
QX ONE™ Software

Regulatory Edition

User Guide

Version 1.4



BIO-RAD

QX ONE Software Regulatory Edition

User Guide

Version 1.4

For Research Use Only

BIO-RAD

Bio-Rad Technical Support Department

The Bio-Rad Technical Support department in the U.S. is open Monday through Friday, 5:00 AM to 5:00 PM, Pacific time.

Phone: 1-800-424-6723, option 2

Email: Support@bio-rad.com (U.S./Canada Only)

For technical assistance outside the U.S. and Canada, contact your local technical support office or click the Contact Us link at bio-rad.com.

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Revision History

Document	Date	Description of Change
QX ONE Software User Guide, Regulatory Edition Version 1.4 DIR 10000148670 Ver D	December 2023	Added new Software Settings tab in Version 1.4
QX ONE Software User Guide, Regulatory Edition Version v1.3 DIR 10000148670 Ver C	January 2023	Update for Version 1.3, as follows: <ul style="list-style-type: none"> ■ Update screen shots to show in the software toolbar the percentage of disk space available on the touch screen computer hard drive instead of the number of plates than can be run. ■ Add important note regarding foil piercing on all wells in a plate (including excluded wells), although droplets are not generated or read in excluded wells.
QX ONE Software User Guide Regulatory Edition Version 1.2	December 2021	Update user guides with Version 1.2 enhancements, including <ul style="list-style-type: none"> ■ Positive control-based thresholding ■ Ability to enable the User Management module (Standard Edition only) ■ Added user privilege ■ Enhanced data recovery ■ Access to troubleshooting data ■ Ability to view an audit log (Regulatory Edition only)
QX ONE Software User Guide Regulatory Edition	October 2020	Add brief descriptions, bullet points and cross-references to the instrument guide in both software guides

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Chapter 1 About QX ONE Software

A Bio-Rad field service engineer installs your software edition on the QX ONE Droplet Digital PCR System touch screen, which provides the interface to the instrument controls.

Using the software on the touch screen, you can

- Set up customized ddPCR experiments for plate runs in the QX ONE™ Droplet Digital™ PCR (ddPCR™) System
- Create and store templates for plate layouts, thermal cycling protocols, and reports.
- Use the live analysis function during the droplet reading phase
- With the Manage Plate user privilege, cancel runs and reorder plates while they are in the instrument Inbox
- Analyze your data files in a variety of charts and tables in the Analysis module
- Generate reports on your data
- Restrict template access to ensure the use of approved templates only

In the Regulatory Edition, you can

- Produce system and experiment audit logs to ensure clear audit trails for activities and consumable/reagent use through the Event Log, Data Archive, and automatic Lot Management functions
- Safeguard user access with secure logins and traceable user activity

Important: The Regulatory Edition prompts you to log in again and reauthenticate your user credentials. Enter your user name and password, and then tap Sign in.

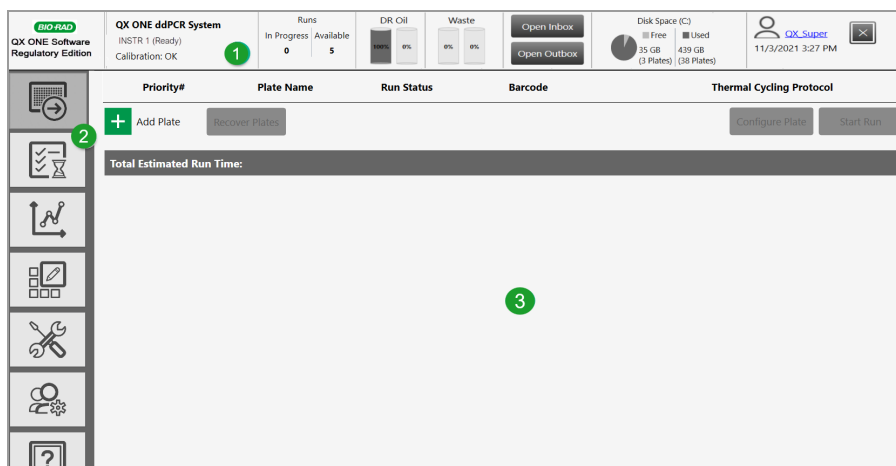
For information on using the instrument, refer to the QX ONE Droplet Digital PCR System Instrument Guide.

The QX ONE guides instruct you to tap options on the touchscreen. If you are using QX ONE Software with a keyboard and mouse, click the options instead.

Tip: You can download and link the software and instrument guides to corresponding buttons in the Help window. For information, see [Linking the User Guides in the Help Window on page 29](#).

Important: The Regulatory Edition provides additional features to permit operation in compliance with Title 21 of the U.S. Code of Federal Regulations Part 11 (21 CFR Part 11) within a closed system. A closed system is defined as “an environment in which system access is controlled by the persons who are responsible for the content of electronic records that are on the system” (Section 11.3(b) (4)).

- The security controls built into the Regulatory Edition must be properly configured and administered by the software administrators in your organization in order to be secure and in compliance with 21 CFR Part 11.
- Bio-Rad makes no claim that the Regulatory Edition is CFR-compliant in and of itself, nor does the company guarantee compliance for the user. Your organization must establish policies and standard operating procedures that work in conjunction with the tools provided by Bio-Rad to ensure compliance with 21 CFR Part 11.
- The Regulatory Edition prompts you to log in again before executing an auditable action.



LEGEND

- 1 The status bar displays information about the instrument and user.
- 2 Tabs provide access to the main functional windows.
- 3 The main pane displays the details of the selected tab.

If QX ONE Software goes into standby mode after being idle, tap in the lockout screen to sign into the software again and display the last active window.

Signing In, Viewing Privileges, and Changing Preferences

Typically, a system or software administrator sets up users and privileges for QX ONE Software, and communicates the information to you.

Note the following:

- You cannot change your user privileges unless you are assigned the Add/Manage Users privilege. For information, see [Viewing User Privileges on page 16](#).
- You can change your user preferences, which are set to defaults. For information, see [Managing Your Preferences on page 18](#).

Signing into the Software

Important: The Regulatory Edition includes audit capabilities. For auditable actions, you are prompted to sign in again before continuing.

To sign in

1. Tap the touch screen to open the Sign in dialog box.
2. Enter the user name and password and tap Sign in.

The screenshot shows a sign-in dialog box with a blue header containing a key icon. Below the header are three input fields: 'User Name' containing 'QXONE_User1', 'Password' containing masked characters, and 'Sign in to: QXONE_TouchScreen'. A 'Sign in' button is located at the bottom right of the dialog. At the bottom left, there is a blue hyperlink that reads 'How do I sign in to another domain?'.

3. Ensure the Do not show EULA on sign in checkbox is selected and tap I Agree.

The screenshot shows a checkbox labeled 'Do not show EULA on sign in' which is checked. To the right of the checkbox are two buttons: 'I Disagree' and 'I Agree'.

Each user must agree to the end user license agreement on initial login in order to use the software. If you clear the checkbox, the End User License Agreement appears the next time you log into the software, and you must agree again to the terms before the software opens. If you do not agree to the EULA, the application closes immediately.

When you agree to the EULA, the dialog box closes and the application opens. Your user name appears in the Instrument Status bar.

The Add Plate window opens on the instrument touch screen.

If you are opening the software on a standalone computer, the Data Analysis window opens.

Viewing User Privileges

In the User Management window, your privileges are identified by the selected checkboxes.

To view your assigned privileges

- ▶ Select the User Management tab.



Unless you are assigned the Add/Manage Users privilege, checkboxes for your assigned privileges are selected but not enabled, as shown in the following graphic. To request changes to your privileges, contact your software administrator.

A screenshot of the 'User Management' software window. The window title is 'User Management'. It features a search bar with 'User Name: USPLEC0TKYF2\QX_User1' and a 'Check Name' button. Below this is a 'Full Name: QX_User1' field. A section titled 'Privileges' contains a list of checkboxes: 'Add/Manage Users' (disabled), 'Create New Templates' (checked), 'View Datafiles (created by other users)' (checked), 'Overwrite Existing Datafile name' (checked), 'System Settings' (disabled), 'Maintenance' (disabled), 'System Data' (checked), 'Access Module Recovery Tool' (disabled), and 'Manage Plate' (checked).

Privilege	Status
Add/Manage Users	Disabled
Create New Templates	Checked
View Datafiles (created by other users)	Checked
Overwrite Existing Datafile name	Checked
System Settings	Disabled
Maintenance	Disabled
System Data	Checked
Access Module Recovery Tool	Disabled
Manage Plate	Checked

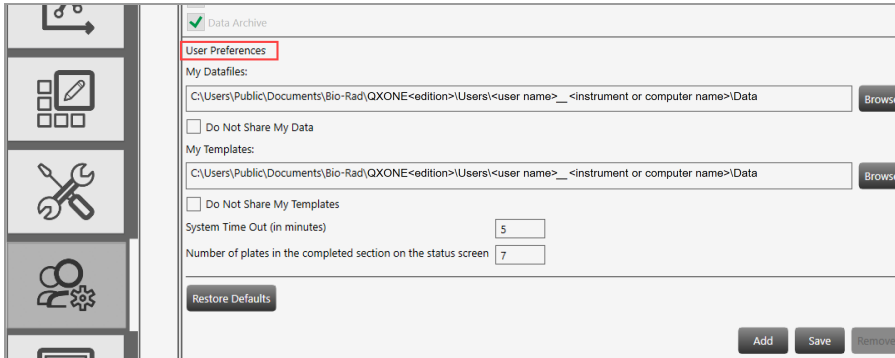
Table 1 lists the available privileges, which can be assigned in any combination.

Table 1. User privileges

Privilege	Purpose
Add and manage users	Add or remove users, set privileges, and change preferences. Important: Users who are assigned the Add/Manage Users privilege can create users and update privileges and preferences for any user. Only the superuser can remove this privilege from user accounts.
Create new templates	Save a design for a plate, thermal cycling protocol, or analysis report as a template.
View data files (created by other users)	See run files that were created from runs executed by other users.
Overwrite existing data file name	Save the file with a new file name. Files are always saved with the extension for the application you are using. For information, see Compatible File Types on page 30 . Note: Users without this permission can open files and perform analysis but cannot create a new file.
System settings	View logs, reprocess data with new calibration values, and change file locations. All users can view the file locations. Important: If your administrator selected the Preferred Locations checkbox in System Settings, individual user location preferences are overridden.
Maintenance	View the event log and the system data settings. Note: All users can reprocess data, view system folder settings, as well as the maintenance log and maintenance reports.
System Data	Move raw data from the touch screen computer to free up disk space. Access troubleshooting data. Recover data from a temporary file created for a failed run.
Access Module Recovery Tool	For manual plate recovery, you can specify the processes to be rerun.
Manage Plate	Cancel runs on the QX ONE Droplet Digital PCR System. Reorder plates that are still in the instrument Inbox.

Managing Your Preferences

Use the User Management window to modify your personal user preferences. Default folder locations appear in your preferences, but you can change them. You can also choose to keep all data files and templates private. The software prompts you to choose either your personal folder or the shared folder each time you save a file or template.



To change your preferences

1. Change any of the following preferences:
 - Enter a different file path for your data files and templates.
 - Select or clear the check boxes to change your data file and template privacy settings.
Important: The paths and checkboxes are disabled if your administrator has set Preferred Locations in System Settings.
 - Enter a different system timeout period.
 - Enter a different total of completed plates to show in the Run Status window, up to a maximum of 100.
2. Do one of the following:
 - If you are setting preferences for a new user, tap Add.
 - If you are updating preferences, tap Save.
3. When the confirmation message appears, tap Yes, and then tap OK.

Signing Out or Changing Users

While the instrument is idle, one user can log out on the touch screen and another user can log in.

Important: If User Management was not enabled during the software installation, the sign in, sign out, and change users functions are not available.

Note the following:

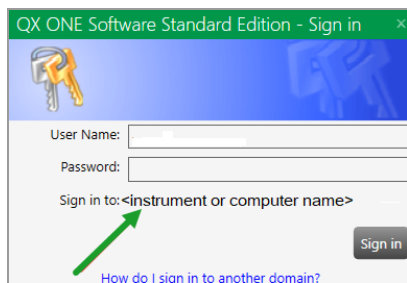
- Do not change users while a run is in progress or data might be affected.
- If the screen is locked and the initial user left unsaved changes, an advisory prompt appears. Click Save before proceeding or the previous user's work is lost.

To sign out

1. Tap the user name link in the upper-right corner and select Sign Out.
2. Tap Yes to confirm.

To change users

1. Tap anywhere in the lockout screen to display the Sign in window.
2. Enter a user name.
 - The domain name appears below the user login fields. If you are on the same domain as the previous user, you can enter your user name only.



- If the user is on a different domain, enter the domain name followed by a backslash and the user name.

<domain name>\<user name> (for example, global\john_smith)
3. Enter the password and tap Sign in.

Instrument Status Bar

An instrument status bar appears above all windows except the analysis displays, which open in a separate module.

The status bar on the touch screen displays the information and indicators shown below



LEGEND

- 1** Software name and version

- 2** Instrument name and status information

- 3** Number of runs in progress and runs available

- 4** Oil and waste levels

- 5** Open or close the Inbox or Outbox

- 6** Used and free disk space
Storage availability is displayed in GB and by number of plates that you can run before running out of space on the touch screen computer.
Note: When QX ONE Software detects low disk space, the software displays an advisory prompt to archive data.








- 7** Name of the current user, along with the current date and time

- 8** Closes the QX ONE Software application

Tabs to Functional Windows

Table 2 describes the functional areas and primary windows in QX ONE Software.

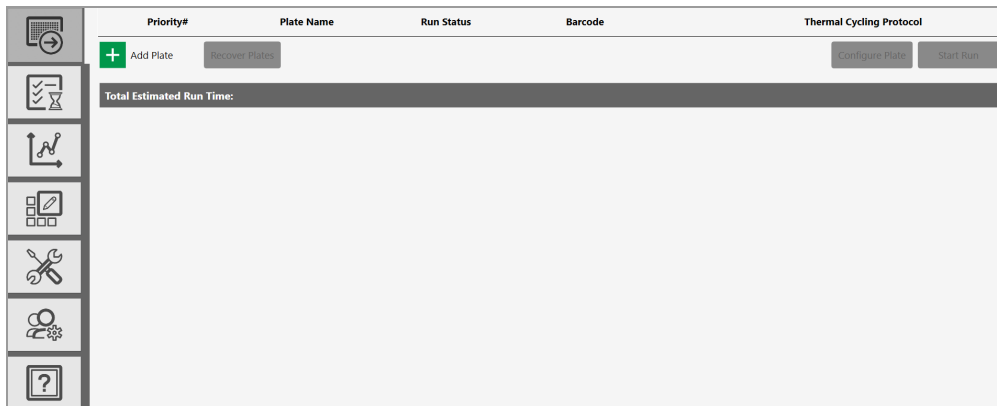
Table 2. Window Tabs

Tab	Name	Purpose
	Add Plate	<ul style="list-style-type: none"> ■ Add and configure a plate and protocol for a ddPCR run ■ Recover a plate from a failed run
	Run Status	<ul style="list-style-type: none"> ■ In the top pane, view the runs in progress ■ In the bottom pane, view up to 100 completed runs
	Data Analysis	<ul style="list-style-type: none"> ■ Access the Data Analysis and Gene Study modules <p>Note: In QX ONE Software, Gene Study is available on a standalone computer, but not from the touch screen.</p>
	Templates	<ul style="list-style-type: none"> ■ Set up templates for plates thermal cycling protocols, and reports, and search for existing template files
	System	<ul style="list-style-type: none"> ■ View storage locations, logs, and maintenance reports ■ Archive data, access troubleshooting information, and recover data from a temporary file created for a failed run <p>Important: Available functionality depends on your assigned user privileges. Instrument calibration is available only to the Bio-Rad service engineer.</p>
	Users	<ul style="list-style-type: none"> ■ View the user privileges you have been assigned, and view and modify your personal preferences ■ Create, edit, or remove QX ONE Software users (if you are assigned the Add/Manage Users privilege)
	Help	<ul style="list-style-type: none"> ■ Access software version information, current calibration values, End User License Agreement company website, and open source software license information <p>Tip: You can also link the user and instrument guides to the labeled buttons. For information, see Linking the User Guides in the Help Window on page 29.</p>

Add Plate Window

On the QX ONE Droplet Digital PCR System touch screen, QX ONE Software opens to the Add Plate window, where you can set up a plate for an experiment and start a ddPCR run. You can also recover a plate that experienced a failure during the run.

Note: If you are using the software on a computer other than the touch screen, the Add Plate window is not accessible and QX ONE Software displays the Data Analysis window by default.



From the Add Plate window you can

- Add plates in the software
- Recover a plate from a failed run
- Access the Plate and Protocol Configuration window to configure your plates and PCR protocols
- Run experiments on your plates and protocols

QX ONE Software enables each button sequentially (Add Plate, Configure Plate, Start Run) when you complete the prerequisite tasks. If the QX ONE Droplet Digital PCR System experienced a failure during the run, the Recover Plate button is enabled. For more information on adding and recovering plates, refer to the QX ONE Droplet Digital PCR System Instrument Guide.

Run Status Window

You can view the Run Status window on the QX ONE Droplet Digital PCR System touch screen.

Note: If you are using the software on a computer other than the touch screen, the Run Status window is not available.

Users with the Manage Plate user permission can reorder plates in the software that are still in the instrument Inbox and cancel plates before or during the run. For information, see the QX ONE Droplet Digital PCR System Instrument Guide.

The Run Status window displays information on

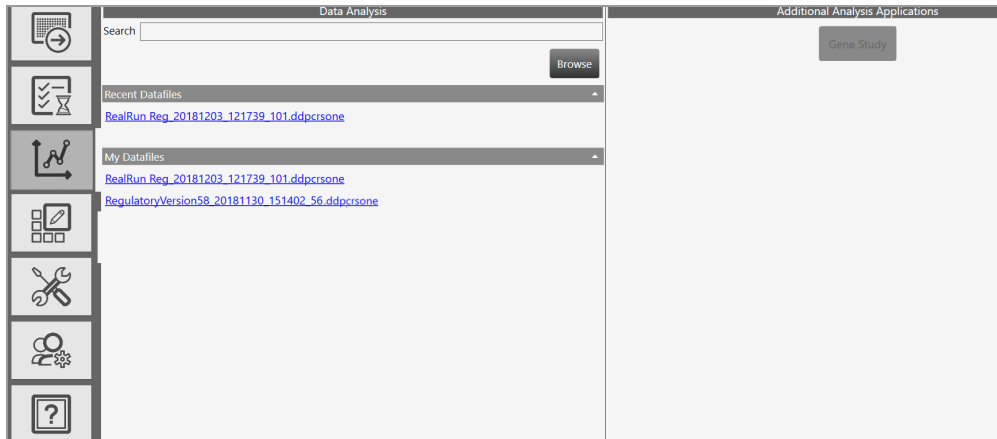
- The runs in process in the top pane
- Up to 100 completed runs for the current user in the bottom pane, including plate failures and recoveries

Note: You set the number of completed runs to show in your user preferences. For information, see [Managing Your Preferences on page 18](#).

Plate Name	Barcode	Run Status	Location	Time Remaining	Time Elapsed
Total Time Remaining: 00:00					
Plate Name	Barcode	Run Status	Run Completed	File Name	
test	12-02-03-04-05	✓	09/10/2020 11:17:16 AM	test_20200910_110343_208.ddpcrsone	
test	12-02-03-04-05	!	09/09/2020 04:44:01 PM	test_20200909_164352_938.ddpcrsone	
test	01-12-03-04-05	✓	09/09/2020 03:33:02 PM	test_20200909_151736_372.ddpcrsone	
test	12-02-03-04-05	✓	09/09/2020 03:20:40 PM	test_20200909_151735_216.ddpcrsone	
RDQ_Template	01-12-03-04-05	✓	09/20/2019 01:01:32 PM	RDQ_Template_20190920_123908_946.dpcrsone	

Data Analysis Window

The Data Analysis window displays a list of analysis files created at the end of each run.



From the left panel, you can select files from the following storage areas to open in the Data Analysis module:

- Recent Datafiles
 - A list of files that you have opened.
- My Datafiles or System Datafiles
 - If the system administrator has
 - Not set shared locations in System Settings, all data files are automatically saved to the file path specified in the user's preferences.
 - Set shared locations in System Settings, all data files are automatically saved to the path specified for Datafile Storage Location. Preferred locations override individual user preferences.

Important: For either choice, the specified path must be a local folder on the QX ONE Droplet Digital PCR System touch screen computer.

Note: For information on files types for your software and edition, see [Compatible File Types on page 30](#).

- From the right panel, you can access the Gene Study module. For information, see [Gene Study Module on page 139](#).

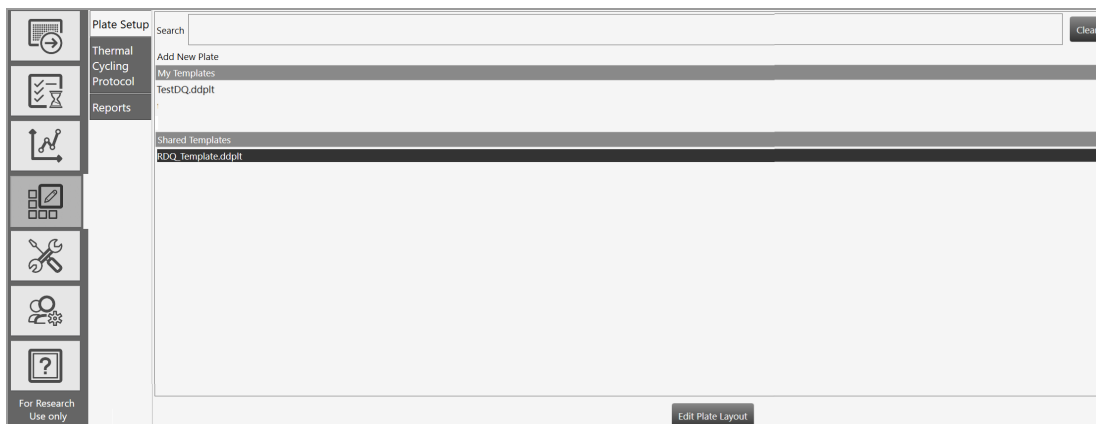
Chapter 1 Creating or Modifying Templates

The Template Setup window allows you to

- Create new plate, thermal cycling protocol, and report templates
- Search for existing templates
- Modify existing templates

If you are assigned the Create New Template user privilege, you can save new or modified templates for reuse. You can save templates to a personal or system folder (My Templates or System Templates, respectively), or you can save them to the Shared Templates location.

Note: If your system administrator has specified Preferred Locations in the System Settings window, the System Templates location overrides the folder specified in your user preferences..

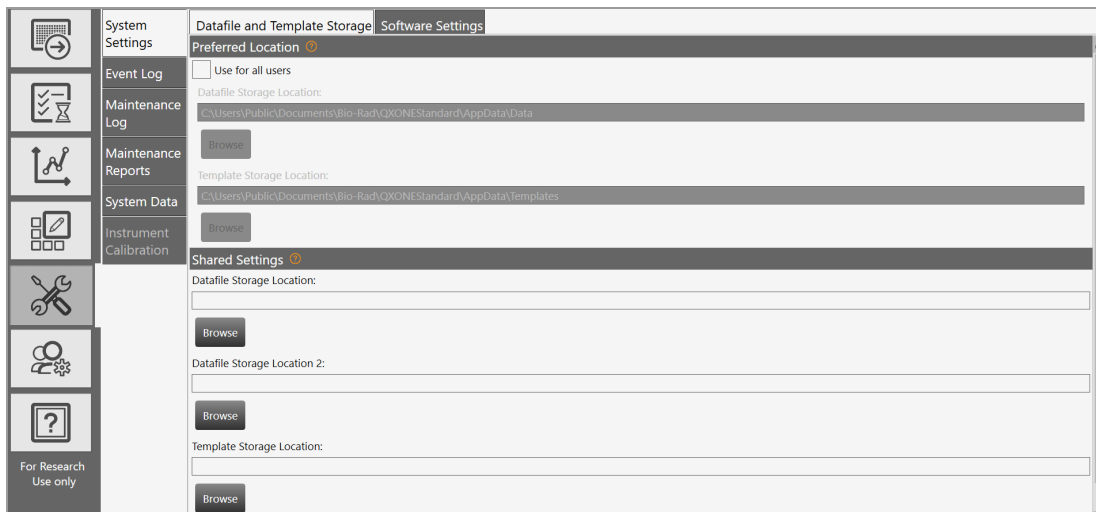


For information on creating or editing templates, see

- [Creating or Modifying Plate Templates on page 33](#)
- [Creating or Editing Thermal Cycling Protocol Templates on page 55](#)
- [Creating or Modifying Report Templates on page 63](#)

System Status Window

The System Status window displays information about your QX ONE Droplet Digital PCR System and QX ONE Software.



Depending on your permission level, you can

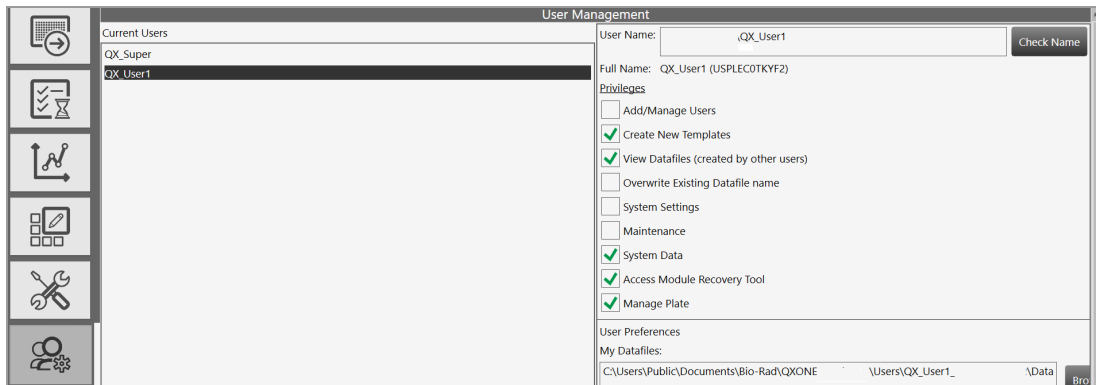
- View or change shared storage folder locations
 - Important:** System administrators can override individual storage locations and set Preferred Locations for data files and templates. Only administrators can establish or change these locations.
- View event and maintenance logs, and maintenance reports
- Archive raw data, recover the data from a failed plate run that is stored in a temporary file, and access troubleshooting data for review.

