

# QC Data Management Solutions

Introduce your laboratory to a whole new world of Unity data management solutions



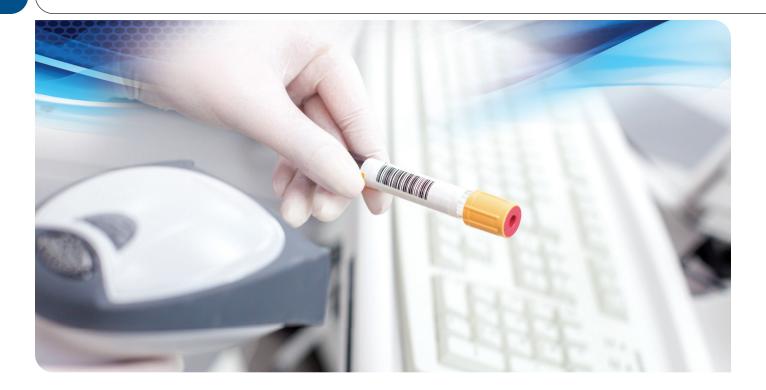


# Commitment to Quality Control

Using our comprehensive product line of independent controls is an important step toward helping you improve the reliability of your laboratory results. The ability to successfully manage and interpret your quality control results is also essential to producing solid, dependable laboratory outcomes.

Bio-Rad Laboratories offers a vision and a commitment to quality control that is unsurpassed in the clinical laboratory industry. Today, your laboratory can be connected to the Unity Interlaboratory Program, the world's largest community of quality control users. Improve patient test results and cost effectiveness with quality control products, quality control data management solutions, industry-leading interlaboratory comparisons and personalized service from Bio-Rad.



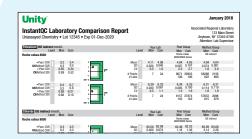


# Unity Interlaboratory Program

Participation in an interlaboratory program is extremely important for laboratories to help ensure the reliability and precision of test systems. No program in the world is more powerful and effective at providing information and helping to improve laboratory analytical performance than the Unity Interlaboratory Program.

- Benefit from peer QC data generated from more than 59,000 instruments in 100+ countries
- Recognize analytical process improvement opportunities
- Increase confidence in proficiency survey outcomes
- Identify unrecognized trends or shifts that may occur between proficiency surveys
- Receive on-demand interlaboratory comparison reports

- Receive monthly reports with regular data submissions
- Submit data in real time using one of our Unity software solutions
- Detect and identify potentially important analytical errors
- Meet accreditation and regulatory requirements



# Receive On-demand InstantQC Reports Get started at QCNet.com today!

InstantQC Reports allow you to compare your control results to other laboratories at any time. These on-demand reports are particularly useful for troubleshooting problems with test system performance.



#### The Advantages of Participating in the Unity Interlaboratory Program

#### **Detecting Errors in Your Test System**

Without a high quality interlaboratory program, your laboratory may not be aware of gradual or sudden changes in your test system that may be caused by events such as reagent or calibrator reformulations, standardization changes, or instrument software changes. An interlaboratory program may offer early awareness of shifts and trends to help avoid costly test repeats and unnecessary troubleshooting.

#### Your Proficiency Program is Not Enough

Proficiency surveys provide a snapshot in time and should not be used as a substitute for daily quality control with an interlaboratory program.

- Acceptable performance on the day of the proficiency testing does not guarantee testing reliability every day
- Participation in an interlaboratory program is the recommended way to improve confidence in test system performance every day, especially with an interlaboratory program that offers an option to receive instant interlaboratory feedback on-demand

#### Some advantages for participating in an interlaboratory QC program are:

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

#### Detecting and identifying bias in a measurement procedure

Bias can be caused by events such as reagent or calibrator lot changes or reformulations, changes in calibration traceability to reference systems, or instrument software changes. Comparison of an individual laboratory's QC result to a peer group mean value can identify a trend or shift, or ascertain if other laboratories are experiencing the same changes (see Subchapter 3.3.1)."

#### Supplementing PT/EQA programs

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

> - CLSI, C24, 4th ed. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. 7.2 Using Interlaboratory Quality Control to Assess a Quality Control Program.



### Choose From Four Unity Solutions

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

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

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

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





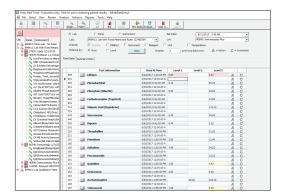






Want to know more? Discover the power of Unity Solutions at www.bio-rad.com/qc-datamanagement





