheme, such as: ProxyPwd, PWD, LicenseKeyUsername, LicenseKeyPassword, and ImportLicenseID. This file is responsible for shared application configurations.

Integration with Enterprise Access Control (LDAP)

Unity Real Time does not integrate with LDAP, Active Directory, or Kerberos.

Anti-Virus Integration

Unity Real Time does not place any restrictions on the use of commercial antivirus software and updates. All data sets can be monitored by antivirus software.

Client System Permissions

On the client computer, a minimum of power user rights are needed for the following paths:

C:\MSSQL, C:\Program Files\Bio-Rad Laboratories\Unity Real Time, and the registry key [HKEY_LOCAL_MACHINE\SOFTWARE\Bio-Rad Laboratories].



Note: SS Registry key for 64-bit users:

[HKEY_LOCAL_MACHINE\SOFTWARE\Wow6432Node\Bio-Rad Laboratories\QC OnCall].

User Roles

Administrator can determine permissions within application based on login, giving different degrees of privileges depending on what role each user will play.

Auditing

Unity Real Time provides an audit system to log events related to QC data manipulation. However, this does not track attempted logins or other access related functions.

Vulnerability

Vulnerabilities, also known as CVEs, for the Microsoft SQL Express 2005 redistributable package can be found at the United States National Vulnerability Database (NVD) (<http://web.nvd.nist.gov/view/vuln/search?execution=e2s1>).

Unity Real Time Disaster Recovery and Backups

Backing Up the Database

Unity Real Time provides a backup utility that performs a SQL backup. The backup creates a *.BAK file on the local hard drive and then has the ability to move these files to a network location. You can perform one-time backups, or set scheduled backups on a daily, weekly, or monthly routine.

Alternate functionality exists in Unity Real Time to archive the database as flat files. However, based upon certain Microsoft deprecated features, this archive function only applies to those using Microsoft SQL Server 2008/2008 R2 or less. Please consult with the Bio-Rad support representative if you have any further questions or concerns.

Disaster Recovery

If backups are stored off-site, the application may be reinstalled and the database backup file restored. All data and configuration would then be recovered.

Depending on the Unity Real Time database size, the restore process could vary upon environmental variables to recover the database and clients back to their fully operational condition. Please contact Bio-Rad Software Support for assistance in planning for this scenario.

Unity Real Time HIPAA Compliancy

The following provides a description of the datasets that are generated, stored, or transferred by Unity Real Time.

With the advent of the Health Insurance Portability and Accountability Act (HIPAA), there may be concern about the use of software in the laboratory environment that may violate patient privacy rights.

- QC data management software from Bio-Rad simply computes and transmits QC data from quality control samples.



Note: Bio-Rad does not enter into Business Associate Agreements (BAA) related to Unity Real Time or remote desktop support. However, Bio-Rad will escalate Confidentiality Disclosure Agreements (CDA) to our legal department for review and consideration.

- QC Connectivity software from Bio-Rad does have the capability to harness patient information from a laboratory instrument during interfacing. However, during the data stream collection process, patient samples are separated from QC samples and purged from the local system.
- If any patient data is inadvertently transmitted and imported as quality control, the Bio-Rad QC data management software does not have the capabilities to read any demographic data, so this would automatically de-identify the data.
- Bio-Rad support personnel offer remote access to the client's environment via Zoom or Citrix GoToAssist (Citrix online). Remote access is initiated and controlled by the end-user at all times.
- All Bio-Rad employees with potential access to PHI from a Bio-Rad Laboratories covered entity client are required to adhere to the Bio-Rad HIPPA policies and procedures.

General Data sets	
Personnel information:	Account contact information for each lab number such as company address, phone number, e-mail address, etc.
Configuration of structural information:	Lab number, lot number, test, and instrument information
Protected Health Information (PHI):	No
Financial information:	No
Public information:	No
Other classified information:	No

HIPAA Transactions and Code Sets (TCS)	
Claims processing and/or transmission	No
Encounters processing and/or transmission	No
Claims status inquire and/or response	No
Claims payment, explanation of benefits (EOB), and/or electronic remittance advice (ERA)	No
Patient eligibility	No
Health plan authorization and/or certifications	No
Health insurance benefits enrollment and/or maintenance	No
Health insurance premium payments and/or processing	No

Unity Real Time Certifications and Regulations

- Unity Real Time is not considered a regulated FDA product.
- Unity Real Time facilitates compliance with regulatory and accreditation requirements with the following regulatory agencies and/or guidelines:
 - CAP accreditation requirements
 - CLIA requirements
 - CLSI guidelines
 - ISO 15189 standard
 - ISO 9001:2008
 - Various other local regulatory and accreditation requirements worldwide

Unity Real Time Development Life Cycle

Bio-Rad software engineering projects use agile software development. Agile software development allows Bio-Rad to follow an iterative design process in which we draft a design specification in parallel with our prototype development process.

As the prototype goes through iterations, the specifications are reviewed and updated to reflect the changes made to the prototype. After the final prototype is complete (ensuring all customer requirements are met), the product concept, which was identified and researched in the design specification and prototyping phase, is finalized into fully functional software code. After the software code is complete, Software Development and Quality Assurance fully test the software.

Change Management and Testing

As part of the agile software development process, we invite customers to become involved in the beta testing of all service packs prior to their official release. We work with customers in either a test or live environment to beta test changes and ensure a smooth transition to the released version.

Software Quality Assurance

Bio-Rad performs a vigorous testing process for each update and new product release and includes:

- Unit testing (development)
- Specific use case testing
- Regression testing
- Integration testing with supported operating systems (i.e., service packs, hot fixes)
- Virus scan with TrendMicro

Unity Real Time Support

The Bio-Rad Laboratories Software Support Team provides telephone and e-mail support for Bio-Rad software products and integration services. We do not support Customer or Reseller supplied third party products, although whenever possible, our team will offer advice and suggestions regarding the use, configuration, and faultfinding of such products in relation to Bio-Rad software.

In all cases, Bio-Rad Laboratories (hereafter called the Vendor) operates a remote web assistance tool, whereas the Customer must provide appropriate remote access facilities for Bio-Rad Laboratories to be able to provide the best support possible.

Description of Software Support

Software Support shall be performed by the Vendor as needed and requested by the Customer. Software Support is all-inclusive of software support services rendered by the Vendor for the duration of the Software Subscription purchased by the customer. Software Support can be the first point of contact for all issues that impact the operation of the Vendor's software, however we may not be the only point of contact for hardware issues.