Note: The Instrument Calibration tab is enabled only for the Bio-Rad service engineer user account.

User Management Window

The User Management window displays your active user privileges and user preferences. Your privileges are assigned to you by a user (usually an administrator) with the Add/Manage users privilege. You cannot change privileges, but you can change the default settings in user preferences.

Note: Users who are not assigned any of the privileges listed can still execute runs and use the Analysis module.



Help Window

The Help window provides links to important information about QX ONE Software and Bio-Rad Laboratories, Inc.

The screenshot shows the QX ONE Software Regulatory Edition interface. At the top, there is a status bar with the Bio-Rad logo, system information (QX ONE ddPCR System SIMULATOR Ready, Calibration: OK), and various operational metrics: Runs (0 In Progress, 5 Available), DG Oil (0% Probes, 0% Oil), DR Oil (100% Oil, 0% Waste), and Waste (0% Oil, 0% Waste). There are also buttons for 'Open Inbox' and 'Open Outbox', a disk space indicator (105 GB Free, 358 GB Used, 22%), and a user profile for 'QX_Super' with a timestamp of 10/7/2021 11:16 AM.

The main content area is titled '© 2021 Bio-Rad Laboratories, Inc. All rights reserved.' and contains the following links and information:

- [QX ONE Software Regulatory Edition Version 1.2.0.134](#)
- [Current calibration values from QX ONE](#)
- [EULA](#)
- [Bio-Rad Website](#)
- [Software Licenses](#)

For technical support questions and product information, please contact us at:
Email: support@bio-rad.com
Phone: 1-800-4-BIORAD(1-800-424-6723)

There are two sets of buttons: 'View Software Manual' and 'Browse', and 'View Instrument Manual' and 'Browse'.

At the bottom left, there is a 'For Research' tab.

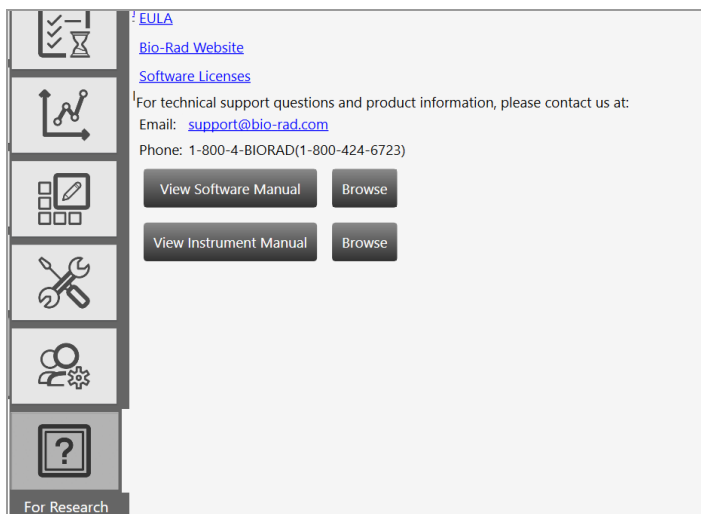
Select the Help tab to display links to

- Software version information
- End user license agreement (EULA); see [Appendix B, End User License Agreement](#) for information.
- Bio-Rad technical support
- Bio-Rad web site
- Open-source software license information

Note: You can also link PDFs of the instrument and software user guides. For information, see [Linking the User Guides in the Help Window on page 29](#).

Linking the User Guides in the Help Window

To facilitate access to user assistance documentation, you can link the instrument guide for the QX ONE Droplet Digital PCR System and the user guide for your software edition (standard or regulatory).



Important: If you have not received PDFs of the instrument guide and applicable user guide, you can download them from the [Bio-Rad website](#).

To link the guides

1. Navigate to the following folder:
C:\ProgramData\Bio-Rad*<Standard or Regulatory>*
2. Within the folder, create another folder and rename it UserGuides.
3. In QX ONE Software, select the Help tab, and then click the Browse button beside View Software Manual or View Instrument Manual.
4. Navigate to the User Guides folder and click Open.
QX ONE Software links the guide. To open the PDF, click the View <manual> button.
5. Repeat for the remaining guide.

Compatible File Types

This section describes the file types you can open in QX ONE Software.

The following applies if your organization is using more than one edition of the software:

- You can open files created using Regulatory Edition only in Regulatory Edition.
- If you open a .qlps or .ddpcrs file in QX ONE Software, Regulatory Edition, the file opens and is saved as a .ddpcrsone file.

Table 3. Compatible file types

File Type	Extension	Details
Plate template	.ddplt	Plate template file containing setup details to perform experiments; this file type opens in the Plate Editor.
Plate template	.csv	Importable plate template file containing setup details in CSV format; this file type opens in the Plate Editor.
Protocol	.ddthp	Protocol template file containing setup details to perform experiments; this file type opens in the Protocol Editor.
Data	.ddpcrsone	Contains the results of an experiment run performed on the QX ONE Instrument using QX ONE Software, Premium Edition. Note: If you open a .ddpcrs file in QX ONE Software, the file is saved as a .ddpcrsone file.
Data	.qlps	File type from earlier QuantaSoft™ regulatory versions, for two-channel experiment runs and data analysis; this file type opens in the Analysis module.

Chapter 1 Creating or Modifying Templates

The Template Setup window allows you to

- Create new plate, thermal cycling protocol, and report templates
- Search for existing templates
- Modify existing templates

If you are assigned the Create New Template user privilege, you can save new or modified templates for reuse. You can save templates to a personal or system folder (My Templates or System Templates, respectively), or you can save them to the Shared Templates location.

Note: If your system administrator has specified Preferred Locations in the System Settings window, the System Templates location overrides the folder specified in your user preferences..



For information on creating or editing templates, see

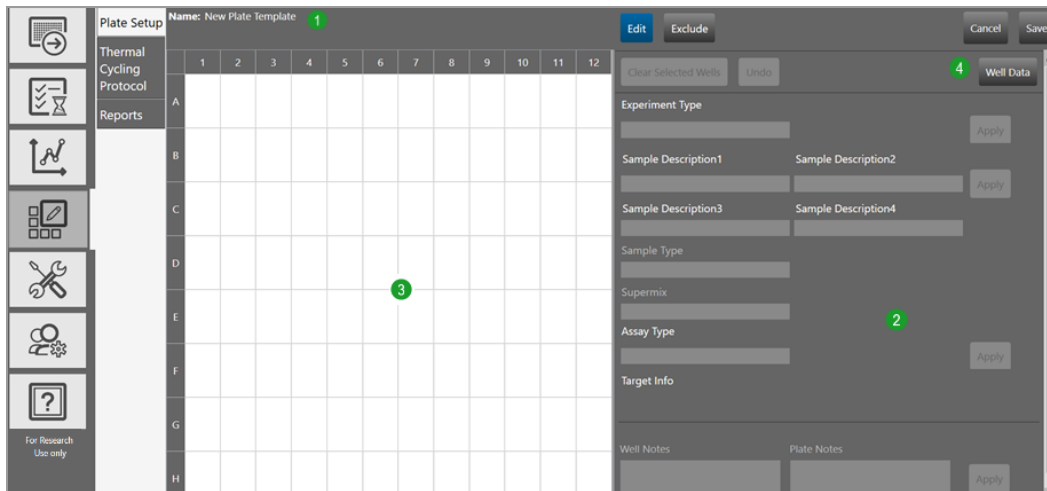
- [Creating or Modifying Plate Templates on page 33](#)
- [Creating or Editing Thermal Cycling Protocol Templates on page 55](#)
- [Creating or Modifying Report Templates on page 63](#)

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Creating or Modifying Plate Templates

If you are assigned the Create New Templates user privilege, you can save a plate as a template for reuse.

When you choose to add or modify a plate template, the Plate Editor opens, featuring options to set up your samples in the plate layout and exclude certain wells from droplet generation and droplet reading or droplet reading only.



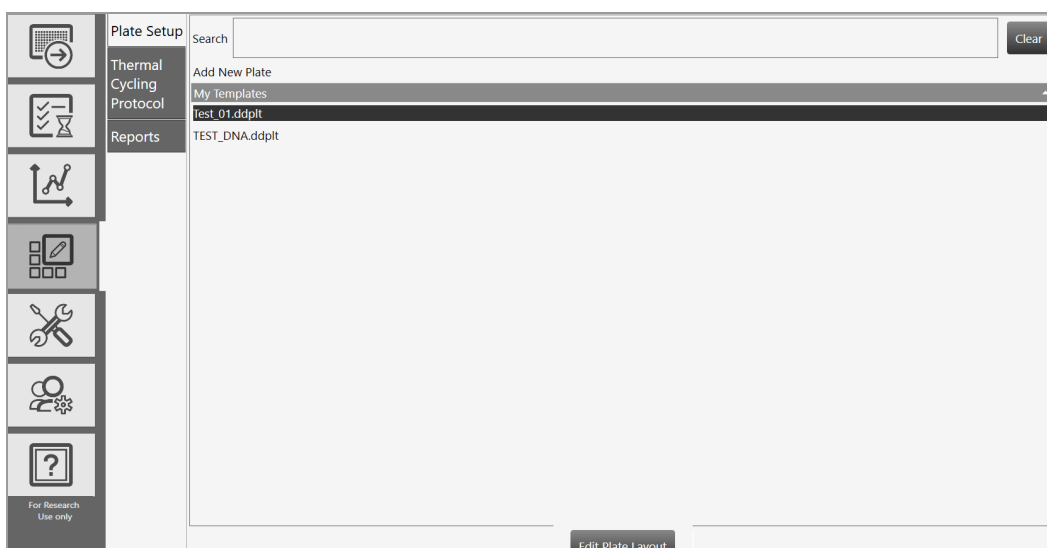
LEGEND

- 1 Buttons at the top of the window provide quick access to plate editing functions.
- 2 The right pane contains the interface for defining your experiment parameters.
- 3 The left pane displays the plate grid and configuration information in each well.
- 4 The Well Data button toggles to the Well Data table, where you can see your plate setup in a tabular format, and then back to the Plate Editor. When the Well Data table appears, the button name changes to Plate Layout. You cannot edit the Well Data table.

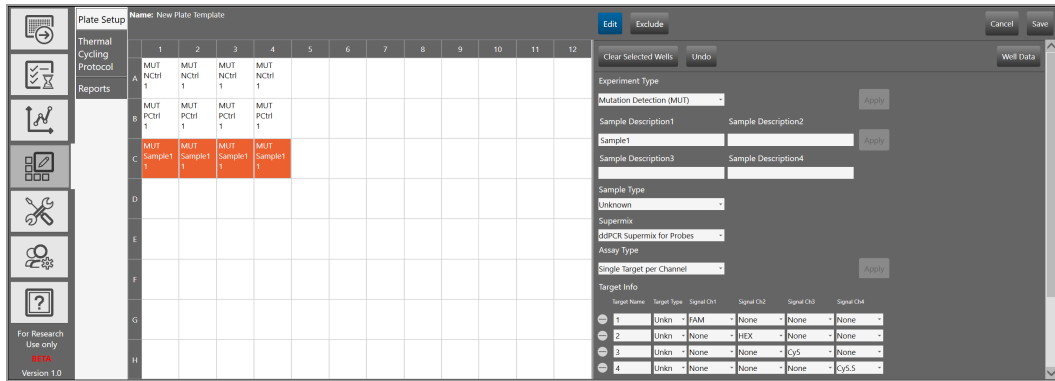
Templates that are available to you appear in the default view of the Template Setup tab, as follows:

- Templates created and saved by any user, and designated as shared, appear under Shared Templates.
- Templates you created and saved, which are saved to the path you specified in your user preferences, and appear in your My Templates folder.

Important: If your system administrator has selected the Preferred Locations checkbox in System Settings, all run files and templates are saved to that location, overriding the location indicated in your user preferences.



From the Template Setup or Add Plate window, you can create or modify plate templates. From the Template Setup window, you can also modify reports.



For detailed information on creating protocol templates, refer to the QX ONE Software User Guide.

Opening a New Plate Template

You can open a blank plate template from either the Template Setup window or the Add Plate window.

- Use Template Setup if you are creating one or more templates to store for future use.
- Use Add Plate if you are creating a template from a plate you are about to run.

To open a new plate template from the Template Setup window

1. Tap the Template Setup tab.



2. Tap Plate Setup.
3. Tap Edit Plate Layout.

The Template Editor opens, displaying a blank plate layout.

To open a new plate template from the Add Plate window

1. Tap the Add Plate tab.



2. Select Plate Setup.

The Plate Configuration window opens to the Plate Information tab by default.

3. Under Plate Template, tap Create New.

The Template Editor opens, displaying a blank plate layout.

Opening an Existing Plate Template

You can open an existing plate template from either the Template Setup window or the Add Plate window.

- Use Template Setup if you are editing one or more templates to store for future use.
- Use Add Plate if you are editing a template from a plate you are about to run.

To open an existing plate file from the Template Setup window

1. Tap the Template Setup tab.



The Plate Setup window appears by default and a list of available plate templates appears.

2. Select a template and tap Edit Plate Layout.

Tip: You can also double-click the template file to open it.

The Plate Editor opens, displaying the plate template as it is currently configured.

To open an existing plate template from the Add Plate window

1. Tap the Add Plate tab.
2. Under Choose existing, select a template from the drop-down list.

The template Plate Editor opens, displaying the template as it is currently configured.

Template Plate Editor Window

Use the Template Plate Editor to

- Create new or edit existing plate template files, and save new or modified templates for reuse
- Add up to four sample descriptions per well
- Exclude wells from droplet generation and droplet reading, or just droplet reading

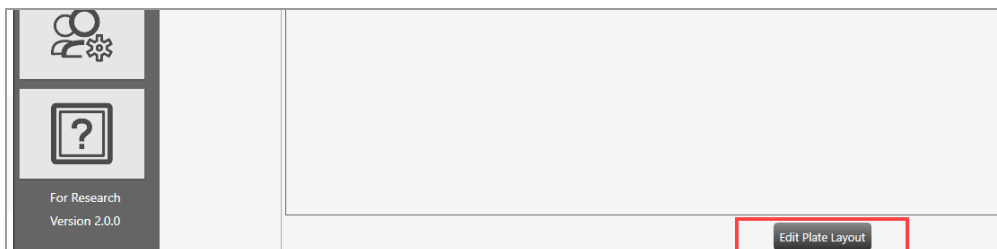
Important: When you create an experiment from a template with wells excluded in the plate layout, the instrument pierces the foil for all wells in the physical plate, but generates and/or reads droplets for active wells only.

To open the template plate editor

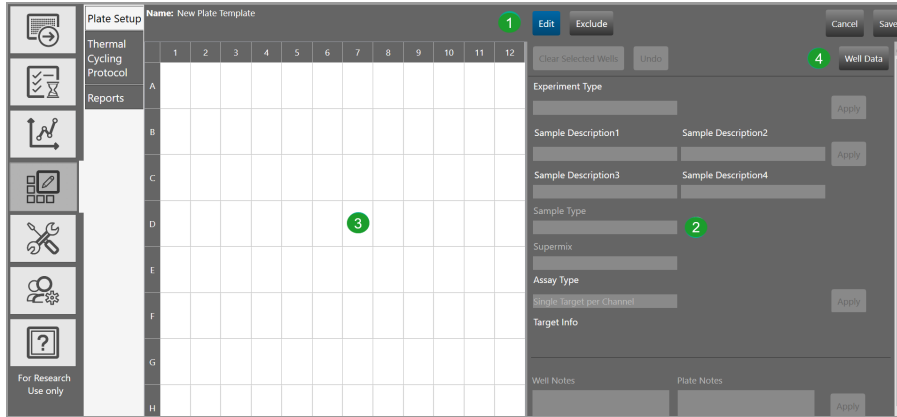
1. Click the Templates tab on the left.



2. In the Templates window, tap Edit Plate Layout



You can also open the template plate editor from the Add Plate window.



LEGEND

- 1 The Edit and Exclude buttons are accessible from the top of the screen.

- 2 The right pane contains the interface for defining your experiment parameters.

- 3 The left pane displays the plate grid and configuration information in each well.

- 4 The Well Data button toggles to the Well Data table, where you can see your plate setup in a tabular format, and then back to the Plate Editor. When the Well Data table appears, the button name changes to Plate Layout.

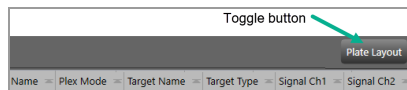


Plate Editor Tools

Use the buttons described in [Table 4](#) when you are creating a template or defining an experiment in the Plate Template Editor.

Table 4. Plate Editor Buttons

Button	Description
Edit	Allows you to <ul style="list-style-type: none">■ Set the experiment type, sample name and type, supermix, and assay type■ Set the target name, type, and fluorophore for each channel■ Add well or plate notes
Exclude	Toggle button that allows you to include or exclude wells from droplet generation and droplet reading, or from droplet reading only
Cancel	Allows you to cancel and return to the Template Setup window
Save	Opens a dialog box where you can enter a file name and storage location
Clear Selected Wells	Allows you to delete information from selected wells
Undo	Allows you to reverse your last action Note: This button is enabled only after you have applied at least one experiment parameter (for example, the selection for Experiment Type).
Well Data or Plate Layout	Toggle button that allows you to access the Well Data table and return to Plate Layout view
Apply	Applies your entries and choices for selected wells

Template Setup — Setting Up Your Wells

When you open the Plate Editor from the Template Setup tab, the Edit button is selected by default. You can assign different experiment parameters to each well or groups of wells.

The screenshot shows the 'Plate Setup' interface. On the left is a sidebar with icons for Thermal Cycling Protocol, Reports, and a 'For Research Use only' section. The main area is a grid with columns 1-12 and rows A-G. The first two columns of rows A-G contain the text 'MUT DNA1 1'. To the right of the grid is a configuration panel with the following sections:

- Experiment Type:** Mutation Detection (MUT) (with an Apply button)
- Sample Descriptions:** Sample Description1 (DNA1), Sample Description2 (DNA2), Sample Description3, and Sample Description4 (with an Apply button)
- Sample Type:** Unknown (dropdown)
- Supermix:** ddPCR Supermix for Probes (dropdown)
- Assay Type:** Single Target per Channel (dropdown, with an Apply button)
- Target Info:** A table with columns: Target Name, Target Type, Signal Ch1, Signal Ch2, Signal Ch3, Signal Ch4.

Target Name	Target Type	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4
1	Unkn	FAM	None	None	None
2	Unkn	None	HEX	None	None
3	Unkn	None	None	Cy5	None
4	Unkn	None	None	None	Cy5.5

For each well, or group of wells, you must

- Choose an experiment type
- Select a sample type
- Select a supermix
- Select an assay method

Optionally, you can

- Enter up to four sample descriptors for each well
- Modify fluorophore assignments
- Add notes for each well
- Add notes for the plate

If you are creating a new template, the grid is blank. If you are editing an existing template, previously saved information appears when you select one or more configured wells.

To define well parameters

1. Select a well or group of wells.
2. From the Experiment Type dropdown list, select a new or different experiment type. For more information, see [Experiment Types on page 44](#).
3. In the Sample Description fields, enter or change up to four words or phrases that describe the sample. For more information, see [Sample Descriptions on page 45](#).
4. From the Sample Type dropdown list, select a new or different sample type. For more information, see [Sample Types on page 45](#).
5. From the Supermix dropdown list, select or change the supermix. For more information, see [Supermixes on page 46](#).
6. The Assay Type field populates automatically based on your experiment selection. To change it, select a different assay type from the dropdown list. For information, see the fluorophore options in [Assay Types and Fluorophores on page 47](#).

Note: Available assay types vary, depending on the selected experiment type.

7. (Optional) Under Target Info, change the fluorophore assigned to a channel.

The fluorophore information populates automatically for each target, with the maximum number of rows allowed for the assay method, but you can modify the default fluorophore assignments, if applicable.

- a. Tap the field dropdown arrow and select an alternative.
- b. To delete a row, tap the minus (-) icon next to the target.
- c. To re-add a row, tap the plus (+) icon.

8. (Optional) To clear one or more wells at any time, select the wells and tap Clear Selected Wells.
9. Tap Apply.

Note: You must tap Apply for the software to recognize your new or edited information, and before you can save the template. Once applied, you can pause on a well to see the corresponding information in a tool tip.

DQ	DQ	DQ	DQ	DQ	DQ	DQ
NTC/1cpd	0.125 cpd	0.25 cpd	0.5 cpd	1 cpd	2 cpd	Ch1
HSV	Experiment Type: Direct Quantification (DQ)			ISV-1	HSV-1	
B2M	Sample Description 1: 0.5 cpd Ch1/1cpd Ch2			2M-Hex	B2M-Hex	
Sample Type: Unknown						
Supermix: ddPCR Supermix for Probes						
Assay Type: Single Target per Channel						
DQ	Target Information:			IQ	DQ	
NTC	HSV-1, Unknown, FAM			1cpd Ch1	2 cpd Ch1	
HSV	B2M-Hex, Unknown, HEX			ISV-1	HSV-1	
B2M-Hex	B2M-Hex	B2M-Hex	B2M-Hex	B2M-Hex	B2M-Hex	

10. Exclude wells in the plate from droplet generation and droplet reading, or from droplet reading only. For information, see [Template Setup – Excluding Wells](#).

Important: The QX ONE Droplet Digital PCR System processes all 96 wells in the plate by default. If you have filled fewer than 96 wells with sample or buffer, you should exclude the remainder.

11. If you are finished with your plate configuration, tap Save in the upper-right corner and then in the Save dialog box, enter a new name for the template and tap Save again.

Note: You must save the template with a new name. You cannot overwrite existing templates. If you tap the Save button before the plate layout is complete, the file closes and you must reopen it from the saved template location.

Experiment Types

QX ONE Software offers the experiment types described in [Table 5](#), each enabling different assay options and analysis tools. You can assign multiple experiment types across the plate, but you can assign only one experiment type to each well.

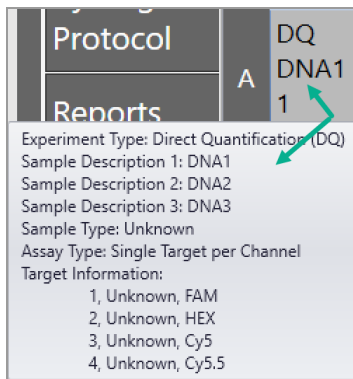
Table 5. Experiment types

Type	Description
Direct quantification (DQ)	DQ uses absolute quantification to determine the concentration (copies/ μ l) of target DNA copies in a sample. DQ measures the number of positive and negative droplets for each target in a well based on their fluorescence amplitude, and uses a Poisson algorithm to calculate the starting concentration of each target DNA molecule. Note: The ABS experiment type created in QuantaSoft Software versions 1.4 through 1.7 is automatically mapped into the software as a DQ experiment type.
Copy number variation (CNV)	CNV determines concentration (as with DQ) and calculates the copy number of an unknown (CNV) target relative to a known reference or references within the same well.
Mutation detection (MUT)	MUT determines concentration (as with DQ) and calculates the fractional abundance of an unknown mutant present at a low frequency in a wild-type background.
Rare event detection (RED)	RED determines the concentration of a known mutant or a rare target species relative to a given reference species within a large pool of background DNA.
Drop-off (DOF)	DOF determines absolute quantification of targets for assays designed to detect non-wild type sequences, such as indels and genome edits; DOF is designed to support an assay strategy where one probe counts all alleles and one “drop-off” probe sits on top of a predicted cut site or mutation site.
Gene expression (GEX)	GEX determines concentration (as with DQ) and calculates relative expression levels of an unknown target relative to a known reference or references within the same well.
Residual DNA quantification (RDQ)	RDQ provides a precise method for residual host cell DNA quantification. Note: Users can enter a conversion factor to calculate the mass for a well, up to three decimals. The software displays the result in the Molecular Weight column of the Data Table.

Sample Descriptions

QX ONE Software allows you to enter descriptive words or phrases for your sample in up to four fields per well. Descriptors can include information such as research type, dilution factors, and so forth.

Tip: Only the information from the first field appears in the Plate Editor layout. However, you can see entries in the second, third, and fourth fields in the Well Data table, or you can pause on a well to display a tool tip, as shown in the following graphic.



Sample Types

You can assign multiple sample types within the plate, but you can assign only one sample type to each well.

QX ONE Software provides four sample types for selection:

- Unknown
- NTC (no template control)
- Pos Ctrl (positive control) where one or more targets are expected
- Neg Ctrl (negative control), where no response is expected

Supermixes

QX ONE Software offers five PCR supermixes. Each supermix is optimized to deliver maximum PCR efficiency and sensitivity for the amplification and detection of DNA and RNA targets.

