SP11.2 Edition

Unity Real Time® 2.0

Unity Real Time® 2.0 Quick Guide

This Quick Guide is derived from the comprehensive Unity Real Time® 2.0 Reference Guide. It is designed to provide easy access to commonly used functions and workflows, not to replace the full guide. For complete details and advanced features, refer to the full Reference Guide available through the **Help** menu or via the link located at the bottom of the Unity Real Time® 2.0 application.

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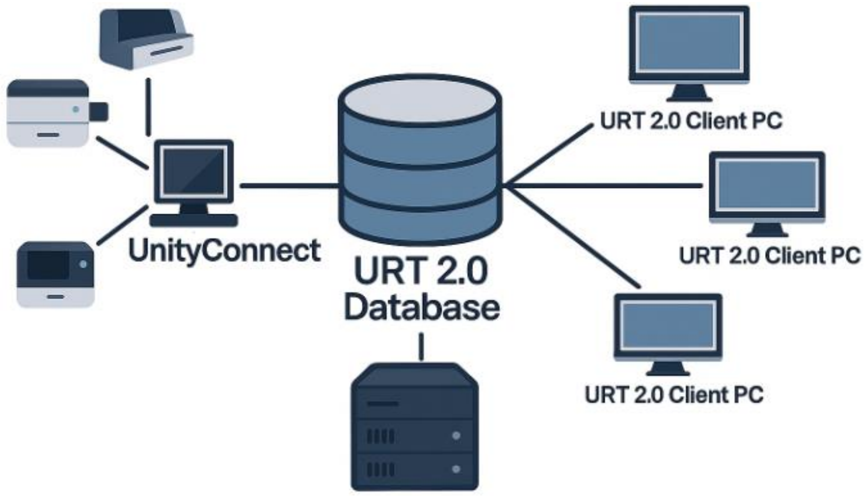
INTRODUCTION

Unity Real Time® 2.0 is Bio-Rad's advanced solution for managing quality control (QC) data in the laboratory. The system works in tandem with **UnityConnect™**, Bio-Rad's connectivity platform, which enables seamless integration between your laboratory instruments and Unity Real Time® 2.0. UnityConnect™ includes both software and hardware components that capture QC data directly from your instruments and transfer it into the QC management system.

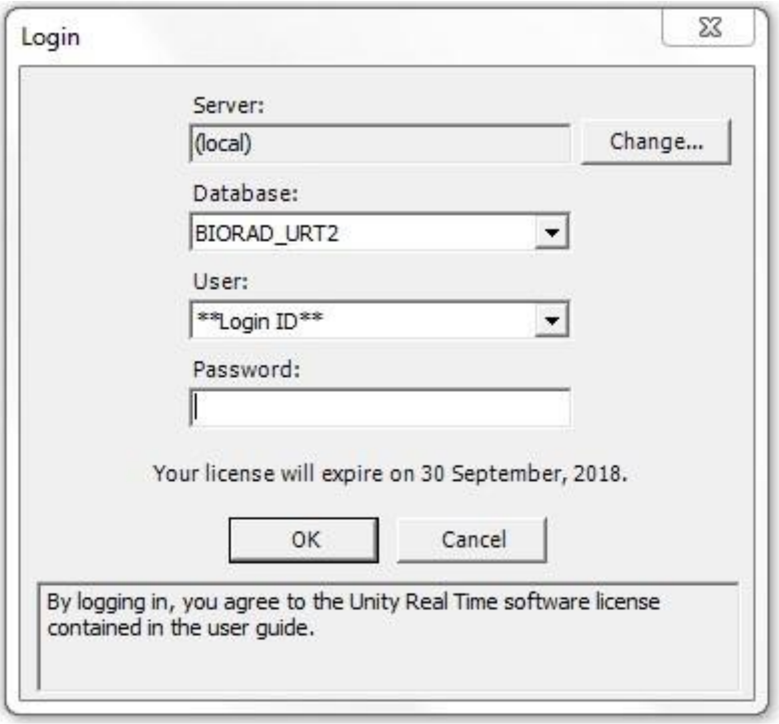


A typical UnityConnect™ implementation uses a dedicated hardware interface to link laboratory instruments with the Laboratory Information System (LIS). This hardware intercepts instrument output at the communication layer, ensuring data capture without altering or delaying the normal LIS workflow. UnityConnect™ software then parses the raw instrument data, extracts quality control (QC) information, and applies standardized mapping rules to convert it into a format compatible with Unity Real Time® 2.0. This process includes validation checks, error handling, and secure transmission protocols to maintain data integrity. By automating QC data import, UnityConnect™ eliminates manual transcription, reduces human error, and ensures compliance with laboratory quality standards.

HOW DO I LOG IN TO UNITY REAL TIME® 2.0?

1. Double-click the Unity Real Time® icon on your computer desktop.

2. The Login dialog box appears.
   - Select the database you wish to log in to from the Database drop-down list
   - Select your username in the User drop-down list
   - Enter your password
3. Click OK to launch Unity Real Time® and accept the license agreement.



Unity Real Time accounts are kept within the database and has no external connections.

LAB NUMBERS

A **Bio-Rad Unity Real Time® lab number** is a unique six-digit identifier assigned to each laboratory within the Unity Real Time system. It serves as the primary reference for linking your lab's data, configurations, and participation in Bio-Rad's quality control programs.

If you need to request new lab numbers, please reach out to Bio-Rad software support at techsupport.anzcdg@bio-rad.com.

ADD LAB NUMBER

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

1. Use one of the following methods to open the Lab dialog box:
    - Click Lab 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. Type the necessary changes.
4. Click Update.
5. Click Close to close the Lab dialog box or Lot to go to the Lot dialog box

Note: An asterisk (*) identifies required fields.

You must have the Manage labs/lots/tests permission to use this function.

You can change and update any information except for the lab number.

You cannot update a closed lab number; you must first open it.

> Note: The details in the lab number are important because they are used to contact labs when the need arises. Please fill in all required fields especially the address and email with a contact who administers Unity Real Time.

HOW DO I ADD A NEW LOT NUMBER?

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.

Bio-Rad master lot numbers consist of five digits ending in zero. The lot number for Bio-Rad control products is located on the outside of the control product box, on the control product label, and in the package insert. The final zero of the master lot number is changed to a number to identify each individual control level (for example, 1, 2, or 3 designating level 1, level 2, or level 3). Data can be entered on nine levels of control. However, only four levels can be viewed and selected for test evaluation at a time.

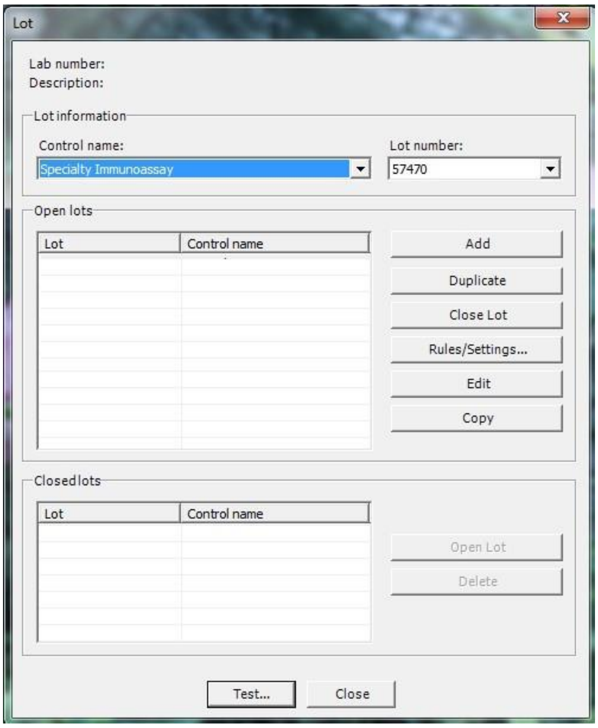
ADD A BIO-RAD LOT NUMBER

<u>You must have the Manage labs/lots/tests permission to use this function.</u>

1. Use one of the following methods to open the Lot dialog box:
   - Click Lot 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.
3. Select the master lot number for the control from the Lot number list.
4. Click Add.
   - The new lot number appears at the bottom of the Open lots list.

