UnityConnect 2

User Guide

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(UnityConnect 2 Version 3.8)

BIO-RAD

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CHAPTER 1

Getting Started

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Software Version

This guide is current as of UnityConnect 2 service pack 3.5.

Welcome

UnityConnect 2 connects your lab systems (instrument, LIS, middleware, etc.) to your Unity QC software (Unity Real Time). This connection allows QC data to flow from your lab systems to the Unity QC software without the need to manually enter data.

Benefits of UnityConnect 2

UnityConnect 2 offers additional benefits that simplify deployment and usability when automating QC results.

- Centralized SQL Server database management
- Web-enabled for intranet remote management
- Centralized code mapping support for multiple Unity QC configurations
- Single point of configuration simplifies Unity QC test configuration updates
- Customized alerts
- Concurrent user access
- Modern User Interface (UI)
- International language support

Notes and Important Items

This guide uses symbols to indicate notes and important items that provide additional information and information of special importance, pictured below:

Note

A note indicates information supplementing the main text. A note supplies information that may only apply in special cases. For example:

Note: The **Error** column gives the reason the data was rejected.

Important

An important item provides information essential to the completion of a task. Do not disregard information in an important note. For example:

Important: When your lot switch occurs, correctly manage the lot switch in the software at that time. Otherwise, data that belongs with the new lot will incorrectly be placed with the old lot.

Data Delivery Methods

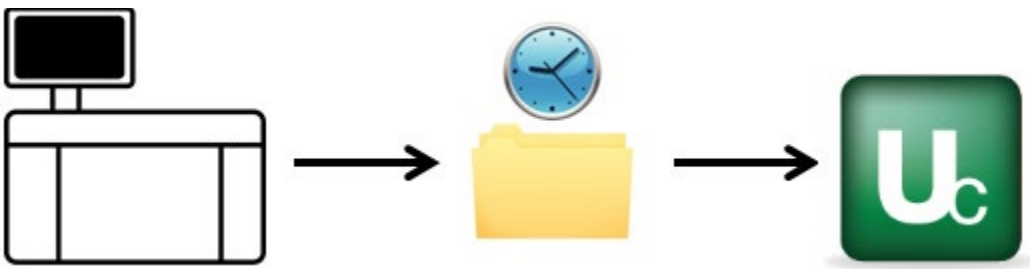
Your lab is set up with one or more of the following three possible data delivery methods. Your IT department, coupled with Bio-Rad's support specialists, should be able to assist you in determining which method your lab is using.

Data Stream

- Run time data streaming is an automated process, at times bi-directional, for laboratory device auto-verification.
- Data streams over in "run time" as QC is being run.
- QC data transmits directly from the data source (instrument, LIS, middleware) to UnityConnect 2 via additional hardware devices as needed either by serial (RS232) or TCP (RJ45) connection.

Scheduled

- UnityConnect 2 is set up to monitor a designated folder at scheduled intervals and to pull any available data from that folder. The scheduled intervals could be every few seconds, minutes, days, weeks, etc.
- QC data does NOT cross in "real time." However, depending on how frequently it is scheduled, it can appear so (if perhaps it pulls data every few seconds or minutes that contains new record only).
- The scheduled connectivity process can be automated or semi-automated:
  - **Automated**: The lab's IT has programmed the LIS/middleware to be automatically read by UnityConnect 2 or to automatically create a data file and place it in the designated folder for UnityConnect 2 at scheduled intervals.
  - **Semi-Automated**: A lab team member must manually create a QC data file and save it to a designated folder that UnityConnect 2 is programmed to read.



File Upload

- This is a manual process.
- QC data does NOT cross over in “real time.”
  - Those in the lab may create a data file as frequently as they like, but typically will create their QC file and upload it to UnityConnect 2 at the end of each month.
  - Users may create a QC data file from their instrument/LIS/middleware. The file can be saved on their computer, a network, a disc or thumb drive, etc. The location does not matter as long as they can browse to the file.

CHAPTER 2

Layout

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Access and Login

Log in to UnityConnect 2 using the same ID and password used for your Unity QC software.

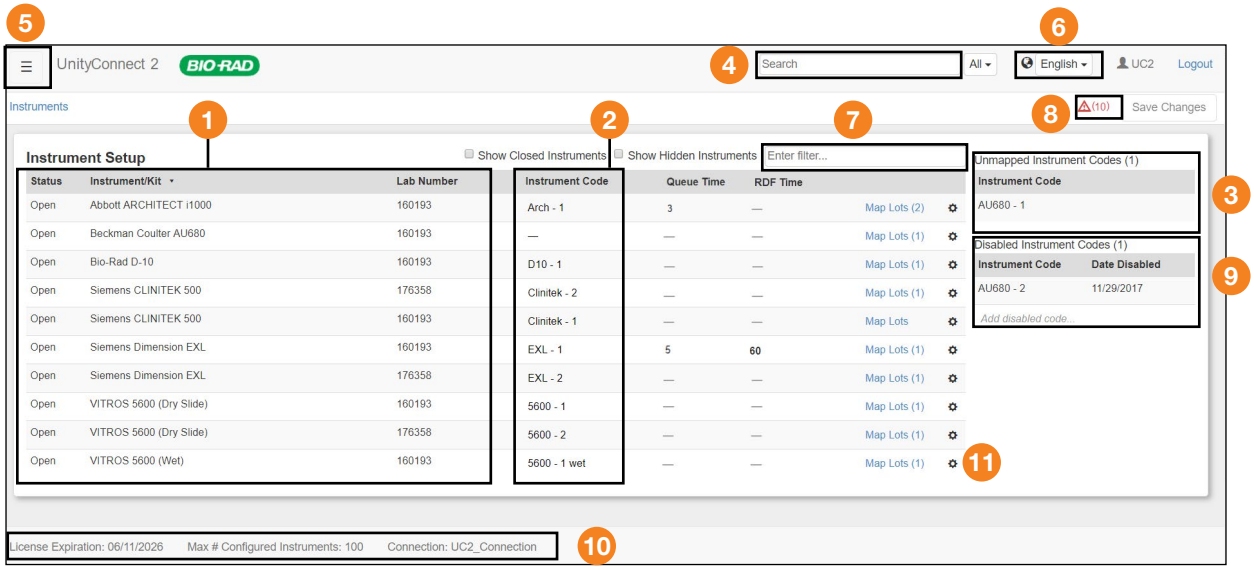
- If you are accessing UnityConnect 2 on the computer where its database is set up, go to: http://localhost:8080/unityconnect
- If you are accessing UnityConnect 2 from another network computer, go to: http://***computer name***:8080/unityconnect

> **Note**: The bold italicized portion indicates the actual name of the computer where the service is set up.

General Layout

Any time a code for a new instrument, control lot, test, or qualitative response is introduced into UnityConnect 2, you will need to map the new item.

The general layout and features of the UnityConnect 2 software are pictured below. Each numbered circle corresponds to different features, described in detail below the image.



1 Status, Instrument/Kit, and Lab Number

Information in the first three columns from the left, labeled **Status**, **Instrument/Kit**, and **Lab Number**, shows information for the Unity QC software setup.

2 Instrument Code

Information on the right, labeled **Instrument Code**, shows information crossing over from the lab's data source (instrument, LIS, or middleware).

3 Unmapped Instrument Codes

Unmapped Instrument Codes are listed on the far right. This list shows items pending mapping from the instrument, LIS, or middleware. The drop-down menu under the **Instrument Code** column allows you to select from the pending **Unmapped Instrument Codes**.

> **Note**: Mapping new items will be covered in detail in Chapter 4, **Code Mapping**.

4 Search box

You can search for a specific instrument, lot, or test in the **Search box** to locate an item more quickly.

5 Triple bar icon

Clicking on the **triple bar icon**  opens a menu with options to access **Map Local Codes**, **File Upload**, and **Settings** features. The icon turns green when you hover or click on it.

6 Language Selection

To change the **Language Selection** setting, click the drop-down menu next to the globe icon in the upper right-hand corner. The default language setting is English.

7 Filter

Search for items by filtering for Instrument, Lot, and Test.

8 Alert icon

An **Alert icon** will appear when mapping is required. The number in parentheses next to the icon indicates the total number of unmapped codes on that page, or subsequent pages, for either instrument codes, control codes, test codes and/or response codes. Click on the **Alert icon** to view details. If applicable, click on the alert details to navigate to subsequent screens for performing the necessary code mapping.

9 Disabled Instrument Codes

These are codes crossing over from the data source (instrument, LIS, or middleware) that should not be mapped or imported into Unity QC software. See “Disable Items” on page 33 for detailed steps on how to **Disable Instrument Codes**.

10 Connection and License Information

The bottom of the screen shows information pertaining to **License Expiration date**, **Max # Configured Instruments** (maximum number of instruments configured), and Connection.

11 Cog icon

The **Cog icon** allows for additional functionality at each stage of the mapping process. For example: at the Instrument Setup, the cog icon allows the user to Hide, Duplicate, Enable Reagent Queueing or Enable Redundant Data Filter. At the Lot Setup, the cog icon allows the user to “Duplicate.”