Important: Use of unapproved supermixes can harm the instrument and void the warranty.

ddPCR Supermix	Description
Multiplex Supermix	For use in nucleic acid sample preparations to amplify and detect DNA targets in probe-based experiments involving multiple targets. Note: Bio-Rad recommends using ddPCR Multiplex Supermix for Cy5 and Cy5.5 probes assays.
Supermix for Probes (No dUTP)	For use in nucleic acid sample preparations, with sensitivity for the amplification and detection of DNA targets using hydrolysis probe-based assays.
Supermix for Probes	For use in sample preparation with uracil N-glycosylase (UNG) decontamination protocols to prevent the reamplification of carryover PCR products between experiments.
Supermix for Residual DNA Quantification	For use in residual DNA detection.
One-Step RT Advanced Kit for Probes	For use in absolute quantification of target RNA molecules.
EvaGreen® Supermix	For use in gene expression.

The One Step RT ddPCR Advance Kit for Probes supermix is time and temperature-sensitive. Therefore, if you are performing an experiment using this supermix, it is important that the plate does not sit idle in one of the Inbox slots.

To perform an experiment using this kit

1. Wait until all plates in the QX ONE Droplet Digital PCR System have processed and then place the One Step RT plate into the first slot.
2. Quickly set up and start the run.

Assay Types and Fluorophores

QX ONE Software offers the assay methods explained in [Table 6](#).

Table 6. Assay types

Assay type	Description
Single target per channel	<p>Method assuming up to four probe colors (FAM, HEX/VIC, Cy5 and Cy5.5) and up to four targets per well, with a single target detected per channel.</p> <p>This is the default assay type, with the maximum four rows displayed. You can delete up to three rows.</p>
Amplitude multiplex	<p>Method to increase multiplexing up to eight targets per well, with one or two targets detected per channel. The maximum of eight rows are displayed. You can delete up to seven rows.</p>
Probe mix triplex	<p>Triplex mode that allows two groups of three targets each.</p> <p>Group 1 has one target in FAM, one target in HEX/VIC, and one target in both channels. Group 2 has one target in Cy5, one target in Cy5.5, and one target in both. You can delete a group, but not the individual targets within the group.</p> <p>Note: The channels within a group are not interchangeable; therefore FAM is always paired with HEX/VIC and so forth.</p>
Advanced classification	<p>Method to increase multiplexing rate in any combination of targets detected per channel. This method requires manual classification of droplets.</p>
Basic drop-off	<p>This mode allows two groups of two targets each. The first group appears by default, with one target in FAM <u>and</u> HEX/VIC and one target in FAM <u>or</u> HEX/VIC.</p> <p>This assay type is available only for the DOF experiment type.</p> <p>You can add one more group of two targets, with one target in Cy5 <u>and</u> Cy5.5, one target in Cy5 <u>or</u> Cy5.5. You can delete a group, but not the individual targets in the group.</p> <p>Note: The channels within a group are not interchangeable; therefore FAM is always paired with HEX/VIC and so forth.</p>

Table 6. Assay types, continued

Assay type	Description
Double drop-off	<p>This assay type is available only for the DOF experiment type, and allows two groups of three targets each.</p> <p>The first group appears by default, and looks for one target in FAM <u>and</u> in HEX/VIC (target type reference) one target in FAM (target type unknown), and one target in HEX/VIC (target type unknown).</p> <p>You can add the second group to look for one target in Cy5 <u>and</u> Cy5.5 (target type reference, with two reference copies), one target in Cy5 (target type unknown), and one target in Cy5.5 (target type unknown).</p> <p>By default, all reference copies are set to 2.</p> <p>The channels are static for each group. (Channel 1 FAM is always paired with Channel 2 HEX/VIC, Channel 3 Cy5 is always paired with Channel 4 Cy5.5..)</p>

The experiment type you select determines the available assay methods. [Table 7](#) displays the sample type associated with each assay method.

Table 7. Assay types by experiment type

Assay type	Experiment type						
	DQ	CNV	MUT	DOF	GEX	RDQ	RED
Single target per channel	✓	✓	✓		✓	✓	✓
Amplitude multiplex	✓	✓	✓		✓	✓	✓
Probe mix triplex	✓	✓	✓		✓	✓	✓
Advanced classification	✓						✓
Basic drop-off				✓			
Double drop-off				✓			

QX ONE Software automatically populates the fluorophore in each channel for each target but you can change the default selections.

Use [Table 8](#) to select from the fluorophore options for each assay method listed.

Table 8. Fluorophore options

Assay method	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4
Single target per channel, for 1 to 4 targets	FAM	HEX	Cy5	Cy5.5
	None	VIC	None	None
		None		
Amplitude multiplex, for 1 to 8 targets	FAM Hi	HEX Hi	Cy5 Hi	Cy5.5 Hi
	FAM Lo	HEX Lo	Cy 5 Lo	Cy 5.5 Lo
	None	VIC Hi	None	None
		VIC Lo		
		None		
Probe mix triplex, for 6 targets	FAM	HEX	Cy5	Cy5.5
	None	VIC	None	None
		None		
Advanced classification	FAM	HEX	Cy5	Cy5.5
	+1-10	1 to 10	1 to 10	1 to 10
	None	VIC	None	None
		1 to 10		
		None		

Template Setup – Excluding Wells

Optionally, you can exclude wells from the Droplet Digital PCR run.

Important: The QX ONE Droplet Digital PCR System processes the entire 96-well plate by default. If you have added your sample to fewer than 96 wells in the plate, you must exclude the remainder.

The GCR96 cartridges that are inserted into the instrument contain six separate sections, each with two rows of eight wells each. The QX ONE Droplet Digital PCR System automatically generates droplets by section rather than by well or by individual column. In the QX ONE Software well exclusion design, the first two columns represent the first section, the second two columns the second section, and so forth.

When you select Droplet Generation and Droplet Reading, the software allows you to exclude each section from both processes, but if you try to exclude an odd number of columns, QX ONE Software automatically selects the remaining column.

When you select Droplet Reading, the software allows you to exclude any well or group of wells from the droplet reading phase.

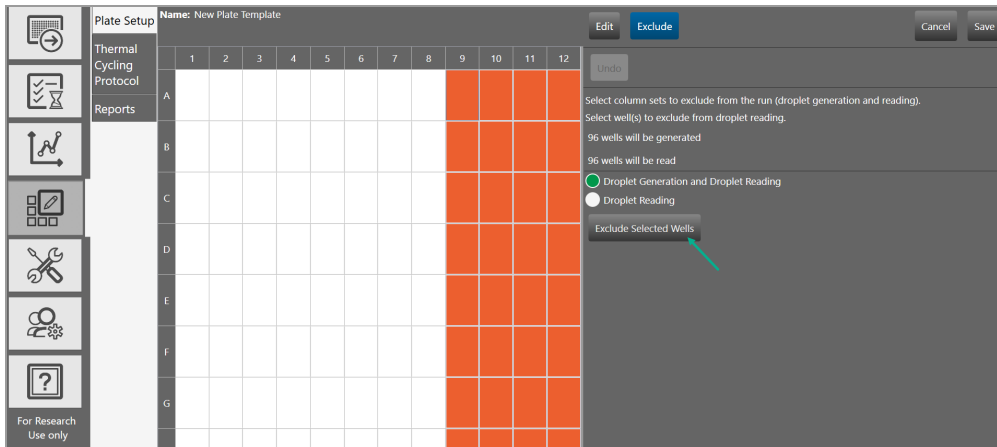
Wells excluded from droplet generation and droplet reading are displayed with a criss-cross pattern.

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												

Wells excluded from droplet reading are identified by a diagonal pattern.

To exclude columns from droplet generation and droplet reading

1. Select one or more column pairs to exclude, and then tap Droplet Generation and Droplet Reading.



Note: If you selected an odd number of columns, the software automatically selects the remaining column to represent a section. You can exclude that column from droplet reading only.

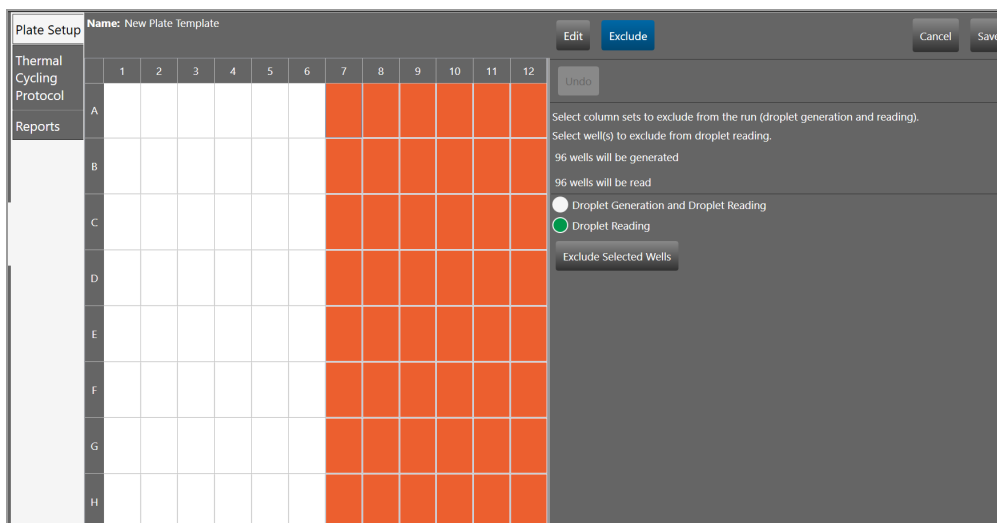
2. Tap Exclude Selected Wells.

To exclude wells from droplet reading

1. Select one or more wells to exclude, either individually or in groups, and then tap Droplet Reading.

Tip: To exclude multiple wells, press the CTRL key, and then select the wells to exclude.

2. Tap Exclude Selected Wells.



Note: The Exclude Selected Wells button is a toggle button. If you select wells that have been excluded, the button name changes to Include Selected Wells. If you excluded one or more wells that should be read, you can select the wells and then tap the button to include them.

Creating and Storing Plate Templates from CSV Files

You can create a plate template in a spreadsheet application, save it in .csv format (CSV), and then store it for use in your droplet reading runs.

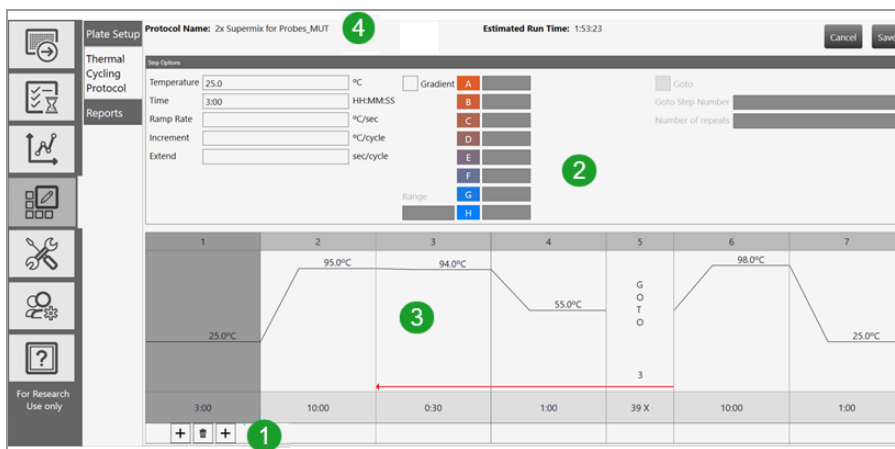
Note the following:

- When you create a CSV template, the headings for the columns containing the experiment information must match the fields and order in the Plate Editor. If they do not match, an error message appears when you select the template.
- After you specify the information in row 1, do not change the field entries until you install a new software version or edition.
- You can store the CSV file in any location, but the Browse option defaults to your personal templates storage folder defined in your user preferences (see [Managing Your Preferences on page 18](#)), or the shared or preferred location specified by your system administrator (see [Shared Settings on page 152](#)).
- CSV templates do not appear in the Templates window. You can select a CSV template file from the Plate Setup dropdown list, or, after you tap Browse, you can navigate to the storage folder and select the file.

Creating or Editing Thermal Cycling Protocol Templates

Thermal cycling protocols are specific to the thermal cycling ddPCR phase. When you add or modify a protocol template from the Template Setup window, the Protocol Editor opens. By default, the editor opens to a generic 4-step protocol, which includes standard protocol controls to quickly create protocols, as well as the ability to

- Quickly calculate a gradient for a specific temperature range and run time for the plate type
- Edit protocol steps
- Save protocols for reuse



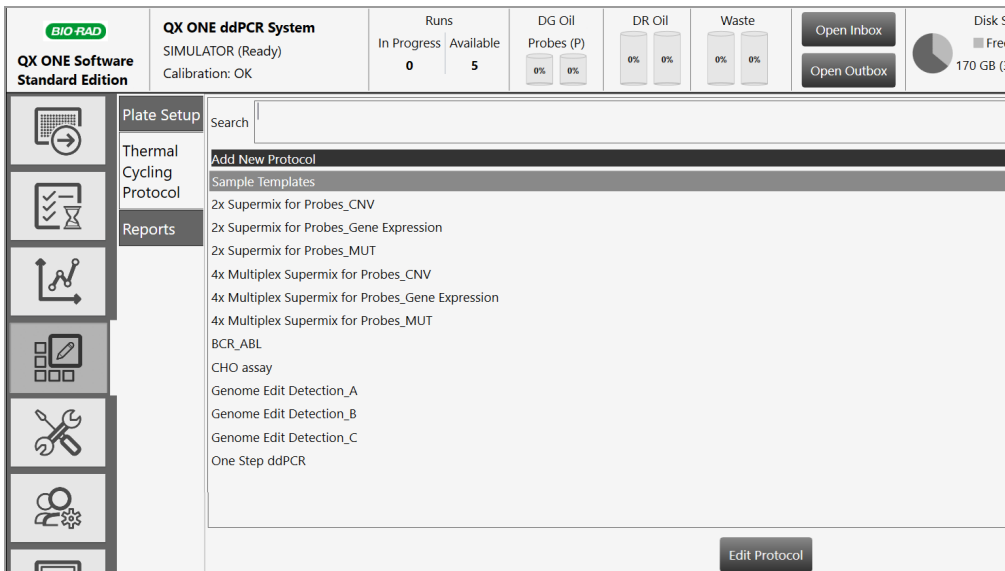
LEGEND

- 1 The lower pane displays the following toolbar commands:
 - The trashcan command deletes the selected step.
 - The plus sign to the left of the trashcan adds a step before the selected step.
 - The plus sign to the right of the trashcan adds a step after the selected step.
-
- 2 The upper pane displays the protocol controls that you can use to customize the protocol.

LEGEND , CONTINUED

- 3 The main pane displays a graphical representation of the protocol.
- 4 The information bar provides quick access to the name of the protocol, view the estimated protocol run time, and to save or cancel changes to the protocol.

From the Templates tab you can access the Protocol Templates window, where you can create a new or open an existing protocol template in the Protocol Editor window. Using the Protocol Editor, you can create custom protocols that are specific to the thermal cycling phase of the QX ONE Droplet Digital PCR System.



For detailed information on creating protocol templates, refer to the QX ONE Software User Guide.

Opening a New Thermal Cycling Protocol

QX ONE Software provides the following two options to open a new protocol template:

- From the Template Setup window
- From the Add Plate window

To open a new protocol template from the Template Setup window

1. In the Template Setup window, select the Thermal Cycling Protocol tab.

The Thermal Cycling Protocol window appears, displaying a list of sample and custom protocol templates.

2. Tap Add New Protocol.

The Protocol Editor window opens, displaying the default 4-step protocol.

To open a new protocol template from the Add Plate window

1. In the Plate Setup window, tap Add Plate.

2. After the plate is loaded, tap Configure Plate.

The Plate Setup window opens, displaying the Required Plate Information window.

3. In the Thermal Cycling Protocol pane, tap Create New.

The Protocol Editor window appears, displaying the default 4-step protocol.

Opening an Existing Thermal Cycling Protocol

QX ONE Software provides sample thermal cycling protocol templates that you can edit and save as new templates. You can also edit and save a custom protocol as a new protocol template.

To open an existing protocol from the Template Setup window

1. Select the Thermal Cycling Protocol tab.

The Thermal Cycling Protocol window appears, displaying a list of sample protocol templates.

2. Locate the protocol of choice.
3. Select the protocol and tap Edit Protocol at the bottom of the window.

The protocol opens in the Thermal Cycling Protocol Editor window.

4. (Optional) tap Save to save the protocol with a new name or in a new storage location.

To open an existing protocol from the Add Plate window

1. In the Plate Setup window, tap Add Plate.
2. After the plate is loaded, tap Configure Plate.

The Plate Setup window opens, displaying the Required Plate Information window.

3. In the Thermal Cycling Protocol pane, tap the Choose Existing dropdown arrow, and then select an existing protocol.
4. Tap the “i” button to the right of the dropdown arrow.

The Protocol Editor window opens, displaying the selected protocol in a pop-up window.

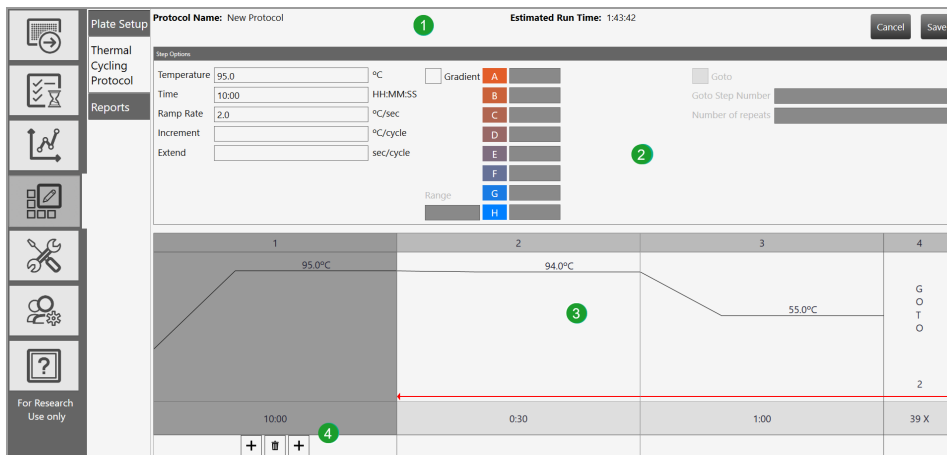
5. Tap Edit.

Thermal Cycling Protocol Editor Window

The Thermal Cycling Protocol Editor includes

- Standard protocol controls to quickly create or edit protocols
- Ability to quickly calculate a gradient for a specific temperature range and run time for the plate type
- Ability to edit protocol steps and save protocols for reuse

By default, the window opens to a generic protocol with four steps.



LEGEND

- 1 The top section provides quick access to the name of the protocol, estimated protocol run time, and save or cancel functions.
- 2 The upper pane displays the protocol controls that you can use to customize the protocol.
- 3 The main pane displays a graphical representation of the protocol.
- 4 The lower pane displays the following toolbar commands:

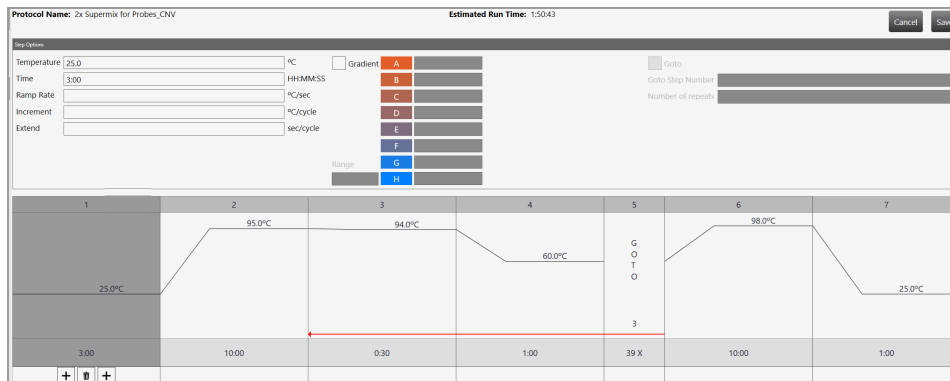



- The trashcan command deletes the selected step.
- The plus sign to the left of the trashcan adds a step before the selected step.
- The plus sign to the right of the trashcan adds a step after the selected step.

Adding Steps to a Protocol Template

To add a step

1. In the Protocol Configuration window, determine where to insert the new step. Step 1 is selected by default. You can add a step before or after an existing step.



2. On the graph, select a step and do one of the following:
 - To insert the new step before the selected step, tap the + icon to the left of the trash can.

 - To insert the new step after the selected step, tap the + icon to the right of the trash can.
3. Do one of the following:
 - To make the step a gradient step, tap the Gradient checkbox.
 - To make the step a goto (repetition) step, tap the Goto checkbox.
Note: If the step type can be converted to Goto, the Goto checkbox is enabled.
4. Do one of the following:
 - To adjust the values in the protocol step options before saving, see [Adjusting Step Options on page 61](#).
 - To save the protocol with the default step values, tap Save. In the Save dialog box, enter a name for the protocol and tap Save again.
Note: The protocol closes after you save it. You can reopen the protocol from the Protocol Templates window.

Adjusting Step Options

QX ONE Software enables you to change the step options in an existing or added step to customize the protocol. You can set values for the following step types:

- Temperature
- Gradient
- Goto

Important: You can save the changes to the steps as you go, or save them all at once when you are finished with your modifications.

To configure a temperature step

1. From the graph, select the temperature step containing the parameters to be changed.
Temperature steps contain a single temperature line.
2. Under Step Options, change or enter the following values where applicable:
 - Temperature (° C)—target temperature (0 to 100° C) for the step
 - Time (HH:MM:SS)—hold time (0–64800 sec) for the step
The hold time is the duration after the block has reached the target temperature.
 - Ramp Rate (° C/sec)—(Optional) the rate (0.1–5° C per second) at which the instrument heats or cools to achieve the target temperature.
 - Increment (° C/cycle)—(Optional) the degrees to increase or decrease the step's temperature with each successive cycle. The entry must be between -10 and 10° C
 - Extend (sec/cycle)—(Optional) amount of time (-60–60 sec) to increase or decrease the step's hold time with each successive cycle.

To configure a gradient temperature step

1. From the graph, select the gradient step containing the parameters to be changed.
2. Under Step Options, change or enter the following values where applicable:
 - Temperature (° C)—temperature (30.0–99.0° C) of the last row in the plate.
 - Time (HH:MM:SS)—hold time (0–64800 sec.) for the step.

Hold time is the duration after the block has reached the target gradient.

Note: Note: Setting the time to 0 sec instructs the instrument to hold at the current step until resumed manually from the instrument's user interface.

- Extend (sec/cycle)—(Optional) amount of time (-60–60 sec) to increase or decrease the step's hold time with each successive cycle.
- Range—(1°–16° C) range between the lowest temperature and the highest temperature.

Note: The temperatures for rows A through H automatically populate with updated values when you change the temperature or temperature range. You can also change the temperature for each row, and the temperature and range are automatically updated.

To configure a goto (repetition) step

A Goto step loops back to an earlier step and repeats a sequence.

1. From the graph, select the Goto step containing the parameters to be changed.
2. Under Step Options, change the following value, if applicable:
 - Goto step number—step to which to return to repeat a sequence
 - Number of repeats—number of times to repeat the sequence

Deleting Steps from a Protocol Template

Important: You cannot undo this function. Take care when deleting steps.

To delete a step in the protocol

1. Select the step in the graph.
2. Tap Delete Step.
3. Save the protocol.

Creating or Modifying Report Templates

If you are assigned the Create New Templates user privilege, you can create and save a report template by editing the default report structure or by opening and editing an existing report.

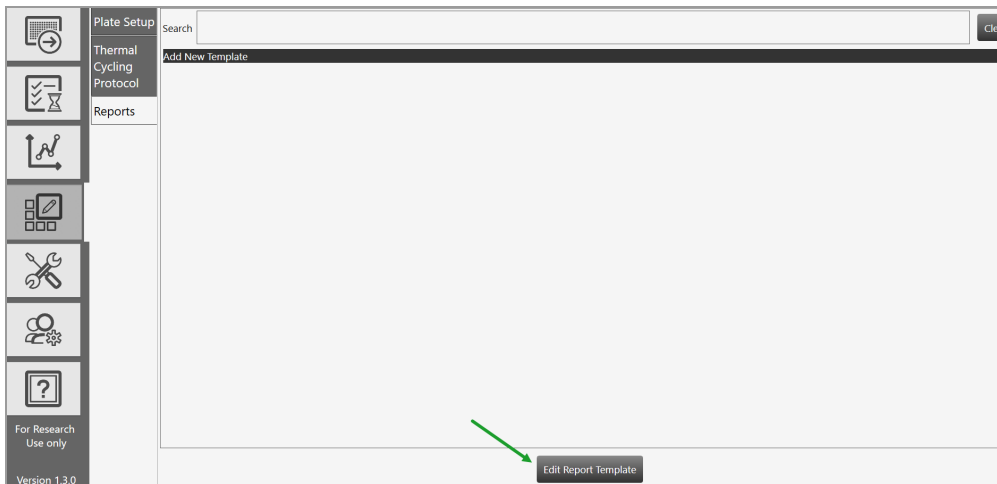
To create or edit a report template

1. Select the Template Setup tab.



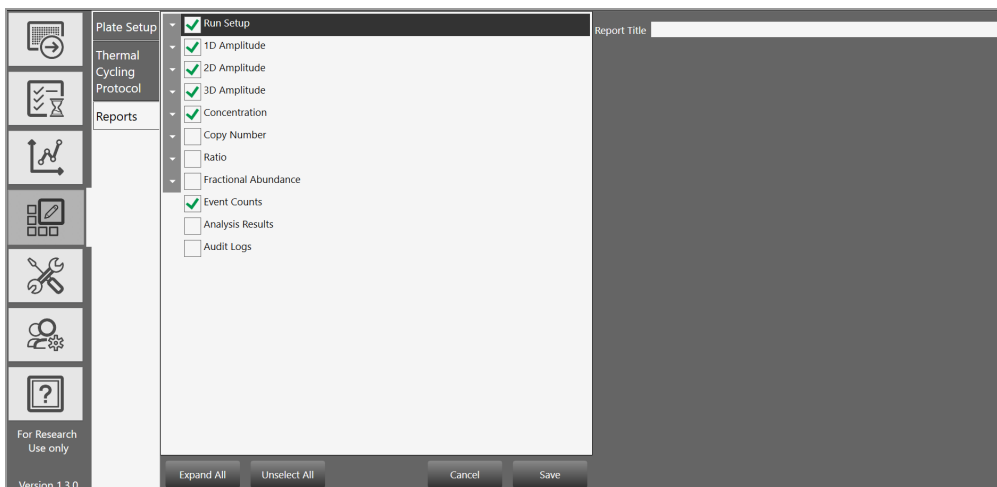
2. Tap Reports and do one of the following:

- To create a new template, tap Add New Template. and tap Edit Report Template.
- To open an existing template, select the template and tap Edit Report Template.