Level of Support

Support is provided and is integrated into the Vendor's support processes. Standard Coverage is included with the software subscription purchased by the Customer with no further cost. This level of support is provided by the appropriate Vendor help desk personnel upon receipt of the Support Request from the Customer. This represents general support. If this level of support cannot resolve the problem, the Support Request is then escalated to the Vendor's Level 2 support personnel, which are then passed to the product specialists.

Response Time

For Standard Coverage, the response time following any service call should be 48 business hours or less. The response time begins when the request is logged with the Vendor Customer Contact System and ends when the Software Support representative closes the incident ticket.

After-Hours Work

Please e-mail us at unity_support@bio-rad.com or leave a voicemail on our phone system during non-business hours including most major U.S. holidays.

Training

On-site and live phone training are available for an extra fee. However, Bio-Rad Software Support does include information on usage that may be supplemented by directing the user to our online training materials.

Upgrades

Upgrades and updates can be managed by automatic product updates using customer's Internet access; however, Software Support is available to assist with upgrade issues that affect the operation of the Vendor's software.

Customer Assistance

During the support call and resolution process, the Customer representative may be requested to carry out certain tasks in order for progress to be made. This must be carried out within a reasonable time and feedback given to the Vendor support representative as soon as possible.

Remote/VPN Access

Bio-Rad supports our products remotely through two different Vendor solutions.

- GoToAssist by Citrix Online
End-to-end Secure Sockets Layer (SSL) port 443 and 128-bit Advanced Encryption Standard (AES) encryption. No unencrypted information is ever stored on their system.
- Zoom
Zoom end-to-end (E2E) chat encryption allows for a secured communication where only the intended recipient can read the secured message. Zoom uses public and private keys to encrypt the chat session with Advance Encryption Standard (AES256). Session keys are generated with device-unique hardware IDs to prevent data from being read from other devices. This ensure that the session cannot be eavesdropped on or tampered with.

On-Site Visits

Bio-Rad offers on-site visits for an extra fee. Please contact your local Bio-Rad Sales Representative for more information.

Temporary “Work-Around(s)”

Where no immediate solution is available to solve the issue raised by the customer, it may be necessary to introduce a temporary “work-around” solution while a permanent solution is investigated, tested, and implemented. This work-around will be designed to provide a basic functioning solution. This may involve changes to or implementation of manual working processes at the customer site, or a reversion to an earlier version of the Vendor system configuration. Where such a work-around is proposed by the Vendor, projected completion time lines for the implementation of a complete resolution will be given. Concerning achievement of Service Level, a temporary work-around will be an acceptable substitute for a permanent solution.

Software Solution

A Software Solution is generally defined as a request for support to fix a defect in existing software or a request for support that involves a workable solution to overcome that defect without changing the software. The Vendor will determine the appropriate solution for these requests.

Enhancement

An enhancement is generally defined as any request to make modifications to the functionality of an existing software product or any request to add functionality to an existing software product. The Vendor will determine the appropriate solution, if any, for these requests.

Software Support Hours and Contact Info

Inside the United States	
Phone:	800-854-6737; option 3
E-mail:	unity_support@bio-rad.com
Hours of operation:	5:00 a.m. to 5:00 p.m. PST, Monday through Friday excluding most major U.S. holidays. After hours, please leave a voice message or send an e-mail for a return call the following business day.
Outside the United States	
Phone:	Contact your local Bio-Rad office or Sales Representative
E-mail:	unity_support@bio-rad.com

Updating and Upgrading the Software

Automatic Updating

Unity Real Time provides the option to automatically receive and apply service packs via the Internet. (This is performed on port 80 by default). Bio-Rad will also provide service packs via e-mail or a download site for customers who prefer to apply service packs manually.

Microsoft Compatibility

When Microsoft makes a service pack or hotfix available, Bio-Rad installs them in a test environment and validates the basic operability of our products. It is the customer's responsibility to install, in accordance with Microsoft operating system software program guidelines, the Microsoft service packs and hot fixes on their network servers and technology-related assets.

Update Notification

The software prompts users, regardless of update permissions, that an update is available. Users with update permission may install the update.



Important: Make sure you back up the current database before you install any upgrade.

Frequency of Updates

- Updates and service packs are created when needed. The release dates of updates are up to the discretion of product management. There is no rotation or set schedule currently in place for development of updates or service packs.

Configure Unity Real Time

In This Chapter

Overview	430
Configure Data Entry	431
Configure Actions and Comments	432
Configure Database Updates	433
Configure Product Updates	434
Configure Notifications	435
Configure Transmission	435
Configure License Updates	436
Configure the Report Format	436
Configure Proxy Server Settings	437
Configure Unity Interlaboratory Report Frequency and Language	437

Overview

Unity Real Time provides different configuration options for you to customize the software.



Note: You can use Unity Real Time without changing any settings or configurations. The software will use the default selections.



You must have the “Edit Setup options” permission to perform this function.

See the following sections for more information about the configuration options:

- Configure Data Entry (page 431)
- Configure Actions and Comments (page 432)
- Configure Database Updates (page 432)
- Configure Notifications (page 435)
- Configure Product Updates (page 434)
- Configure Transmission (page 435)
- Configure License updates (page 436)

- Configure the Report Format (page 436)
- Configure Proxy Server Settings (page 437)
- Configure Unity Interlaboratory Reports (page 437)

Configure Data Entry

You can configure data entry for the following options:

▶ **Current data**

These options determine the summary statistics that appear on the Single Test Data Entry dialog boxes and the default data entry mode.

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Click the **Configure Unity Real Time** tab.

- 3 Select the data entry configuration options:

- **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 (Default)**

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

- **Group**

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



Tip: You can 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.

- 4 Select the default data entry mode:

- **Point (Default)**

Select this option if you usually enter single point data (a single value per level for each test).

- **Summary**

Select this option if you usually enter summary data (mean, SD, and number of points per level for each test).



Tip: You can also click the **Point Data** tab or the **Summary Data** tab on the Single Test Point Data Entry dialog box, the Single Test Summary Data Entry dialog box, and the Multi Test Data Entry dialog box to switch between entering point and summary data.

- 5 Click **OK**.

Configure Actions and Comments

You can configure the following action logs and audit trail comments:

Automatic and Require Action Logs

Use these options to automatically prompt a user to enter an action documenting how they addressed a point violating an active SPC rule set to Reject.

- **When and Where Automatic and Require Action Log Messages Would Appear**
 - For **Single Test Point Data Entry** this would occur after entering a run of data and pressing Tab or Enter on the Keyboard.
 - For **Multi Test Point Data Entry** this would occur if the user clicks Save and there are rejected points without a documented action.
 - For **QC data imported through a connectivity program** this would occur in the Bench Review or Supervisor review if the user clicks Save and there are rejected points without a documented action.