CHAPTER 3

Data Delivery

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Data Delivery Methods

Your lab uses one or more of three possible methods for data delivery: **Data Stream**, **Scheduled**, or **File Upload**. Refer to the “Data Delivery Methods” on page 3 for more details about the types of data delivery.

Data Stream and **Scheduled** methods occur on an automated or semi-automated basis, as described on page 3. The **File Upload** method requires manually uploading QC files and is detailed below.

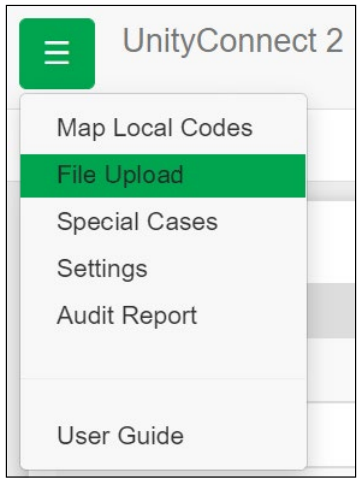
Upload a QC Data File

This information applies to those whose data delivery method requires manually **uploading QC files**.

In order to get your data into your Unity QC software, you will need to create a QC data file from your data source (instrument, LIS, middleware, etc.) and upload it to UnityConnect 2.

Steps for Uploading a QC Data File

1 After you've created your QC file, click the **triple bar** icon and select **File Upload**.



2 If you have more than one channel display name, select the channel that corresponds with your file source.

3 Click **Browse** and select your QC data file.

4 Select the **Beginning Date** and **Ending Date** for the file.

   a) To upload the entire file, leave **First Point In File** and **Last Point In File** selected.

   b) Select **Specific Date** if:

   – the QC file contains more than one month of data.

   – you only want to capture a portion of the data file.

3 Click **Upload**.

Check Upload Status

After you upload your QC data file, the software will start reading and processing that file's contents. You can check the status of that process in the Upload History page so you will know when everything is complete in UnityConnect 2.

There are four possible statuses you may see in the Upload History screen:

- If it states "Uploaded" or "Queued," the file is still waiting to be read.
- If it states "Processing," the file is being read, and it might have found new codes in the file that it is prompting you to map.
- If it states "Done," everything is complete (including any new required mapping), and the data has been imported to your Unity QC software.
- If it states "No Data," then the uploaded file was either incorrect (according to the channel name) or rejected, based upon specific criteria set within the Data File Options.

Steps for Checking the Upload Status

1 From the **File Upload** screen, click **Upload History**.

2 Check the **File Status.** (Click **Upload History** to refresh and view the updated status.)

3 You can return to the mapping screen to see if an alert is prompting you to do new mapping. To do so, click the **triple bar icon**  and select **Map Local Codes**.

Unity QC Software Rejected Data

If data appears to be missing from your Unity QC software, check the Rejection Log within your Unity QC software to see if the missing data is listed. “Rejected data” from the Unity QC software can occur for multiple reasons arising from within the software itself.

Note: This type of “rejection” is different than data rejected due to rule violations. This “rejection” may include dates out of sequence, invalid values, lot expired, etc.

Rejection Log for Desktop Software

This section applies to customers using desktop Unity QC software (Unity Real Time).

If data is missing, check the Rejection Log to see if it was rejected (meaning that the data was processed in UnityConnect 2, but a problem kept it from passing from UnityConnect 2 into the Unity QC software).

If you see rejected data in the Rejection Log, we recommend calling software support to help you resolve the rejection issue.

Steps for Viewing the Rejection Log

1 Click the **Rejection Log** button or select **Tools** > **Utilities** > **Import** > **View Rejection Log**.

2 If needed, make selections in the drop-down menus to filter the list, such as filtering by type of error, and click **Apply**.

3 Review the details of the rejected data listed in the table.

Note: The **Error** column gives the reason the data was rejected.

4 Once the rejections have been addressed, click **Delete**.

Note: Deleting old rejection messages will help avoid later confusion.

CHAPTER 4

Code Mapping

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Overview

"Mapping" means that the codes used to identify the instruments/lots/tests/qualitative responses in your Unity QC software match the codes your data source (instrument/LIS/middleware) uses to identify them. Once items are mapped, UnityConnect 2 can translate incoming data codes into the codes currently used in your Unity QC software.

There are two parts involved in managing a new instrument, control, test, or processing qualitative results:

- **Part 1**: Set up the new control and/or test in your **Unity QC software**. (Refer to your Unity QC software User Guide for more details.)

  Note: Instruments are associated with the test setup in the Unity QC software. There is not a specific "adding instruments" process.

- **Part 2**: Map the new instrument, control, test, or qualitative response in **UnityConnect 2**.

Map a New Instrument

If your lab purchases a new instrument, after setting it up in your Unity QC software and starting to receive data, you will need to map it in the Instrument Setup screen in UnityConnect 2.

Once the instrument is mapped, you will proceed with mapping its controls. (See directions for mapping a new control under "Map a New Control" on page 12.)

Steps for Mapping an Instrument

1 Ensure at least one test is set up in your **Unity QC software** for the instrument. (Refer to your Unity QC software User Guide for more details.)

> **Note**: Instruments are associated with the test setup in the Unity QC software. There is not a specific "adding instruments" process.

2 Access the **Instrument Setup** screen (the default web page upon login). You can also access this screen via the "Instruments" link, located in the toolbar at the top of the screen.

> **Note**: New instrument codes are staged within the "Unmapped Instrument Codes" right-hand navigation bar.

3 Locate the instrument you want to map based on the appropriate identifiers in the **Instrument/Kit** and **Lab Number** columns.

- Filtering can help quickly locate the Instrument/Kit by typing the instrument name in the **Enter filter** search box located to the right of the **Instrument Code** column.

4 Hover over and click the empty space for **Instrument Code**.

5 Click the appropriate drop-down arrow and map the appropriate instrument code.

6 Click **Save Changes**.

Map a New Control

When starting a new control, after configuration has been completed within your Unity QC software, you will need to map the codes (found during processing of data) in the **Lot Setup** screen in UnityConnect 2.

Once the new control and lot codes are mapped, you will also need to map its tests. (Directions for mapping a new test are under "Map a New Test" on page 13.)

Steps for Mapping a New Control

1 Ensure the control and specific lot number is set up in your **Unity QC software**. (Refer to your Unity QC software User Guide for more details.)

2 In the **Instrument Setup** screen, click the **Map Lots** link for the appropriate instrument. The link will indicate the number of unmapped control lots in parentheses.

> **Note**: Access unmapped codes directly by clicking on the red information icon, which displays unfinished lot mapping.

3 Click the **plus icon** ➕ to add additional levels, if needed.

4 Select the desired level number, if needed.

5 Select the appropriate lot code from each drop-down list to map it to the control, lot, and level listed on the left.

6 Click **Save Changes**.

Map a New Test

To start running a new test, after you set it up in your Unity QC software and begin receiving incoming data, you will need to map the test in the Test Setup screen in UnityConnect 2.

If your lab purchases a new instrument, make sure you map the instrument and controls first; then, proceed with mapping the tests. (See directions for mapping a new instrument on page 11 and a new control on page 12.)

Steps for Mapping a New Test

1. Ensure the test is set up in your **Unity QC software**. (Refer to your Unity QC software User Guide for more details.)
2. From the **Instrument Setup** screen, navigate to the **Lot Setup** screen for the appropriate instrument by clicking on the **Map Lots** link on the far right.
3. Click the **Map Tests** link, located to the right of the **Lot Code** column. (The link will include a number in parentheses, indicating the number of tests that need mapping.)
4. For each test that needs mapping, click the drop-down arrow and select the appropriate test code.
5. Click **Save Changes**.
6. If test mapping is needed for other lots, click the toolbar link at the top of the page (next to the **Instruments** link) to return to the **Lots** screen.

Map Qualitative Responses

This information only applies to customers who wish to import results for qualitative or semi-quantitative tests.

Both Bio-Rad and non-Bio-Rad qualitative controls may be transformed with UnityConnect 2.

“Response codes” are the codes or descriptions used for possible test results. For instance, Bio-Rad uses “Negative” as a possible result, but a lab might use “NEG” or “-” instead. The lab codes must be mapped to the Bio-Rad codes.

Steps for Mapping Qualitative Responses

1. Ensure the test is set up in your **Unity QC software**. For non-Bio-Rad controls, the qualitative responses must also be set up. (Refer to your Unity QC software User Guide for more details.)
2. Navigate to the **Test Setup** screen (use the **Map Tests** link for the qualitative control), and click the **Map Responses** link beside the test.
3. For each response listed on the left, select the corresponding response code.
4. Click **Save Changes**.

Map VITROS Slide Generations

This information only applies to those who have a VITROS instrument that uses slide generations (dry slides). There are two process options for managing slide generations: automated and manual. The method you use is based on the information available in the QC data file, and the data delivery method used to pass results from your data source (Instrument, LIS, middleware) to UnityConnect 2.

Note: UnityConnect 2 is designed to have only one test per analyte, with multiple slide generations associated. In the Unity QC software, each slide generation is set up as a different test for the same analyte. This is why you will see references to "test (slide gen)" in the VITROS Slide Generation Management section.