3. Tap the arrow to the left of each category to expand the list of reportable items.

Important: The Audit Log checkbox is enabled in the Regulatory Edition only.

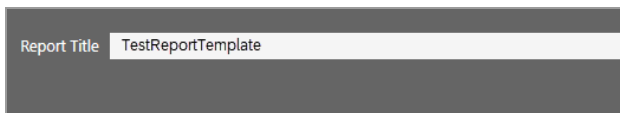


4. Select and clear checkboxes to create the report structure.

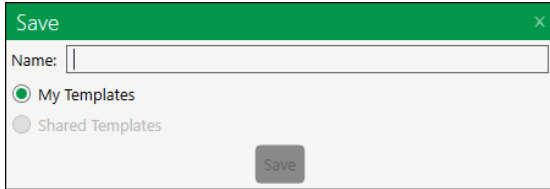
Note: Use the buttons at the bottom of the screen to expand or collapse all categories at once, or to select or clear all checkboxes at once. You can also drag and drop the section to rearrange the order of appearance in the report, and drag and drop items in the section to reorder them.



5. Enter a name for your report in the Report Title field and tap Save.



6. When the Save dialog box appears, enter a file name.



7. Select a storage location. Choose from the following:
 - System Templates (preferred location, if specified by the administrator)
 - My Templates (personal storage location specified in user preferences)
 - Shared Templates (files saved to this location are available to all users)
8. Tap Save again to save the report format as a template.

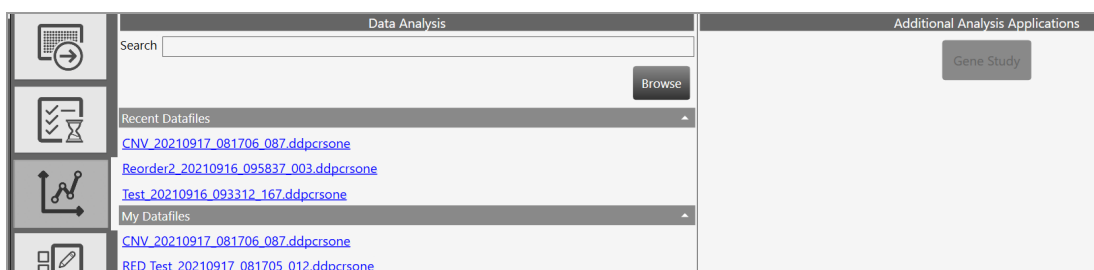
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Chapter 3 Data Analysis Module Overview

As the instrument reads droplets in each well, the QX ONE Droplet Digital PCR System collects raw data. At the end of each run, QX ONE Software uses the raw data to produce a data file, which contains analysis information based on the number of positive and negative droplets identified for each target in each sample. The fraction of positive droplets is fit to a Poisson algorithm to determine the starting concentration of the target DNA molecule in units of copies/ μ l input.

This section summarizes the analysis functionality, and also describes the general options governing your chart displays. More detailed information, including specific information and uses for each analysis window, as well as information on data calculations, is contained in [Chapter 4, Data Analysis Methodology](#).

When you select the Data Analysis tab from the touch screen, you can access the Data Analysis module. When you select the tab from the software installed on a standalone computer, you can also access the Gene Study module.



When you open the data file in the Analysis module, you can view the data with the automatic analysis thresholds and calculations, or you can choose different options to recalculate, replot, or recolor the results.

The Data Analysis module functionality allows you to

- View your droplet data in 1D, 2D, and 3D plots
- Analyze multiple targets within a well using amplitude multiplexing and probe mixing strategies
- Detect genomic editing events and non-wild type events with a “drop-off assay” analysis option
- Visualize and export data with improved flexibility
- Generate reports for different analysis types
- The Gene Study module allows you to
- Collect data by adding one or more data files
- View gene expression calculations across multiple experiments

Important: The Gene Study module is accessible from a standalone computer only. The maximum number of samples you can analyze in a gene study is limited by the size of the RAM and virtual memory of the standalone computer.

Opening a Data File for Analysis

You can open the following file types in the Data Analysis module:

- .qlps
- .ddpcrs
- .ddpcrsone

To open data files, you must be on a computer on which QX ONE Software is installed and have access to the storage locations.

To open a data file for analysis

1. In QX ONE Software, select the Data Analysis tab.



Available data files are displayed under the following headings.

- **Recent Datafiles**

Displays a list of files you have recently opened.

- **System Datafiles or My Datafiles**

Files are always saved to one of the following locations:

- If preferred locations are enabled, then files for all users are saved there and they appear under System Datafiles.
- If preferred locations are not enabled for all users, your files are saved to your personal folder and appear under My Datafiles.

- **Shared Datafiles**

You can also save your data files to a shared location; these appear under Shared Datafiles.

2. Tap a file to open it in the Analysis module.

Tabs for each analysis and data window appear on the left of the Analysis window.

Tip: From the touch screen, you can also open the data file from the Run Status window. In the completed files section, tap the completed run icon (✔) for the file, and then tap Launch Analysis.

Saving a Data File

You can save data files with or without modifications, with the same or different file names, and in the same or different locations.

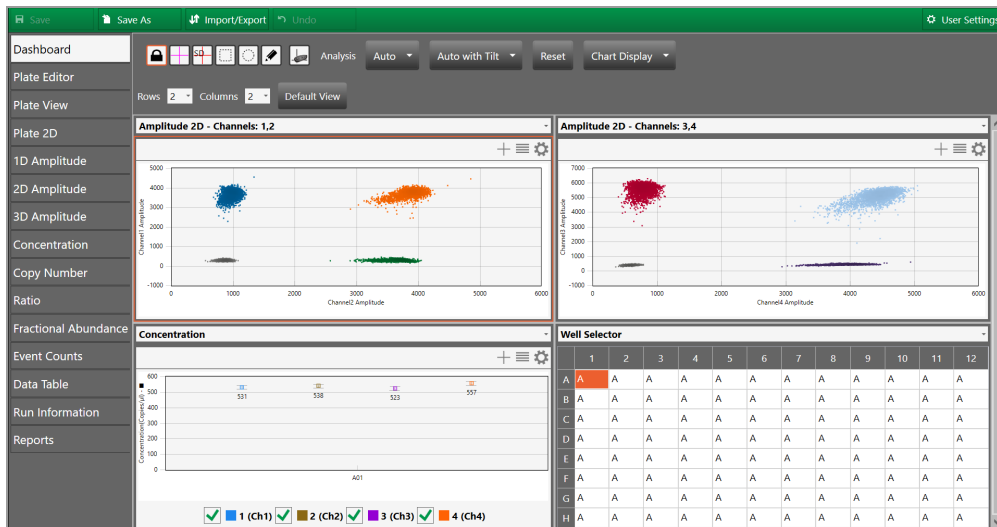
Important: When you save a .q1p.q1ps.ddpcrs file type in QX ONE Software, the software automatically saves the file as a .ddpcrsone file. This creates a new file and does not overwrite the original.

To save a data file

1. Do one of the following:
 - To save the file under the same file name and in the same location, tap Save.
 - To save the file under a different file name or in a different location, tap Save as, and then do one of the following:
 - If you are saving the file under the same name and in the same location, QX ONE Software saves the file immediately.
 - If you are saving the file under a different file name or in a different location, navigate to the new location (if applicable) and enter the new file name. You must be assigned the Overwrite existing file name user privilege to change the file name.
2. Tap Save.

Analysis Dashboard

When you open a data file, the Analysis module opens to a Dashboard window containing default analysis and data panes in a summary view. You can customize the view to change panes, or increase or decrease the number of panes. For information on the available options in the Dashboard view, see [Dashboard Options on page 72](#).



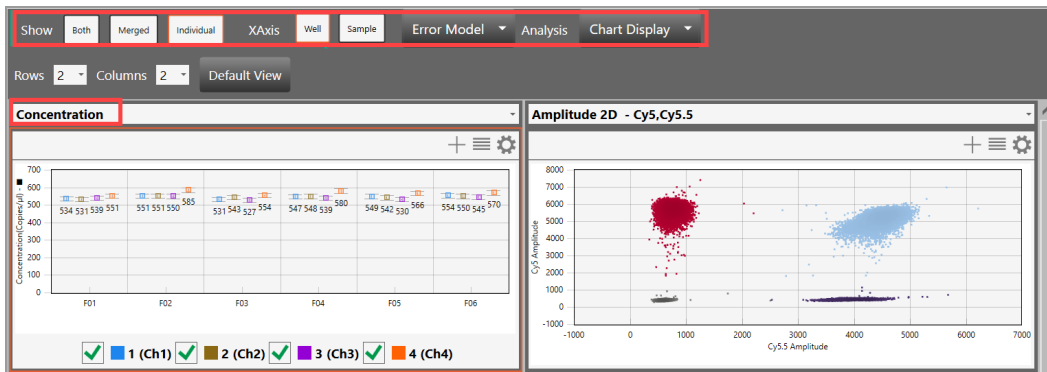
Note: If you open a .qlps file, the Plate Editor opens as the default view and you must select the Dashboard tab to open it.

From the tabs on the left, you can access plate views, amplitude charts, data visualization distribution charts, droplet counts, and a complete data table. You can also view data specific to the run in the Run Information window, and run reports on any of the analysis charts from the Reports window.

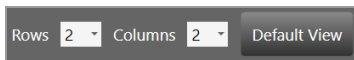
Dashboard Options

From the Dashboard window, depending on the individual dashboard window you have selected, you can use a range of options as described below:

- When you select a window, the options that appear in the menu bar correspond to the options you see if you open the same window from the side menu. For example, if you select the Concentration chart in the Dashboard, the Concentration menu options appear.



- You can reset the entire dashboard display by adding or removing rows or columns to display more or fewer individual windows. For information, see [Modifying the Dashboard Display on page 74](#).



Tap Default View to return to the default display of two rows and two columns.

- From any window you can
 - Expand or collapse the window
 - Copy, save, or print the image
 - Select display, scale, axis, and logarithmic options
 - Use the dropdown list to replace the current display with a different display
 - Use the menu bar options for the particular chart type

Table 9 describes the option sets identified in the following graphic.

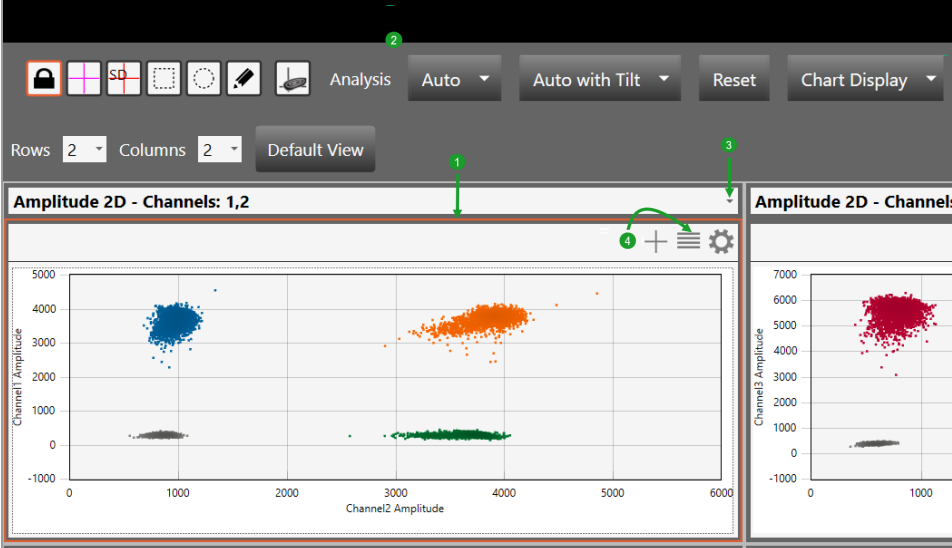


Table 9. Dashboard options

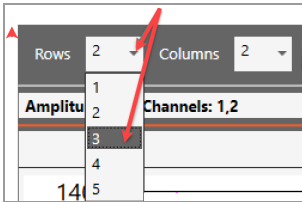
Item	Description
1	Border to identify selected window
2	Toolbar corresponding to the selected window type in the Dashboard
3	Dropdown arrow to replace the current display with a new display
4	Chart options

Modifying the Dashboard Display

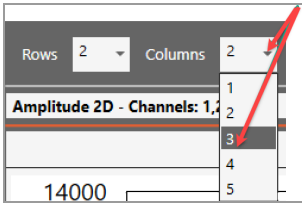
You can modify the column number and row number to display any or all of the analysis windows simultaneously.

To change the number of windows in the display

1. Tap the dropdown arrow for Rows and then select a different number.



2. Tap the dropdown arrow for Columns, and then select a different number.





You can also use the dropdown menus to change the windows that appear in the Dashboard.

To display a different window in a particular Dashboard slot

1. Tap the dropdown arrow in the upper-right corner to display the list of available windows, and then select a window. The dropdown list closes and the window changes immediately.

Analysis Display and Output Options

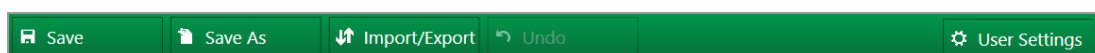
QX ONE Software provides the following option that you can choose or set:

- **Universal Options** — available from the primary toolbar to save, import, or export data files
- **Chart Display Preferences** — to change how your chart appears in the analysis window
- **Chart Scale Options** — to change the scale represented on an axis
- **Chart Menu Options** — available in chart views (from the  icon) to copy, save, and print chart images. In Amplitude charts showing data points, you can show or hide
- **Table Menu Options** — available in table views (from the  icon) to copy data, export data to Excel or CSV files, and show or hide columns

You can also expand the chart display to full-screen size and then return to the original display.

Universal Options

Universal options appear on the top menu bar, and are available from all windows, although functionality within the main option might differ according to the analysis window that appears.



Universal options are explained in [Table 10](#), and are available in all Analysis module windows.

Table 10. Universal options

Option	Description
Save	Saves changes to the analysis file under its current file name or file extension
Save as	Saves the file with a different name If you open a file in the latest application that was created in an earlier application, the file assumes the file extension of the new application. See Saving a Data File on page 70 for information.
Import/export	<ul style="list-style-type: none"> ■ Imports or exports plate setup data to a CSV file ■ Imports or exports plate setup data to a plate template file ■ Exports visible data to a CSV file ■ Exports amplitude, cluster, and linkage data ■ Exports and prints the visible charts for the 2D plate layout
Undo	Enabled in the Plate Editor only, after you have made a change
User Settings	Allows you to restore your user preferences to the default settings

To import or export setup or analysis data

- ▶ Tap Import/Export.

[Table 11](#) describes the available import/export options.

Note: If there is unsaved data, the software prompts you to save the file before its contents can be imported or exported.

Table 11. Import/export options

Import/export option	Description
Import plate setup CSV	Import plate layout data from a CSV file to the Plate Editor Note: This option is only available in the Plate Editor. The new plate layout overwrites the existing layout.
Export plate setup CSV	Export a configured plate layout to a CSV file
Import plate setup	Import a plate layout from a plate template (.ddplt) file Note: This option is only available in the Plate Editor.
Export plate setup	Export the plate layout to a plate template file Note: This option is only available in the Plate Editor.
Export visible data to CSV	Export only the data from the wells you selected in the Well Selector to a CSV file
Export amplitude data	Export the data to an Excel spreadsheet, and indicates whether or not the target was found (1 = yes, 0 = no)
Export cluster data	Export the data to an Excel spreadsheet Note: Includes (for each well) whether or not the target was found (1 = yes, 0 = no), the droplet count, and the mean and standard deviation for each dye, and the cluster ID.
Export linkage data	Exports to a CSV file the number of copies of a target that are present in overabundance, versus. the expected value in copies per μL
Export visible charts	Exports all charts that are displayed
Print visible charts	Prints all charts that are displayed

Table 12 shows where the options are available.

Table 12. Option availability

Import/export option	Plate editor	Plate view	Plate 2D	Ampl plots	Data visual charts	Event counts	Data table
Import plate setup from CSV	✓						
Export plate setup to CSV	✓						
Import plate setup	✓						
Export plate setup	✓						
Export visible data to CSV				✓	✓	✓	✓
Export amplitude data	✓	✓	✓	✓	✓	✓	✓
Export cluster data	✓	✓	✓	✓	✓	✓	✓
Export linkage data	✓	✓	✓	✓	✓	✓	✓
Export visible charts			✓	✓	✓	✓	
Print visible charts			✓	✓	✓	✓	

Note: Amplitude plots are available in 1D, 2D and 3D, and Data Visualization charts are Concentration, Copy Number, Ratio, and Fractional Abundance. In the Dashboard view corresponding options are available for each plot or chart displayed.



Expanding or Reducing the Chart

You can expand or reduce the chart size in the following windows:

- Dashboard
- 1D Amplitude
- 2D Amplitude
- 3D Amplitude
- Concentration
- Copy Number
- Ratio
- Fractional Abundance
- Event Counts

If you expand an amplitude or data visualization chart to full size, the Well Selector and the Well Data table are hidden from view until you collapse the chart again.

To expand or reduce the chart size

1. To increase the chart size to the full window, tap the  icon in the upper-right corner of the chart.
2. To reduce the window to its original size, tap the  icon.

Selecting Chart Display Preferences

The Chart Display preferences primarily control font sizes and positioning. [Table 13](#) explains each preference, as well as the windows in which it is available.

Table 13. Chart display preferences

Preference	Window	Description
Channel or Dye	Plate 2D 1D Amplitude 2D Amplitude 3D Amplitude	Select Channel or Dye to identify your chart accordingly <ul style="list-style-type: none"> ■ If you select Channel, the channel number appears as the chart title ■ If you select Dye, FAM, HEX, Cy5, or Cy5.5 appears as the chart title
Axis Data Label Size	1D Amplitude 2D Amplitude 3D Amplitude Concentration Copy Number Ratio Fractional Abundance Event Counts	Select a different font size
Chart Data Label Size	Concentration Copy Number Ratio Fractional Abundance Event Counts	Select a different font size
Chart Marker Size	Concentration Copy Number Ratio Fractional Abundance	Select a different marker size
Chart Marker Label Position	Concentration Copy Number Ratio Fractional Abundance	Reposition the marker label

1. Tap the Chart Display button.

To select chart display preferences

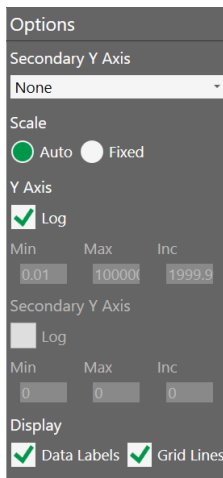
1. Tap the Chart Display button.
2. Select your options.

The display changes immediately to reflect your choices.

3. Do one of the following:
 - To save your choices as your default settings, tap Save as my default. When the success message appears, tap OK to close the dialog.
 - To close the menu without saving the settings, tap anywhere in the chart display.

Selecting Chart Scale and Label Options

Chart scale options primarily control chart scale and label displays.




Each preference, as well as the windows in which it is available, is explained in [Table 14 on page 82](#).

Table 14. Chart scale options

Option	Description
Scale	<p>Appears in options for all charts</p> <p>The Scale option determines the numerical range for your chart data:</p> <p>Auto — Selected by default; QX ONE Software automatically displays a scale to match the data distribution.</p> <p>Fixed — Selecting Fixed enables the Axis fields, and allows you to manually adjust the range and increment.</p>
Axis	<p>Appears in options for all charts</p> <p>When the Axis fields are enabled, you can manually adjust the minimum (Min) and maximum (Max) points for the data display on each axis, as well as the increments (Incr).</p> <p>X — Horizontal axis Y — Vertical axis</p> <p>Note: You can modify the x axis scale in the 2D Amplitude chart only.</p>
Secondary Y Axis	<p>Appears in options for Concentration only</p> <p>From the dropdown list, you can select from Channel 2 concentration, ratio, copy number, or fractional abundance to display the corresponding data in a secondary row on the y axis.</p>
Log	<p>Appears in options for all Data Visualization charts (Concentration, Copy Number, Ratio, and Fractional Abundance)</p> <p>You can select the Log checkbox to display the y axis in base 10 logarithmic format.</p> <p>Note: In the Concentration chart, you can also select Log for the secondary y axis.</p>
Inverse	<p>Appears in options for Ratio and Fractional Abundance only</p> <p>The Inverse option equals the opposing number of the Ratio data point to a total of 2, and the opposing number of the Fractional Abundance data point to a total of 100.</p>
Data labels	<p>Appears in options for all Data Visualization charts</p> <p>A data label appears by default for each point in the chart, but you can clear the checkbox to remove the labels.</p>
Grid Lines	<p>Appears in options for all charts</p> <p>Gridlines appear by default. You can clear the check box to remove them.</p>

To select chart scale and label options

1. Tap the  icon in the upper-left corner of the chart to display the corresponding chart options.
2. To manually define the chart scale, select Fixed.

Note: Auto is the default setting.
3. In the Min, Max, and Inc fields, enter your lower and upper limits, and the increment, for the y axis. For 2D Amplitude, you can also change the scale on the x axis.
4. For Concentration, Copy Number, Ratio, Fractional Abundance, and Event Counts, select an option for a secondary y axis display. To change to a base 10 logarithmic scale on the y axis, select the Log checkbox.
5. For Ratio and Fractional Abundance, to view an inverse calculation, select the Inverse checkbox.
6. To remove the data labels or grid lines from the display, clear the Data Labels or Grid Lines checkbox.

Using Chart Menu Options

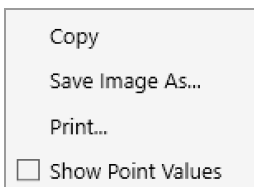


Chart menu options are explained in [Table 15](#).

Table 15. Chart menu options

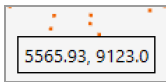
Option	Description
Copy	Copies the chart to the clipboard, which you can paste into a separate document, such as an MS Word file
Save Image as	Saves the chart as an image file
Print	Prints the image
Show Point Values	Shows corresponding point values when you pause on a data point <div data-bbox="534 1602 698 1682" data-label="Image">  </div> <p>Tip: Select the Show Point Values checkbox to see the data. Data is available for 1D and 2D amplitude only.</p>

Chart menu options are available in the following windows:

- 1D Amplitude
- 2D Amplitude
- 3D Amplitude
- Concentration
- Copy Number
- Ratio
- Fractional Abundance
- Event Counts

To use the chart menu options

1. Select one or more wells in the Well Selector.

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E	A	A	A	A	A	A						
F	A	A	A	A	A	A						
G	A	A	A	A	A	A						
H	A	A	A	A	A	A						

Corresponding data appears in the Well Data table and the chart.

Well	Target	Conc(copies/μL)	Status	Experiment	SampleType
F01	1	534	OK	DQ	Unknown
F01	2	531	OK	DQ	Unknown
F01	3	539	OK	DQ	Unknown
F01	4	551	OK	DQ	Unknown
F02	1	551	OK	DQ	Unknown
F02	2	551	OK	DQ	Unknown
F03	2	550	OK	DQ	Unknown

2. In the upper-right corner of the chart, tap the menu icon (☰) and select from the dropdown list.
 - Select Copy to copy the chart to the Clipboard. To paste the data, navigate to the location (such as a Word file), right-click and select Paste.
 - Select Save Image As and follow the prompts to save the file.
 - Select Print and follow the prompts to print the image.
3. Tap anywhere in the display to close the dialog box.

Using Table Menu Options

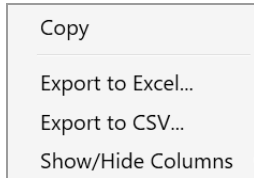


Table menu options are explained in [Table 16](#).

Table 16. Table options

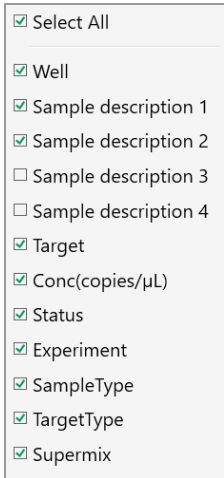
Option	Description
Copy	Copies the information from the selected wells to the clipboard
Export to Excel	Exports the data to an .xlsx file
Export to CSV	Exports the data to a .csv file
Show/Hide Columns	<p>Add or remove columns from a table display</p> <p>When you select Show/Hide Columns, the following dialog box opens. Select or clear check boxes to show or hide columns in the data table.</p> 

Table menu options are available in the following windows:

- 1D Amplitude
- 2D Amplitude
- 3D Amplitude
- Concentration
- Copy Number
- Ratio
- Fractional Abundance
- Event Counts

Tip: You can access the menu icon from the individual windows, or from the windows in the Dashboard display.

To use the table menu options

If you are using these options in the Data Table, skip to Step 3.

1. Select wells in the Well Selector.

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E	A	A	A	A	A	A						
F	A	A	A	A	A	A						
G	A	A	A	A	A	A						
H	A	A	A	A	A	A						

Corresponding data appears in the Well Data table.