▶ Automatic action logs

The user has the option to continue without entering an action.

▶ Require action logs

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 automatically open 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. These comments are displayed in the Audit Trail Report. See “Audit Trail Events” on page 440 for a list of events that generate an audit trail.

Select Actions and Comments

1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

2 Click the **Configure Unity Real Time** tab.

3 Select each check box for the function you want:

- Automatic action logs
- Require action logs
- Require audit-trail comments

4 Click **OK**.

Configure Database Updates



Note: You must have Internet access to use this function.

You can configure Unity Real Time to automatically update the following information in the database.



Tip: Use this function to make sure your software always has the most up-to-date information.

▶ Automatic analytical goals and peer group updates

Select this check box if you want Unity Real Time to automatically update analytical goal and consensus group information when it is updated in the Unity Interlaboratory Program. Features that use this information are Chart Graph Against, Data Analysis Grid, Analytical Goals, Measurement Uncertainty Report, and Westgard Advisor.

▶ Automatic code list updates

Select this check box if you want Unity Real Time to automatically update code list information when it is updated in the Unity Interlaboratory Program. This include Lots, Tests, Instruments, Methods, Reagents, etc.

▶ Automatic instrument setup updates

Select this check box if you want Unity Real Time to automatically update instrument setup information when it is updated in the Unity Interlaboratory Program. This information comes from the Bio-Rad Unity Interlaboratory Program and includes the most common combinations of tests, methods, reagents, unit of measure, and temperature. Having this information available often makes setting up a new test easier.

▶ Get EI Data

Select this check box if you want Unity Real Time to retrieve current Bio-Rad elnsert data that can be used to set your evaluation means and/or SD/CVs as fixed values for rule evaluation.



Important: You should update the database on a regular basis If you choose not to update the database automatically. At a minimum, all users should regularly update their code list files.



Note: Unlike the other database updates, EI data is not added to the code list. Each time the “Get EI Data” check mark is selected in the Evaluation Mean/SD dialog box, data is retrieved from the Bio-Rad elnsert. Internet access is required to use the Get EI Data feature.

Select Database Update Options

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Click the **Configure Unity Real Time** tab.
- 3 Select each check box for the database update option you want:
 - Automatic analytical goals updates
 - Automatic code list updates
 - Automatic instrument setup updates
 - Get EI Data
- 4 Click **OK**.

Configure Product Updates



Note: You must have Internet access to use this function.

You can configure Unity Real Time to automatically process service pack updates to the software. When you use the automatic product update function, the **Product Update** dialog box appears when you log on to Unity Real Time.

When the **Product Update** dialog box appears, you can do any of the following:

- Download and install the update.
- Download the update to a location you specify and install at a later time.
- Close the dialog box without taking any action. The software notifies you again of updates the next time you log on.

If you choose not to automatically process updates, a message appears stating a service pack is available when you log on to Unity Real Time. The message requests that you contact your Bio-Rad software support representative who will give you instructions on how to access the service pack.



Important: Customers using Data Innovations to import QC data into Unity Real Time should not select the option for Product Updates. Updating Unity Real Time without also addressing Data Innovations can disrupt the automatic import of QC data.

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Click the **Configure Unity Real Time** tab.
- 3 Select the **Automatic product updates** check box.
- 4 Click **OK**.

Configure Notifications

Expired Lot Notification

You can configure Unity Real Time to display a message each time a user opens a data entry dialog box for a test in a lot expiring in 30 or fewer days.

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Click the **Configure Unity Real Time** tab.
- 3 Select the **Expired lot notification** check box.
- 4 Click **OK**.

You can select the **Do not display this message again** check box to stop the message from appearing.

Connectivity Notification

If selected, a message will appear after updating a test configuration (method, instrument/kit, reagent, or unit of measure) reminding you to make the same update in your connectivity solution (i.e. UnityConnect 1). Some connectivity solutions, such as UnityConnect 2, automatically update test configuration when a change is made in Unity Real Time, which means this selection could be turned off.

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Click the **Configure Unity Real Time** tab.
- 3 Select the **Connectivity Notification** check box.
- 4 Click **OK**.

You can select the **Do not display this message again** check box to stop the message from appearing.

Configure Transmission



Note: You must have Internet access to use this function.

You can configure Unity Real Time to automatically send data to Bio-Rad.

- ▶ **Data review transmission (for InstantQC)**
Use this function if you want to send point data from the Bench Review and/or Supervisor Review to the Unity Interlaboratory Program for inclusion in InstantQC Reports.
- ▶ **Automatic monthly transmission**
Use this function if you want to automatically send monthly data to the Unity Interlaboratory Program on a selected day of the month.



Tip: Use either or both of these functions to make sure your data is always sent to Bio-Rad on time.
As a general rule, data must be sent to Bio-Rad by the seventh day of the following month.

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Click the **Configure Unity Real Time** tab.

- 3 Select each check box for the function you want. Leave the check box cleared if you do not want to use a function.

- Data review transmission (for InstantQC)
- Automatic monthly transmission



Note: The Unity Real Time software must be running in order to submit data when using the Automatic monthly transmission function.

- 4 Click **OK**.

Configure License Updates

You can configure Unity Real Time to display a message upon log when the database license is due to expire in 30 or fewer days.

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Click the **Configure Unity Real Time** tab.

- 3 Select the **Automatic license updates** check box.

- 4 Click **OK**.

Configure the Report Format

By default, Unity Real Time generates reports that can be printed or exported to Crystal Reports (*.rpt format). You can configure Unity Real Time to generate intralaboratory reports in PDF format. You can view, print, and save the reports using the free Adobe Reader software.

- 1 Click the **Tools** menu and then click **Setup**.

The **Setup** dialog box appears.

- 2 Click the **Configure Unity Real Time** tab.

- 3 Select the **Generate PDF reports** check box if you want to create intralaboratory reports in PDF format.

- 4 Click **OK**.

Configure Proxy Server Settings

Configure the proxy server settings if you are unable to access the Bio-Rad server directly through Unity Real Time due to your local network security.

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Click the **Configure Unity Real Time** tab.
- 3 Select the **Use Proxy Server** check box.
- 4 Type the IP address for the proxy server in the **Proxy IP address** field.
- 5 Type the port number in the **Proxy port** field.
- 6 Select the version from the **Proxy specification version** list.
- 7 Select the **Enable HTTP Keep-Alives** check box to maintain a persistent connection through the proxy server, if needed.
- 8 Select the **Use proxy authentication** check box if users are required to enter a login ID and password to access the Internet on their local network.
- 9 **Use proxy authentication only:** Type the user name, password, and domain in the respective fields.