Automated Process

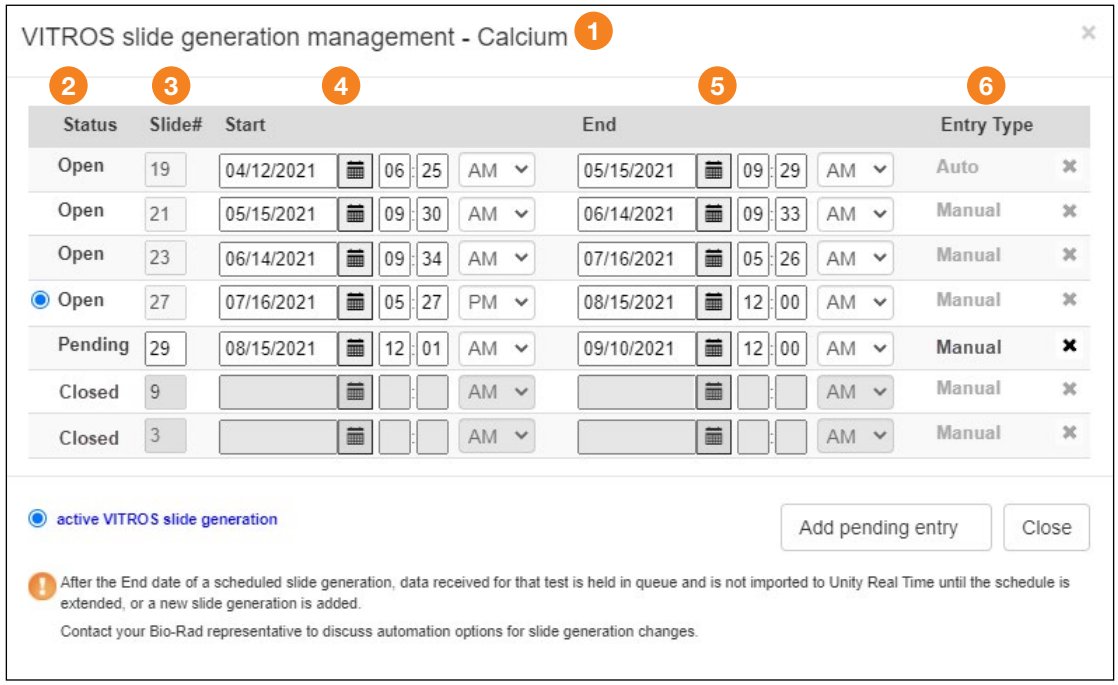
The automated process is the ideal method for managing slide generations. Assuming the QC data file contains the slide generation number for each result, UnityConnect 2 will automatically map the slide generation number to the test, create a new test in the Unity QC software, and import QC data in the Unity QC software. This option will save both time and effort in managing your QC data for VITROS dry slide tests.

Note: Refer to your instrument, LIS, or middleware user manual to determine if your QC data file can be generated to include slide generation information.
Instruments set up to stream QC data to UnityConnect 2 are more likely to be compatible with the automated process.
Contact Bio-Rad's software support or your local field application specialist for assistance with the initial UnityConnect 2 configuration for the automated process.

Manual Process

The manual process is used if your QC data file does not include the slide generation information. In this case, you must manually map the QC results to the appropriate slide generation number based on the date/time the QC was run. QC data for a test using dry slides cannot be transmitted to the Unity QC software until the slide generation is mapped in UnityConnect 2.

VITROS Slide Generation Management Window



1 Analyte

The test name of the analyte is listed at the top of the window.

2 Status

Information in the first column shows the test (slide gen) status in the Unity QC software.

- **Open** - The test (slide gen) is in the **Open Test List** in the Unity QC software.
- **Closed** - The test (slide gen) is in the **Closed Test List** in the Unity QC software.
- **Pending** - The slide generation was set up in UnityConnect 2, but data has not yet been processed to add the test to the Unity QC software.

> **Note**: A test (slide gen) that shows a status of **Closed** in your Unity QC Software cannot receive QC data from UnityConnect 2. To add data after a test (slide gen) has been closed, move the test (slide gen) to the **Open Test List** in the Unity QC Software before transmitting data from UnityConnect 2.

The blue radio button in front of the **Status** column indicates which is the **active VITROS slide generation**. The active slide generation is the last slide generation that was imported into the Unity QC Software. If all assigned End dates have passed, the blue radio button will remain with the most recently active slide generation until a new slide generation entry is added.

> **Note**: Only a test (slide gen) with a status of **Open** or **Pending** will be assigned as the **Active Slide Generation** or receive QC data from UnityConnect 2.

3 Slide

This column indicates the slide generation number that will be assigned to the QC results when imported into the Unity QC software.

4 Start and End

Each slide generation must be assigned a start date and time and an end date and time to indicate which test (slide gen) in the Unity QC software to map to. Only one slide generation can be active at any given time. The start and end dates for one slide generation cannot overlap with another.

If the end date for the most current slide generation has expired, all QC data for the test will be held in queue within UnityConnect 2 until one of the following occurs:

- The end date for the existing slide generation is extended.
- A new slide generation entry is added for the test.

Note: QC results held in the UnityConnect 2 queue due to an expired end date, will not be reflected in the Unity QC software rejection log.

Note: You cannot track QC results for more than one slide generation during the same time period.

Note: Start and End dates may be assigned only in UnityConnect 2, even if a slide gen is set up in Unity QC software.

5 Add pending entry

Use this button to set up a new slide generation. The status of this entry will be Pending until one of the following occurs:

- The first run of QC for the defined start and end date range is completed and a test (slide gen) is automatically created in the Unity QC software.
- The test is manually added directly in the Unity QC software.

Note: A new slide generation number can be manually added from the **Test Setup** page in the Unity QC software. However, the start and end dates may be defined only in UnityConnect 2.

6 Entry Type

This column indicates if the test (slide gen) was added by Automated or Manual configuration.

Note: Slide generations with the status of Pending may be removed by clicking the **X** in this column.

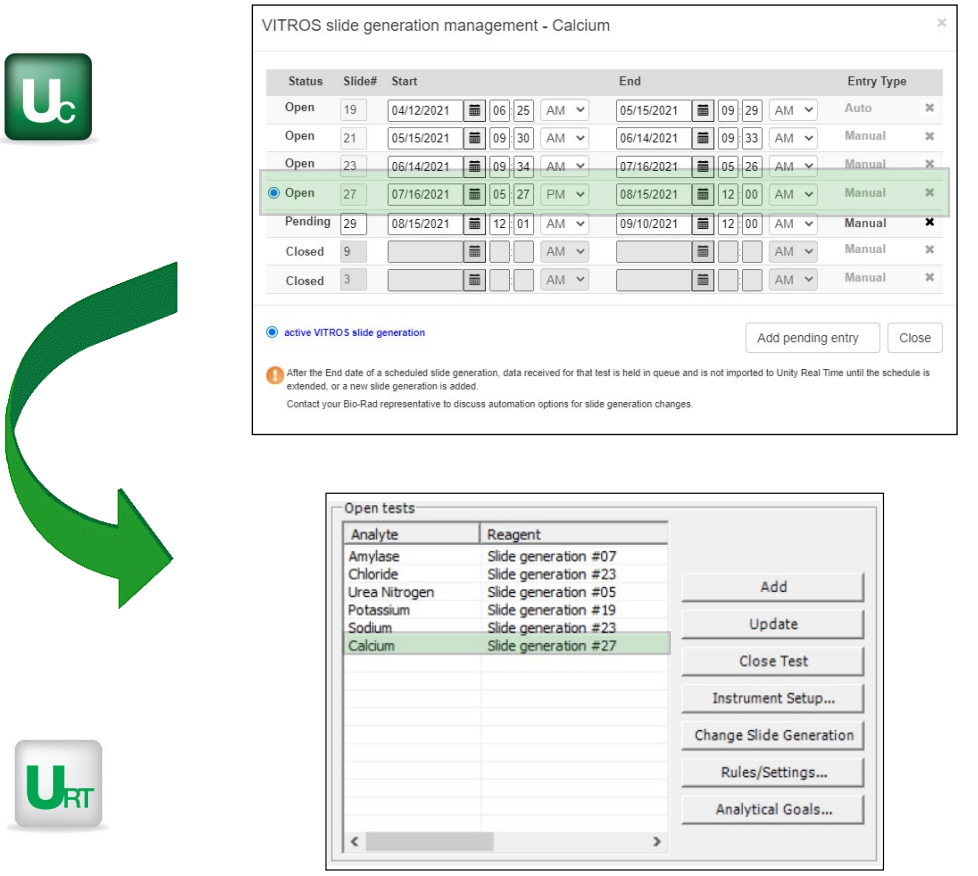
Steps for Manually Adding a New Slide Generation from UnityConnect 2

This method can save steps in your workflow, and is useful if you do not need to duplicate the fixed evaluation means and SDs from the current slide generation to the new slide generation.

Note: Rule evaluation will not begin for the new slide generation's QC results until the specified number of data points are collected in Unity Real Time or a new fixed mean and SD are added.

Refer to "Steps for Manually Adding a New Slide Generation from Unity Real Time" on page 19 if you want to duplicate the fixed evaluation mean and SD from the current slide generation number to the new slide generation.