Well Data							+ ☰
	Well	Target	Conc(copies/μL)	Status	Experiment	SampleType	
▾	F01	1	534	OK	DQ	Unknown	⬆
	F01	2	531	OK	DQ	Unknown	
	F01	3	539	OK	DQ	Unknown	
	F01	4	551	OK	DQ	Unknown	
	F02	1	551	OK	DQ	Unknown	
	F02	2	551	OK	DQ	Unknown	
	F02	3	550	OK	DQ	Unknown	⬇

2. In the upper-right corner of the table, tap the menu icon (☰) and select from the dropdown list.
 - To copy the data from the selected wells to the Clipboard, select Copy.

Note: To paste the data, navigate to the location (for example, an Excel file) and then right-click and select Paste.
 - To export your data, select Export to Excel or Export to CSV, and then follow the prompts to save the file.

Note: Exporting to Excel exports the data in spreadsheet format, while Exporting to CSV exports the data in comma-delimited format.
 - To show or hide the corresponding column in the table, select Show/Hide Columns, and then select or clear checkboxes.
3. Tap anywhere in the display to close the dialog box.

Plate View Windows

In the QX ONE Software Analysis module you can open the following windows that contain data on all wells in the run:

- **Plate Editor (analysis view)** — Displays the experiment type, sample names, sample types, supermixes, and assay type for each well in the run (similar to the Template Setup Plate Editor)
- **Plate View** — Displays concentration results in a text format for each processed well
- **2D Plate View** — Displays a two-dimensional amplitude chart for each processed well

Plate Editor — Analysis View

You can use the Plate Editor tab in the Analysis module to select wells, and then view or change the experiment parameters. Similar to other Plate Editor displays, the Analysis Plate Editor displays the experiment information for each well in the run.

Wells you select in the Analysis Plate Editor determine the data initially displayed in other analysis windows.

The screenshot displays the Plate Editor window in the QX ONE Software Analysis module. The main area is a grid of wells, labeled A through H and 1 through 12. Each well contains the text 'DQ 4 Color'. The right-hand side of the window features a configuration panel with the following sections:

- Clear Selected Wells** and **Undo** buttons.
- Experiment Type**: A dropdown menu set to 'Direct Quantification (DQ)' with an 'Apply' button.
- Sample Description**: Four input fields labeled 'Sample Description1' through 'Sample Description4', each with an 'Apply' button.
- Sample Type**: A dropdown menu set to 'Unknown'.
- Supermix**: A dropdown menu with the text 'Supermixes for Probes (this is...)'.
- Assay Type**: A dropdown menu set to 'Single Target per Channel' with an 'Apply' button.
- Target Info**: A table with columns for Target Name, Target Type, Signal Ch1, Signal Ch2, Signal Ch3, and Signal Ch4. It lists four targets:

Target Name	Target Type	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4
1	Unkn	FAM	None	None	None
2	Unkn	None	HEX	None	None
3	Unkn	None	None	Cy5	None
4	Unkn	None	None	None	Cy5.5

Plate View

The Plate View tab provides, within the plate layout grid, a text view of the calculated concentration for each target in each well processed in the run. For information on the concentration results in chart format, see [Concentration on page 123](#).

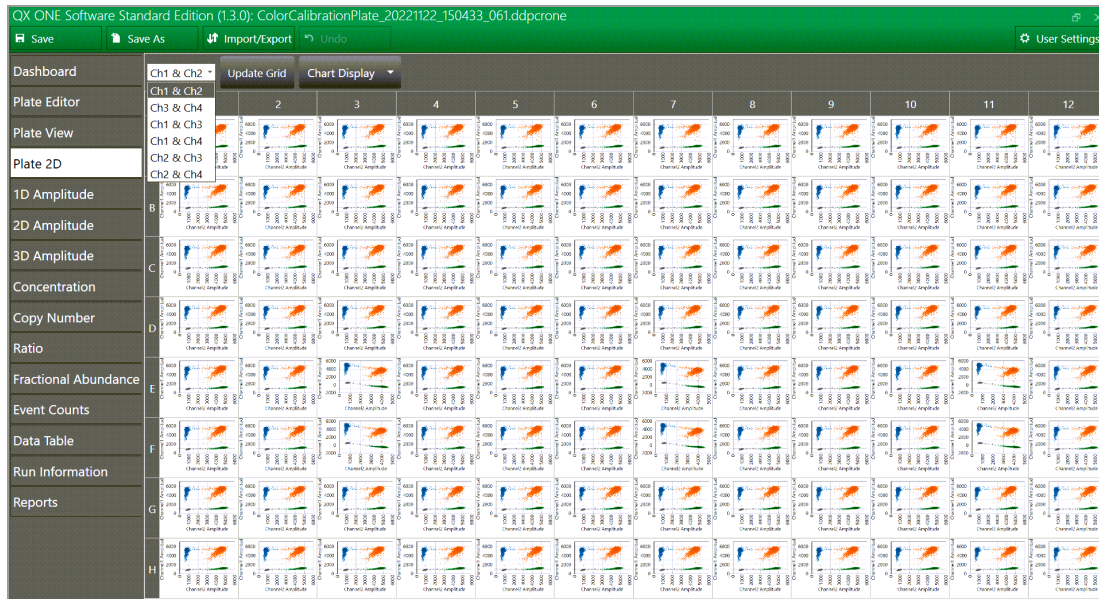
Save Save As Import/Export Undo User Settings												
Dashboard	1	2	3	4	5	6	7	8	9	10	11	12
Plate Editor	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color
Plate View	U1 30.87	U1 21.19	U1 520.3	U1 28.69	U1 11.26	U1 14.46	U1 524.5	U1 18.98	U1 33.27	U1 17.65	U1 33.55	U1 38.79
Plate 2D	U2 37.85	U2 17.22	U2 19.06	U2 20.34	U2 29.28	U2 28.56	U2 34.47	U2 26.17	U2 34.02	U2 33.17	U2 25.72	U2 32.45
1D Amplitude	U3 22.54	U3 04.86	U3 23.93	U3 25.76	U3 21.27	U3 06.94	U3 27.47	U3 17.79	U3 29.71	U3 24.66	U3 32.83	U3 24.75
2D Amplitude	U4 56.75	U4 31.73	U4 54.32	U4 48.68	U4 41.32	U4 555.7	U4 39.33	U4 48.25	U4 46.42	U4 47.64	U4 35.93	U4 57.27
3D Amplitude	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color
Concentration	U1 33.29	U1 27.73	U1 29.04	U1 14.55	U1 26.06	U1 40.19	U1 529.5	U1 27.23	U1 34.84	U1 28.21	U1 33.14	U1 34.17
Copy Number	U2 28.05	U2 27.94	U2 35.54	U2 40.89	U2 25.59	U2 28.57	U2 30.89	U2 41.35	U2 39.24	U2 32.46	U2 41.21	U2 540.8
Ratio	U3 21.24	U3 26.07	U3 15.81	U3 22.42	U3 21.05	U3 22.81	U3 35.26	U3 30.31	U3 47.65	U3 49.25	U3 23.38	U3 35.92
Fractional Abundance	U4 59.42	U4 41.18	U4 54.26	U4 52.67	U4 60.95	U4 57.86	U4 60.48	U4 57.84	U4 50.73	U4 60.02	U4 56.77	U4 65.42
Event Counts	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color
Data Table	U1 42.42	U1 24.96	U1 32.11	U1 30.58	U1 27.62	U1 27.34	U1 37.44	U1 26.62	U1 33.85	U1 36.25	U1 536.7	U1 38.18
Run Information	U2 543.4	U2 41.81	U2 40.33	U2 39.55	U2 527.8	U2 36.33	U2 29.13	U2 40.87	U2 42.85	U2 32.16	U2 46.32	U2 39.92
Reports	U3 33.99	U3 36.95	U3 22.79	U3 31.11	U3 35.35	U3 30.65	U3 30.77	U3 22.05	U3 42.49	U3 536.9	U3 31.39	U3 34.69
	U4 59.11	U4 51.01	U4 51.26	U4 42.94	U4 46.17	U4 57.62	U4 50.19	U4 49.51	U4 56.72	U4 50.69	U4 51.15	U4 52.82
	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color
	U1 55.49	U1 44.89	U1 47.35	U1 521.4	U1 34.06	U1 26.72	U1 24.23	U1 37.67	U1 27.09	U1 34.07	U1 25.71	U1 42.92
	U2 49.61	U2 543.4	U2 44.99	U2 48.42	U2 46.77	U2 31.86	U2 541.4	U2 38.47	U2 50.98	U2 45.85	U2 55.72	U2 44.33
	U3 36.08	U3 20.99	U3 38.07	U3 32.61	U3 27.27	U3 25.64	U3 37.72	U3 533.6	U3 26.99	U3 38.53	U3 34.28	U3 36.48
	U4 69.72	U4 54.95	U4 64.65	U4 60.79	U4 63.16	U4 47.74	U4 52.02	U4 56.76	U4 47.85	U4 58.12	U4 556.8	U4 60.51
	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color	DQ 4 Color
	U1 56.53	U1 34.43	U1 48.25	U1 39.42	U1 56.78	U1 34.63	U1 56.47	U1 37.76	U1 48.05	U1 39.71	U1 54.65	U1 15.56
	U2 56.84	U2 29.27	U2 63.48	U2 42.32	U2 56.88	U2 45.35	U2 50.45	U2 35.03	U2 54.07	U2 29.39	U2 49.82	U2 46.34
	U3 562.5	U3 30.19	U3 53.83	U3 41.78	U3 43.66	U3 40.77	U3 34.51	U3 30.74	U3 46.53	U3 31.94	U3 45.88	U3 43.58

2D Plate View

To facilitate comparisons of amplitude in the processed wells, the Plate 2D tab provides a two-dimensional amplitude view in a separate chart for each well in a single display. To see a larger representation of a well, select the well in the 2D Amplitude view.

To view different color arrays

- ▶ Select the channel combination from the dropdown on the left, and then click Update Grid.



Analysis Windows

In its Analysis module, QX ONE Software provides amplitude displays and data visualization charts in the Analysis module. For more information on each chart, see [Chapter 4, Data Analysis Methodology](#).

Amplitude Charts

Amplitude charts illustrate the droplets by degree of dye fluorescence. QX ONE Software displays fluorescence for positive and negative targets identified with FAM, HEX/VIC, Cy5, and Cy5.5 fluorophores in the following analysis windows:

- 1D Amplitude
- 2D Amplitude
- 3D Amplitude

Data Visualization Charts

Data visualization charts show calculations based on positive droplet concentrations. QX ONE Software counts the number of positive and negative droplets for each fluorophore in each sample, and then fits the fraction of positive droplets to a Poisson algorithm to determine the starting concentration of the target DNA molecule in units of copies/ μ l input in the following analysis windows:

- Concentration
- Copy Number
- Ratio
- Fractional Abundance

When you open the analysis data file in QX ONE Software and select one or more wells in the grid, the software plots each calculated Poisson distribution average as a data point in the grid. You can pause on the data point to see the high, median, and low numbers.

Note: You can display the data using a confidence level of either 68% or 95% (default setting).

Event Counts

Event counts record the number of droplets in which the target was found (positive) and was not found (negative). The Event Counts tab shows a bar chart view of the number of positive, negative, and total droplets for each of the targets in each of the selected wells.

Data Windows

QX ONE Software provides the following table views for your well and run data:

- **Data Table** — available from the main tabs on the left, shows your configured experiment parameters, plus all calculations from the run
Note: You can display the data in individual well format, merged format, or both.
- **Plate Well Data Table** — available in plate setup windows (including the Analysis module Plate Editor), shows only your configuration information for each individual well
- **Analysis Well Data Table** — available in the Analysis module, shows a subset of configuration and run data for the wells selected in the Well Selector

Data Table Tab

The Data Table window contains columns of data generated for each target in each well, as droplet clusters are identified through thresholding or manual clustering tools.

Well	Sample description 1	Target	Conc(copies/µL)	Experiment	Sample Type	Target Type	Supermix	DyeName(s)	Copies/20µL Well	To
A06	4 Color	1	514	DQ	Unknown	Unknown	ddPCR Su...	FAM	10289	
A05	4 Color	4	541	DQ	Unknown	Unknown	ddPCR Su...	Cy5.5	10826	
A05	4 Color	3	521	DQ	Unknown	Unknown	ddPCR Su...	Cy5	10425	
A05	4 Color	2	529	DQ	Unknown	Unknown	ddPCR Su...	HEX	10586	
A05	4 Color	1	511	DQ	Unknown	Unknown	ddPCR Su...	FAM	10225	
A04	4 Color	4	549	DQ	Unknown	Unknown	ddPCR Su...	Cy5.5	10974	
A04	4 Color	3	526	DQ	Unknown	Unknown	ddPCR Su...	Cy5	10515	
A04	4 Color	2	520	DQ	Unknown	Unknown	ddPCR Su...	HEX	10407	
A04	4 Color	1	529	DQ	Unknown	Unknown	ddPCR Su...	FAM	10574	
A03	4 Color	4	554	DQ	Unknown	Unknown	ddPCR Su...	Cy5.5	11086	
A03	4 Color	3	524	DQ	Unknown	Unknown	ddPCR Su...	Cy5	10479	
A03	4 Color	2	519	DQ	Unknown	Unknown	ddPCR Su...	HEX	10381	
A03	4 Color	1	520	DQ	Unknown	Unknown	ddPCR Su...	FAM	10406	
A02	4 Color	4	532	DQ	Unknown	Unknown	ddPCR Su...	Cy5.5	10635	
A02	4 Color	3	505	DQ	Unknown	Unknown	ddPCR Su...	Cy5	10097	
A02	4 Color	2	517	DQ	Unknown	Unknown	ddPCR Su...	HEX	10344	
A02	4 Color	1	521	DQ	Unknown	Unknown	ddPCR Su...	FAM	10424	
A01	4 Color	4	557	DQ	Unknown	Unknown	ddPCR Su...	Cy5.5	11135	
A01	4 Color	3	523	DQ	Unknown	Unknown	ddPCR Su...	Cy5	10451	
A01	4 Color	2	538	DQ	Unknown	Unknown	ddPCR Su...	HEX	10757	
A01	4 Color	1	531	DQ	Unknown	Unknown	ddPCR Su...	FAM	10617	

Data Table Column Definitions

Table 17 defines each field in the Data Table.

Table 17. Data Table columns

Column name	Content description
Well	The well location in the plate Note: The instrument accepts 96-well plates only.
Sample description 1 Sample description 2 Sample description 3 Sample description 4	Words or phrases to describe the sample in each well Note: Only the sample description 1 data appears in plate layout views but you can pause on a well in the Plate Editor to display a tool tip containing the entries in all completed Sample description fields.
Target	Target name from Plate Editor tab
Conc(copies/ μ L)	Concentration of the target molecules recorded as copies per microliter
pg/ μ L	Mass concentration of DNA in the well in pg/ μ l
Status	Contains either Check, OK, Multi, or Manual <ul style="list-style-type: none"> ■ If Check, either the automatic analysis for the well failed or fewer than 10,000 droplets were counted in the well ■ If OK, enough droplets were counted to trigger automatic analysis ■ If Multi, the data was automatically analyzed as part of a multi-well selection ■ If Manual, the droplets were analyzed manually
Status Reason	Identifies the reason for the status (unsuccessful automatic analysis, not enough droplets counted, or droplets analyzed manually)
Experiment	Experiment type selected for the well in the Plate Editor
SampleType	Sample type selected for the well in the Plate Editor
TargetType	Target type selected for each dye(FAM, HEX or VIC, Cy5 and Cy5.5) in the Plate Editor

Table 17. Data Table columns, continued

Column name	Content description
Supermix	Supermix selected for the well in Plate Editor
DyeName(s)	Dye assigned to channels (1, 2, 3, and 4, respectively) for the well in the Plate Editor
Copies/20 μ LWell	Concentration of the target normalized to a volume of 20 μ L
TotalConfMax	For merged wells the high error bar for the target concentration of the combined wells at a 95% confidence interval
TotalConfMin	For merged wells the low error bar for the target concentration of the combined wells at a 95% confidence interval
PoissonConfMax	Maximum target concentration normalized for the high error bar of the droplet Poisson distribution for the 95% confidence interval
PoissonConfMin	Minimum target concentration normalized for the low error bar of the droplet Poisson distribution for the 95% confidence interval
Accepted Droplets	Total number of droplets accepted by quality algorithm
Positives	Number of droplets that contain the target
Negatives	Number of droplets that do not contain the target
Copies/ μ L linked molecules	Shows number of copies of a target that are present in overabundance versus the expected value in copies per μ L
CNV	Copy number calculated for the target relative to the reference
TotalCNVMax	For merged wells, the high error bar for the copy number of the combined wells at a 95% confidence interval
TotalCNVMin	For merged wells, the low error bar for the copy number of the combined wells at a 95% confidence interval

Table 17. Data Table columns, continued

Column name	Content description
PoissonCNVMax	Maximum copy number normalized for the high error bar of the droplet Poisson distribution for the 95% confidence interval
PoissonCNVMin	Minimum copy number normalized for the low error bar of the droplet Poisson distribution for the 95% confidence interval
ReferenceCopies	Copy number identified for the reference target in the Plate Editor
UnknownCopies	This field is currently unused in QX ONE Software
Threshold1	Threshold value of first threshold line from left to right and bottom to top
Threshold2	Threshold value of second threshold line from left to right and bottom to top
Threshold3	Threshold value of third threshold line from left to right and bottom to top
ThresholdSigmaAbove	Distance of the threshold from the mean of the negative cluster, as a multiple of the negative cluster standard deviation
ThresholdSigmaBelow	Distance of the threshold from the mean of the positive cluster, as a multiple of the positive cluster standard deviation
ReferenceUsed	Identifies which target was used as a reference
Ratio	The ratio of the target against the identified reference
TotalRatioMax	For merged wells the high error bar for the ratio of the unknown against the reference of the combined wells at a 95% confidence interval
TotalRatioMin	For merged wells the low error bar for the ratio of the unknown against the reference of the combined wells at a 95% confidence interval

Table 17. Data Table columns, continued

Column name	Content description
PoissonRatioMax	Maximum ratio of the unknown against the reference normalized for the high error bar of the droplet Poisson distribution for the 95% confidence interval
PoissonRatioMin	Minimum ratio of the unknown against the reference normalized for the low error bar of the droplet Poisson distribution for the 95% confidence interval
FractionalAbundance	Calculation of fractional abundance of this unknown target vs. the reference target
TotalFractionalAbundanceMax	For merged wells the high error bar for the fractional abundance of the combined wells at a 95% confidence interval
TotalFractionalAbundanceMin	For merged wells the low error bar for the fractional abundance of the combined wells at a 95% confidence interval
PoissonFractionalAbundanceMax	Maximum fractional abundance normalized for the high error bar of the droplet Poisson distribution for the 95% confidence interval
PoissonFractionalAbundanceMin	Minimum fractional abundance normalized for the low error bar of the droplet Poisson distribution for the 95% confidence interval
MeanAmplitudeOfPositives	Mean amplitude value of all droplets that contain the target
MeanAmplitudeOfNegatives	Mean amplitude value of all droplets that contain no target
MeanAmplitudeTotal	Mean amplitude value of all droplets
ExperimentComments	Data populates this field only from files created in QuantaSoft™ versions 1.4 – 1.7, if comments were added.
MergedWells	Identifies which wells were merged together

Table 17. Data Table columns, continued

Column name	Content description
TotalConfidenceMax68	For merged wells the high error bar for the target concentration of the combined wells at a 68% confidence interval
TotalConfidenceMin68	For merged wells the low error bar for the target concentration of the combined wells at a 68% confidence interval
PoissonConfidenceMax68	Maximum target concentration normalized for the high error bar of the droplet Poisson distribution for the 68% confidence interval
PoissonConfidenceMin68	Minimum target concentration normalized for the low error bar of the droplet Poisson distribution for the 68% confidence interval
TotalCNVMax68	For merged wells the high error bar for the copy number of the combined wells at a 68% confidence interval
TotalCNVMin68	For merged wells the low error bar for the copy number of the combined wells at a 68% confidence interval
PoissonCNVMax68	Maximum target concentration normalized for the high error bar of the droplet Poisson distribution for the 68% confidence interval
PoissonCNVMin68	Minimum target concentration normalized for the low error bar of the droplet Poisson distribution for the 68% confidence interval
TotalRatioMax68	For merged wells the high error bar for the ratio of the unknown against the reference of the combined wells at a 68% confidence interval
TotalRatioMin68	For merged wells the low error bar for the ratio of the unknown against the reference of the combined wells at a 68% confidence interval
PoissonRatioMax68	Maximum ratio of the unknown against the reference normalized for the high error bar of the droplet Poisson distribution for the 68% confidence interval

Table 17. Data Table columns, continued

Column name	Content description
PoissonRatioMin68	Minimum ratio of the unknown against the reference normalized for the low error bar of the droplet Poisson distribution for the 68% confidence interval
TotalFractionalAbundanceMax68	For merged wells the high error bar for the fractional abundance of the combined wells at a 68% confidence interval
TotalFractionalAbundanceMin68	For merged wells the low error bar for the fractional abundance of the combined wells at a 68% confidence interval
PoissonFractionalAbundanceMax68	Maximum fractional abundance normalized for the high error bar of the droplet Poisson distribution for the 68% confidence interval
PoissonFractionalAbundanceMin68	Minimum fractional abundance normalized for the low error bar of the droplet Poisson distribution for the 68% confidence interval plate list after correcting the issue
TiltCorrected	Indicates if tilt correction was applied to the well Note: Tilt correction rotates the angles from the double-negative cluster centroid to each droplet, such that the two single positive cluster centroids are orthogonal with the double-negative cluster centroid.
Ch1+Ch2+	Number of droplets that contain both channel 1 and channel 2 targets
Ch1+Ch2-	Number of droplets that contain just the channel 1 target
Ch1-Ch2+	Number of droplets that contain just the channel 2 target
Ch1-Ch2-	Number of droplets that contain neither channel 1 nor channel 2 targets
Ch3+Ch4+	Number of droplets that contain both channel 3 and channel 4 targets
Ch3+Ch4-	Number of droplets that contain just the channel 3 target

Table 17. Data Table columns, continued

Column name	Content description
Ch3-Ch4+	Number of droplets that contain just the channel 4 target
Ch3-Ch4-	Number of droplets that contain neither channel 3 nor channel 4 targets

Plate Well Data Table

From the Plate Editor you can access a window containing the Well Data table, which displays configuration and run information on all wells containing sample.

Note: You cannot edit this table.

Table 18. Plate Well Data Table columns

Column name	Content description
Well	Well number (A01 through H12)
Sample description 1 Sample description 2 Sample description 3 Sample description 4	Words or phrases to identify each sample, as entered in the Plate Editor Note: You can enter up to four sample descriptions for each well.
Perform Droplet Generation	Yes, if droplets were generated in the well No, if they are not
Perform Droplet Reading	Yes, if wells are read No, if they are not
Target name	Target name entered in the Plate Editor tab
Conc (copies/ μ L)	
Status	

Table 18. Plate Well Data Table columns, continued

Column name	Content description
Experiment type	Experiment Type selected in the Plate Editor: <ul style="list-style-type: none"> ■ Direct Quantification (DQ) ■ Copy Number Variation (CNV) ■ Mutation Detection (MUT) ■ Rare Event Detection (RED) ■ Drop-off (DOF) ■ Gene Expression (GEX) ■ Residual DNA Quantification (RDQ)
Sample Type	Sample type selected in the Plate Editor: <ul style="list-style-type: none"> ■ Unknown ■ No template control (NTC) ■ Positive control (Pos Ctrl) ■ Negative control (Neg-Ctrl)
Target Type	Target type selected in the Plate Editor tab
Supermix name	Supermix selected in the Plate Editor: <ul style="list-style-type: none"> ■ ddPCR Multiplex Supermix ■ ddPCR Supermix for Probes (no dUTP) ■ ddPCR Supermix for Probes ■ ddPCR Supermix for Residual DNA Quantification ■ One-Step RT-ddPCR Advanced Kit for Probes
DyeName(s)	Dye assigned to channels 1, 2, 3, and 4, respectively, for the well in the Plate Editor
Accepted Droplets	Total number of droplets accepted by quality algorithm
Positives	Number of droplets that contain the target
Negatives	Number of droplets that do not contain the target
Plate Notes	Entries by the user

Plate Editor Well Data Table

A well data table containing both configuration and run data appears in the analysis windows, next to the Well Selector. This table displays a subset of data columns for only the wells selected in the Plate Editor or Well Selector. [Table 19](#) defines each column in the consolidated table.

Table 19. Fields in the Analysis Well Data table

Column name	Content description
Well	The well location in the plate the sample is from
Perform Droplet Reading	Yes or No
Experiment Type	Experiment type from the Plate Editor
Sample description 1 – 4	The sample name used to identify the well in the Plate Editor tab
SampleType	Sample type from the Plate Editor
Supermix Name	Supermix from the Plate Editor
Assay type	Assay type selected in the Plate Editor
Target Name	Target Name from Plate Editor tab
TargetType	Target type assigned to the target in the Plate Editor
Signal Ch1	Selected fluorophore in Channel 1
Signal Ch2	Selected fluorophore in Channel 2
Signal Ch3	Selected fluorophore in Channel 3
Signal Ch4	Selected fluorophore in Channel 4
Reference Copies	Copy number identified for the reference target in the Plate Editor tab
Well Notes	Entries by the user
Plot?	If selected, target will be used to calculate the copy number for the well
RDQ Conversion Factor	The Residual DNA Quantification conversion factor for the well Note: RDQ is only available in Residual DNA Quantification experiments.

Viewing Run, Lot, and Audit Information

Use the Run Information window to view the information about the plate and run. You can also view or add post-run notes regarding the plate. In Regulatory Edition, you can also view the audit logs.