Note: This allows customers to automatically pass through the proxy server without entering this login ID and password.

- 10 Click **OK**.

Configure Unity Interlaboratory Report Frequency and Language

You can 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
- Bias and Imprecision Histogram
- Statistical Profile Report

- 1 Click the **Tools** menu and then click **Setup**.
The **Setup** dialog box appears.
- 2 Click the **Configure Unity Real Time** tab.

3 Select the report frequency for each report from the respective lists:

- Laboratory Performance Overview
- Laboratory Comparison Report
- Laboratory Histogram
- Bias and Imprecision Histogram
- Statistical Profile

4 Select the report language from the **Language** list.

5 Click **OK**.

Supplemental Information

In This Chapter

Action Log Messages	439
Audit Trail Events	440
Rejection Log Messages	443

Action Log Messages

The following is a list of the pre-defined action messages and their code numbers. If you add custom action messages, the action is added to the bottom of the list. You can drag and drop the action to place it where you want in the list or click the header bar to sort the list alphabetically. 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
17	Maintenance: daily
18	Maintenance: monthly
19	Maintenance: semi-annual

Action Log Messages	
Action Log Messages (continued)	
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 265 for more information.

Audit Trail Events
Accepted/rejected status changed
Analytical goal rule status changed
Analytical goal selection changed
Cyclic evaluations activated/deactivated
Data deleted from within data entry
Data deleted using Delete Range of Data
Data inserted
Data moved to different configuration
Data point edited
Data point date/time changed
Designer lot edited
Expected response changed
Fixed mean added or changed
Fixed standard deviation added or changed
Imprecision-BV
Imprecision-BV: Goal CV (%)
Imprecision-BV: Decision Limit 1
Imprecision-BV: Decision Limit 2

Audit Trail Events (continued)
Imprecision-BV: Decision Limit 3
Imprecision-BV: Target Value
LIME evaluations activated/deactivated
Lot number edited after data entry
RiliBÄK maximum deviation (mzA) changed
RiliBÄK maximum imprecision changed
RiliBÄK maximum inaccuracy changed
RiliBÄK target value changed
Medical Relevance
Medical Relevance level-dependent status
Medical Relevance status
Medical Relevance: Target Value
Number of decimal places changed
Number of points before rule evaluation changed
Number of series per day changed
Reagent/Calibrator lot Updated
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
Series starting time changed
State of the Art
State of the Art: CV% Selection
State of the Art: Decision Limit 1
State of the Art: Decision Limit 2

Audit Trail Events (continued)
State of the Art: Decision Limit 3
State of the Art: Target Value
Test information has been updated
Total Error-BV
Total Error-BV: Bias Goal CV (%)
Total Error-BV: Bias Goal CV (%) level
Total Error-BV: Bias Goal CV (%) status
Total Error-BV: Imprecision Goal CV (%)
Total Error-BV: Imprecision Goal CV (%) level
Total Error-BV: Imprecision Goal CV (%) status
Total Error-BV: Target Value
Total Error-BV: Target Value scope
Total Error-BV: Target Value frequency
Total Error-BV: TEa p < .05

Rejection Log Messages

The following is a list of the messages that appear on the Rejection Log to correct errors from connectivity solutions.

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
Date out of range
Date out of sequence
Date/Time invalid
Failed validity check
Instrument code invalid
Invalid Action Code
Invalid Day
Invalid Hour
Invalid Date Time
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

Rejection Log Messages (continued)
Record type invalid
Result invalid
RiliBÄK Test has been locked
Temperature code invalid
Temperature invalid for selected analyte
Test closed
Test not defined
Time out of sequence
Unable to create new test
Unit code invalid
Unit invalid for selected analyte

References

In This Chapter

Articles	445
Books.....	446
Guidelines	446

Articles

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Books

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Guidelines

- 1 The Clinical and Laboratory Standards Institute's Guidance for statistical quality control (C24-Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions).
- 2 National Committee for Clinical Laboratory Standards. Evaluation of precision performance of clinical chemistry devices (2nd edition); Tentative Guideline. NCCLS document EP5-T2 (ISBN 1-56238-145-8). NCCLS, 771 East Lancaster Avenue, Villanova, Pennsylvania, 1985, 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 or analytical goal with a status of Warn or Reject.

Affiliated Data Exception Report



Note: Affiliated Reports are optional. Contact the Bio-Rad QC Program Representatives to request Affiliated Reports.

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.

affiliated group

A group of laboratories in the Unity Interlaboratory Program comparing their results and essentially becoming their own consensus group. Contact the Bio-Rad QC Program Representatives to request any of the available Affiliated Reports.

Affiliated Laboratory Comparison Report



Note: Affiliated Reports are optional. Contact the Bio-Rad QC Program Representatives 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 the Bio-Rad QC Program Representatives 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 the Bio-Rad QC Program Representatives to request Affiliated Reports.

Affiliated Reports allow a group of laboratories to compare results, essentially becoming 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 goals

Analytical goals are used as a retrospective review tool in conjunction with SPC rules and can optimize the QC effort and cost. Analytical goals are configured on a test-by-test basis; only one analytical goal can be used at a time. The following analytical goals are available in Unity Real Time:

- Imprecision-BV
- Total Error-BV
- Medical Relevance
- State of the Art

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. The following formula is used 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 in contrast 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 groups

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.

critical systematic error

Critical Systematic Error (SEcrit) is determined by the formula Sigma - 1.65. SEcrit describes the probability of error detection for a critical systematic error.

Critical Systematic Error = Sigma - 1.65

cumulative mean

The mean of all accepted data points entered for a test. If a fixed mean is not defined, the software uses the cumulative mean for rule evaluation.

CV (coefficient of variation)

The coefficient of variation is the standard deviation expressed as a percentage of the mean. The following formula is used 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. The following formula is used 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 set

A group of data points having some elements in common (for example, the lab or lot numbers, panel assignments, data entry dates, and so on). Use data sets to compare data on the Data Analysis Grid and to determine the scaling (mean and $\pm 3SD$ range) of the Y-axis on the Levey-Jennings chart, Bar chart, Youden chart, and Yundt chart.