Repeat steps 2–4 to add additional lots.

Click Close to close the Lot dialog box or Test to go to Test dialog box



ADD A NON-BIO-RAD LOT NUMBER

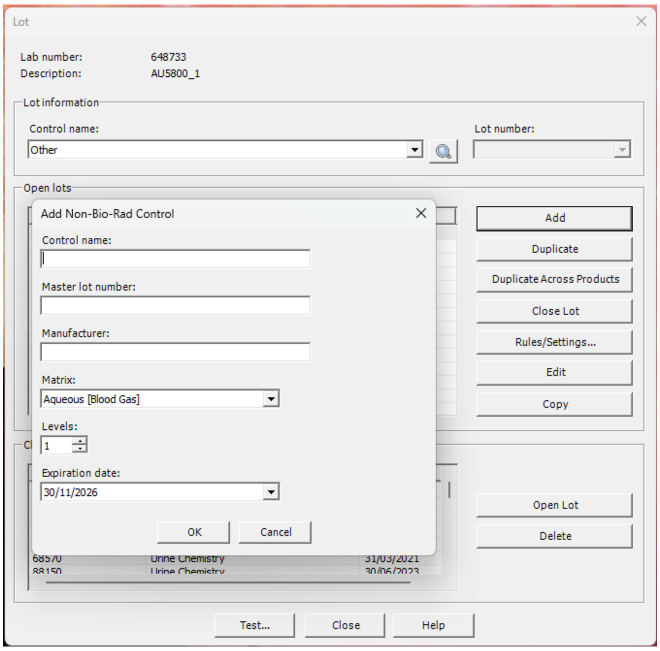
You can use Unity Real Time® for performance tracking of non-Bio-Rad control products. All Unity Real Time® reports and charts are available. However, Unity™ Interlaboratory Reports are **NOT** available for non-Bio-Rad control products.

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.

- Do not create lot numbers starting with a Zero 0.
- Always add more levels than you need because they cannot be added later

<u>You must have the Manage labs/lots/tests permission to use this function.</u>

1. Use one of the following methods to open the Lot dialog box:
    - Click Test 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.
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: Data can be entered on nine levels of control. However, only four levels can be viewed and selected for test evaluation at a time.
9. Click the arrow in the Expiration date field and select an expiration date for the lot from the calendar.
10. Click OK.
    - The lot number appears the bottom of the Open lots list.
11. Click Close to close the Lot dialog box or Test to go to Test dialog box



HOW DO I DUPLICATE AN EXISTING 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 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

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

1. Use one of the following methods to open the Lot dialog box:
   - Click Lot on the toolbar.
   - Click the Select menu and then click Lot.
2. Press CTRL+F3 on the keyboard.
3. Select the lot number in the Open lots list you want to duplicate.
4. Click Duplicate.
5. The Duplicate Lot dialog box appears and shows the current lot number at the top.
6. Select the new lot number from the New lot number list.
7. Select the check box for each lab you want the lot duplicated to.
8. 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.
9. The new lot number appears below the previous lot number in the Open lots list.
10. Repeat steps 2–7 as needed to duplicate other lot numbers.
11. Click Close to close the Lot dialog box.

DUPLICATE A NON-BIO-RAD LOT NUMBER

1. Use one of the following methods to open the Lot dialog box:
    - Click Lot 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 the arrow 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.
    - Repeat steps 2–7 to duplicate the lot number for all lab numbers as needed.
8. Click Close to close the Lot dialog box.

COPY A LOT NUMBER TO OTHER LAB NUMBERS

1. Use one of the following methods to open the Lot dialog box:
    - Click Lot 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 copy.
3. Click Copy.
4. The Copy Lot dialog box appears.
5. Select the lab number you want to copy the lot to.
6. Select the appropriate check box for each item to copy, if applicable:
    - Fixed means
    - Fixed SDs
    - Target values for Analytical Goals
7. Click OK.
    - Repeat steps 2–6 as needed to copy additional lot numbers.
8. Click Close to close the Lot dialog box.

HOW DO I ADD A NEW TEST?

Unity Real Time® defines tests using six parameters. In combination with the lab number and lot numbers, these parameters uniquely identify your QC data in the Unity™ Interlaboratory Program.
The six test parameters are:

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

<u>You must have the Manage labs/lots/tests permission to use this function.</u>

ADD TESTS MANUALLY

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 Test 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 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 if the reagent manufacturer and the instrument/kit manufacturer are the same.
    - Alternate formulation/standardization
    - 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

> The Alternate formulation/standardization option is not commonly used. Do not use this option unless instructed by Bio-Rad QC Program Representative. 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.

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. Selective 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.
11. Click Add.

ADD TESTS WITH A CODE OF "OTHER" IF THEY ARE NOT IN TEST LIST

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

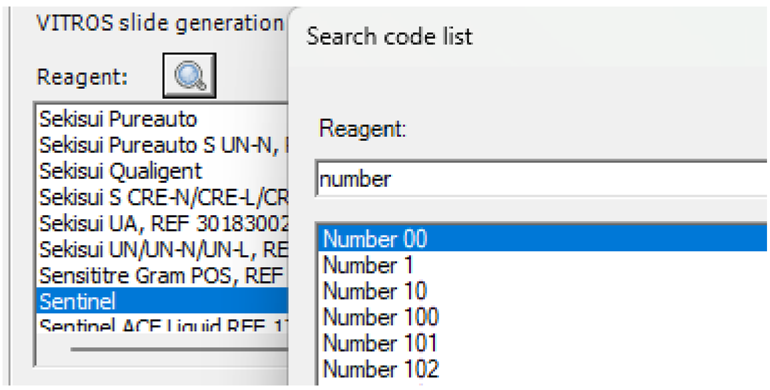
1. Select a lot in the Lab navigation tree.
2. Use one of the following methods to open the Test dialog box:
   - Click Test on the toolbar.
   - Click the Select menu, point to Test, and then click Test.
   - Press F3 on the keyboard.
3. Select the test parameter from each of the respective lists in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

Note: When configuring tests in Unity Real Time® using the **"Other"** option for all fields, additional tests not listed in the standard code list can be created by using the **Reagent** field.

1. **Select Reagent Type**
   Click on the **Reagent** field and search for "Number" in the code list.
2. **Choose a Numbered Reagent**
   From the list (e.g., *Number 00, Number 1, Number 100*), select an available reagent number.
3. **Build Additional Test Configurations**
   Use the selected reagent number to create new test configurations that are not included in the predefined code list.

IMPORTANT:

Each test must have a unique configuration. **No two tests can be created using the same reagent configuration.**



HOW DO I SET UP WESTGARD RULES?