You can also view the Audit Log. For information, see [Viewing the Audit Log on page 138](#).

Run Details		Audit Log																																					
Instrument Serial Number:	Charlie06	<table border="1"> <thead> <tr> <th colspan="4">Post Run Plate Notes:</th> </tr> <tr> <td colspan="4" style="height: 50px;"></td> </tr> <tr> <th colspan="4">Lot Information</th> </tr> <tr> <th>Type</th> <th>Barcode</th> <th>Lot Number</th> <th>Expiry Date</th> </tr> </thead> <tbody> <tr> <td>GCR 96 Cartridge</td> <td>1018061301A210001</td> <td>1823G□□□□□</td> <td>07/23/2020</td> </tr> <tr> <td>Droplet Generation C</td> <td>31 33 00 00 00 00 00</td> <td></td> <td>05/30/2019</td> </tr> <tr> <td>Droplet Generation C</td> <td>31 33 00 00 00 00 00</td> <td></td> <td>01/01/1900</td> </tr> <tr> <td>Droplet Reader Oil</td> <td>31 33 00 00 00 00 00</td> <td></td> <td>05/30/2019</td> </tr> <tr> <td>Droplet Reader Oil</td> <td>31 33 00 00 00 00 00</td> <td></td> <td>05/30/2019</td> </tr> </tbody> </table>		Post Run Plate Notes:								Lot Information				Type	Barcode	Lot Number	Expiry Date	GCR 96 Cartridge	1018061301A210001	1823G□□□□□	07/23/2020	Droplet Generation C	31 33 00 00 00 00 00		05/30/2019	Droplet Generation C	31 33 00 00 00 00 00		01/01/1900	Droplet Reader Oil	31 33 00 00 00 00 00		05/30/2019	Droplet Reader Oil	31 33 00 00 00 00 00		05/30/2019
Post Run Plate Notes:																																							
Lot Information																																							
Type	Barcode			Lot Number	Expiry Date																																		
GCR 96 Cartridge	1018061301A210001			1823G□□□□□	07/23/2020																																		
Droplet Generation C	31 33 00 00 00 00 00				05/30/2019																																		
Droplet Generation C	31 33 00 00 00 00 00				01/01/1900																																		
Droplet Reader Oil	31 33 00 00 00 00 00				05/30/2019																																		
Droplet Reader Oil	31 33 00 00 00 00 00				05/30/2019																																		
Plate Name:	C06_Test0434_P1																																						
Date of Run:	6/4/2019 12:02:42 PM																																						
User Name of Run Initiator:	\BRR&D																																						
Thermal Cycling Protocol Name:	BioProbes_94C_Final																																						
Supermix Type:	ddPCR Supermix for Probes (No dUTP)																																						
Number Of Wells Generated:	96																																						
Number Of Wells Read:	96																																						
Oil Name:	Probes																																						
Initial Wait Elapsed Time	0h 8m 22s																																						
DG Elapsed Time	0h 27m 23s																																						
Droplets Wait Time	0h 4m 39s																																						
TC Elapsed Time	2h 10m 44s																																						
DR Elapsed Time	3h 23m 57s																																						
Run Status:	Run completed with errors																																						
Software Version:	1.0.736																																						
File Name:	1.7360																																						

1	2	3	4	5	6	7
25.0°C	95.0°C	94.0°C	60.0°C	G O T O 3	98.0°C	25.0°C
1:00	10:00	0:30	1:00	39 X	10:00	1:00

Chapter 4 Data Analysis Methodology

As summarized in [Chapter 3, Data Analysis Module Overview](#), the software presents analysis data in several different formats. When you open the data file in the Analysis module, you can view the data with the automatic analysis thresholds and calculations or you can choose different options to recalculate, replot, or recolor the results.

Data is shown in the following formats:

- Amplitude, which shows each droplet in each well in a scatter plot, in one-dimensional, two-dimensional, or three-dimensional views
- Data visualizations, which show estimated target molecule concentration, ratio, and fractional abundance of one target against another target based on selected error model and confidence interval

Note: Copy number variation is also calculated if the user ran a CNV experiment.

- Event counts, which are precise counts of positive and negative droplets for each target in each well

Amplitude Plot Analysis Options

QX ONE Software provides three amplitude plot displays in which you can view the data with automatic thresholding where applicable, or choose different options to replot or recolor the results.

In the 1D amplitude and 2D amplitude plots, you can

- Show well calculations

Note: The 1D amplitude plot shows the data for each selected well in its own section, while the 2D amplitude plot shows all selected wells together.

- Modify automatic thresholds calculated by QX ONE Software
- View data in a heat map
- View histograms (1D amplitude tab only)
- Re-apply automatic analysis
- Apply tilt correction to automatic analysis

In the 3D amplitude plot, you can

- Rotate the plot to gain a better view of the droplets in 3D orientation
- View thresholds previously set in 1D or 2D amplitude display
- View 2D data behind 3D droplets in clusters or heat maps

Table 20 explains the analysis options that are available in both 1D amplitude and 2D amplitude plots.

Table 20. 1D and 2D amplitude tool options




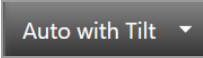

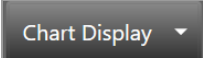
Icon	Mode	Description
	View mode	Data appears with the thresholds or clusters assigned by QX ONE Software. When this icon is selected, the view is locked and you cannot modify the thresholds.
	Heat map	Shows the distribution of droplets, with higher density of droplets shown as hot.
	Automatic analysis	Disables tilt correction and automatically reanalyzes the data.
	Automatic analysis with tilt correction	Enables tilt correction and automatically reanalyzes the data. Note: Tilt correction rotates the angles from the double-negative cluster centroid to each droplet, such that the two single positive cluster centroids are orthogonal with the double-negative cluster centroid.
	Reset	Resets the data to the original automatically analyzed data.
	Chart display options	Choose whether to display axis with channel number or fluorophore, and change the size of axis markers, data labels, and axis labels.

Table 21 explains the analysis options available only for 1D amplitude plots.

Table 21. 1D amplitude tool options








Icon	Mode	Description
	Automatic thresholding	<p>Individual Wells: Clusters are generated for each selected well separately.</p> <p>Combined Wells: Droplets from all selected wells are combined, and clusters are generated on that combined set.</p> <p>Positive Control Wells: Thresholds are generated for each channel based on any positive controls currently selected, and applies those thresholds to all currently selected wells.</p> <p>Note: If you change the thresholds manually, you can tap Reset to return to the automatic thresholds.</p>
	Threshold, single well	<p>For a single well or multiple wells, the user can manually input thresholding values in the 1D amplitude plot.</p> <p>You can tap anywhere in the plot to apply threshold lines to the data.</p> <p>To adjust the threshold values</p> <ul style="list-style-type: none"> ■ Drag the lines horizontally in the plot area ■ Enter a new threshold value in the boxes at the end of each threshold line ■ Tap the up and down arrows to incrementally adjust the numbers
	Threshold, multiple wells	
	Threshold, single well SD	<p>For a single well or multiple wells, QX ONE Software automatically calculates and populates thresholding values with standard deviations (SD).</p> <p>Important: SD thresholds are not recommended for RMD, since these clusters are not typically located at right angles to each other.</p> <p>Note: The SD thresholds are set at a limit that is less than the mean number of positive targets, and more than the mean number of negative targets. Starting from where the user taps in the plot, SD locates the threshold between the positive and negative clusters such that the classification error is minimized.</p>
	Threshold, multiple wells SD	
	Show histogram	Hides or displays histogram plots for 1D amplitude

Table 22 explains the analysis options available only for 2D amplitude plots.

Table 22. 2D amplitude tool options

Icon	Mode	Description
	Automatic thresholding	<p>Individual Wells: Clusters are generated for each selected well separately.</p> <p>Combined Wells: Droplets from all selected wells are combined, and clusters are generated on that combined set.</p> <p>Positive Control Wells: The software generates thresholds for each channel based on any positive controls currently selected, and applies those thresholds to all currently selected wells.</p> <p>Note: If you change the thresholds manually, you can tap Reset to return to the automatic thresholds.</p>
	Threshold line	<p>Use the Threshold line icons to establish thresholds across a pair of channels, dividing droplets into distinct clusters separated by different colors.</p> <p>You can tap anywhere in the plot to apply threshold lines to the data.</p> <p>To adjust the threshold values, you can</p> <ul style="list-style-type: none"> ■ Drag the lines horizontally or vertically in the plot area ■ Enter a new threshold value in the boxes at the end of each threshold line ■ Tap the up and down arrows to incrementally adjust the numbers
	Threshold line SD	<p>QX ONE Software automatically calculates and populates threshold line values with standard deviations (SD).</p> <p>Important: SD thresholds are not recommended for RMD, since these clusters are not typically located at right angles to each other.</p> <p>Note: The SD thresholds are set at a limit that is less than the mean number of positive targets, and more than the mean number of negative targets. Starting from where the user taps in the plot, SD locates the threshold between the positive and negative clusters such that the classification error is minimized.</p>




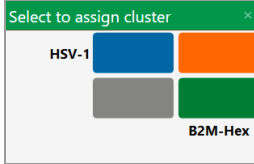
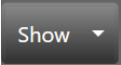
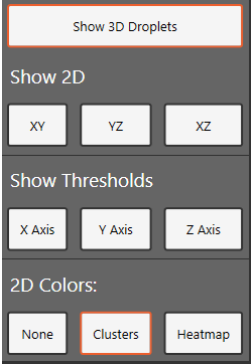
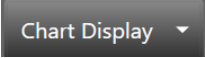
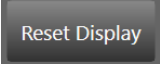
Icon	Mode	Description
	Threshold cluster square	Use the Threshold Cluster icons to establish thresholds across a pair of channels, dividing droplets into distinct clusters separated by different colors.
	Threshold cluster circle	To classify your droplets, you can
	Threshold cluster freeform	<ul style="list-style-type: none"> ■ Tap any of the three Threshold Cluster Mode buttons (square, circle, or free form) ■ Draw the chosen shape around the cluster of droplets <p>Note: When using the cluster mode tools to draw a shape around a cluster of droplets, a dialog box with color selections by target appears in the window to help you select the correct target combination.</p>  <p>Target names are shown along the two axes based on the signal values assigned during plate setup. Tap the colored box that best represents the location of the cluster of droplets selected to automatically classify the droplets as positive or negative for each given target.</p> <p>Note: The Cluster dialog box display varies according to the plex mode.</p>

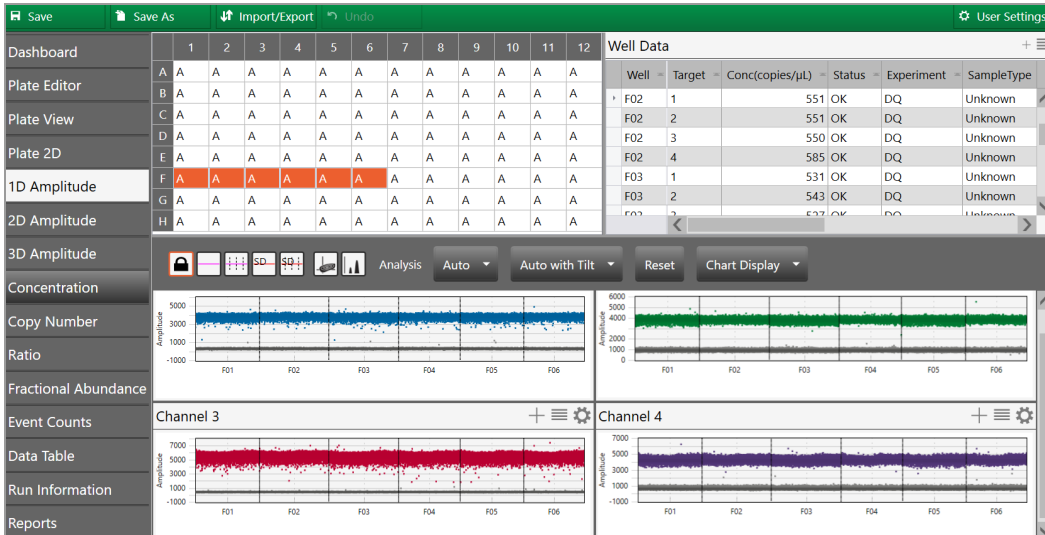
Table 23 explains the analysis options available only for 3D amplitude plots.

Table 23. 3D amplitude tool options

Icon	Mode	Description
	dropdown menu containing options for data visualization 	Choose to show 3D droplets, 2D amplitude data behind the 3D clusters, thresholds, and 2D color options.
	Axis titles	Choose whether to display axis with channel number or fluorophore name.
	Reset	Reset the display to the default orientation.

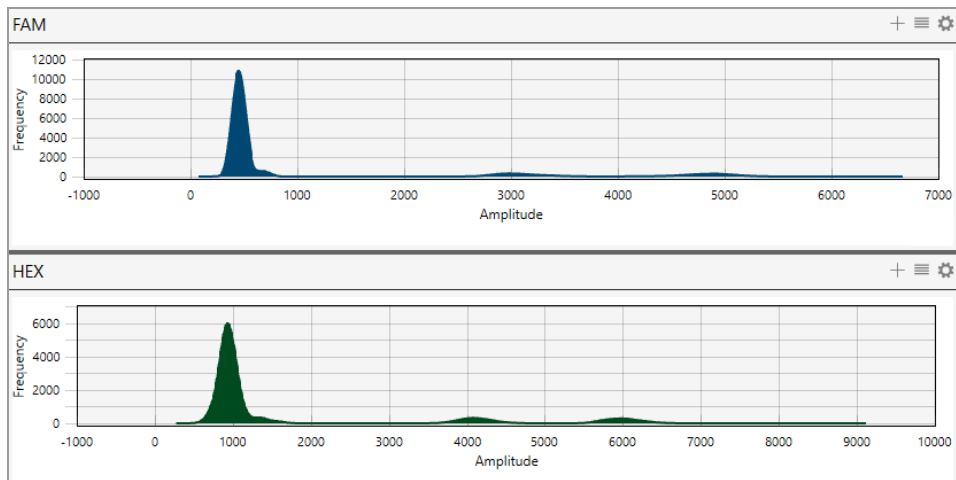
1D Amplitude

Use the 1D Amplitude analysis window to view droplet amplitudes for each channel, in selection order, for each well selected in the Well Selector.



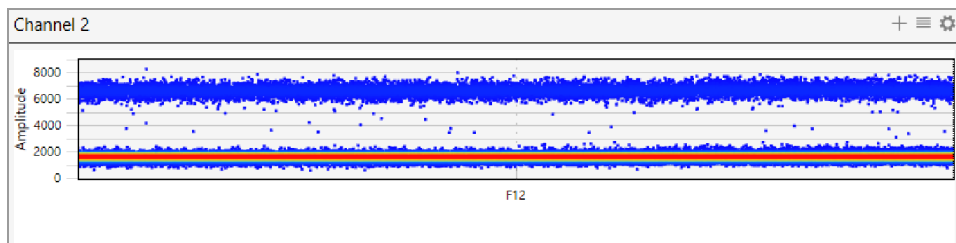
The 1D Amplitude plots illustrate

- All accepted droplets, with a visual representation of the positive and negative droplets in each well
 - Positive droplets appear in color, while negative droplets appear in gray.
 - The Well Selector displays an A in each well where QX ONE Software automatically thresholded the droplet data. An M appears in any well in which you manually changed the threshold.
- Amplitude in a histogram plot



Note: The Histogram icon is enabled by default so a Histogram plot appears automatically for each fluorophore (channel).

- Amplitude in a Heat Map view



When you select the 1D Amplitude tab, the toolbar options that allow you to change thresholds and show or hide the heat map and histogram appear above the plots.



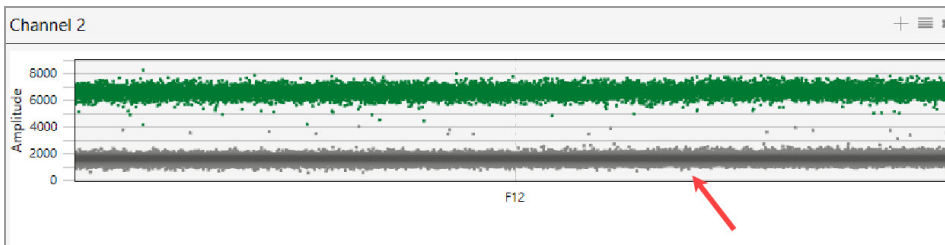
Note: For detailed information on each toolbar option, see [Amplitude Plot Analysis Options on page 104](#).

Default color assignments for 1D amplitude plots are

- Positive FAM = Blue
- Positive HEX = Green
- Positive Cy5 = Red
- Positive Cy5.5 = Violet
- Negative = Gray


The images in this section display data from a direct quantification experiment involving four targets:

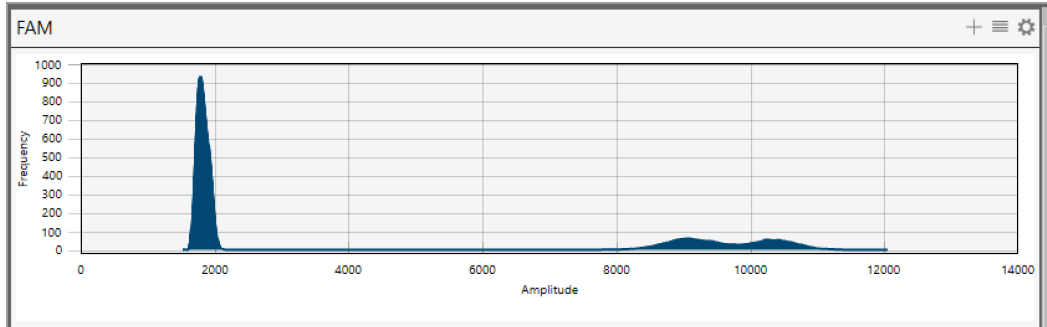
Negative droplets appear in grayscale in each plot.



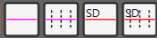
For experiments where enough droplets are recognized, QX ONE Software automatically configures an amplitude threshold, which distinguishes between positive and negative droplets.

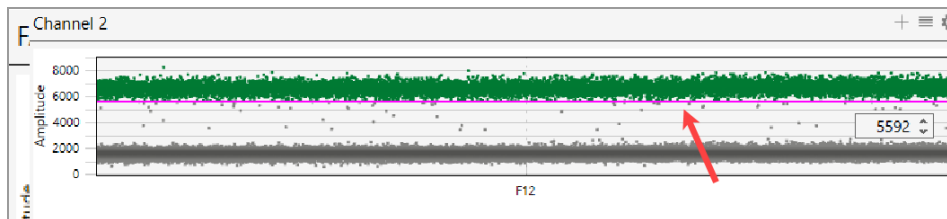
Note: Well data must meet certain quality metrics (minimum of 10,000 droplets) before the software will automatically calculate a threshold above which droplets are considered positive. You can use the manual thresholding tools to ensure correct quantification of positive and negative droplets.

By default, the Histogram icon () is enabled so the Histogram plot automatically appears with the amplitude plot.



To manually adjust the thresholds

1. Select one or more wells.
2. Tap any of the threshold icons () to set manual thresholds:
 - Regular threshold for a single well; when multiple wells are selected, you can set a different threshold for each well
 - Regular threshold for multiple wells, where you can set one threshold for all selected wells
 - Standard deviation threshold for a single well; when multiple wells are selected, you can set a different threshold for each well
 - Standard deviation for multiple wells, where you can set one threshold for all selected wells
3. Tap on the location in the plot where you want to draw the new threshold.
4. When the line appears, use the up or down arrows, or tap and drag the threshold, to adjust the location.



QX ONE Software displays the manual threshold and changes the color of the droplets that are now above or below the threshold.


Note: You can also manually enter a threshold number.

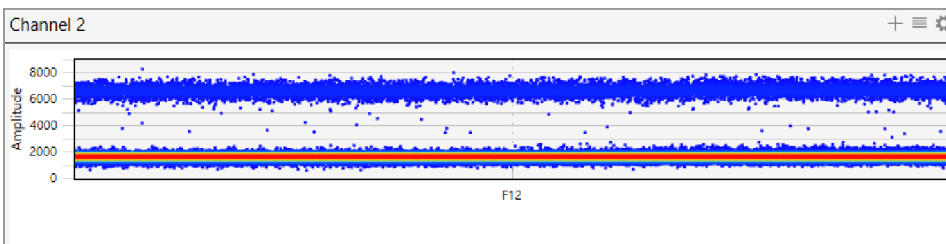
When you manually modify a threshold, the well selector displays an M for manual instead of the A for Automatic.

/ / / / / / / /	A	A	A	A	A	A
/ / / / / / / /	A	A	A	A	A	A
/ / / / / / / /	A	A	A	A	A	M
/ / / / / / / /	A	A	A	A	A	A

5. (Optional) To reset to the automatic threshold, tap Auto.
6. (Optional) To adjust the automatic threshold to consider tilt correction, tap Auto with Tilt.
7. (Optional) To reset everything to the original display, tap Reset.

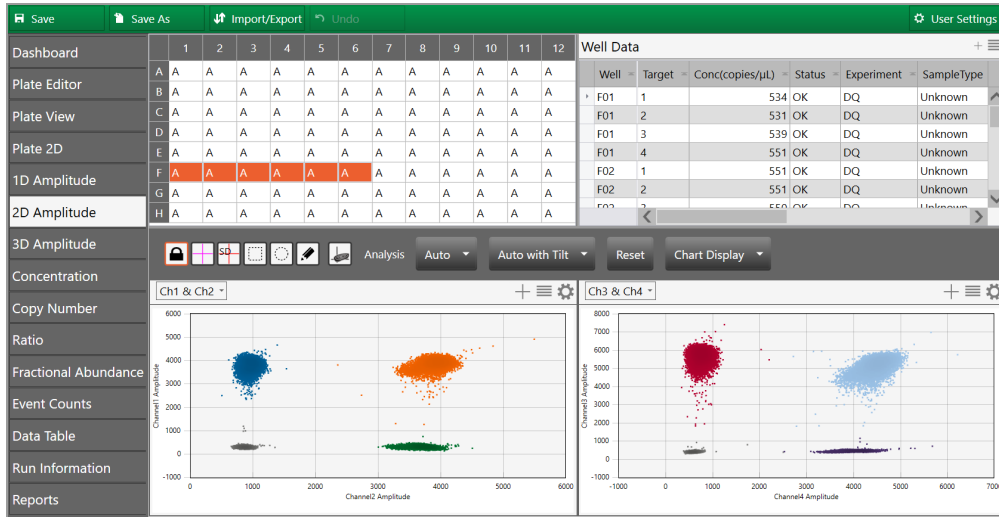
To view a heat map representation of the plot data

- ▶ Tap the heat map () icon.

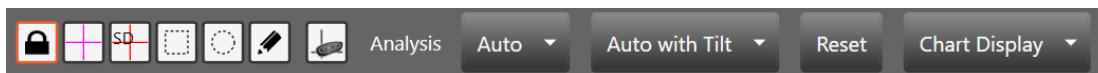


2D Amplitude

For the wells you select in the analysis view of the Plate Editor, the 2D Amplitude window illustrates fluorescence for four targets. The images in this section display data from an experiment involving four targets. Each plot shows individual cluster representations for first and second target positive droplets, droplets containing both targets, and droplets containing neither target.



When you select the 2D Amplitude tab, the toolbar options allow you to change thresholds, manually cluster wells, and show or hide the heat map above the plots.



For detailed information on each toolbar option, see [Amplitude Plot Analysis Options on page 104](#).

Default color assignments for 2D amplitude plots are:


Positive FAM	=	Blue
Positive HEX/VIC	=	Green
Positive FAM and HEX/VIC	=	Orange (may appear brown on some monitors)
Positive Cy5	=	Red
Positive Cy5.5	=	Violet
Positive Cy5 and Cy5.5	=	Light Blue
Double negative	=	Gray

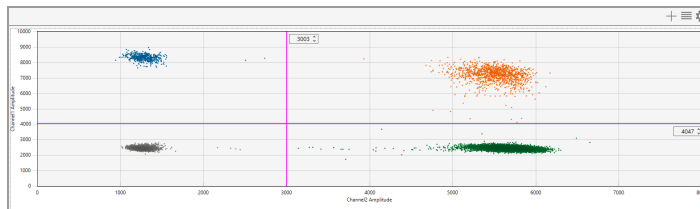
Note: Well data must meet certain quality metrics (minimum of 10,000 droplets) before QX ONE Software will automatically calculate a threshold above which droplets are considered positive. You can use the manual thresholding tools to ensure correct quantification of positive and negative droplets.




To use the 2D amplitude tools

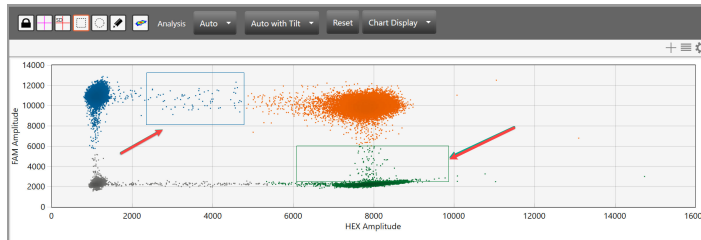
1. Open your data file in the Analysis module and select the 2D Amplitude tab.
2. Choose a threshold line or cluster option.

Note: Use the cluster option when the data is not orthogonal and the threshold lines do not adequately divide the populations of droplets.

- To adjust threshold lines, select a threshold line type () and then tap in the plot to apply crosshair lines. Use any of the following methods:
 - Drag the lines horizontally or vertically in the plot area.
 - Enter a new threshold value in the boxes at the end of each threshold line.
 - Tap the up and down arrows to incrementally adjust the numbers.