EI (Electronic Insert or eInsert)

EI data (Electronic Insert data) is lot-specific data for Bio-Rad products. For Bio-Rad products that have eInsert data available, Unity Real Time 2 can be configured to use this data to set fixed means and SD/CVs for rule evaluation. Additionally, customizable product inserts are available from My eInserts on QCNet.com.

evaluation mean/SD

The mean and SD Unity Real Time uses to evaluate a data point. If a fixed mean/SD is defined in Unity Real Time, this is what will be used. If a fixed mean/SD is not defined, then it will use the cumulative or floating mean/SD. These are based on the calculated data entered by the lab and can shift over time. You can view the evaluation statistics by clicking the Information symbol  for a row of data on the Single Test Point data entry dialog box.

fixed statistics

Fixed statistics refers to specifying (fixing) the evaluation mean and/or SD/CV for a test.

floating mean

Often used interchangeably with cumulative mean, although they are different. Cumulative is the mean of all accepted data points entered for a test. Using a floating mean allows you to define the start date of the cumulative statistics.

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.

imprecision-BV

An analytical goal targeting test imprecision based on biological variation data and laboratory-selected performance goals. Imprecision-BV is based on published “within-subject” biological variation data, rather than consensus group performance. Imprecision-BV can be used for any analyte for which limits are published.

inactive rule

A SPC rule or analytical goal with a status of “Off.”

InstantQC

An instant interlaboratory program option for comparing to other laboratories’ data on demand.

InstantQC Reports

When sending data to the Unity Interlaboratory Program, the reviewed data points appear on InstantQC Reports on www.QCNet.com after a short processing time. InstantQC Reports are useful for troubleshooting test system issues in real time because of the instant access to the latest consensus group information.

interlaboratory

Comparative results between laboratories used to determine values and assess test methods.

intralaboratory

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 Comparison Report is automatically generated each month you submit data; however, you can specify a different report frequency. See “Configure Unity Interlaboratory Report Frequency and Language” on page 437 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 standard deviation (SD)
- Laboratory coefficient of variation (CV)
- Number of points reported by the laboratory
- Coefficient of variation ratio (CVR) for the Peer and Method groups
- Standard deviation index (SDI) for the Peer and Method groups

The Laboratory Comparison Report also contains the monthly and cumulative Peer and Method group statistics for:

- Mean
- Standard deviation (SD)
- Coefficient of variation (CV)
- Number of points reported
- Number of laboratories reporting

The Laboratory Comparison Report also includes a modified Youden chart which allows you to visually evaluate the bias and imprecision for each test compared to the Peer and Method consensus groups.

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 and Language” on page 437 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. Labels and arrows clearly indicate values that fall outside of (above or below) the 2 SD range. 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 and Language” on page 437 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. May need to investigate test system performance.
- 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 farther 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 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 multi-rule 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. The following formula is used to calculate the mean:

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

Where:
 \sum = 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.

Medical Relevance

An analytical goal described as the total error that would cause a clinician to change a patient's diagnosis, prognosis, or treatment plan. This is based on confirming test imprecision within specified limits. Medical Relevance can distinguish statistical error from medically important changes when used as a feedback tool.

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. 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 447.

probability of false rejection (Pfr)

A QC performance characteristic describing how often a run is rejected when there are no errors.

pupil

The inner circle on a Yundt plot representing the smaller CVR of two data sets.

QC (quality control)

In the clinical laboratory, QC is a system designed to increase the probability each reported result is valid and can be used with confidence by a health care provider when making diagnostic or therapeutic decisions.

Qualitative Urine Chemistry Report



Note: The Qualitative Chemistry Report is optional. Contact the Bio-Rad QC Program Representatives to request this report.

The Qualitative Urine Chemistry Report is one of the Unity Interlaboratory Reports and is available for Bio-Rad Liquichek Urinalysis, qUAntify and qUAntify Plus Controls.

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

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

Qualitative Microscopic Report



Note: The Qualitative Microscopic Report is optional. Contact the Bio-Rad QC Program Representatives to request this report.

The Qualitative Microscopic Report is one of the Unity Interlaboratory Reports and is available for Bio-Rad Liquichek Urinalysis, qUAntify and qUAntify Plus Controls.

- Graphics simulate your average response and the group's average response.
- Your lab's daily responses appear above the graphics; an arrow indicates the majority group response.

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 Unity Real Time groups together for statistical profile rule evaluation (for example, within run and between run).

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). The following formula is used to calculate the SD:

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

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 SDI is helpful to evaluate performance. This statistic, which is usually obtained by participation in an external QC or proficiency testing program, is used to compare a laboratory's results to its consensus group. The Bio-Rad Unity Interlaboratory Program uses the consensus group value as the target value. The following formula is used to calculate the SDI:

$$SDI = \frac{\bar{x}_{Lab} - \bar{x}_{Group}}{s_{Group}}$$

Where:
 \bar{x}_{Lab} = Laboratory mean
 \bar{x}_{Group} = Consensus group mean
 s_{Group} = Consensus group standard deviation

shift

A type of systematic error evidenced by an abrupt change in the mean of the control values.

Sigma Metrics

A numeric value that characterizes method performance in terms of the number of standard deviations or sigmas that fit within the tolerance limit or quality requirement of a test. The following formula is used to calculate the Sigma Metric.

$$\text{Sigma} = [(\%TE_a - \%bias)/\%CV]$$

- Where:
- TE_a = Allowable total error or CLIA PT criterion for acceptable performance
 - $\%bias$ = The observed inaccuracy or systematic error of the method
 - $\%CV$ = The observed imprecision or random error of the method

Sigma Metrics Graph

The Sigma Metrics Graph is an evolution of power function graphs and critical error graphs. The Sigma Metrics Graph shows the potential capability of achieving or satisfying the stated quality requirement. In routine operation, the actual achievement of this quality is assured by applying the proper QC procedure.

Sigma Metrics provide a universal benchmark for process performance. The performance of all processes can be characterized on the Sigma scale. Values typically range from 2 to 6, where the goal for “world class quality” is 6. The bold vertical line displays the Sigma Metric of a test and the key on the right of the graph details the different SPC rules from Westgard Advisor that will detect nearly every critical error. If the Sigma Metric is less than 3, the process is so unreliable it should not be used for routine production. A process with a low Sigma Metric costs time and effort to maintain.

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.

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 the Bio-Rad QC Program Representatives to request this report.

The Statistical Profile Report is one of the Unity Interlaboratory reports and it 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.

State of the Art

An analytical goal used to confine test imprecision within specified limits with the idea the imprecision for each test should be equal to or less than the best imprecision achievable by technology. State of the Art uses consensus group information from the Unity Interlaboratory Program.

The “best imprecision achievable” is defined as the imprecision calculated for a specific consensus group—Peer, Method, or All Labs. Peer is the ideal consensus group for comparison, but the Method and All Labs consensus groups provide alternatives when a representative Peer group is not available or the Peer group is unacceptably small.