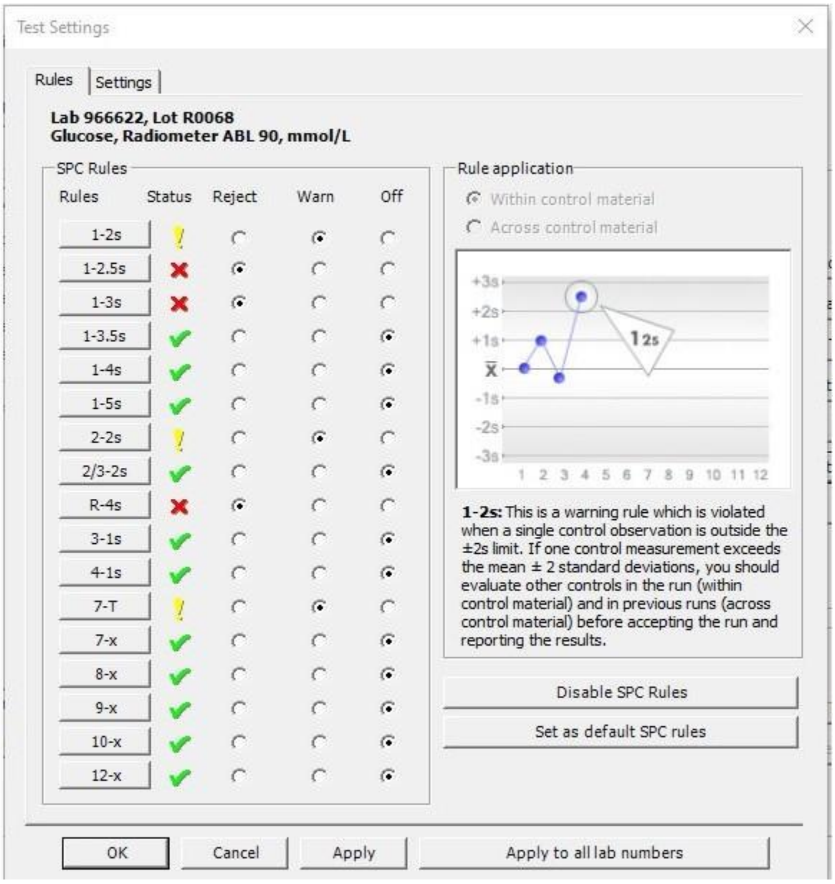
Unity Real Time® 2.0 provides statistical process control (SPC) rules and analytical goals to monitor test performance. Unity Real Time® 2.0 evaluates data points against the active SPC rules to determine whether to accept or reject the data. The software provides 17 different SPC rules, each of which can be set to Reject, Warn, or Off.

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.

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.

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



RULE STATUS

You can set SPC rules to any of the following status:

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 Tests Data Entry dialog boxes and on interlaboratory 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

SELECT SPC RULES

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

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.

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

Tip: You can click a rules button 1-3s to view information about the rule.

Click the Within control material or Across control material option to view the applicable information if the application of the rule is within or across control materials.

Select SPC Rules at the Test Level

1. Select a test in the Lab, Panel, or Instrument navigation tree.
2. Click SPC Rules 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

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

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?

5. Click Yes.

Note: For a summary of the SPC rules and further information on SPC rules see the reference Guide.
When you have no Evaluation mean / SD the SPC rules will use the floating Mean / SD.

HOW DO I SET UP TARGET MEANS AND SD?

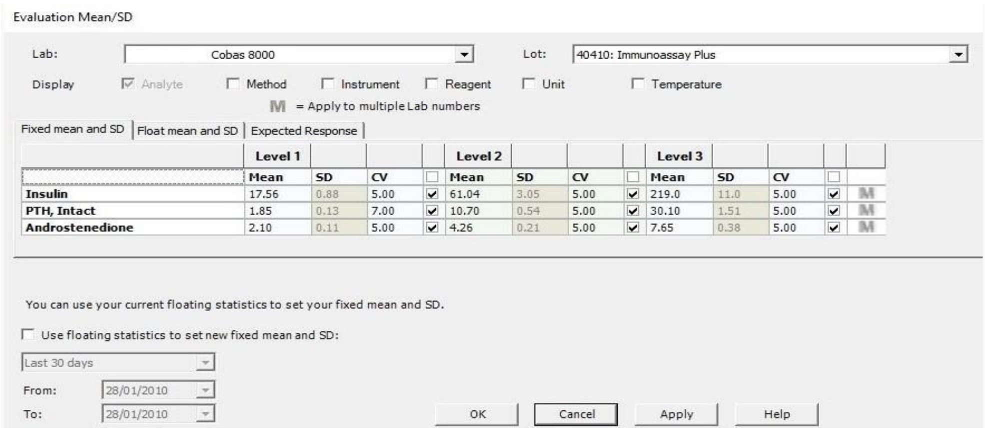
Unity Real Time® begins SPC rule evaluation immediately if using both a fixed mean and a fixed SD, even if the test does not have the specified number of points before rule evaluation begins (the default is twenty). Unity Real Time® uses the floating mean and/or floating SD when a fixed mean or fixed SD is not specified.

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

SET A FIXED MEAN AND/OR FIXED SD

1. Select a lot or test in the Lab navigation tree.
2. Do not double-click the test to open the Single Test Data Entry screen, otherwise you will not be able to edit the Evaluation Mean/SD.
3. Click 

on the toolbar
   - The Evaluation Mean/SD dialog box appears
4. Select the lab number from the Lab list.



5. Select the lot number from the Lot list
6. Select from display check box for the information you want to appear in analyte column:
   - Method
   - Instrument
   - Reagent
   - Unit
   - Temperature
7. Click in the Mean field and type the mean for the test.
8. Click in the SD field and type the fixed SD for the test.
9. Repeat steps 6 to 7 for each test as needed.
10. Click Apply.
11. Click OK to close the Evaluation Mean/SD dialog box.

USE FLOATING STATISTICS TO SET A FIXED MEAN

Note: If you cannot edit mean data, close the Evaluation Mean/SD dialog box, close the Single Test Data Entry, then re-open the Evaluation Mean/SD dialog box.

1. Select a lot or test in the Lab 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:
   - 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

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 step 7.
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. Click Apply.
11. Click OK.