Note: If a new slide generation is set up in UnityConnect 2, the new test (slide gen) will be added to Unity Real Time when the first run of QC is imported.



Important for "File Upload" Users: To avoid QC results importing into the incorrect test (slide gen) in Unity Real Time, make sure to update slide generation numbers and dates/times before uploading your QC data file.

1 Navigate to the **Test Setup** screen and click the **VITROS slide generation** link in the **Reagent** column.

The **VITROS slide generation management** dialog box will open.

2 Click the **Add pending entry** button.

3 Enter the new slide generation number.

4 Select a start date and time and an end date and time for the new slide generation. Do not overlap dates and times with another slide generation.

5 Click **Close**.

The first time QC data for this date range is processed, the new test (slide gen) will be added to the Unity QC Software and the status in UnityConnect 2 will change to **Open**.

Note: Pending Slide generations can also be edited from the **VITROS slide generation management** window.

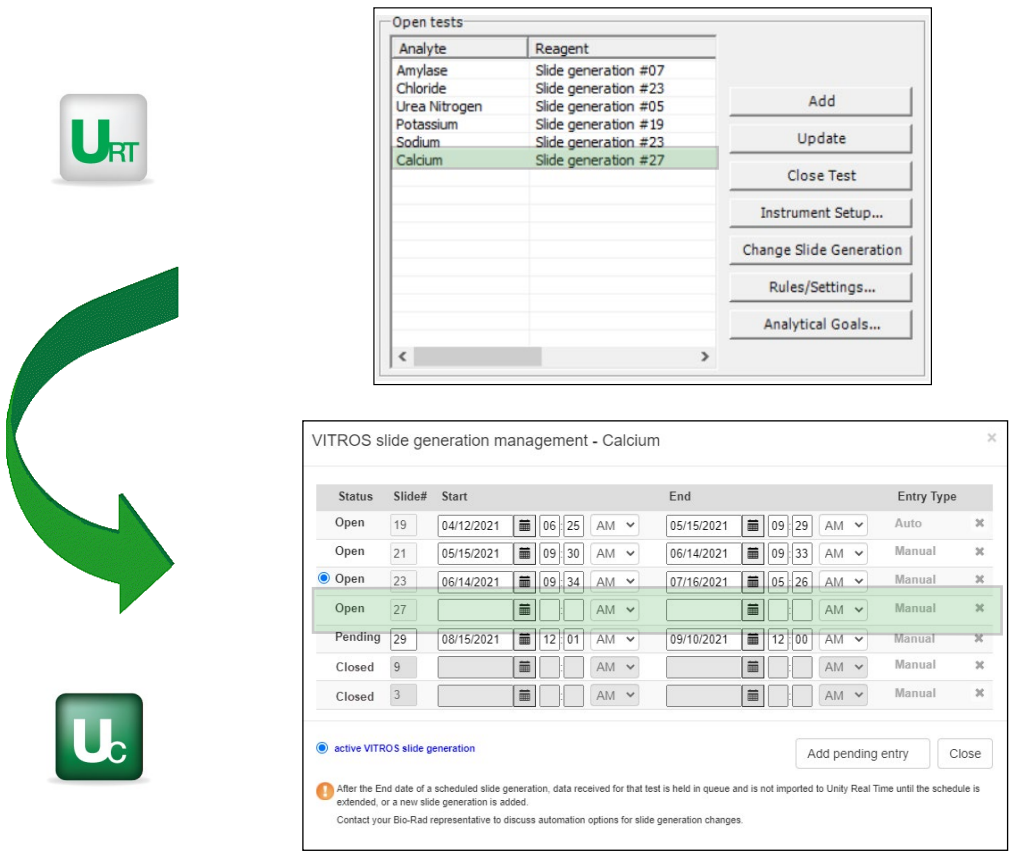
Steps for Manually Adding a New Slide Generation from Unity Real Time

Initiating the new slide generation setup from Unity Real Time provides the benefit of duplicating the fixed evaluation mean and SD from the current slide generation to the new one. These duplicated means and SDs can be edited once enough data has been collected to establish evaluation statistics based on the new slide generation.

Refer to “Steps for Manually Adding a New Slide Generation from UnityConnect 2” on page 17 if you do not plan to duplicate the fixed evaluation mean and SD.

Note: Rule evaluation will not begin for the new slide generation’s QC results until the specified number of data points are collected in Unity Real Time or a new fixed mean and SD are added.

Note: If a new slide generation is set up in Unity Real Time, the slide generation will automatically be added to UnityConnect 2, but the start and end dates can only be defined from UnityConnect 2.



Important for “File Upload” Users: To avoid QC results importing into the incorrect test (slide gen) in Unity Real Time, make sure to update slide generation numbers and dates/times before uploading your QC data file.

1 Open **Unity Real Time**.

2 Navigate to the **Test Setup** screen.

Refer to the Unity Real Time User Guide for more details, if needed.

3 Select the appropriate test and click the **Change Slide Generation** button.

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

5 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.

6 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.

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

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

8 Click **OK**.

The new slide generation will be added to the **VITROS slide generation management** screen in UnityConnect 2. Start and end dates and times must be added from UnityConnect 2.

9 Open **UnityConnect 2**.

10 Navigate to the **Test Setup** screen and click the **VITROS slide generation** link in the **Reagent** column.

The **VITROS slide generation management** dialog box will open.

11 Update the End date and time fields for the current slide generation number.

12 Select a start date and time and end date and time for the new slide generation. Do not overlap dates and times with another slide generation.

13 Click **Close**.

Workflow Considerations

Ultimately, the goal is to report accurate QC results which will increase quality in your laboratory and maintain the accuracy of Unity Interlaboratory consensus group data. Using the automated process is recommended.

For the manual process, entering accurate start and end dates for slide generations will prevent lost data and help maintain quality. In daily practice, monitoring inventory will help enable the entry of accurate dates. Initial estimated dates may need to be adjusted as you near the end of your supply of the current slide generation materials. During times when changes may need to be made to slide generation start and end dates, be sure staff training and software permissions allow for updates in the UnityConnect 2 software.

Alert Notifications for Unmapped Codes

If you prefer to manage the upload process directly to follow through with code mapping requirements, then email alerts may not be needed. However, email alerts can be used to notify a user, or multiple users, when the uploaded file is being “Processed,” indicating that code mapping may be required in order to finalize the QC automation process.

The following steps will assist you in setting up email alerts.

Steps for Configuring Email Alerts

1 Click the **triple bar icon** ☰ and select **Settings**.

> **Note**: Default settings are for English **Language** and a **Notification Interval** of 15 minutes. Notification Interval determines how often the program will check for required mapping and send an email alert.

2 Click **Add New Entry** to add a user email address. Repeat this action for all additional desired addresses.

> **Note**: Disable email addresses at any time by clicking the toggle icon on (Green) or off (Grey). Remove email addresses by hovering next to the toggle icon and clicking the **X**.

3 Click **Save Changes**.

Received Email Alerts

The email alert will contain information regarding the type (Instrument Codes, Lot Codes, Test Codes or Response Codes) and the total count of unmapped codes that require user intervention. The email provides a direct link to the UnityConnect 2 web application, allowing the user to log in from any PC and perform the mapping requirement.

CHAPTER 5

Lot Switches

In This Chapter

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Overview

This section addresses how to manage a lot switch. The process you'll follow for a lot switch depends on the type of data delivery method your lab uses. (Further information about the various methods is available in the section for "Data Delivery Methods" on page 8.)

Data Stream Method

There are two possible ways to handle lot switches if your connectivity method is a data stream. The directions you will need to follow depend on the type of codes that come from your data source (instrument, LIS, or middleware):

- **Unique Lot Codes**: If the codes in your data source change from lot to lot, we call those "unique" codes. Each lot and level has a unique identifier, so UnityConnect 2 is able to detect when you have started a new lot because it receives new codes for it.
- **Generic Lot Codes**: If the codes in your data source stay the same from lot to lot (or the bar codes stay the same from lot to lot), we call those "generic" codes. UnityConnect 2 cannot detect when you have started a new lot because the incoming codes have not changed.

Streaming Unique Codes

This applies if your connectivity method is a data stream, and your data source (instrument/LIS/middleware) uses unique lot codes. (Information about determining your type of source codes is in the previous section, **Streaming Method**.)

There are two parts involved for a lot switch in the Unity software:

- **Part 1**: Duplicate the lot in the Unity QC software. (If needed, refer to your Unity QC software User Guide for directions.)
- **Part 2**: Map and duplicate lots in UnityConnect 2:
  - When alerted, map the new lot.
  - Duplicate the tests from the old lot to the new lot.

> **Note**: If you have multiple mirror instruments running all of the same controls/tests, you can save time during a lot switch by completing the mapping for one instrument, then duplicating that instrument to the remaining instrument(s).

Steps for Mapping a New Lot

1. Ensure the new lot is set up in the **Unity QC software**.
2. When the alert indicates mapping is needed, click the **Map Lots** link for the instrument that requires mapping.
3. Click the **plus icon** to add additional levels, if needed.
4. Select the level number you want to add, if needed.
5. Select the appropriate lot code from each drop-down list to map it to the control, lot, and level listed on the left.
6. Click **Save Changes**.
7. Click the **cog icon** for the original lot number and click **Duplicate**.