- To adjust thresholds using the cluster option, select a cluster type (  ) and draw the chosen shape around the cluster of droplets to classify.

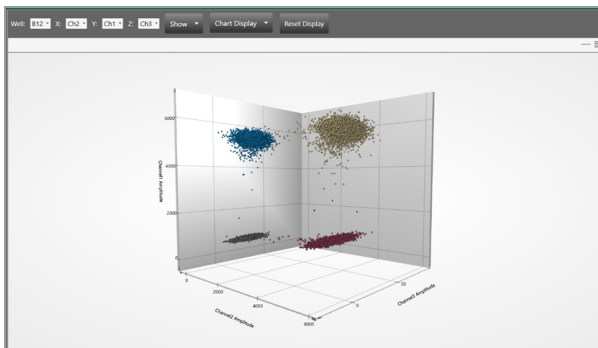


3. (Optional) To reset to the automatic threshold, tap Auto.
4. (Optional) To adjust the automatic threshold to consider tilt correction, tap Auto with Tilt.
5. (Optional) To reset everything to the original display, tap Reset.

3D Amplitude

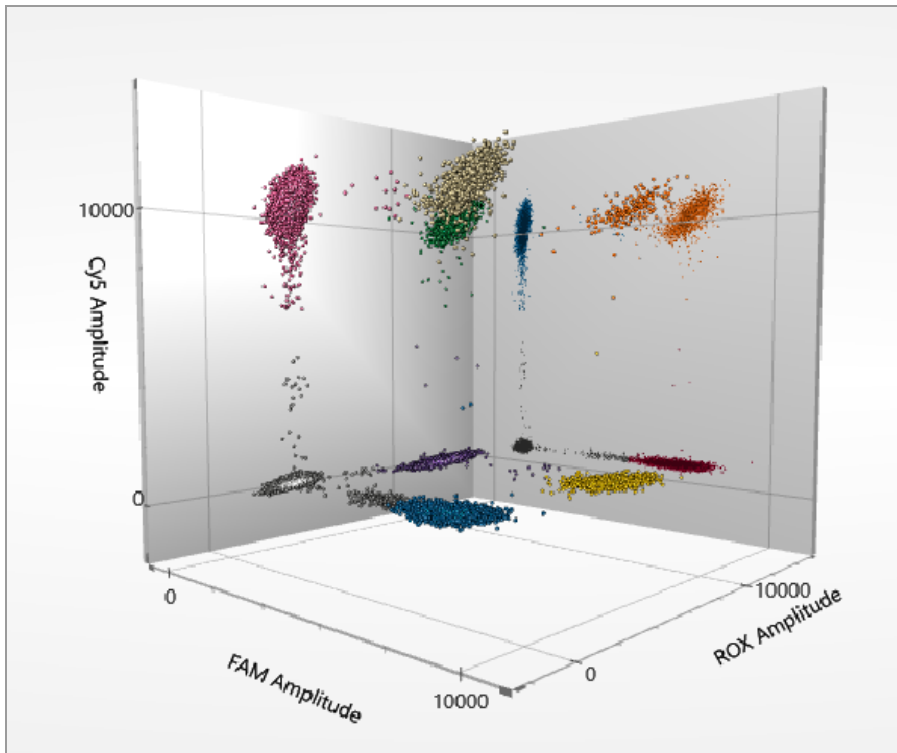
When you select the 3D Amplitude tab, the toolbar options that allow you to select the well and choose which channels to display appear above the chart.

For the well selected from the toolbar, the 3D amplitude plot illustrates three targets in a single chart.

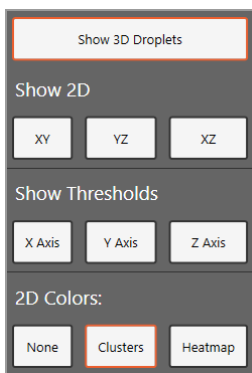


To use the different 3D amplitude viewing tools

1. Select Well.
2. Select the dye for the x, y, and z axis.



3. Tap Show and the following menu appears:

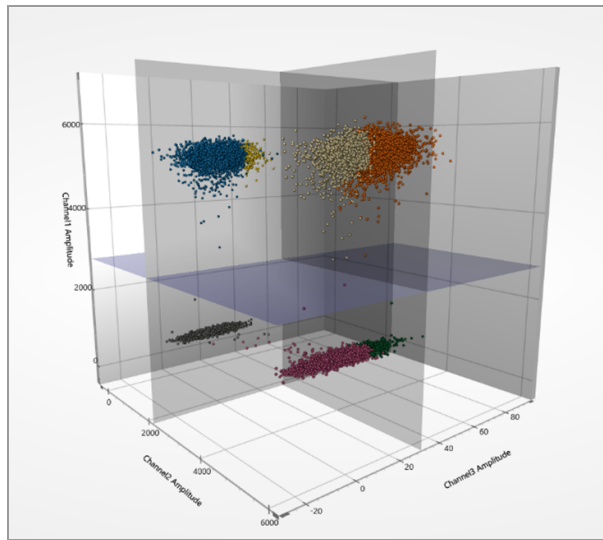


4. Select one or more of the Show 2D options to display 2D amplitude data behind the 3D droplets.

Show 3D Droplets is selected by default. You can also show

- 2D data on different axis combinations
- Display thresholds on the x, y, and z axis

Note: You must set the thresholds on the 1D or 2D amplitude plots to display them in 3D. .



- 2D colors in clusters or a heat map
5. Tap Chart Display to show the labels by color or by channel.
 6. Tap Reset Display to return to the default display.

Data Visualization Chart Analysis Options

QX ONE Software also provides chart displays where you can view the data from the original calculations, or choose different options to recalculate the results.



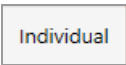

In charts reflecting Data Visualization distributions, you can

- Show individual or merged well data
- Change the error model and confidence level

Note: For event counts, you can also alter the view mode to see positive, negative, or all droplet counts.

[Table 24](#) explains the available options.

Table 24. Chart tool options for Data Visualization distribution charts

Icon	Mode	Description
	Show both	Shows the calculated total or percentage as a merged calculation for all selected wells and as an individual calculation for each selected well
	Show merged	Shows the calculated total or percentage as a combined number for all selected wells with the same parameters Note: Well setup must match for each well before the software can merge them.
	Show individual	Shows the calculated total or percentage as an individual calculation for each selected well
	X-axis well	Shows the well number on the x axis


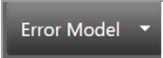
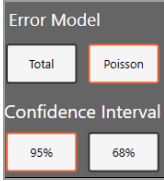
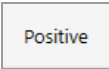
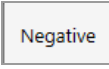

Icon	Mode	Description
	X-axis sample	<p>Shows a partial sample name on the x axis</p> <p>Note: You can select Well and Sample simultaneously.</p>
	Error model and confidence interval	<p>Select an error model and confidence level</p> <p>Note: The default choices are Poisson and 95%, to yield the highest confidence in the results.</p>  <p>Important: The software uses the following multipliers in its calculations:</p> <ul style="list-style-type: none">■ For 95% confidence interval, the sigma multiplier is 1.96■ For 68% confidence interval, the sigma multiplier is 1.0

Table 25 identifies the additional options available in the Event Count window. These options are available for event counts only.

Table 25. Additional options for event counts

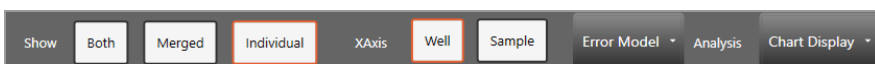
Icon	Mode	Description
	View mode positive	Displays in a bar chart the number of positive droplets for each target in each well
	View mode negative	Displays in a bar chart the number of negative droplets for each target in each well
	View mode total	Displays in a bar chart the number of total droplets in each well



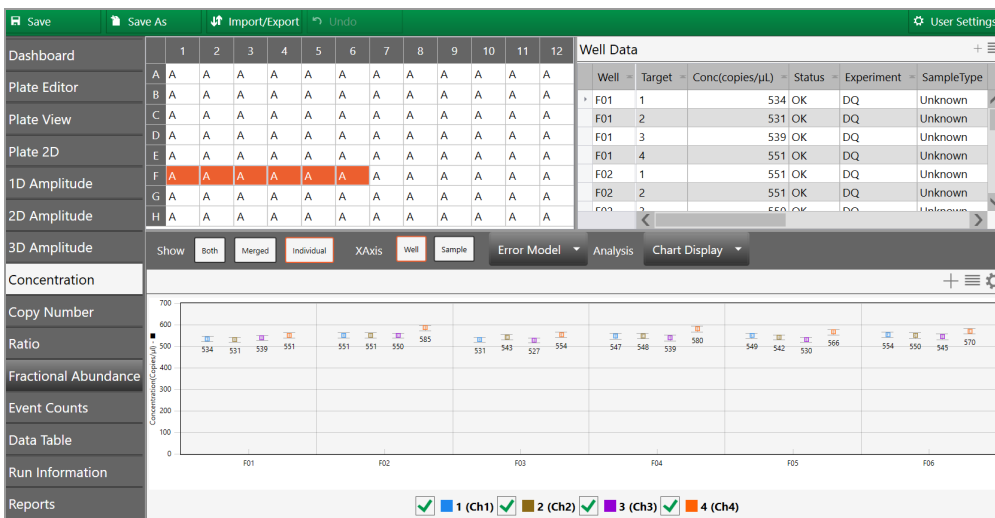
Concentration

Concentration measures the number of copies of the target molecules in each μl of sample based on the default settings. Use the toolbar to merge or separate the calculated results for each well, and to recalculate your results based on a different error model and confidence interval.

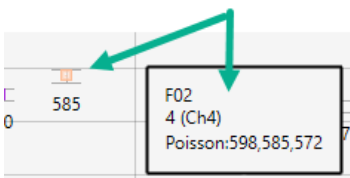
For information on toolbar options, see [Data Visualization Chart Analysis Options on page 120](#).



The following image displays concentration data, across a sequence of wells.



QX ONE Software plots the averaged concentration for each target as a data point. Pause on a data point to see the high, median, and low numbers.



Concentration Calculation

The software uses the formula and variables shown below.

$$c = -\ln\left(\frac{N_{neg}}{N}\right) / V_{droplet}$$

Where:

-ln	Negative natural logarithm
V_{droplet}	Volume of droplet
N_{neg}	Number of negative droplets
N	Total number of droplets

Confidence Interval Calculation

Note: If you select a 68% confidence interval, the multiplier is changed from 1.96 to 1.00.

$$p = \frac{N_{neg}}{N}$$

$$\partial_{N_{neg}} = \sqrt{Np(1-p)}$$

$$N_{neg.min} = N_{neg} - 1.96 * \partial_{N_{neg}}$$

$$N_{neg.max} = N_{neg} + 1.96 * \partial_{N_{neg}}$$

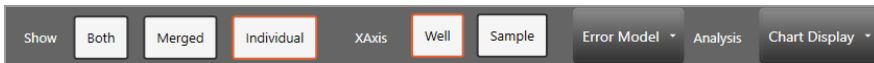
Where:

$V_{droplet}$	Volume of droplet
N_{neg}	Number of negative droplets
N	Total number of droplets
p	p-value (probability of finding the target in the sample)
∂	Delta

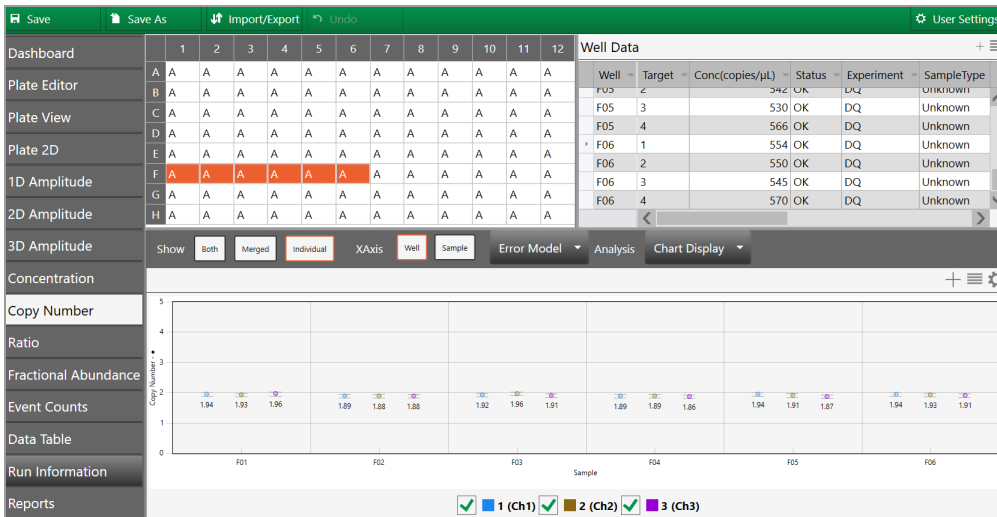
Copy Number

Important: To see copy number variation data, you must run a copy number variation (CNV) ddPCR experiment.

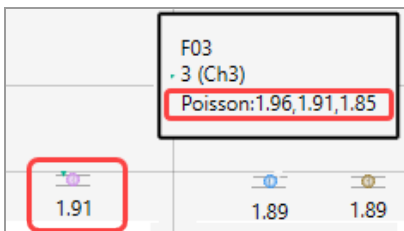
Copy number measures the count of the target gene, relative to the reference gene, to calculate the number gene targets per genome. Use the toolbar to merge or separate the calculated results for each well, and to recalculate your results based on a different error model and confidence interval. For information on toolbar options, see [Data Visualization Chart Analysis Options on page 120](#).



The following image displays copy number data, across a sequence of wells.



QX ONE Software plots each copy number variation as a data point. Pause on a data point to see the high, median, and low numbers.



Copy Number Calculation

The software uses the formula and variables shown below.

$$CNV = \frac{A}{B} N_B$$

Where:

A	Target concentration
B	Reference concentration
N_B	Number of reference copies in genome (usually 2)

Confidence Interval Calculations

Note: If you specify the lesser confidence interval when you define your error model, the software uses 68% in its calculations instead of 95%.

$$CI_{CNV} = N_B \cdot \frac{A}{B} \sqrt{\frac{CI_A^2}{A^2} + \frac{CI_B^2}{B^2}}$$

$$(CNV_{low_95\%}, CNV_{hi_95\%}) = (CNV - (1/2)CI_{CNV}, CNV + (1/2)CI_{CNV})$$

Where:

A	Target concentration
B	Reference concentration
N_B	Number of reference copies in genome (usually 2)
CI_A	Poisson confidence interval of target (95% max - 95% min)
CI_B	Poisson confidence interval of reference (95% max - 95% min)

Notes:

Copy Number analysis involves determining the number of copies of a given target DNA sequence as compared to an invariant reference DNA sequence. Use the CNV analysis to determine structural variations, such as ploidy changes (addition or deletion of chromosomes), deletions (missing partial chromosomes) or duplications (repeated target sequences) in the genome.

The ability to discriminate between consecutive CN states has been a technical challenge in copy number assessment. Fundamentally, as CN state increases, the percentage difference in target genomic material between states decreases. For example, for a given target locus, a CN of 3 is 50% more abundant in concentration per genome than a CN of 2, while a CN of 5 is only 25% more abundant per genome than a CN of 4, and so on.

Due to the massive partitioning of the reaction across up to 20,000 droplets per well, and the absolute nature and precision of the ddPCR concentration measurement, ddPCR CNV analysis enables the quantitative discrimination required to resolve consecutive copy number states beyond CN 3. For example, a 20% difference in target concentration between a CN 5 versus CN 6 sample can be reproducibly resolved using ddPCR. This discrimination is both a function of concentration differences between consecutive CN states, as well as the amount of DNA assayed per well.

Ratio

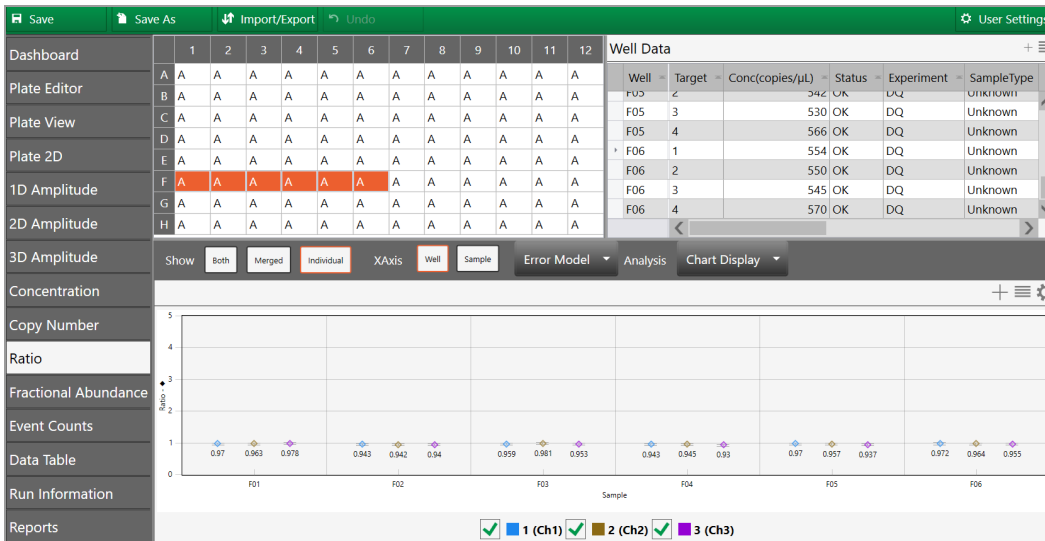
Ratio determines the quotient of two target molecules in each μl of sample based on the default settings.

T1:T2

Use the toolbar to merge or separate the calculated results for each well, and to recalculate your results based on a different error model and confidence interval. For information on toolbar options, see [Data Visualization Chart Analysis Options on page 120](#).



The following image displays ratio data, across a sequence of wells.



QX ONE Software plots each ratio as a data point. To see the confidence level numbers, pause on the data point.

Ratio Calculation

The software uses the formula and variables shown below.

$$r = \frac{A}{B}$$

Where:

A	Target concentration
B	Reference concentration

Note: If no reference is selected, the target with the highest dye concentration in the highest channel will automatically be considered as the reference. If multiple references are selected, the geometric mean is used.

Confidence Interval Calculations

Note: If you specify the lesser confidence interval when you define your error model, the software uses 68% in its calculations instead of 95%.

$$CI_r = \frac{A}{B} \sqrt{\frac{CI_A^2}{A^2} + \frac{CI_B^2}{B^2}}$$

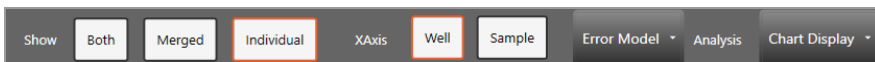
$$(r_{low_95\%}, r_{hi_95\%}) = (r - (1/2)CI_r, r + (1/2)CI_r)$$

Where:

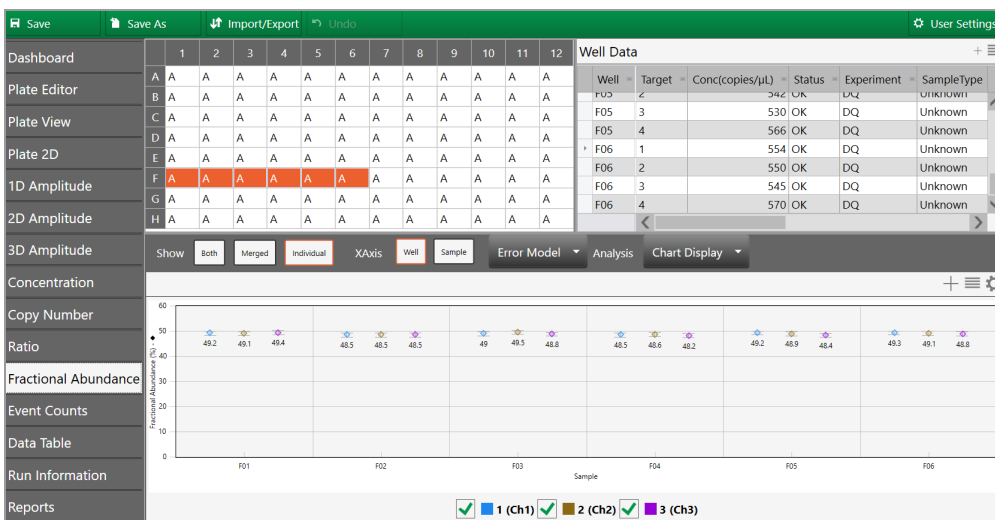
A	Channel 1 target concentration
B	Channel 2 target concentration
CI_A	Confidence interval of Channel 1 target (95% max - 95% min)
CI_B	Confidence interval of Channel 2 target (95% max - 95% min)

Fractional Abundance

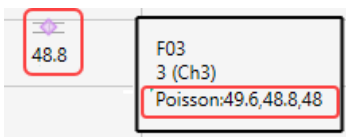
Fractional Abundance determines the relative abundance of your targets in each μl of sample based on the default settings. Use the toolbar to merge or separate the calculated results for each well, and to recalculate your results based on a different error model and confidence interval. For information on toolbar options, see [Data Visualization Chart Analysis Options on page 120](#).



The following image displays fractional abundance data across a sequence of wells.



QX ONE Software plots the fractional abundance as a data point. To see the high and low confidence interval numbers, pause on the data point.



Fractional Abundance Calculation

The software uses the formula and variables shown below.

$$f = \frac{A}{A + B}$$

Where:

A	Target concentration
B	Reference concentration

Note: If no reference is selected, the target with the highest dye concentration in the highest channel will automatically be considered as the reference. If multiple references are selected, the geometric mean is used.

Confidence Interval Calculations

Note: If you specify the lesser confidence interval when you define your error model, the software uses 68% in its calculations instead of 95%.

$$CI_f = \frac{1}{(A + B)^2} \sqrt{B^2 CI_A^2 + A^2 CI_B^2}$$

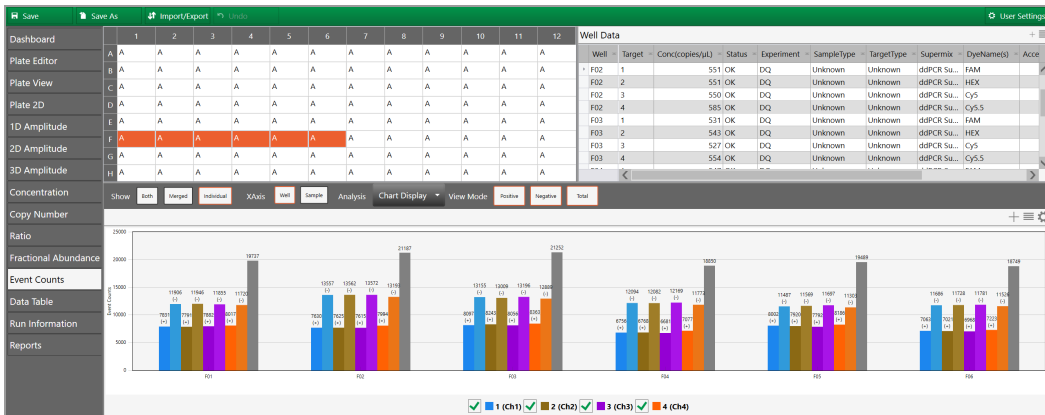
$$(f_{low_95\%}, f_{hi_95\%}) = (f - (1/2)CI_f, f + (1/2)CI_f)$$

Where:

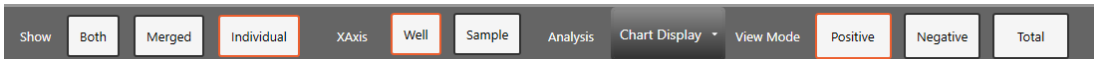
A	Channel 1 target concentration
B	Channel 2 target concentration
CI_A	Confidence interval of Channel 1 target (95% max - 95% min)
CI_B	Confidence interval of Channel 2 target (95% max - 95% min)

Event Counts

The Event Counts tab shows a bar chart view of the number of positive and negative droplets for each of the targets in each of the selected wells.



Use the toolbar to change the display by combining or separating data for each well. You can also show data by well name or by sample name, and you can show any combination of positive, negative, or combined droplet counts.



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Chapter 5 Analysis Module Reporting

Use the Reporting function to create a variety of reports in the QX ONE Software Analysis module.

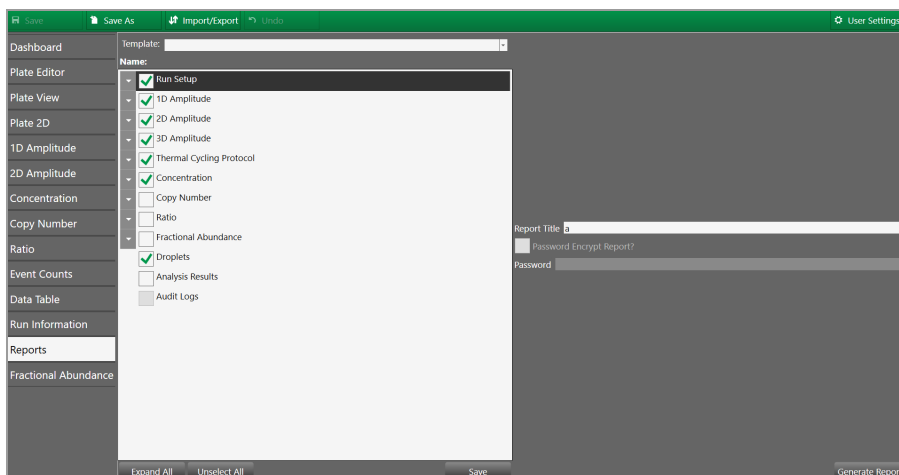
You can create reports on the fly from any analysis file or, if you need to generate specific reports on a regular basis, you can set up report templates for reuse.

This section contains information on how to create analysis reports.