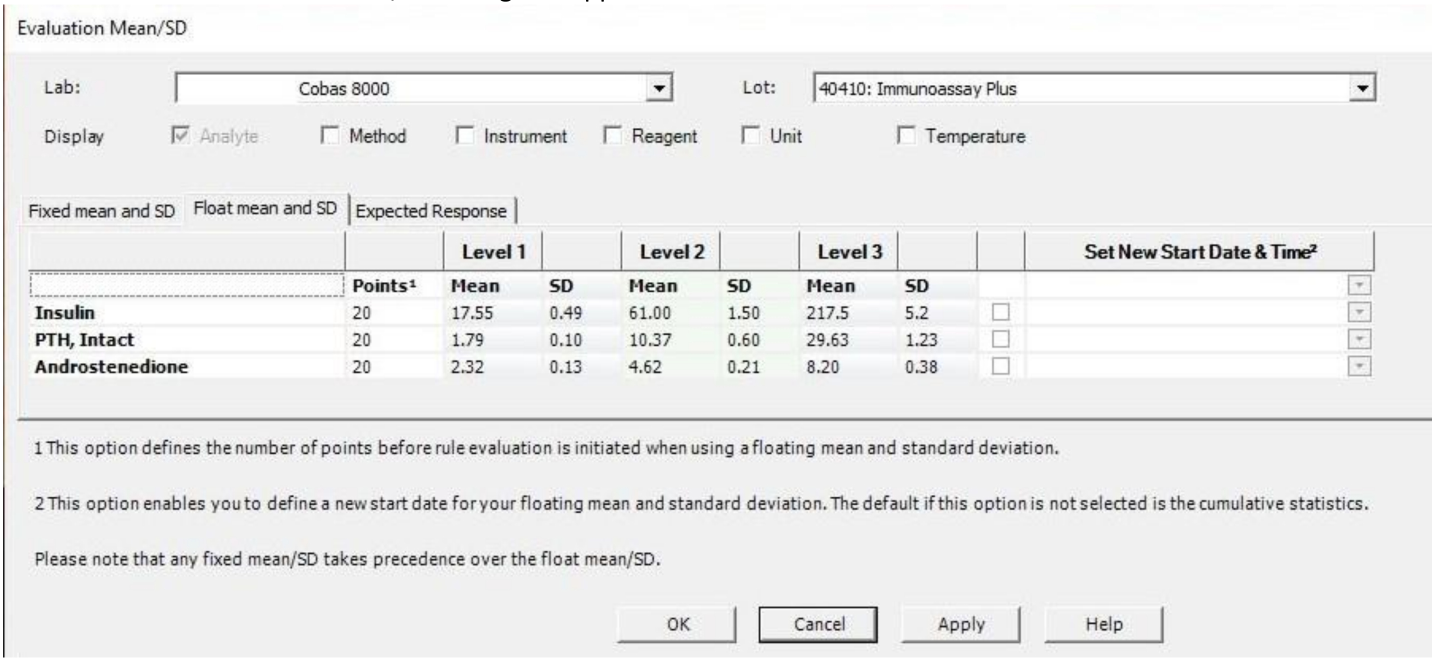
Note: If you cannot edit mean data, close the Evaluation Mean/SD dialog box, close the Single Test Data Entry, then re-open the Evaluation Mean/SD dialog box.

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 

on the toolbar.
   - The Evaluation Mean/SD dialog box appears.



Click the Float Mean and SD tab.

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:
   - Method
   - Instrument
   - Reagent
   - Unit
   - Temperature
6. Click in the Points field and type the number of data points that must be entered before rule evaluation begins when using floating statistics.
7. 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
8. Click in the Set New Start Date and Time field and edit the date and time you want to start calculating the floating statistics. The date and time cannot be later than the current date and time.

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

HOW DO I PERFORM A BENCH REVIEW OR SUPERVISOR REVIEW?

Regulatory agencies require the documentation of QC data review. The Bench Review and Supervisor Review simplifies this process and provides and electronic trail of the review at two levels.

Bench Review

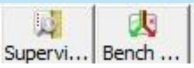
The laboratory personnel performing the testing reviews QC results and documents any QC corrective actions or comments

Supervisor Review

Supervisory personnel retrospectively evaluate QC results and monitor lab performance

Unity Real Time® documents the Bench Review and Supervisor Review using the Data Review Report which can be printed or saved to a file.

PERFORM A BENCH REVIEW OR SUPERVISOR REVIEW

Select a Data Set for Review 

1. Click the Review menu and then click Bench Review or Supervisor Review or the toolbar
2. Click the appropriate button according to how you want to perform the review:
   - Lab
   - Panel
   - Instrument
3. Select an option for the data to review:

All Data
Selected by default. Bench Review and Supervisor Review display all data, regardless of whether any active rules were violated.

Include Rule Violations or Data with Actions or Comments
Bench Review and Supervisor Review display:

- Data points violating a rule with a **Reject** or **Warn** status
- Data points with no rule violations but with associated actions or comments

Include Only Rule Violations
Bench Review and Supervisor Review display only data points violating a rule with a **Reject** or **Warn** status.

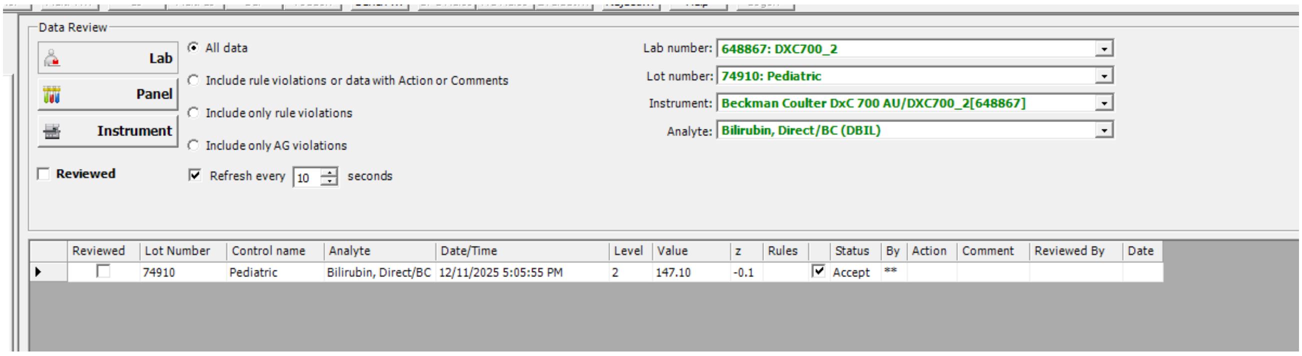
Include Only AG Violations
Bench Review and Supervisor Review display only data points violating **Analytical Goals** rules.

· Data violating a rule with a status of “Reject” is highlighted in red.

· Data violating a rule with a status of “Warn” is highlighted in yellow.

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.

4. If reviewing by Lab:
   - select the lab number from the Lab number drop-down list or select (All)
   - select the lot number from the Lot number drop-down list or select (All)
   - select the instrument from the Instrument drop-down list or select (All)
   - select the Analyte from the Analyte drop-down list or select (All)



5. If reviewing by Panel, select the panel from the Panel list or select (All).
6. If reviewing by Instrument, select the instrument from the Instrument list or select (All).
7. The Bench Review and Supervisor Review shows the following information:
   - Data in the selected data set includes any items selected in the Show Data Review Columns dialog box
   - Data violating a rule with a status of Reject is highlighted red
   - Data violating a rule with a status of Warn is highlighted yellow
   - Data not violating a rule but within the same run as a data point violating a rule with a status of Reject or Warn is highlighted white
   - Non-suspect data or accepted runs are highlighted in white

Important: Do **not** select "All" for the fields if you plan to leave the review screen open. When results are displayed in your review, they are locked in the database.
This lock remains until you either close the review screen or complete the review.
While locked, those results will **not** appear on another user's review list.

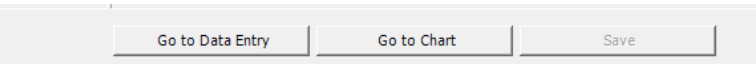
REVIEW LEVEY-JENNINGS CHART FROM REVIEW SCREENS

You can choose to review the data using a Levey-Jennings Chart and the Data Entry dialog box in addition to the Bench Review or Supervisor Review grid. View a Levey-Jennings Chart

1. From the Review grid, click Go to Chart.
2. Investigate the suspect QC data. Position the mouse over the QC data points to view the details.
3. Click x in the upper right corner to close the Levey-Jennings Chart and return to the review grid.

VIEW THE DATA ENTRY SCREEN FROM REVIEW

1. Click Go to Data Entry to open the Data Entry dialog box for the test.



From here you can

- Click an arrow in the Y/N column to manually change the accept/reject the status of a data point
- Click the Action column to add an action to a row of data or to view existing actions.
- Click the Comment column to add a comment to a row of data or to view existing comments.