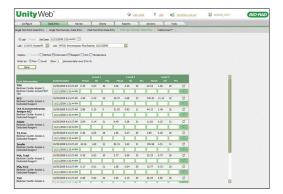
#### **Unity Real Time LT**





#### **Entry-Level Desktop QC Data Management Solution**

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



#### **UnityWeb**





#### **Entry-Level Online QC Data Management Solution**

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

# Connectivity



#### **Basic**

#### WebConnect



#### **Automated Uploads to Unity Software**

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

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

#### **Advanced**

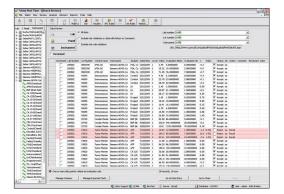
#### UnityConnect



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

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

#### **Advanced User Options**



#### **Unity Real Time**





#### **Expert QC Data Management Solution for Desktop Users**

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

# Unity Real Time online (SD: [1] 30.06/2.32. [2] 78.14/2.71. [3] 178.56/5.54

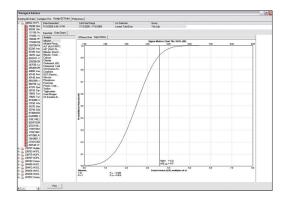
#### **Unity Real Time online**





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



# **Unity** "alert

#### **Westgard Advisor**







#### **Automatic QC Rules Selection Engine**

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

#### **Unity Alert**







#### **Continuously Monitor QC Status**

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

#### **Advanced User Options**



#### **Bio-Rad Mission: Control**



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

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

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





#### Bio-Rad Mission: Control allows you to:

- Determine your laboratory's Risk Management Index (RMI)
- Evaluate your test method performance based on your QC results
- Quantify the likelihood and severity of reporting incorrect patient results
- Assess how much you can lower your risk, based on instrument performance
- Create a QC Plan by confidently selecting rules and frequency that fit your risk tolerance

#### Minimize your risk of reporting unreliable patient results

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

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



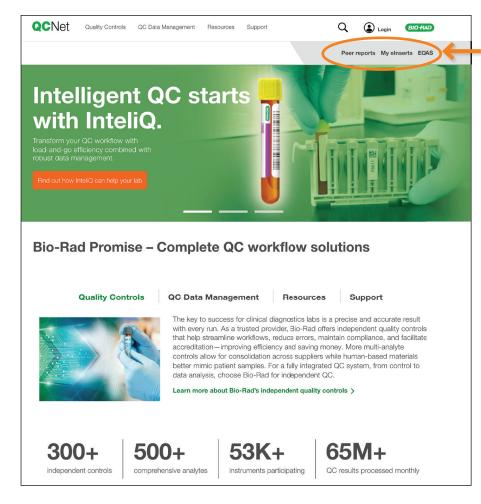
#### **Regulatory Requirements**

"The laboratory shall design quality control procedures that verify the attainment of the intended quality of results."

- ISO 15189:2012(E), Subclause 5.6.2.1

# QCNet is the Leading QC Portal on the Internet

Learn more about the many QC tools and resources from Bio-Rad at www.QCNet.com



#### Quick Links to the most-used features

#### **Unity Reports**

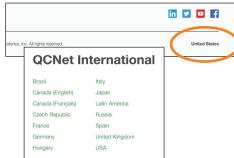
• Get your Unity Reports in just a few clicks.

#### My elnserts

Access product inserts

#### **EQAS**

- View Reports
- Access EQAS Online
- Training/Tutorials
- View Product Information

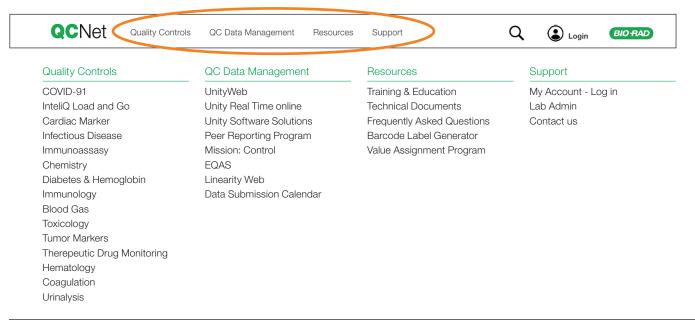


#### Access country-specific information

At the bottom of the QCNet home page, click on the country name shown to access the pop-up menu, then select the desired country\*.

\*Not all countries are available

#### Explore the drop-down menus to find more online QC tools on QCNet



#### **Ordering Information**

| Cat #  | Description  | Cat #  | Description                                     |  |  |
|--|--|--|---|--|--|
| Unity Real Time LT   |  | Unity Real Time online                                   |   |  |  |
| 804<br>805-1   | Installation Package Single use Unity Real Time LT | 804-W1   | Unity Real Time online Annual subscription      |  |  |
| 825i Unity Remote Installation & Training Single use   |  | Westgard Advisor   |   |  |  |
|  |  | 811-1  | Westgard Advisor Annual subscription            |  |  |
| UnityW   | eb   |  |   |  |  |
| 870-1  | -1 UnityWeb Annual subscription                    |  | Unity Alert                                     |  |  |
|  |  | 806-1  | Unity AlertAnnual subscription                  |  |  |
| WebConnect   |  | 825i   | Unity Remote Installation & Training Single use |  |  |
| 870-W1   | WebConnect 2.0Annual subscription                  |  |   |  |  |
| 825i   | Unity Remote Installation & Training Single use    | Cat #  | Description                                     |  |  |
| UnityConnect  820-1 UnityConnect SoftwareAnnual subscription  825i Unity Remote Installation & Training Single use |  | <b>Bio-Rad Mission: Control</b> 1100002 Mission: Control |   |  |  |
| Unity Real Time  |  |  |   |  |  |
| 804  | Installation Package Single use                    |  |   |  |  |
| 804-1  | Unity Real Time Annual subscription                |  |   |  |  |
| 825i   | Unity Remote Installation & Training Single use    |  |   |  |  |

#### **EQAS**

An independent, external assessment of laboratory performance in comparison to your peers.

QCNet.com/eqas

#### Independent QC

Ongoing, proactive, unbiased daily QC that helps identify errors as they occur or begin to trend.

QCNet.com/independentqc

#### Unity

QC Data Management tools that help you create a strategy to reduce risk and streamline QC workflow.

QCNet.com/datamanagement



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