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, July 2009).

suspect data

Data points violating any SPC rule or analytical goal 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. The following formula is used to calculate the TE:

$$\text{Laboratory TE} = [\text{Laboratory Bias}(\%)] + z\text{-factor} \times (\text{Laboratory Imprecision \%})$$



Note: Unity Real Time uses a z-factor of 1.65 which corresponds to a 95% confidence interval.

TE_a specifications are available from several sources as described in “Determine Quality Requirements for the Test” on page 30.

- Total error < allowable total error = test results are generally considered reliable.
- Total error > allowable total error = corrective action should be taken as quality specifications are not being met.

TE_a (allowable total error)

Allowable total 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. The following formula is used to calculate the TE_a:

$$\text{TE}_a = z\text{-score} \times (\text{Desirable Imprecision \%}) + [\text{Desirable Bias \%}]$$

Total Error-BV

An analytical goal used as a quality appraisal tool. Total Error-BV sets upper and lower limits of performance for each test based on the TEa using biological variation data and laboratory-selected performance goals. Total Error-BV provides feedback on laboratory bias, imprecision, and TE.

trend

A type of systematic error causing a gradual, often subtle increase or decrease in control values and, possibly, patient results.

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. The following formula is used 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.....	463
Subscription or Charge Based Content and/or Services	464
Warranty Information	465
User Content.....	465
Personal Information.....	466
Storage and Loss of Use, and Limitation of Liability	466
Indemnification	466
Proprietary Information	466
Export Restrictions	466
Severability	467
Applicable Laws	467
Trademark Notices	467

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Index

A

accuracy 447
action log and actions
 add a custom action 205
 bench and supervisor reviews 210
 data entry 209
 delete an action 207
 edit an action 206
 overview 204
 setup action filter 208
 set up automatic action logs 209
 Set up automatic action logs 209
 sort the action log 206
 turn off automatic action logs 209
 unsuppress an action 207
action log messages 439
actions and comments 432
actions and comments by instrument 212
active rule 447
add
 Bio-Rad lot number 85
 lab number 79
 non-Bio-Rad lot number 86
 tests 97
 code of “other” 102
 direct method 97
 indirect method 97
 instrument setup 100
 manually 97
 non-Bio-Rad qualitative tests with qualitative responses 99
 tests to panel 118
 user 65
add a signature to report reviews 278
additional lab number 79
adjust column widths 46
administration/setup permissions 71
Advanced Tool, Westgard Advisor 347
Affiliated Data Exception Report 300, 447
affiliated group 447
affiliated lab number 79
Affiliated Laboratory Comparison Report 297, 448
 Abbreviated Summary 299, 448
affiliated reports 297, 448
all labs group 449

allowable total error (TEa) 196
Allowable Total Error (TEa) 17, 328
analyte 95, 449
analytical goals
 consensus groups 135
 description 449
 imprecision-BV 140, 452
 medical relevance 145
 overview 134
 performance goals 136
 retrospective evaluation 137
 rules status 137
 state of the art 147, 460
 total error-BV 142, 461
analytical process 449
apply rules, Westgard Advisor 349
arrange order of tests 105
arrange the order of lab numbers 83
arrange the order of lot numbers 92
assign lab numbers to users 68
audit trail 449
 audit trail events 266, 440
 Audit Trail Report 265
audit trail comments, require 213
automatic monthly transmission
 activate 280

B

backup and restore 390
bar chart 228
 create 228
 customize 229
 customize for qualitative tests 222, 230
basic QC statistics 11
bench review and supervisor review 180
 analytical goal and rule violations 180
 Data Review report 190
 document the review 184, 189
 InstantQC 187
 manage columns 188
 manage expected tests 189
 overview of the process 181
 perform 182
 refresh review window 188
 review data 183
 rule status 184

save and transmit 184, 185
select a data set for review 182
view data entry 183
view Levey-Jennings chart 183
warning messages 186

bias 449
Bias and Imprecision Histogram Report 293, 450

C

calculate a control mean and range 14
calculate the mean 135
calibrator lot tracking
 calibrator date/time 152, 242
 calibrator lot 152, 242
CAP accreditation requirements 312
change a data point's accepted/rejected status 175
change the date and time for a row of data 160
chart options
 fill background 238
 grid lines and color 239
 header 241
 show legend 240
charts
 Bar 227
 Levey-Jennings 217, 365, 454
 Multi-LJ 223
 OPSpecs Chart 341
 Save and Print 246
 Sigma Metrics Chart 345
 Youden 222, 230
 Yundt 233
choose goals based on required quality 34
CLIA 450
 requirements 10, 308
close
 lab number 82
 lot number 91
 tests 104
CLSI 450
Coefficient of Variation (CV) 16
Coefficient of Variation Ratio (CVR) 17
comments 210
 bench and supervisor reviews 211
 data entry 211
 overview 210
 view 211

comprehensive reports 283, 294
condense data 385
configure
 alerts, data analysis grid 198
 database updates 433
 data entry 431
 Data Set A, data analysis grid 200
 Data Set B, data analysis grid 201
 data sets, data analysis grid 195
 notifications 435
 product updates 434
 proxy server settings 437
 QC Items 42
 report format 436
 TEa, data analysis grid 196
 transmission 435
 Unity Interlaboratory report frequency 437
 Unity Interlaboratory Report language 437
connectivity
 Rejection Log Messages 443
consensus groups 135, 284, 335, 450
contact Bio-Rad 3
control materials, identify 31
copy
 lot number 90
create
 panel 118
create a panel and add tests 118
critical systematic error 450
cumulative mean 450, 451
customize the toolbar 49
CV 451
 set floating 113
 use floating to set fixed 112
CV (Coefficient of Variation) 16
CVR 451
CVR (Coefficient of Variation Ratio) 17

D

data analysis grid
 alerts 199
 configure data set A 200
 configure data set B 201
 configure general tab 203
 configure TEa 196
 create template 199

data set configuration 195
examples of comparisons 192
export 199
formulas 204
print 199
view 192

database
 backup and restore 390
 compatibility and settings 416
 condense data 385
 configure 430
 database permissions 72
 delete a range of data 387
 disaster recovery and backups 423
 export data 384
 move data 389
 reconcile database 386
 sizing recommendations 419
 update automatically 382
 updates 433
 view and update database information 380

data entry
 change the date and time for a row of data 160
 date, set and change 158
 enter multi test data 169
 enter single test point data 164
 enter single test summary data 166, 167
 navigate the single test dialog boxes 161
 overview 149
 overview of multi test data entry 168
 overview of point data entry 161
 overview of summary data entry 165
 overview of the single test data entry dialog boxes 150, 151
 permissions 173
 qualitative data 167
 set date feature 158

data groups 122, 451
 define 123
 edit 124

data handling permissions 74

data review permissions 74

data set 451
 define a data group 123, 124
 delete
 data row 178
 delete data 178

lab number 84
lot number 93
panel 121
range of data 387
tests 106
user 67
determine quality requirements for the test 30
download Adobe Reader 63
duplicate
 Bio-Rad lot number 87
 non-Bio-Rad lot number 88
 tests 104