2. Click x in the upper right corner to close the Data Entry screen and return to the review grid.

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.

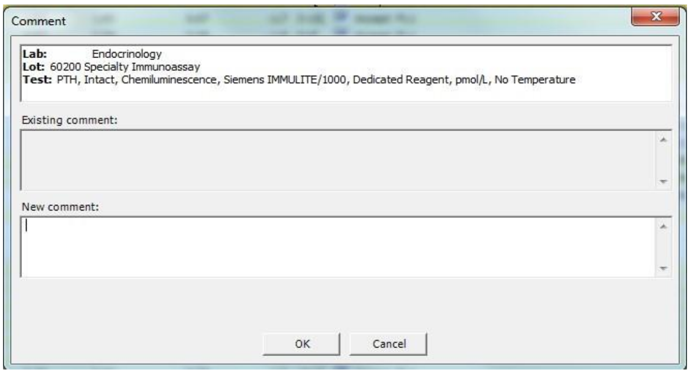
Add an Action or comment in the Review

All data violating a rule with a status of Reject should have an appropriate corrective action documented.

1. Click in the Action column for the QC data you want to add an action to.
2. The action box will allow you to select actions from a list.
3. Select an action and click Apply.

All data violating a rule with a status of Reject should have an appropriate comment documented.

1. Click in the Comment column for the QC data you want to add a comment to.
2. The Comment box will display existing comments and all you to free text your comment
3. Type the comment in the New Comment field and click OK.



Document the Review

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 a 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

You cannot save the review until you have indicated review of all data

4. Click Save.

CREATE THE DATA REVIEW REPORT

The Data Review Report documents the review of point data from the Bench and Supervisor Review.

1. Perform a Bench Review or Supervisor Review.
2. Click the Reports menu and then click Data Review.
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 an ending date for the report.
5. For Panels, select the panel name from the Panel list or select All Panels.
6. For Instruments, select the instrument name from the Instrument list or select All Instruments.
7. Select the lab number from the Lab list or select All Labs.
8. Select the lot number from the Lot list or select All Lots.
9. Select the instrument from the Instrument list or select All Instruments.
10. Click OK. The report opens as a PDF document.
11. Print or save the report as required.
12. Click in the upper right corner to close the report.

HOW DO I ADD ACTIONS AND COMMENTS BY INSTRUMENT?

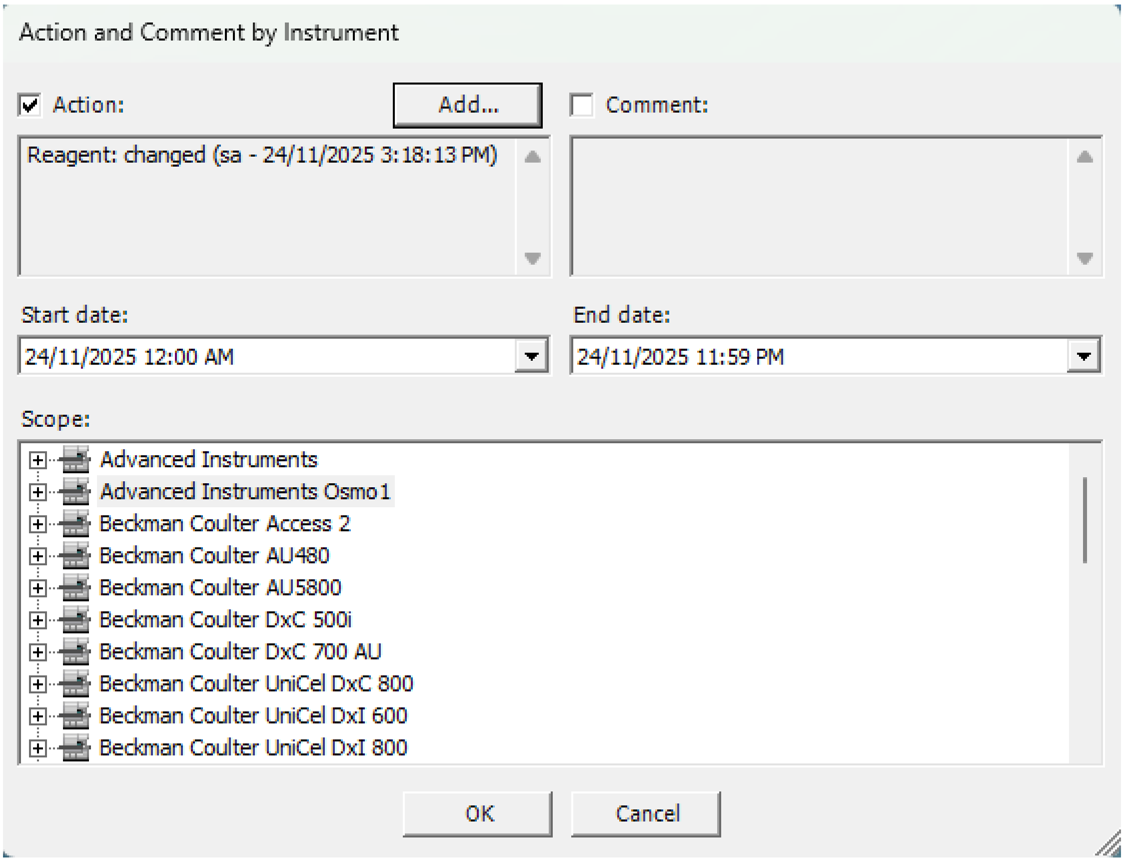
You can simplify the documentation procedure by adding an action or comment one time and applying it to all tests performed on an instrument. This saves time by documenting actions such as instrument maintenance and calibration which apply to all tests performed on an instrument.

You can apply actions and comments by instrument to:

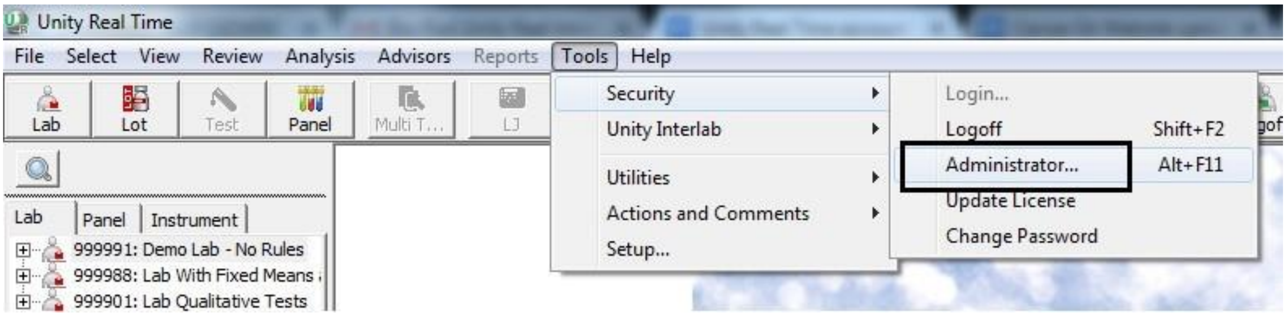
- Instrument – applies the action/comment to all tests, including all lab and lot numbers, performed on the instrument
- Lab number – applies the action/comment to all tests performed on the selected instrument/lab number combination
- Lot number – applies the action/comment to all tests performed on the selected instrument/lab number/lot number combination