> **Note**: Duplicating will transfer the tests' mapping from the old lot to the new lot to save time.

8. Make sure that the correct new lot is selected in the **To** field and click **Apply**.

> **Note**: Once you've duplicated, you can click the **Map Tests** link to see that the new lot's tests have already been mapped based on the previous lot's tests.

Streaming Generic Codes

This applies if your connectivity method is a data stream, and your data source (instrument/LIS/middleware) uses generic lot codes. (Information about determining your type of source codes is on page 23 under “Streaming Method.”)

After the last run on the old lot and before the first run on the new lot, you must manually change the lot codes of the old lot in UnityConnect 2. The lot codes for the old lot and the new lot cannot be the same, so the old codes must be adjusted before data starts crossing for the new lot.

Important: When your lot switch occurs, correctly manage the lot switch in the software at that time. Otherwise, data that belongs with the new lot will incorrectly be placed with the old lot.

Once the old lot codes are changed and the new lot is run, UnityConnect 2 will alert you that the codes for that new lot need to be mapped.

There are two parts involved for a lot switch in the Unity software:

- **Part 1**: Duplicate the lot in the Unity QC software. (If needed, refer to your Unity QC software User Guide for directions.)
- **Part 2**: Manage lots in UnityConnect 2:
  - After the last run of the old lot, change the lot code for that old lot.
  - Start running the new lot.
  - When alerted, map the new lot.
  - Duplicate the tests from the old lot to the new lot.

Steps for Changing Old Lot Codes (Prior to the New Lot Being Run)

1. Click the **Map Lots** link for the instrument that will be starting a new lot.
2. Click on the lot code for each level of the old lot, and manually type a change to the lot code (such as typing “old”) so it no longer shows the same code that the new lot will use.
3. Click **Save Changes**.

Steps for Mapping a New Lot (After the New Lot is Run)

1 Ensure the new lot is set up in the **Unity QC software**.

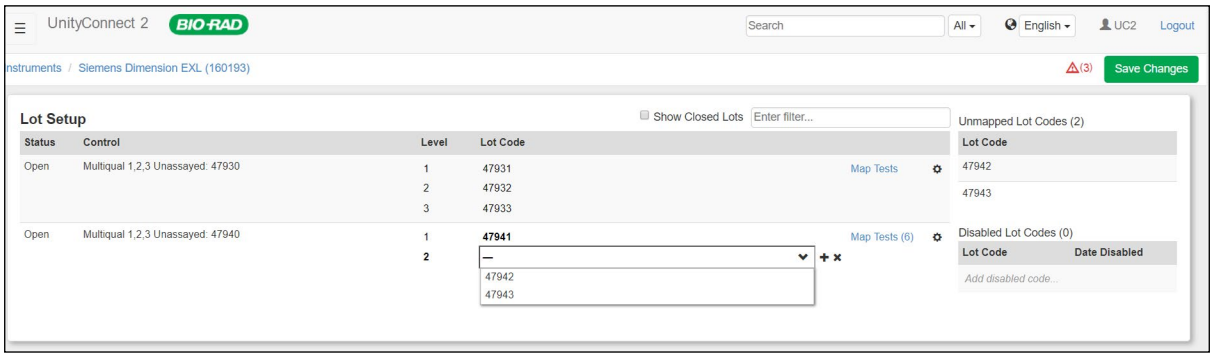
2 When the alert indicates mapping is needed, click the **Map Lots** link.

3 Click the **plus icon** ➕ to add additional levels, if needed.

4 Select the level number you want to add, if needed.

5 Select the appropriate lot code from each drop-down list to map it to the control, new lot number, and level listed on the left.

6 Click **Save Changes**.



7 Click the **cog icon** ⚙ for the original lot number and click **Duplicate**.

> **Note**: Duplicating will transfer the tests' mapping from the old lot to the new lot to save time.

8 Make sure the correct new lot is select in the **To** field and click **Apply**.

> **Note**: Once you've duplicated, you can click the **Map Tests** link to see that the new lot's tests have already been mapped based on the previous lot's tests.

Scheduled Method

Scheduled Unique Codes

This applies if your lab's connectivity method is scheduled uploads. (For information about the various connectivity methods, see "Data Delivery Methods" on page 8.)

There are two parts involved for a lot switch in the Unity software:

- **Part 1**: Duplicate the lot in the Unity QC software. (If needed, refer to your Unity QC software User Guide for directions.)
- **Part 2**: Map and duplicate lots in UnityConnect 2:
  - When alerted, map the new lot.
  - Duplicate the tests from the old lot to the new lot.

Steps for Mapping a New Lot

1. Ensure the new lot is set up in the **Unity QC software**.
2. When the alert indicates mapping is needed, click the **Map Lots** link for the instrument that requires mapping.
3. Click the **plus icon** ➕ to add additional levels, if needed.
4. Select the lab number you want to add, if needed.
5. Select the appropriate lot code from each drop-down list to map it to the control, lot, and level listed on the left.
6. Click **Save Changes**.
7. Click the **cog icon** ⚙ for the original lot number and click **Duplicate**.

   Note: Duplicating will transfer the tests' mapping from the old lot to the new lot to save time.

8. Make sure the correct new lot is selected in the **To** field and click **Apply**.

   Note: Once you've duplicated, you can click the **Map Tests** link to see that the new lot's tests have already been mapped based on the previous lot's tests.

Scheduled Generic Codes

If your lab is set up with a scheduled data delivery method, and your data source (instrument/LIS/middleware) uses generic codes, contact software support regarding assistance with lot switches.

File Upload Method

There are two possible ways to handle lot switches if your connectivity method involves uploading files. The directions you will need to follow depend on the type of codes that come from your data source (instrument, LIS, or middleware):

- **Unique Lot Codes**: If the codes in your data source change from lot to lot, we call those "unique" codes. Each lot and level has a unique identifier, so UnityConnect 2 is able to detect when you have started a new lot because it receives new codes for it.
- **Generic Lot Codes**: If the codes in your data source stay the same from lot to lot (or the bar codes stay the same from lot to lot), we call those "generic" codes. UnityConnect 2 cannot detect when you have started a new lot because the incoming codes have not changed.

Uploading Unique Codes

This applies if your connectivity method is a file upload, and your data source (instrument/LIS/middleware) uses unique lot codes. (Information about determining your type of source codes is under "Data Stream Method" on page 23.)

There are two parts involved for a lot switch in the Unity software:

- **Part 1**: Duplicate the lot in the Unity QC software. (If needed, refer to your Unity QC software User Guide for directions.)
- **Part 2**: Map and duplicate lots in UnityConnect 2:
  - Upload your QC data file as usual. (Directions for uploading files are under "Steps for Uploading a QC Data File" on page 9.)
  - When alerted, map the new lot.
  - Duplicate the tests from the old lot to the new lot.

> **Note**: If you have multiple mirror instruments running all of the same controls/tests, you can save time during a lot switch by completing the mapping for one instrument, then duplicating that instrument to the remaining instrument(s).

Steps for Mapping a New Lot

1. Ensure the new lot is set up in the **Unity QC software**.
2. When the alert indicates a mapping is needed, click the **Map Lots** link for the instrument that requires mapping.
3. Click the **plus icon** ➕ to add additional levels, if needed.
4. Select the levels you want to add, if needed.
5. Select the appropriate lot code from each drop-down list to map it to the control, lot, and level listed on the left.
6. Click **Save Changes**.

7 Click the **cog icon** for the original lot number and click **Duplicate**.

> **Note**: Duplicating will transfer the tests' mapping from the old to the new lot to save time.

8 Make sure the correct new lot is selected in the **To** field and click **Apply**.

> **Note**: Once you've duplicated, you can click the **Map Tests** link to see that the new lot's tests have already been mapped based on the previous lot's tests.

Uploading Generic Codes

This applies if your connectivity method is a file upload, and your data source (instrument/LIS/middleware) uses generic lot codes. (Information about determining your type of source codes in under "Data Stream Method" on page 23.)

If you create and upload one QC data file at the end of the month, but a lot switch occurred in the middle of the month, you will upload that file for the first part of the month (the old lot's data), then upload it again for the second part of the month (the new lot's data).

After uploading the final data for the old lot and before uploading the beginning data for the new lot, you must manually change the lot codes of the old lot in UnityConnect 2. The lot codes for the old lot and the new lot cannot be the same, so the old lot's codes must be adjusted before the new lot is uploaded.

Once the new lot's data is uploaded, UnityConnect 2 will alert you that the codes for that new lot need to be mapped.

There are two parts involved for a lot switch in the Unity software:

- **Part 1**: Duplicate the lot in the Unity QC software. (If needed, refer to your Unity QC software User Guide for directions.)
- **Part**: Manage lots in UnityConnect 2:
  - Upload the first part of the month before the lot switch occurred. (Directions for uploading QC data files are under "Upload a QC Data File" on page 8.)
  - Manually change the lot code for the old lot.
  - Upload the second part of the month after the lot switch occurred.
  - When alerted, map the new lot.
  - Duplicate the tests from the old lot to the new lot.

Steps for Changing Old Lot Codes

1 After uploading the first part of the month before the lot switch occurred, click the **Map Lots** link for the instrument that will be starting a new lot.