E

edit
 Bio-Rad lot number 89
 data group 124
 date and time 174
 edit data 174
 non-Bio-Rad lot number 90
 user 67
EI 109, 110, 433
elInsert 109, 110, 433
enter multi test data 169
enterprise level implementation 419
enter qualitative data 167
enter single test point data 164
enter single test summary data 166
error
 determine type 36
 random 38
 relate to possible causes 37
 systematic 38
evaluate test performance 31
evaluation
 set up an expected response 115
evaluation mean and SD 109
 set floating 113
 use floating to set fixed 112
evaluation mean/SD 451
exit the software 42
export data 384

F

fixed mean and SD 109
fixed statistics 452

fixed vs. floating 109
floating mean 452
functions and where to find them 57

G

get EI data 109, 110, 433
good laboratory habits 36
grid display options, Westgard Advisor 332
grid lines and color 239
group login ID and password 69

H

HIPAA compliancy, Unity Real Time 2 424

I

identify appropriate QC materials 31
identify possible QC procedures 34
imprecision 452
imprecision-BV 140, 452
inactive rule 452
insert data 177
Install Unity Real Time® 2 412
InstantQC 187
 activate transmission 281
 definition 452
 overview 192
 reports 284, 305, 452
instrument navigation tree 44
instrument setup 100
 add tests 100
interlaboratory 452
interlaboratory reports 282
ISO 15189 requirements 322
issues to consider 39

K

keyboard shortcuts 50, 51, 216
keys to a productive review of the laboratory quality system 39

L

lab navigation tree 43
lab number 78
 add 79
 additional 79
 affiliated 79
 arrange 83

close 82
delete 84
duplicate 80
open 82
primary 78
types 78
update information 80

Laboratory Comparison Report 288, 452

Laboratory Histogram Report 290, 453

Laboratory Performance Overview Report 286, 453

labs, lots, tests, and panels permissions 73

level 454

levels in use 454

Levey-Jennings Chart 217, 365, 454

- change the status of a data point 218
- create 217

license agreement

- applicable laws 467
- export restrictions 466
- indemnification 466
- license 463
- personal information 465
- proprietary information 466
- storage and loss of use, and limitation of liability 466
- subscription or charge based content and/or services 464
- user content 465
- warranty information 465

license updates 436

Listings Reports

- Labs Listing Report 267
- Lots Listing Report 269
- Panels Listing Report 273
- Test Code Report 274
- Tests Listing Report 271

log off the software 41

log on to database 378

lot expiration notifications 94

lot numbers 84

- add a Bio-Rad lot number 85
- add a non-Bio-Rad lot number 86
- adjust the column widths 93
- arrange the order 92
- close 91
- closed and open 91
- copy 90
- delete 93

duplicate 87
duplicate a Bio-Rad lot number 87
duplicate a non-Bio-Rad lot number 88
edit a Bio-Rad lot number 89
edit a non-Bio-Rad lot number 90
open a closed lot number 92

M

manage expected tests 189
Manufacturer Report 296, 454
master lot number 454
matrix 454
maximum QC 455
mean 12, 455
 set custom fixed 111
 set floating 113
 use Bio-Rad elnser 110
 use floating to set fixed 112
mean and SD
 fixed vs. floating 109
Measurement Uncertainty Report 263
median 455
medical relevance 145, 455
menus and functions 53
method 96, 455
method group 455
Monthly Evaluation Report 285, 455
monthly reports 283, 285
move data utility 389
Multi-LJ Chart
 create 224
 create a template 225
 customize 224
 delete a template 227
 overview 223
 update a template 227
multi test data entry 2, 168

N

navigation tree 43
 instrument navigation tree 44
 lab navigation tree 43
 panel navigation tree 44
Negative Cyclus Report 367
network and interface requirements 421
non-Bio-Rad

Add non-Bio-Rad Qualitative Tests with Qualitative Responses 99
normal and abnormal controls 9
notes about rule evaluation 126
Notes, Tips, Important, and Permission Notes 7

O

open
 lab number 82
 lot number 92
 tests 104
open and closed lab numbers 81
operating point 456
Operator Report 261
 create 262
operator setup 76
OPSpecs Chart 341, 456
 components 342
organization of this guide 3
overview of SPC rules 125
overview of the single test data entry dialog boxes 150, 151

P

panel 456
panel navigation tree 43
panels 118
 create and add tests 118
 delete 121
 remove tests 120
 rename 119
 sort panel names 120
 sort tests 119
password 69
 change a password 70
 expiration 69
 group login ID and password 69
 requirements 69
 set a password expiration 70
peer group 456
percent AQA (SE) 456
performance goals 136
permissions
 administration/setup 71
 data 72
 database 72
 data handling 74
 data review 74

labs, lots, tests, and panels 73
RiLiBÄK 75, 355
set up user permissions 75
user 71
point data 456
Point Data Report 250
 create 251
precision 11, 456
predict the performance of the QC procedures 34
primary lab number 78
print and save charts 246
probability of false rejection 456
program hints 4
 buttons 4
 lists 5
 menu bar and menus 4
 options 5
 tabs 6
 toolbar 4
 unavailable items 6
pupil 456

Q

QC 456
QC procedure, select 35
QC procedures, identify 34
QC procedures, predict performance 34
QC Program Representative 3
qualitative
 Add non-Bio-Rad Qualitative Tests with Qualitative Responses 99
 bar chart 222, 230
 Microscopic Report 303
 Qualitative Worldwide Report 304
 set up an expected response 115
qualitative data entry 167
qualitative evaluation of a test's bias and imprecision 33
quality control
 definition 8