ADD AN ACTION AND/OR COMMENT BY INSTRUMENT

5. Click the Tools menu, point to Action and Comments, and then click Actions/Comments by Instrument. The Action and Comment by Instrument dialog box appears.
6. Select the check box to add action and/or comment.
7. Click in the blank field and type the comment.
8. To add an action click Add.. , select the action/s, apply and close 5. Click the arrow in the Start date field and select the beginning date.
9. Click the arrow in the End date field to select an ending date.
10. 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
11. Click OK

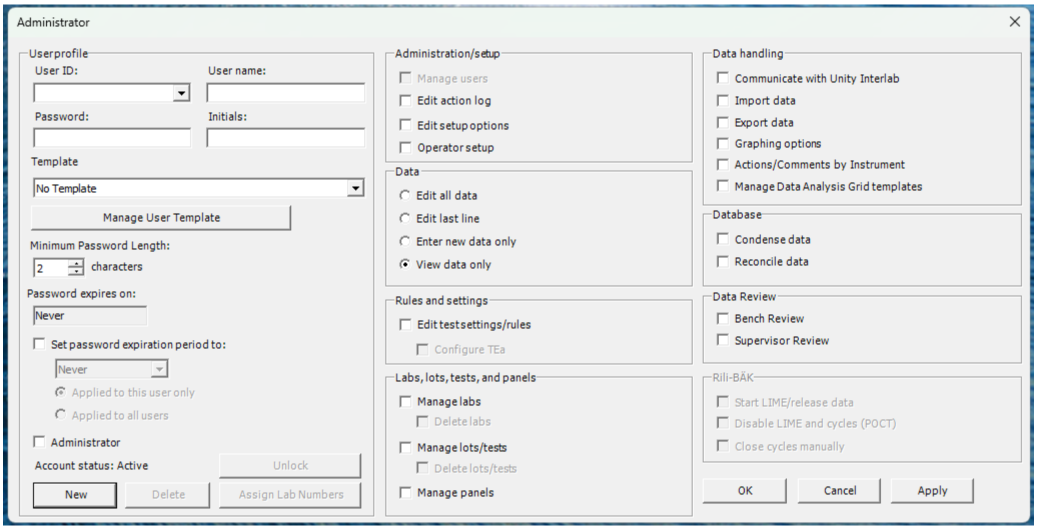


HOW DO I ADD, EDIT AND DELETE UNITY REAL TIME® 2.0 USER?



ADD A USER

1. **Open Admin Panel**
   Go to the Administrator dialog box from the main menu.



2. **Click "New User"** Starts the process of creating a new user profile.
3. **Enter Username** Type a unique login name for the user.
4. **Enter Full Name** Add the user's complete name for identification.
5. **Set the initials that will be used in the data screen**
6. **Set Password** Create a secure password following system rules.
   - Password will need to be reset on first login
7. **Assign Role** Choose the user's role (e.g., standard or admin).
8. **Select Permissions**
   - Check boxes to grant access
   - Clear boxes to remove access
9. **Assign Lab Numbers** Required for user to work in Unity Real Time

For more information on the checkbox settings go to the advanced user guide using the link on the bottom of Unity Real Time® application. (requires internet access)

10. Apply and OK
    - **OK** saves and closes
    - **Apply** saves and lets you add more users

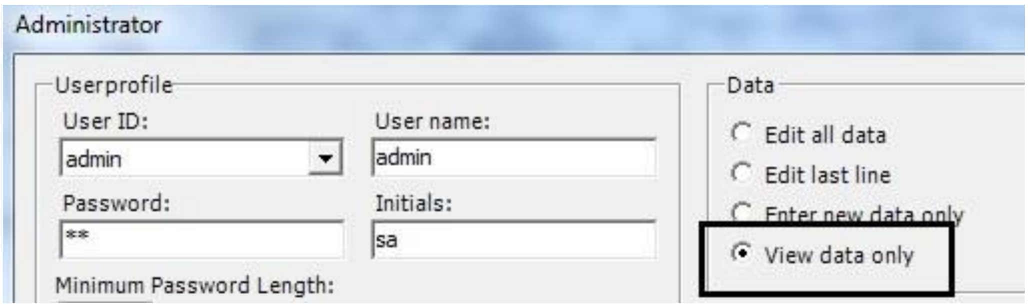
EDIT A USER

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
4. 4 Click APPLY to apply the updated user settings.

DELETE A USER

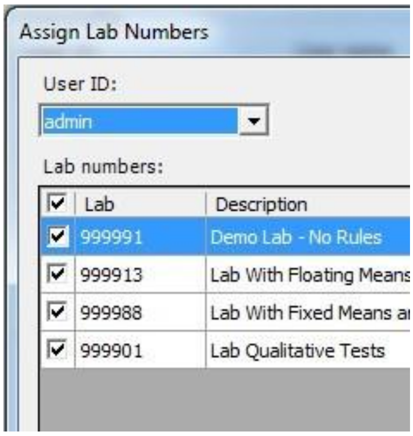
1. Click the Tools menu, point to Security, and then click Administrator.
2. Select the user from the User ID list.
3. Click Delete. A message appears asking for confirmation.
4. Click Yes.
5. Click OK.

Important: The USER ID will remain in Unity Real Time® tracking and should only be removed as a last resort. Instead of deleting the account, **change the password** and set the account to **view-only access**. This ensures the USER ID is never reassigned or used by another person.



ASSIGN LAB NUMBERS TO USERS

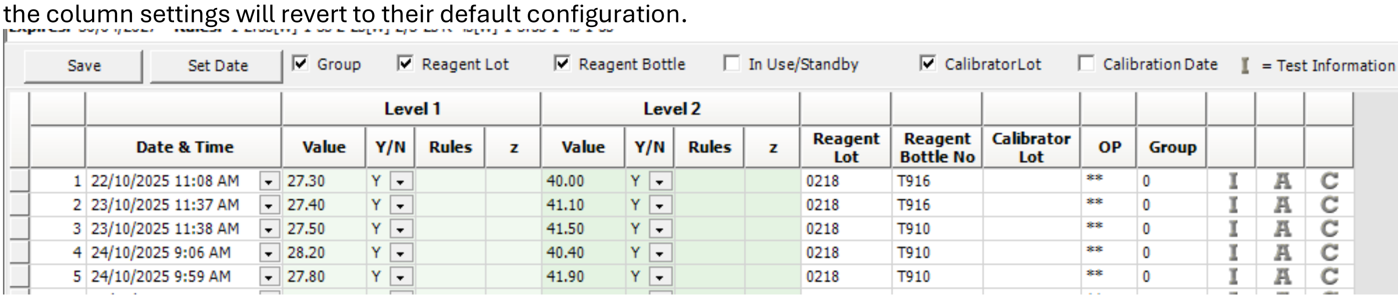
1. Click the Tools menu, Security, and then click Administrator.
2. Select the user from the User ID list.
3. Click Assign Lab Numbers.
4. Select the user from the list.
5. Select one or more lab numbers to assign to the user.
6. Click the apply then OK



ASSIGN GROUP REAGENT CALIBRATOR COLUMNS TO A USER OR ALL USERS

There are two areas where column management can be performed.