2 Click on the lot code for each level of the old lot and manually type a change to the lot code (such as typing “old”) so it no longer shows the same code that the new lot will use.

3 Click **Save Changes**.

Steps for Mapping New Lots

1 Ensure the new lot is set up in the **Unity QC software**.

2 Upload the second part of the month after the lot switch occurred. When the alert indicates mapping is needed, click the **Map Lots** link.

3 Click the **plus icon** ➕ to add additional levels, if needed.

4 Select the level number you want to add, if needed.

5 Select the appropriate lot code from each drop-down list to map it to the control, new lot number, and level listed on the left.

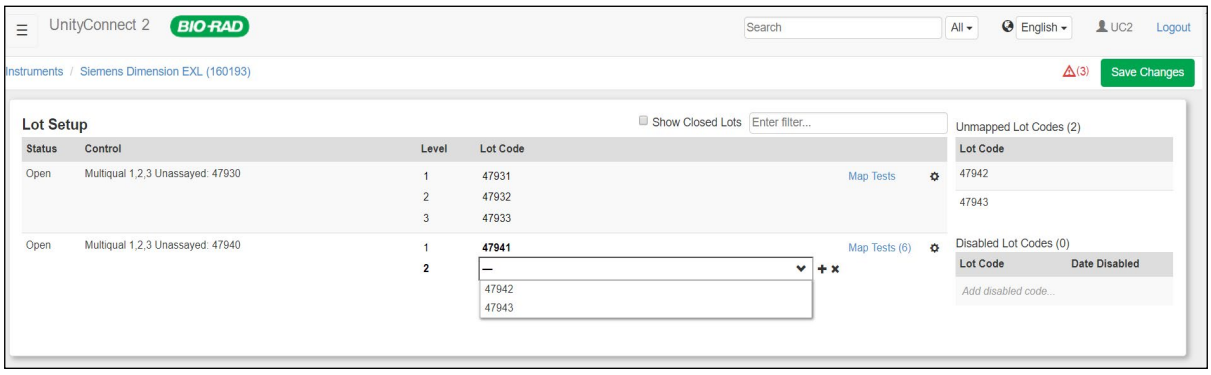
6 Click **Save Changes**.

7 Click the **cog icon** ⚙ for the original lot number and click **Duplicate**.

> **Note**: Duplicating will transfer the tests’ mapping from the old to the new lot to save time.

8 Make sure the correct new lot is selected in the **To** field and click **Apply**.

> **Note**: Once you’ve duplicated, you can click the **Map Tests** link to see that the new lot’s tests have already been mapped based on the previous lot’s tests.



CHAPTER 6

Optional Settings

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Sort By Columns

In the various mapping pages, you can sort items (alphabetically or numerically) in the left-side columns that display your Unity QC software information. (You cannot sort in the right-side columns where you have mapped your source codes.)

Sorting, though not required, can help you locate items more easily. Click the column header to sort the list. Click again to sort in reverse order.

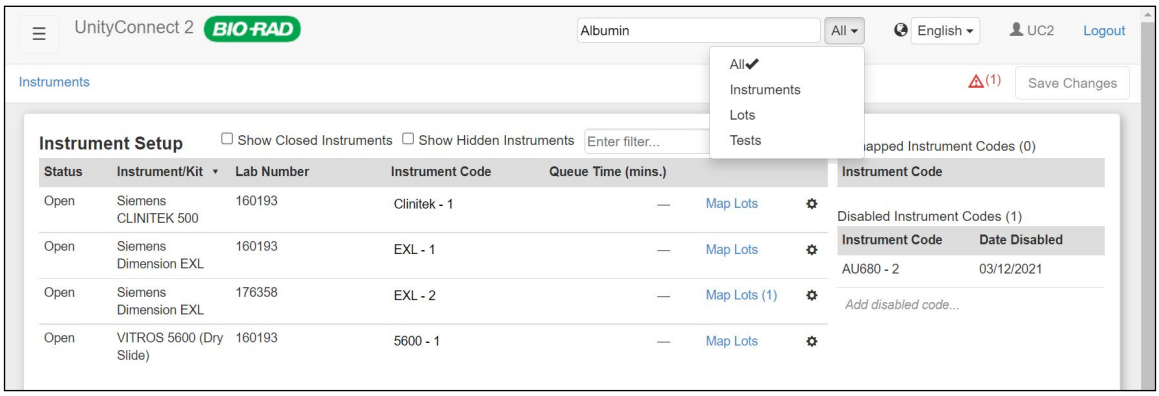
Search

To search quickly for a specific instrument, lot, or test, use the Search field. A search for “sodium,” for example, takes you directly to the associated test rather than having to drill down to the test screen using the mapping links.

Steps for Searching

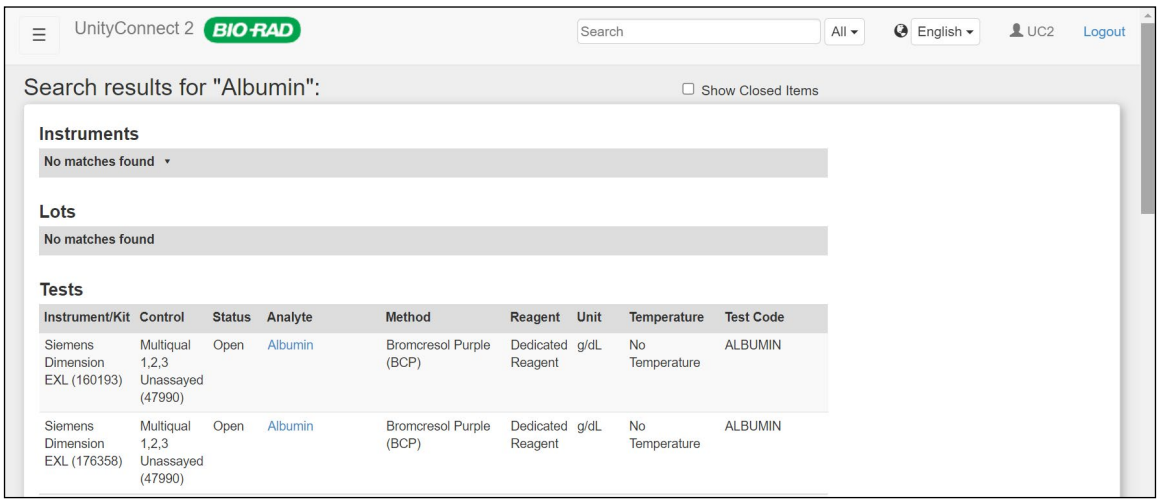
1 Locate the Search field at the top of the screen.

2 Choose a filter from the drop-down arrow next to the Search field to refine your search. (The default search setting is **All**, with options for **Instruments**, **Lots**, or **Tests**.)



Type the item name in the Search field.

3 Click the link for the needed item.



Disable Items

If a code crosses from the data source into UnityConnect 2, but there is no need to include that item in your Unity QC software, the code can be disabled.

Steps for Disabling a Code

1 Locate the unneeded code at the top right of the screen under the section **Unmapped Lot Codes** and click **Disable**.

2 Once disabled, the code moves to the **Disabled Lot Codes** list below, and any associated data will not be imported into the Unity QC software.

3 To manually add to the list of disabled codes, click **Add disabled code** under the **Disabled Lot Codes** section.

4 To reuse a disabled item, click the **X** icon to enable it. You will be prompted to map the item the next time the item is run.

> **Note**: Alternatively, the code can be typed into its respective location prior to the QC run (observing character case sensitivity).

Closed Items

Within your Unity QC software, there may be some closed instruments, lots, or tests. An item is typically marked as closed when it is no longer in use.

Closed items in UnityConnect 2 can be viewed or hidden. Viewing closed items is useful for checking previous or duplicate mapping; hiding closed items prevents clutter and confusion.

To view or hide closed items, use the check box at the top of the screen.

Hide Instruments

Instruments in your Unity QC software that do not need to seen (such as a non-connected instrument for which you manually enter data) can be hidden to help keep screens organized and clutter-free.

Steps for Hiding an Instrument

1 Click the **cog icon** next to the instrument and choose **Hide**.

2 Use the check box (located at the top of the screen) to show or hide those instruments.

Duplicate Instruments

To set up a new instrument with the same lots, tests, and configuration as an existing instrument, the existing instrument can be duplicated.

Duplicating saves time by copying everything from the existing instrument to the new instrument automatically and eliminates the need to map the lots and tests for the new instrument.

Always check that existing lots and tests are set up properly in your Unity QC software before duplicating an instrument.