R

random error 38, 456
range 457
reagent lot tracking
 reagent bottle number/serial number 151, 242
 reagent in use/standby 151, 221
 reagent lot 151, 242

reagent type 96
reconcile the database 386
rejection log messages 443
rejection rule 457
remove tests from a panel 120
rename a panel 119
reports
 Add a Signature to Report Reviews 278
 Audit Trail Report 265
 configure headers 249
 export 277
 Listings Report
 Labs Listing Report 267
 Listings Reports 267
 Lots Listing Report 269
 Panels Listing Report 273
 Test Code Report 274
 Tests Listing Report 271
 Measurement Uncertainty Report 263
 Operator Report 261
 Point Data Report 250
 print 278
 Statistical Report 256
 Summary Data Report 253
 Supervisor's Report 258
 Transmission Data Summary Report 276
 Unity Interlaboratory Reports 282
 Worldwide Report 295
 Westgard Advisor 348
require audit trail comments 213
required quality, choose goals 34
RiLiBÄK
 accuracy and precision 364
 add tests 356
 administrative buttons 362
 analytes listed in Table B1 352
 assessment of control cycles 362
 calculation of internal laboratory error limits 362
 charts 363
 control cycle screen 361
 data entry grid 361
 enter data 361
 evaluation of individual results 361
 internal quality control requirements 353
 part A 352
 part B 352

permissions 355
reports 365
settings 358, 360
target value and deviation 358
rules, qualitative
 set up an expected response 115
rules, SPC 18
rules suggestions
 delete 350
rule status 128
 change accepted/rejected status of data point 176
run 457

S

save and print charts 246
SD 457
 set floating 113
 use floating to set fixed 112
SD and mean
 fixed vs. floating 109
SDI (standard deviation index) 458
SDI (Standard Deviation Index) 14
SD (Standard Deviation) 13
security and access control 422
select a QC procedure 35
semi-quantitative
 Microscopic Report 303
 Qualitative Worldwide Report 304
 set up an expected response 115
set a fixed mean and/or fixed SD/CV 109
set floating statistics as a fixed mean and/or fixed SD 132
set SPC rules 129
 at the lot level 131
 at the test level 130
settings, test 108
set up user permissions 75
shift 458
shortcuts, keyboard 51
sigma metrics 458
 graph 459
Sigma Metrics Chart 345
sigma, six 32
single test point data entry 161
single test summary data entry 165
six sigma 32, 459
slide generation

change slide generation number 115
software support 3
sort
 panel names 120
 tests 105
 tests in a panel 119
SPC rules 125, 459
 1-2.5s 20
 1-2s 19
 1-3.5s 21
 1-3s 20
 1-4s 21
 1-5s 22
 2-2s 22
 2-2s across run violation 23
 2-2s within run violation 23
 2 of 3-2s 24
 3-1s and 4-1s 25
 3-1s within a control level 25
 4-1s across control levels 26
 7-T 26
 8-x within a control level 27
 9-x across control levels 28
 N-x 27
 overview 18
 precedence when showing rule violations 129
 R-4s 24
 rule status 128
 select at the lot level 131
 select at the test level 130
 summary of SPC rules 132
 tabular summary 132
Standard Deviation Index (SDI) 14
Standard Deviation (SD) 13
start the software and log on 40
state of the art 147, 460
Statistical Profile Report 291, 459
Statistical Report 256
statistics, useful 12
submit data 279
 from the bench review or supervisor review 281
 manually 280
 monthly 279
 Transmission Data Summary Report 280
summary data 460
Summary Data Report 253

Summary Data Report, RiLiBÄK 374
supervisor review 180
Supervisor's Report 258
Supervisor's Report, RiLiBÄK 373
support, QC Program Representative 3
support, software 3, 426
suspect data 460
systematic error 38, 460
system requirements, Unity Real Time 2 client 414

T

TE 17, 460
TEa 17, 264
 configure TEa, data analysis grid 196
 medical relevance 146
 total error-BV 146
 Westgard Advisor 328
temperature 96
test parameters 95
test performance, evaluate 31
tests
 add non-Bio-Rad qualitative tests with qualitative responses 99
 add tests 97
 arrange the order 105
 close 104
 delete 106
 duplicate 104
 evaluation mean and SD 109
 instrument setup 100
 open 104
 settings 108
 set up an expected response 115
 update 102
VITROS
 change 115
 update 117
toolbar 46, 47
 buttons 47
 customize 49
total error-BV 142, 461
Total Error (TE) 17
Transmission Data Summary Report 276
trend 461
troubleshoot QC results 35
 bad practices
 recalibrate 36

repeat the control 35
try a new control 35
good practices
 consider common factors on multi test systems 37
 determine the type of error 36
 relate the problem to recent changes 38
 verify and document 38
typographical styles and conventions 6

U

unit of measure 96
UnityConnect
 Rejection Log Messages 443
unity interlaboratory program 279
unity interlaboratory reports 282
 Affiliated Data Exception Report 300
 Affiliated Laboratory Comparison Report 297
 Affiliated Laboratory Comparison Report: Abbreviated Summary 299
 affiliated reports 297
 Bias and Imprecision Histogram Report 293
 comprehensive reports 295
 Manufacturer Report 296
 consensus groups 284
 InstantQC Reports 284, 305
 Laboratory Comparison Report 288
 Laboratory Histogram Report 290
 Laboratory Performance Overview Report 286
 Manufacturer Report 296
 Monthly Evaluation Report 285
 monthly reports 283
 print 285
 qualitative reports 302
 Microscopic Report 303
 Qualitative Worldwide Report 304
 save 285
 Statistical Profile Report 291
 Urinalysis Report 302
 view, print, and save 284
 Worldwide Report 295
update
 lab number 80
 tests 102
 update database automatically 382
 update database from QCNet 383
update the license
 automatically 63

with an XML file 63
Urinalysis Report 461
use Bio-Rad elnsert data 110
use floating statistics to set fixed mean and SD 112
useful statistics 12
user permissions 71
users
 add 65
 assign a lab number 68
 delete 67
 edit 67
 permissions 71
use the set date feature 158

V

verify and document 38
view and update database information 380
view transmission data 280
virtual environments 415
VITROS slide generation number
 change 115
 update 116

W

warning messages
 bench and supervisor reviews 186
warn rule 461
Westgard Advisor 325
 advanced tool 347
 Allowable Total Error (TEa) 328
 apply rules 349
 consensus groups 335
 data grid tab 340
 data requirements 331
 delete historical suggestions 350
 design QC rules 334
 Flowchart of the Westgard Advisor Process 327
 generate rules with defaults 339
 generate rules with the advanced option 338
 generate rules with the wizard 335
 grid display options 332
 maximum QC procedure 345
 overview 325
 Report 348
 specify data requirements 331
 TEa 328

Allowable Total Error (TEa) Options 328
 configure 330
 view existing QC rules 333
 view lab data and group statistics 333
 view OPSpecs charts 341
 view Sigma Metrics chart 345
 Westgard Advisor Report 348
westgard rules 461
Worldwide Report 295, 461
 Qualitative Worldwide Report 304

Y

Youden chart 231
 create 231
 customize 232
 how to use 231
Yundt chart 233
 create 235
 customize 236
 interpreting bias and linearity 235
 interpreting CV 234
 SDI information 233

Z

z-score 17