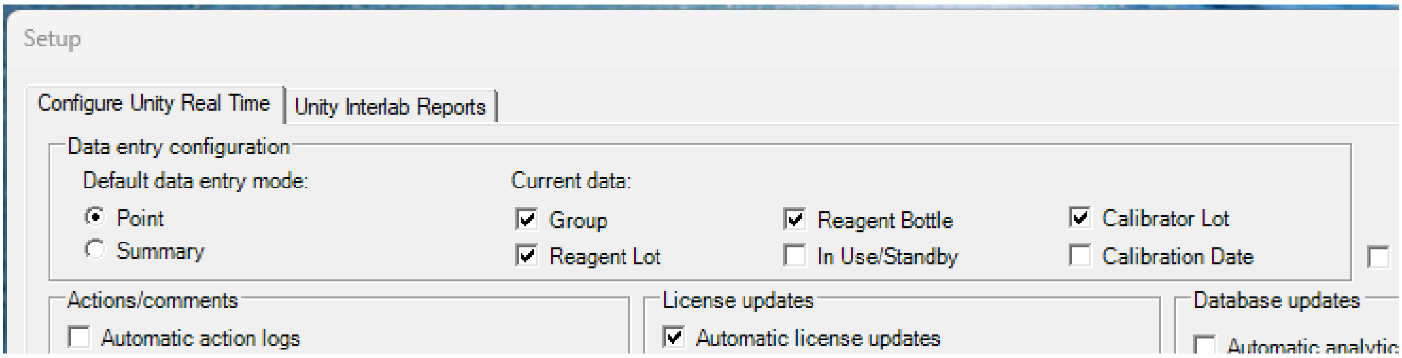
Within the data screen, you have the option to enable or disable columns as needed. However, please note that these adjustments are temporary and will not be retained. When you navigate away from the screen or switch to a different test, the column settings will revert to their default configuration.



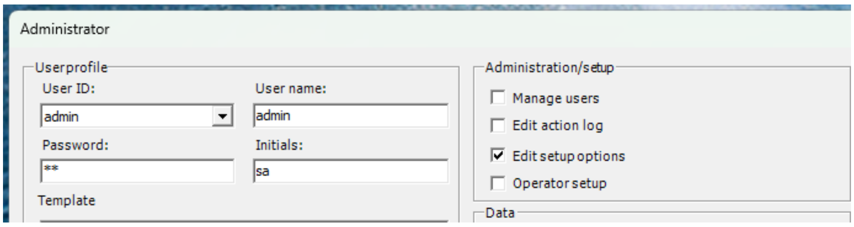
		Level 1				Level 2											
	Date & Time	Value	Y/N	Rules	z	Value	Y/N	Rules	z	Reagent Lot	Reagent Bottle No	Calibrator Lot	OP	Group			
1	22/10/2025 11:08 AM	27.30	Y			40.00	Y			0218	T916		**	0	I	A	C
2	23/10/2025 11:37 AM	27.40	Y			41.10	Y			0218	T916		**	0	I	A	C
3	23/10/2025 11:38 AM	27.50	Y			41.50	Y			0218	T910		**	0	I	A	C
4	24/10/2025 9:06 AM	28.20	Y			40.40	Y			0218	T910		**	0	I	A	C
5	24/10/2025 9:59 AM	27.80	Y			41.90	Y			0218	T910		**	0	I	A	C

Tools – Setup is now the location to globally set the Data Entry configuration

Selecting and deselecting and applying will affect all users.



Anyone can make these changes if they have Edit Setup Options applied to their profile.



If this becomes an issue, please reach out to our technical support team at techsupport.anzcdg@bio-rad.com **and request access to the URT User Manager tool.**

This utility can be added to the Unity Real Time program files directory and provides enhanced functionality, including the ability to modify settings for an individual user or apply changes across all users.

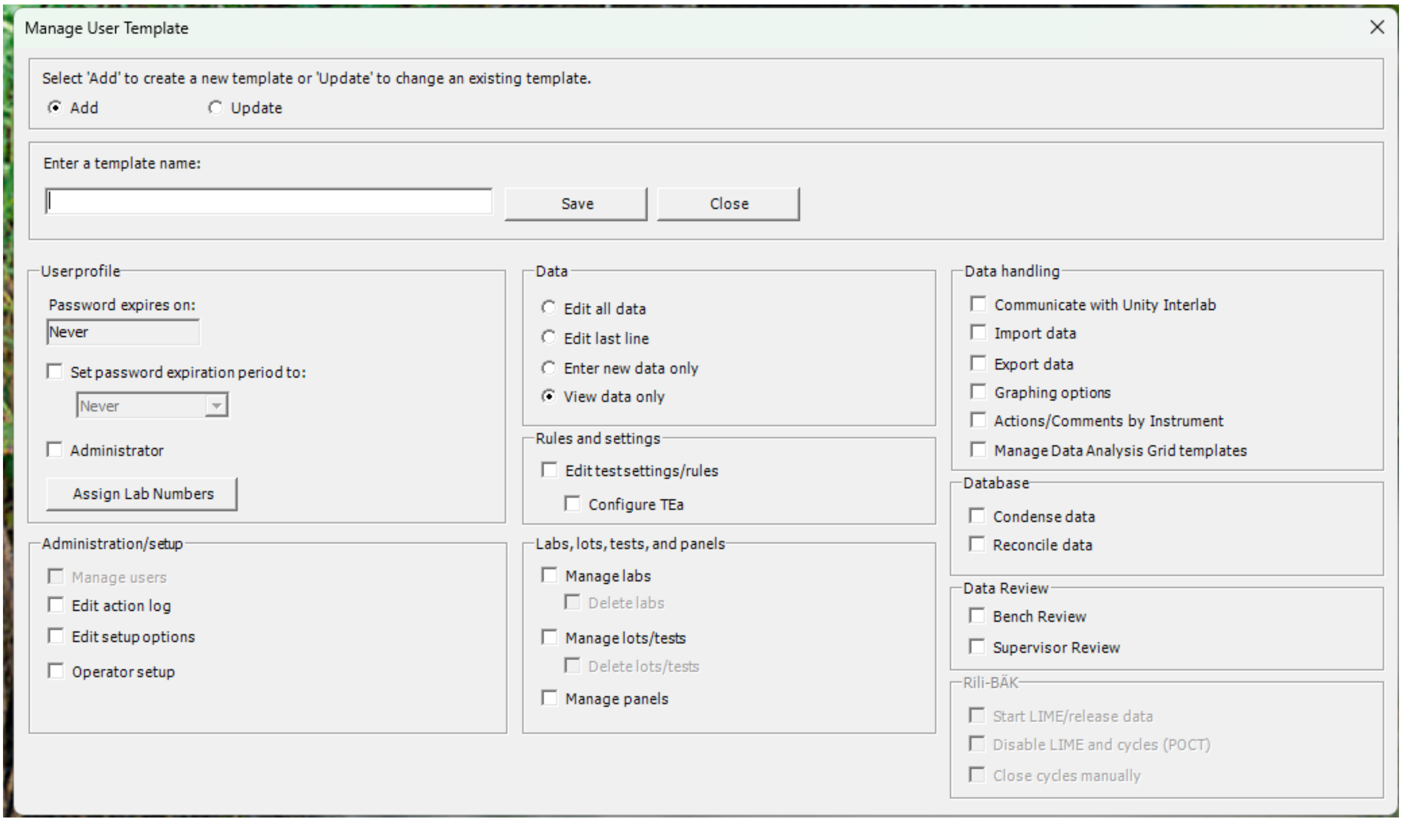
USER TEMPLATES

What Are User Templates?

User templates in **Unity Real Time** are predefined sets of user settings and permissions that can be applied to multiple users. Instead of configuring each user individually, you create a template with common settings (such as permissions, password rules, and default fields). When you assign this template to a user, any updates to the template automatically apply to all users linked to it. This saves time and ensures consistency across your system.