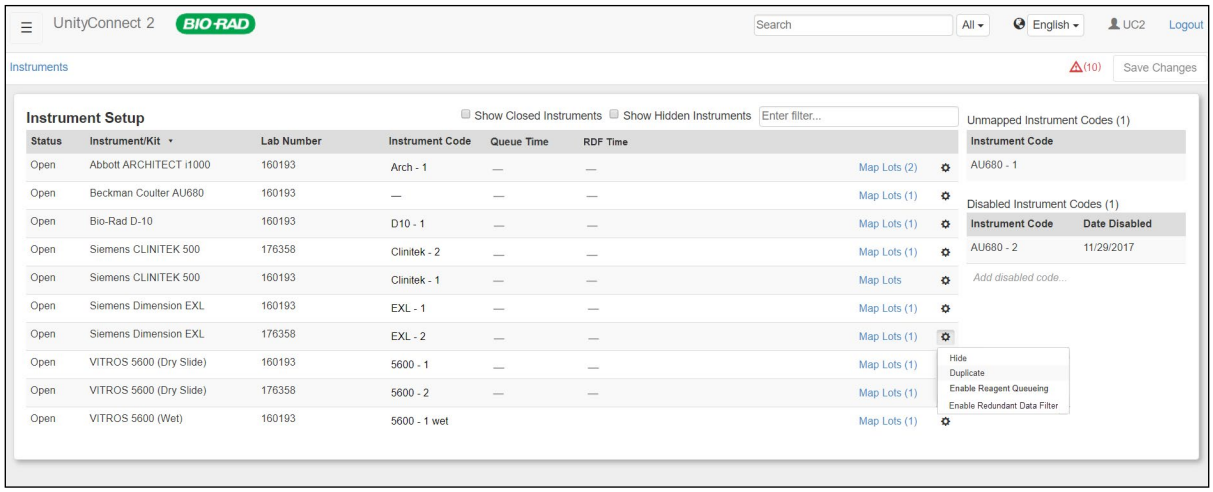
Note: There is also a duplication feature in the Unity QC software that lets you copy one lab number's setup to a new lab number.

Note: If you have multiple instruments running the same controls/tests, you can save time during a lot switch by completing the mapping for one instrument, then duplicating that instrument mapping to the remaining instrument(s).

Steps for Duplicating an Instrument

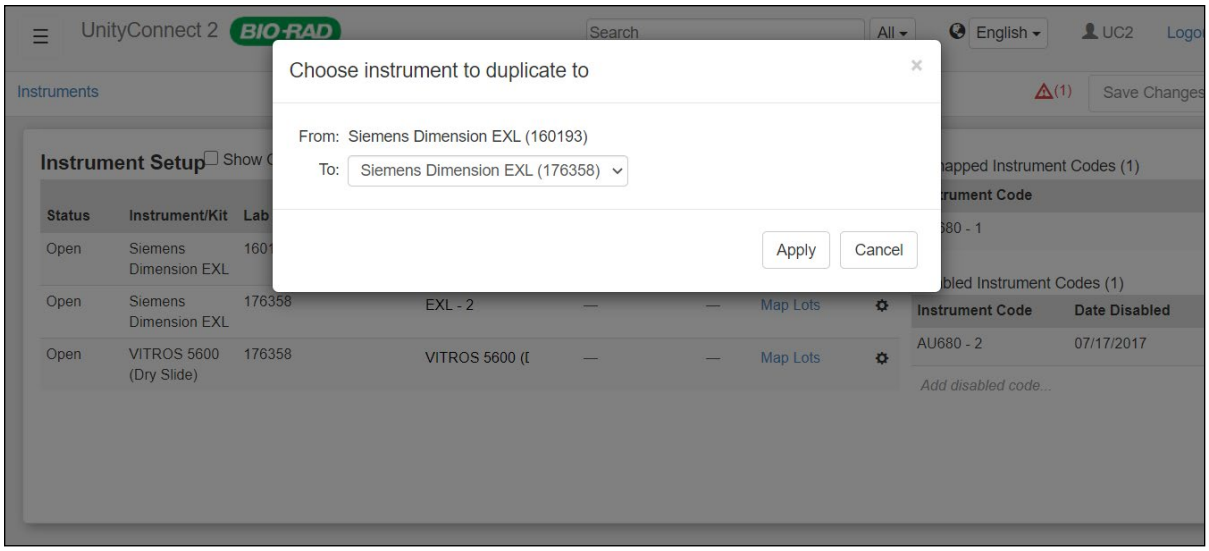
1 Map the new instrument code.

2 Click the **cog icon** next to the original instrument and select **Duplicate**.



3 A pop-out will prompt you to choose the instrument to duplicate to.

4 In the **To** field, select the lab number for the new instrument and click **Apply**.



Note: Since everything is duplicated to the new instrument, no other mapping is needed.

Audit Report

The Audit Report documents and displays a list of auditable events that have been performed in the software, such as:

- Added email address
- Date of Operation
- Deleted code for instrument/lot/test/response
- Deleted email address
- Disabled email address
- Disabled setting
- Duplicated instrument/lot/test/response code to instrument/lot/test/response
- Hidden instrument
- Manually added code to instrument/lot/test/response
- Mapped unmapped code to instrument/lot/test/response
- Modified DFO option of channel display name

Steps to Access the Audit Report

1 Click the **triple bar icon** ☰ and select **Audit Report**.

2 Click a **column header** to sort based on the column.

3 Use the **page number arrows** << 1 >> to navigate through the report.

Note: Sometimes a single action will show up as two separate actions in the Audit Report. For example, modifying an instrument code will be listed with one line for deleting the original code and another line for adding the new code.

Reagent Queueing

Reagent Queueing should be used if your instrument produces both production and stand-by reagent results that require separate grouping of the result runs in the Unity QC software.

Based on the lab's timing procedures for production and stand-by reagents that are uniquely identified in your data source (instrument, middleware or LIS), you can define how long UnityConnect 2 will wait for all levels in use before releasing a test's QC results to the Unity QC software.

Manage the Timing of Data Import According to Levels in Use

For each test in the Unity QC Software, the control levels in use must be defined.
(Refer to the Unity Real Time 2 User Guide for more information.)

If UnityConnect 2 receives results for all enabled test levels, the QC results will automatically be transmitted to the Unity QC software. If one or more enabled test levels is delayed, UnityConnect 2 will hold all results for the test in the queue. When the defined queue time is reached, UnityConnect 2 will transmit the collected results to the Unity QC software.

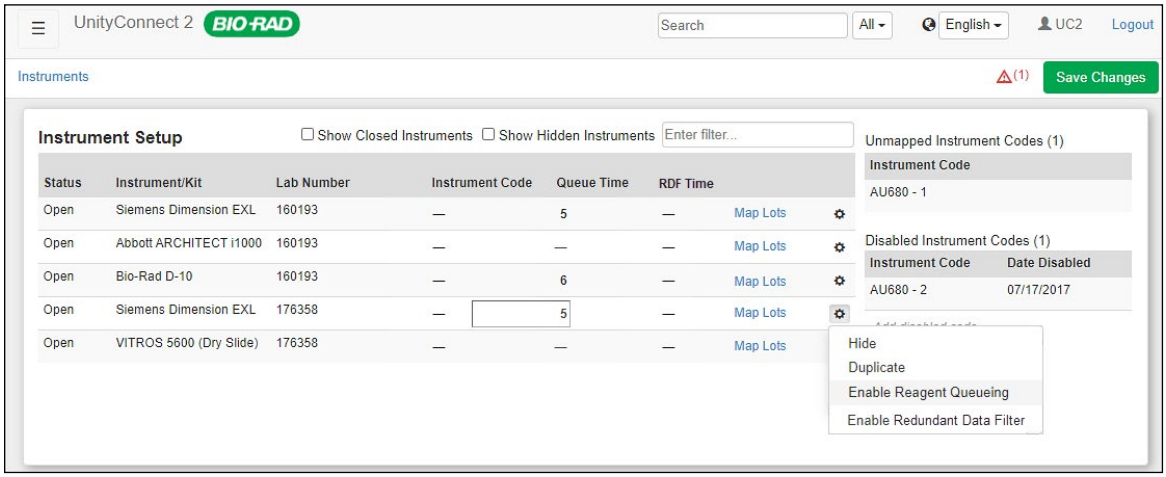
Steps for Defining Reagent Queueing

1 Click the **Cog icon** next to the instrument and select **Enable Reagent Queueing**.

The Queue Time field will become active for the selected instrument.

2 Enter the specified time into the text field in minutes ranging from 1 to 1440 (24 hours).

3 Click **Save Changes**.



Note: If an additional queue time is no longer needed, the user can simply click the **Cog icon** and select **Disable Reagent Queueing**.

Redundant Data Filtering

The Redundant Data Filter (RDF) is a feature used to identify and block transmission of QC results that have already been sent to the Unity QC software. Activating this feature provides the added benefit of more efficient use of the rejection log within the Unity QC software, because the extra work of re-reviewing previously transmitted rejections is avoided. Review time is used to focus on unaddressed items in the Unity QC software's rejection log when determining why QC data was not imported.

The RDF time is typically set based on how often the data source (instrument, middleware, or LIS) continuously creates new data files that contain previously transmitted results. For example, laboratories that use the "Scheduled" Data Delivery Method will often see both new and previously transmitted results in the auto generated QC data file(s). See Data Delivery Methods - Scheduled on page 3 for more information regarding scheduled files.

Manage the RDF Time

The RDF time is typically set based on how often the data source (instrument, middleware or LIS) creates a new data file for transmission. The time can be set for 1 to 1440 minutes (24 hours) by populating the **RDF Time** field. RDF can be activated and managed only from the Instrument Setup page in UnityConnect 2.