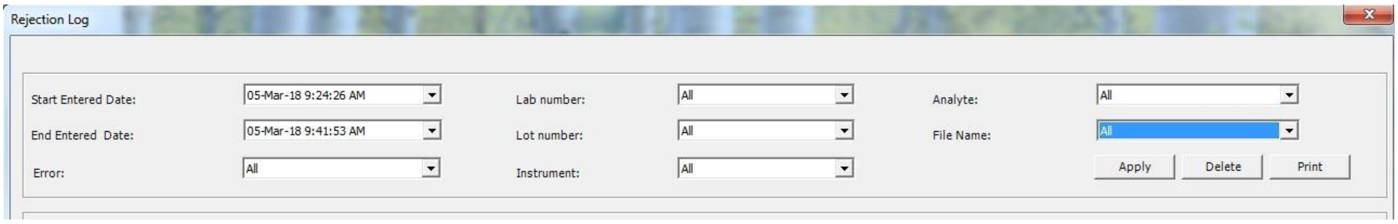
Steps to Set Up a User Template

1. **Open Administrator Panel**
   Go to **Tools > Security > Administrator**.
2. **Click "Manage User Template"**
   This opens the template setup screen.
3. **Create a New Template**
   Enter a template name and description for easy identification.
4. **Define Permissions**
   Select checkboxes for permissions you want included in the template (e.g., Administrator for full access).
5. **Set Default Settings**
   Configure password expiration, inactivity log-off time, and default data entry fields (like reagent lot or calibration date).
6. **Save the Template**
   Click **OK** or **Apply** to save changes.
7. **Assign Template to Users**
   When adding or editing a user, select the template from the list. Updates to the template will automatically apply to all assigned users.



REJECTION LOG

Rejected data is transformed data that was not imported into your QC data management software. The Rejection Log shows the details of all rejected data and provides a description about why the data was rejected. In most cases of rejected data, no action is required. However, in some instances an error message is an indication that configuration adjustments are required. After the configuration adjustments are made, the QC data file must be transformed again.



VIEWING THE REJECTION LOG FROM UNITY REAL TIME

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

- Click 

 on the toolbar.
- Click the Tools menu, Utilities, Import then View rejection log data

If the rejection log in used by many departments and labs you can use the following selection items to reduce the data displayed.

- Start Entered Date : to select start date of the range to view.
- End Entered Date: to select end date range of the data view.
- Error: Select the type of error from the Error list.
- Lab Number: Select a lab number from the Lab Number list or select All.
- Lot Number: Select a lot number from the Lot Number list or select All.
- Instrument: Select an instrument from the Instrument list or select All.
- Analyte: Select an analyte from the Analyte list or select All.
- File Name: Select a file name of an imported file from the list or select All.

Click Apply to refresh the Rejection Log and view your selected data. The Rejection Log appears according to the criteria you selected.

DELETING THE REJECTION LOG

- Best Practices—Fix the issues needing adjustment and Delete Logs.
- Bio-Rad recommends deleting the Rejection Log after each review to eliminate confusion.
- Delete current view will delete the displayed data
- Delete all data will delete all rejection in the log.

Note: All the current rejected data can be removed by going to Tools— Utilities—Import— Delete rejection log...

REJECTION LOG MESSAGES

Lot Expired

This occurs when the QC lot in Unity Real Time® has expired. Data will not automatically transmit into an expired lot. While manual data entry is possible, you will need to enter the date and time when the lot expired.

Lab Closed

The lab configured in UnityConnect™ has been closed in Unity Real Time®. To resolve this issue, either reopen the closed lab or select the correct lab number in the UnityConnect™ transformer configuration under the instrument tab.

Lot Closed

The lot configured in UnityConnect™ has been closed in Unity Real Time®. To fix this, reopen the closed lot or select a new lot number in the UnityConnect™ transformer configuration under the lot tab.

Test Closed

The test configured in UnityConnect™ has been closed in Unity Real Time®. If the settings are correct, reopen the closed test. Alternatively, reselect the appropriate test in UnityConnect™ to match the open test.

Result Invalid

The result contains a symbol such as < or >. Please contact Bio-Rad Laboratories for assistance in setting up a whole number conversion for import. For example, < 0.05 should be converted to 0.05, and the symbol can be added as a comment.

Lot Number Undefined

The lot number selected in UnityConnect™ does not exist in your Unity Real Time® system. This may be due to the lot being deleted or selected from a list of all lots. When choosing a new lot from the dropdown in UnityConnect™, ensure that you select from existing lots.

"Create New Tests as Necessary" Disabled

The test configured in UnityConnect™ does not exist in Unity Real Time®. This error may occur if the test configuration was changed in Unity Real Time® but not remapped in UnityConnect™, or if the test is not set up in the lot being imported. To resolve this, verify the settings in Unity Real Time® and remap the test in UnityConnect™. If you do not wish to capture the test, uncheck the “Enable” box next to the local test code in the transformer configuration row.

Unit/Method Invalid for Selected Analyte

This error occurs when a change has been made to the Bio-Rad Unity™ Codelist. Analytes are regularly reviewed and may be added, removed, or modified. Updated codelists are distributed monthly and applied to Unity Real Time® either automatically or manually, depending on your settings. These updates typically reflect changes in the test kit insert. To resolve the issue, update the test settings in Unity Real Time® and remap the test in UnityConnect™.

Data Entry Locked for This Test

This error indicates that the data point is currently locked, possibly because someone has the test open on the data entry screen. Close the data entry screen and re-import the data to proceed.

DATA ANALYSIS GRID —BASICS

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 setup 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 2 database, allowing users to maintain templates specific to their area.

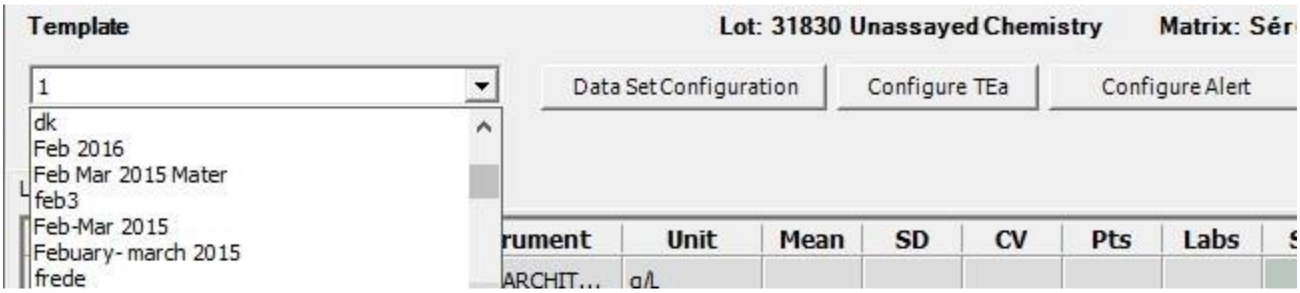
Note: Refer to the Unity Real Time for all functions of the Data Analysis Grid.

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 QC against the Unity consensus group or to your labs cumulative QC results.

VIEW THE DATA ANALYSIS GRID

1. Select a lab number and lot number in the Lab navigation tree to review data.
2. Click the Analysis menu and then click Data Analysis Grid.
3. Select the template from the drop-down menu



EXPORT THE DATA ANALYSIS GRID

Click Export located on the Data Analysis Grid. The Data Analysis Grid opens as a Microsoft Excel file.

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.

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SOFTWARE SUPPORT

If you need assistance with the Unity Real Time® 2 software, call the Software Support number 8.30am-5.30pm AEST.

Australia 1800 224 354

New Zealand 0800 444 067

Email techsupport.anzcdg@bio-rad.com

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