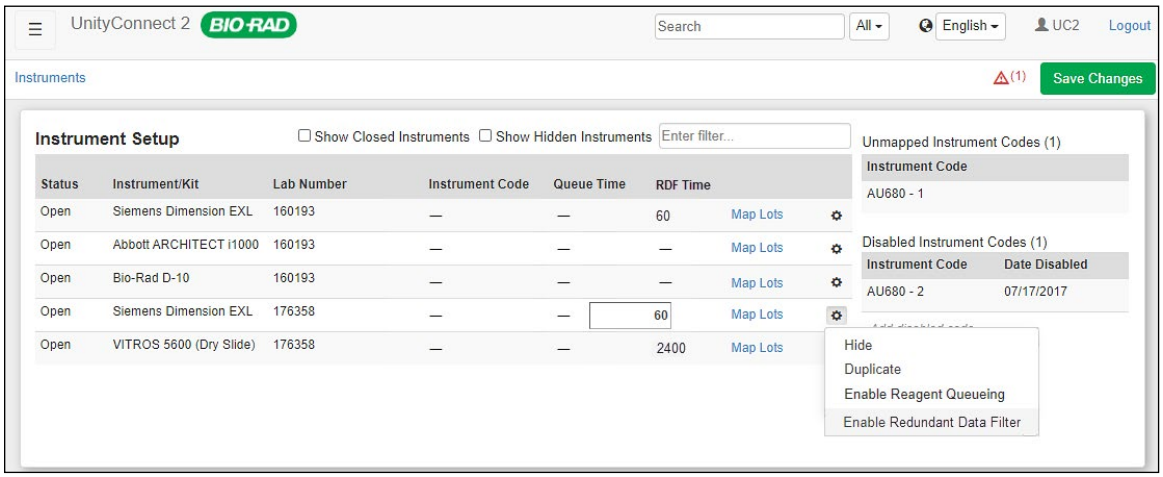
Steps for Defining Redundant Data Filtering

1 Click the **Cog icon** next to the instrument and select **Enable Redundant Data Filtering**.

The **RDF Time** field will become active for the selected instrument.

2 Enter the specified time into the text field in minutes ranging from 1 to 1440 (24 hours).

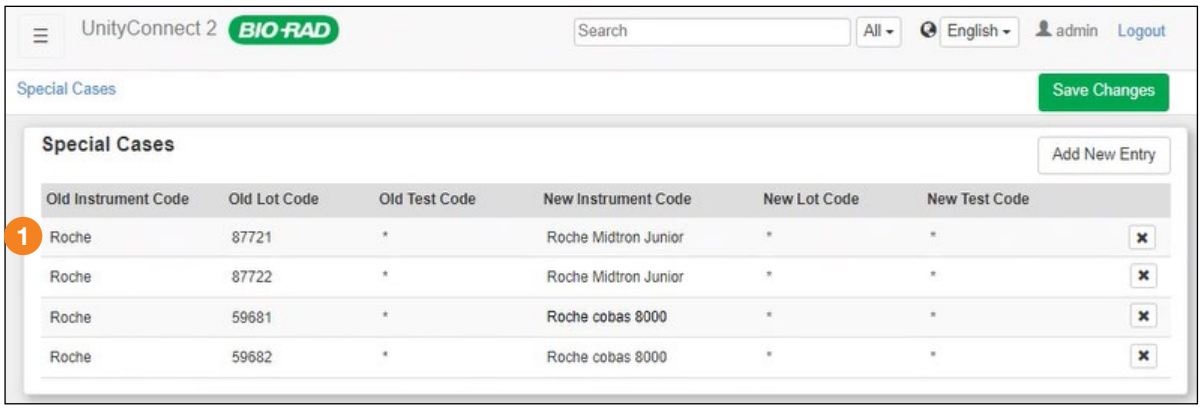
3 Click **Save Changes**.



Note: If an RDF is no longer needed, the user can simply click the **Cog icon** and select **Disable Redundant Data Filter**.

Special Cases

The Special Cases feature is used to map QC data codes coming from the data source which are not unique to a specific instrument, lot, or test. Special Cases allows laboratories to include additional criteria in their mapping to more effectively define instrument, lot, or test codes. There are a wide variety of scenarios that can be addressed with the use of this tool. Two examples of Special Cases are described below. A Bio-Rad Software Support representative is available to assist you in setting up Special Cases.

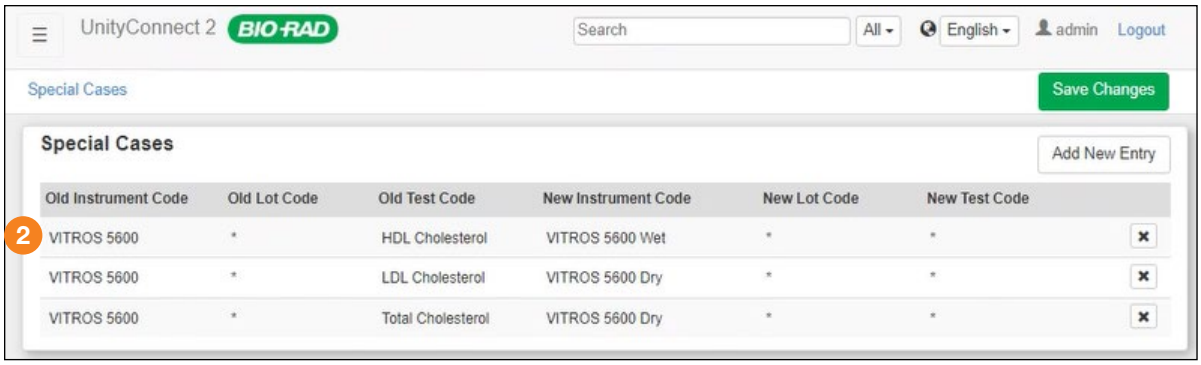


1 A laboratory has a Roche cobas 8000 instrument and a Roche Midtron Junior instrument. QC data for the instruments flows through an LIS or middleware that does not distinguish between the two instruments. A generic code of “Roche” is assigned to both instruments.

However, the laboratory knows that certain controls/tests are run on the cobas 8000, and other controls/tests are run on the Midtron Junior. With the use of Special Cases, the laboratory is able to map a new instrument translation with the combination of the Old Instrument Code and an Old Lot code. This new translation instructs UnityConnect 2 to associate all related lot and test results with the new Roche Midtron Junior Instrument Code.

This mapping is repeated for each level of the defined lot. Similar mapping is completed for lots 59681 and 59682 (each lot level) to create a new instrument code of “Roche cobas 8000.”

Asterisk symbols (*) are used in both the New Lot Code Column and New Test Code Column because the existing codes are unique and no changes are needed. Asterisk symbols (*) are also used in the Old Test Code Column. Since the Old Lot Code (which includes all associated tests) was mapped, there is no need to map each test individually.



2 A laboratory has a VITROS 5600 instrument and uses both wet and dry tests. The laboratory's data crosses from an LIS or middleware that does not distinguish between wet and dry tests. Although the one instrument runs both test types, the Unity software and Interlaboratory Program separate the QC data as a "VITROS 5600 Wet" instrument and a "VITROS 5600 Dry" instrument.

Since both wet and dry tests can be associated with the same lot, the lab will use the old test codes with the generic instrument code (VITROS 5600) to configure the new instrument codes. Wet tests will be mapped to the "VITROS 5600 Wet" instrument and dry tests will be mapped to the "VITROS 5600 Dry" instrument.

Asterisk symbols (*) are used in both the New Lot Code column and New Test Code column because the existing codes are unique and no changes are needed. Asterisk symbols (*) are also used in the Old Lot Code column since the lot code is not used as a part of the configuration.

Steps for Configuring Special Cases

1 Click the **triple bar icon** ☰ and select **Special Cases**.

2 Click the **Add New Entry** button.

3 Click to populate each field in the row.

Enter the asterisk (*) symbol for any field that does not contribute to the new configuration or that does not change when the Special Case is applied.

4 Repeat steps 1-4 (when applicable) for each instrument, lot, and/or test.

> **Note:** Copy/Paste is available to duplicate entries between fields.

5 Click **Save Changes**.

Note: All fields must be populated to save the new mapping. If a value is not needed for a particular item, enter the asterisk (*) symbol as a non-specific or wildcard value. A message will appear prompting the user to enter a value or the asterisk if any fields are empty when Save Changes is selected.

Note: A special case rule can only be mapped and saved once. If the rule is entered again, the user will receive an error message.

Steps for Editing Special Case Rules

1 Click the **triple bar icon** ☰ and select **Special Cases**.

2 Find the appropriate special case rule and click the field to edit.

3 Make the necessary changes and click **Save Changes**.

Steps for Deleting a Special Case Rule

1 Click the **triple bar icon** ☰ and select **Special Cases**.

2 Find the appropriate special case rule and click the **X** icon at the end of the row.

3 Click **Yes** for the deletion confirmation message.

4 Click **Save Changes**.

Note: The row will not be removed until the user clicks **Save Changes**. Multiple rows can be marked for deletion before saving.

CHAPTER 7

Contact Bio-Rad

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Software Support

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

Canada: 800-361-1808

Software Support Representatives are available Monday through Friday, 5:00 am to 4:00 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 field application specialist.

QC Program Representative

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

CHAPTER 8

License, Warranty, and Trademarks

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