Creating Analysis Reports

You can generate PDF reports on selected data in each analysis file.

For the checkboxes you select in the report configuration, the software displays corresponding charts and data for the selected wells. In each report header, the software automatically displays the user name of the person creating the report, date and time stamps, and the name of the analysis file used to generate the report.



To create an analysis report

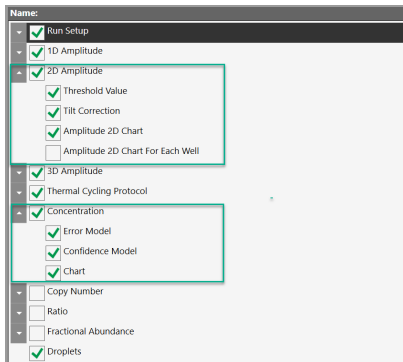
1. Open an analysis data file and tap Reports.

Note: If you make changes to the file, you must save the changes before you can set up and run a report.

2. Do one of the following:

- Work in the default report layout, which appears automatically.
- Select a report template from the Template dropdown list.

3. Under Name, tap the arrow to the left of each item to expand the list of available columns.



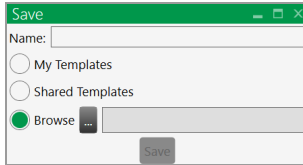
4. Keep the original configuration, or select and clear check boxes to create a new report format.
5. (Optional) Use the options located in the lower portion of the window to expand or collapse the tree, and to select or clear all checkboxes.



6. In the Report Title field, enter a name for your report. You can use up to 30 characters.
7. (Optional) If the report should be private, select the Password Encrypt Report? checkbox and then enter a password in the Password field.

The password must contain between 6 and 20 characters, with at least 1 letter and 1 number.

8. (Optional) To save the structure as a new report template, tap Save and then enter a name, and select a storage location.

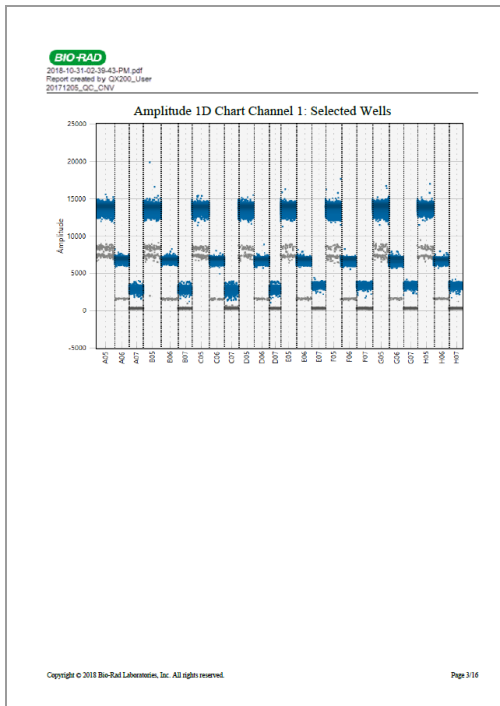


Choose from:

- My Templates, to keep the template for your personal use
- Shared Templates, to make the template available to all users
- Browse, to navigate to a different folder

Note: You can save a template if you are assigned the Create New Templates user privilege.

9. To generate the PDF report, tap Generate Report.
10. When the File Download prompt appears, select Open to open the file immediately or Save to save the file to your C drive.
11. To view a saved file, navigate to the file location and open it in a PDF viewer.



Viewing the Audit Log

You can view the audit log entries for the data file using the Audit Log viewer found in the Run Information tab in the Analysis module.

To view the Audit Log

- ▶ In the Analysis module, select the Run Information tab, and then select the Audit Log tab to display the audit log entries.

Run Details | Audit Log

Datafile Name: C:\ProgramData\Bio-Rad\QXONERegulatory\Temp\TempRunDataFiles\cpjhrkz.ulg\AuditLog.json

User Name: All Change Type: All

Collapse All Expand All

Change#	Date	User Name	Product Name	Product Version	User Full Name	Computer	Reason For Chan.	Type
2	9/16/2021	USPLEC0TKYF2\...	QX ONE Softwa...	1.2.0.134		USPLEC0TKYF2		Run
1	9/16/2021	USPLEC0TKYF2\...	QX ONE Softwa...	1.2.0.134		USPLEC0TKYF2		Run

File Version 2 saved by **USPLEC0TKYF2\QX_Super** (full name) at **9/16/2021 10:08:05 AM** on **USPLEC0TKYF2** version **QX ONE Software Regulatory Edition**

The following are the audit changes:

1)
Change Type **RunEnd** Description **Run End Status: Success**

Run Details | Audit Log

Datafile Name: C:\ProgramData\Bio-Rad\QXONERegulatory\Temp\TempRunDataFiles\cpjhrkz.ulg\AuditLog.json

User Name: All Change Type: All

Collapse All Expand All

Change#	Date	User Name	Product Name	Product Version	User Full Name	Computer	Reason For Chan.	Type
2	9/16/2021	USPLEC0TKYF2\...	QX ONE Softwa...	1.2.0.134		USPLEC0TKYF2		Run
		Change Type	New Value	Old Value			Description	
		RunEnd					Run End Status: Success	
1	9/16/2021	USPLEC0TKYF2\...	QX ONE Softwa...	1.2.0.134		USPLEC0TKYF2		Run
		Change Type	New Value	Old Value			Description	
		RunStart					Run Started	

File Version 2 saved by **USPLEC0TKYF2\QX_Super** (full name) at **9/16/2021 10:08:05 AM** on **USPLEC0TKYF2** version **QX ONE Software Regulatory Edition**

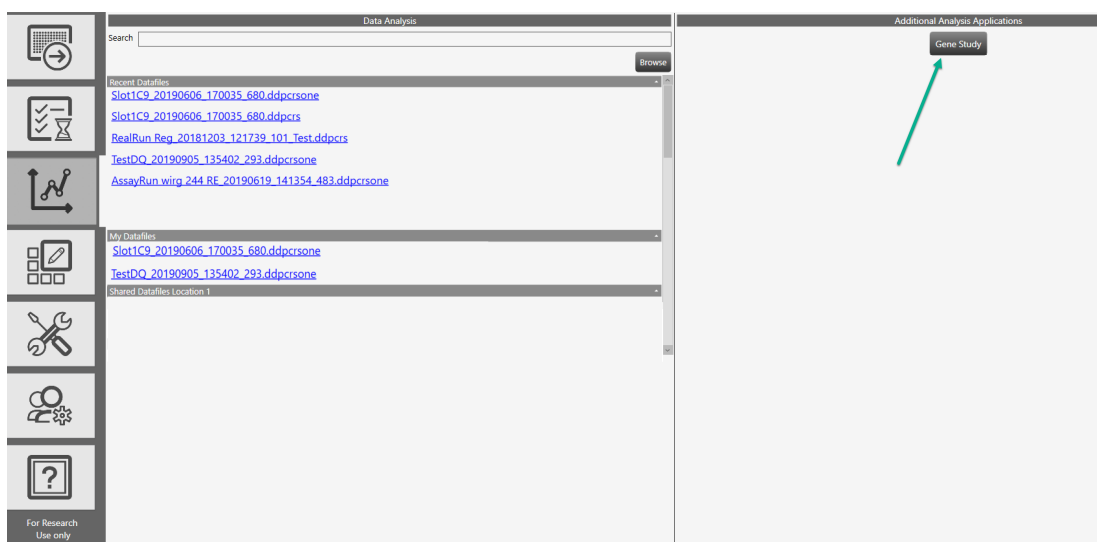
The following are the audit changes:

1)
Change Type **RunEnd** Description **Run End Status: Success**

Chapter 6 Gene Study Module

You access the Gene Study module from the Data Analysis window.

Note: The Gene Study module is not available from the touch screen computer.

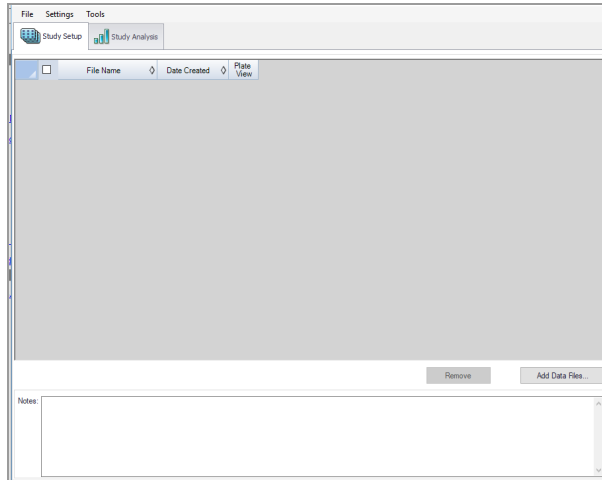


To create a gene study, you add one or more data files and then compare gene expression data from one or more ddPCR experiments.

Note: The maximum number of samples you can analyze in a gene study is limited by the size of the computer's RAM and virtual memory.

To open the Gene Study module

- ▶ Click Gene Study.



The Gene Study dialog box includes two tabs:

- **Study Setup** — manages the run files in the gene study
 - Important:** Adding or removing data files in a gene study does not change the data in the original file.
- **Study Analysis** — displays the gene expression data for the combined runs.

From these tabs you can add files to set up a gene study, analyze your data in charts and plots, and run reports on the gene study data.

Gene Study Options

The Gene Study module provides the menus and corresponding options described below.

- **File** — Open, save, and close the gene study, and add files
- **Settings** — Restore the default layout
- **Tools** — Create a report

To open a gene study file

1. Tap File → Open.
2. In the Open dialog box, navigate to and select the data file, and then tap Open.

To save a gene study file

1. Tap File and select Save or Save As.
2. If prompted, enter a file name and tap Save.
3. If prompted to overwrite an existing file, tap Yes or No.

To close a gene study file

- ▶ Tap File → Close.

Note: If you have not saved the file, an advisory prompt appears.

To add data files

1. Tap File → Add Data Files.
2. In the Open dialog box, navigate to the data files to be added to the study.
3. Select one or more files and then tap Open to add the files to the Gene Study window.

To restore default settings

- ▶ Tap Settings → Restore default settings.

Note: At least one modified data file must be open.

To generate a report

- ▶ See [Gene Study Reports on page 146](#).

Setting up the Gene Study

Use the Study Setup window to

- Add data files to include in the study
- Remove data files from the study
- Select data files for viewing and analysis
- Show the plate view for a data file

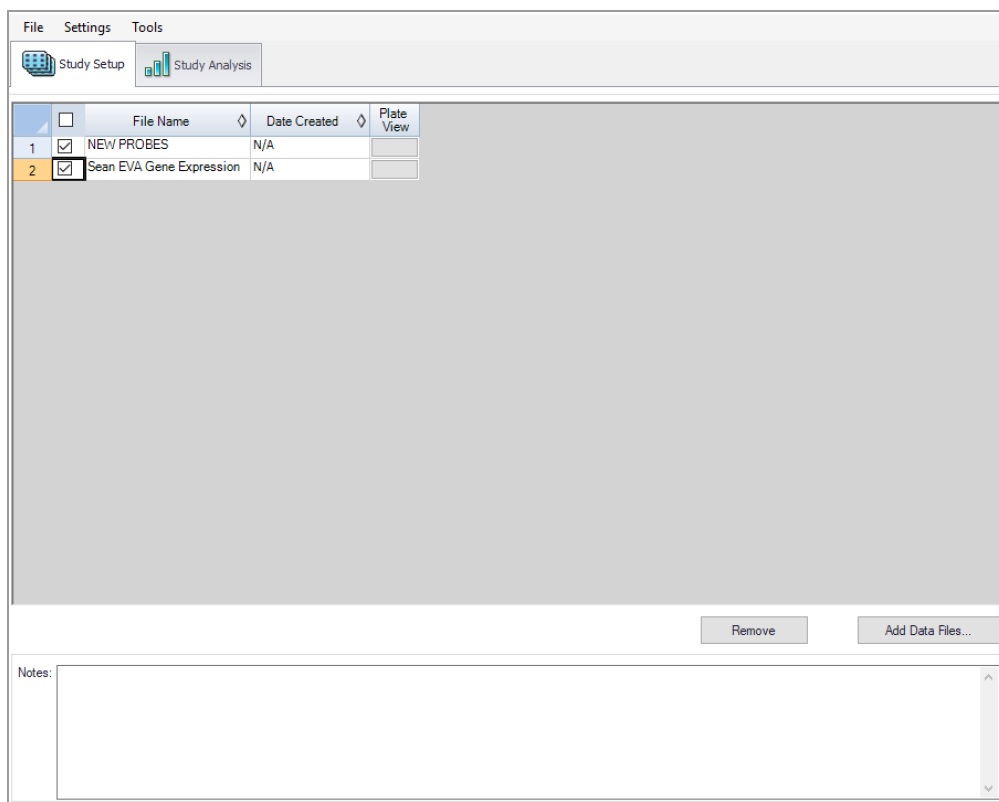
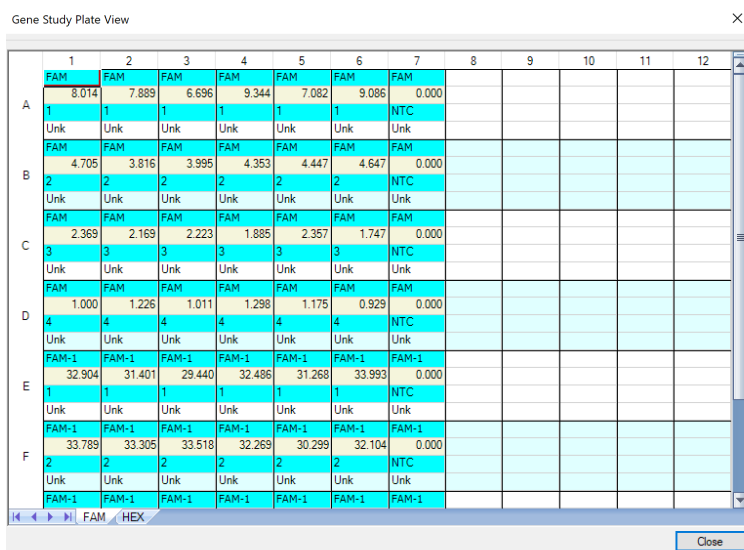


Table 26 defines each column in Study Setup.

Table 26. Gene Study Setup Fields

Column Title	Description
File Name	Name of the data file
Date Created	Date the file was imported into the Gene Study module
Plate View	Opens a map of the plate with the data for each dye in each well included in the Gene Study

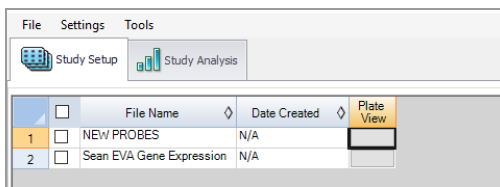


Adding Data Files

To add data files

1. On the Study Setup tab, tap Add Data Files.
2. In the Open dialog box, navigate to the data files to be added to the study.
3. Select one or more files and then tap Open.

The files are added to the Study Setup window.



Removing Data Files

To remove data files

- ▶ Select the checkbox next to the file and then tap Remove.

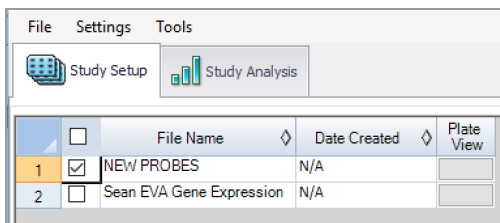
The file is removed from the Study Setup window.

Note: The Remove button is disabled until you select a file.

Selecting Data Files for Analysis

To select data files for analysis

1. Select the checkboxes next to the files to be included in the analysis.

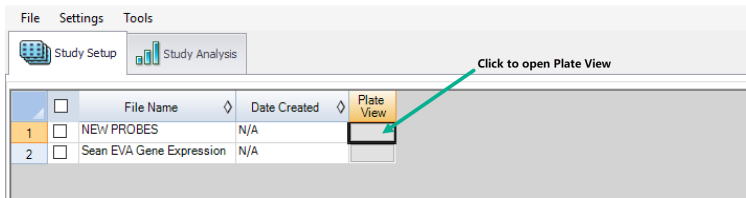


2. Select the Study Analysis tab to see the analysis results.

Showing the Plate View

To show the plate view

1. In the Plate View column, tap the button for the plate view to be displayed.



The Plate view appears.

The screenshot shows a window titled 'Gene Study Plate View' containing a grid with 12 columns and 6 rows (A-F). The grid contains numerical values, 'FAM', 'Unk', and 'NTC' labels. A status bar at the bottom shows 'FAM / HEX' and a 'Close' button.

	1	2	3	4	5	6	7	8	9	10	11	12
A	FAM 8.074	FAM 7.889	FAM 6.696	FAM 9.344	FAM 7.082	FAM 9.086	FAM 0.000					
	1	1	1	1	1	1	NTC					
	Unk	Unk	Unk	Unk	Unk	Unk	Unk					
B	FAM 4.705	FAM 3.816	FAM 3.995	FAM 4.353	FAM 4.447	FAM 4.647	FAM 0.000					
	2	2	2	2	2	2	NTC					
	Unk	Unk	Unk	Unk	Unk	Unk	Unk					
C	FAM 2.369	FAM 2.169	FAM 2.223	FAM 1.885	FAM 2.357	FAM 1.747	FAM 0.000					
	3	3	3	3	3	3	NTC					
	Unk	Unk	Unk	Unk	Unk	Unk	Unk					
D	FAM 1.000	FAM 1.226	FAM 1.011	FAM 1.298	FAM 1.175	FAM 0.923	FAM 0.000					
	4	4	4	4	4	4	NTC					
	Unk	Unk	Unk	Unk	Unk	Unk	Unk					
E	FAM-1 32.904	FAM-1 31.401	FAM-1 29.440	FAM-1 32.486	FAM-1 31.268	FAM-1 33.993	FAM-1 0.000					
	1	1	1	1	1	1	NTC					
	Unk	Unk	Unk	Unk	Unk	Unk	Unk					
F	FAM-1 33.789	FAM-1 33.305	FAM-1 33.513	FAM-1 32.269	FAM-1 30.299	FAM-1 32.104	FAM-1 0.000					
	2	2	2	2	2	2	NTC					
	Unk	Unk	Unk	Unk	Unk	Unk	Unk					
	FAM-1	FAM-1	FAM-1	FAM-1	FAM-1	FAM-1	FAM-1					

2. Click Close to close the view.

Gene Study Reports

Use the Gene Study Report dialog box to arrange the gene study data into a report. Table 34 lists all the options available for a gene study report.

Table 27. Gene Study Report Categories

Category	Option	Description
Header		
	Report Information	Date, user name, data file name, data file path, and the selected well group
	Gene Study File List	List of all the data files in the gene study
	Notes	Notes about the data report
Study Analysis Bar Chart		
	Analysis Settings	List of the selected parameters
	Chart	Gene expression bar chart showing the data
	Target Names	List of targets in the gene study
	Sample Names	List of samples in the gene study
	Data	Spreadsheet that shows the data
	Target Stability	Target stability data
	Inter-run Calibration	Inter-run calibration data
Study Analysis Clustergram, Scatter Plot, Volcano Plot, and Heat Map		
	Analysis Settings	Settings for each chart type
	Chart	Gene expression chart showing the data
	Data	Spreadsheet listing the data in each target

Creating a Gene Study Report

Before creating a report, make any needed adjustments to the gene study data and charts.

To create a gene study report

1. Select Tools → Reports in the Gene Study menu to open the Report dialog box.
2. Select the options you want to include in the report.

The report opens with default options selected. Select or clear the checkboxes to change whole categories or individual options within a category.

For information on the available options to display, see [Gene Study Reports on page 146](#).

3. Change the order of categories and items in a report.

Drag the options to the required position. Note that Items can be reordered only within the categories to which they belong.

4. Click Update Report to update the Report Preview window with any changes.
5. Print or save the report:
 - a. Click the Print Report button on the toolbar to print the current report.
 - b. Select File → Save to save the report in PDF, MHT or MHTML file format and select a location to save the file.

Note: MHT and MHTML are Microsoft formats.
 - c. Select File → Save As to save the report with a new name or in a new location.
6. (Optional) To save the current report settings as a template, select Template → Save or Save As.

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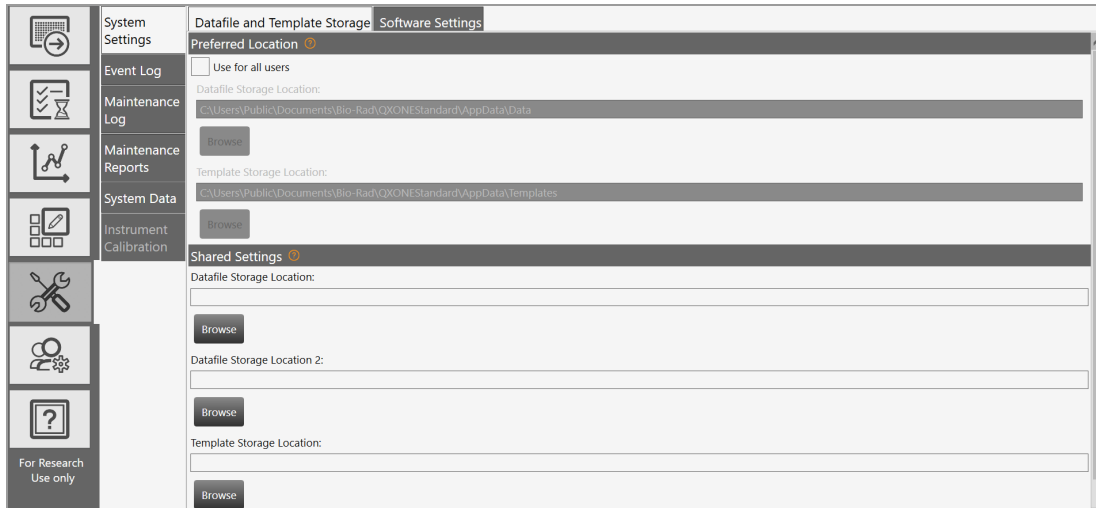
Chapter 7 System Utilities

From the System tab, you can manage tasks related to the instrument, software, data, and storage.

- **System Settings** — View shared and assigned storage locations, and select an alternate graphics rendering method.
- **Event Log** — View logged data about all software activities.
- **Maintenance Log** — Record maintenance activities.
- **Maintenance Reports** — PDF maintenance records from Bio-Rad maintenance.
- **System Data** — Archive raw data to clear up space in your primary storage areas, access data for troubleshooting, and use the data recovery function.

System Settings Tab

When you select the System tab, the System Settings window opens by default.



- Use the Datafile and Template Storage tab to view storage locations:
 - **Preferred Locations** — if the checkbox selected, storage for all users is limited to a single folder for data files and a single folder for templates.
 - **Shared Settings** — if the Preferred Locations checkbox remains cleared, then shared locations can be defined, but remain optional. Users can choose to save their files to their personal folders specified in User Preferences or to the shared location.

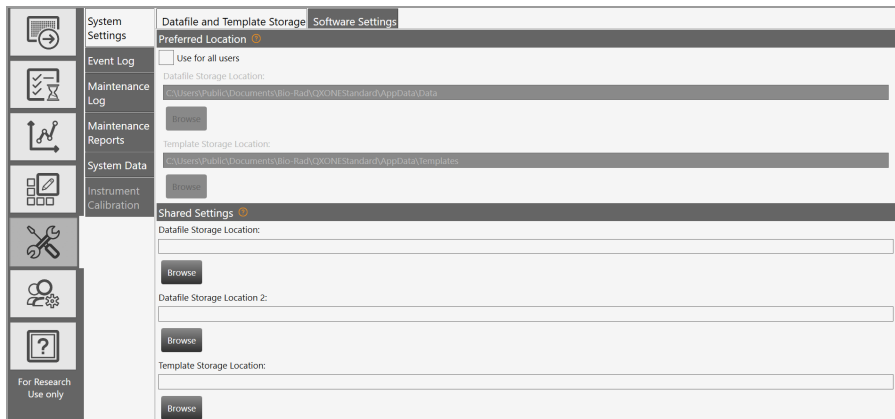
Note: The system administrator specifies shared and preferred storage locations, and can also define a backup location for data file storage if the priority folder is full.

- Use the Instrument tab to select the instrument model that is connected to QX ONE Software.
- Use the Software Settings tab to change the graphics rendering method.

Preferred Location

If the administrator sets Preferred Location file paths, then data files and templates for all users are automatically saved to the specified folders. Preferred Locations override selections in individual user preferences.

Important: Only users assigned the System Settings user privilege can set preferred locations.



To specify preferred locations

1. Select the Use for all users checkbox.
2. (Optional) Keep the default paths or modify them to alternative secure storage locations.
3. Tap Save.
4. When the confirmation message appears, tap OK.

Shared Settings

Under Shared Settings, you can choose to save your files to locations that are available to all users.

The screenshot shows the 'System Settings' window with a sidebar on the left containing categories like System Settings, Event Log, Maintenance Log, Maintenance Reports, System Data, Reprocess Data, Instrument Calibration, Instrument Check, and Tools. The main area is titled 'Datafile and Template Storage' and 'Instrument'. It includes a 'Preferred Location' field with a help icon, a checked 'Use for all users' option, and fields for 'Datafile Storage Location' and 'Template Storage Location' with 'Browse' buttons. A red box highlights the 'Shared Settings' section, which contains a 'Datafile Storage Location' field with the text '<location available to all users>', a 'Browse' button, a 'Datafile Storage Location 2' field with the text '<backup location available to all users>', another 'Browse' button, a 'Template Storage Location' field, and a 'Save' button.

The software allows the software administrator to set a primary storage folder and a backup storage folder. Bio-Rad recommends routinely checking available storage space and if necessary, using the Archive function.

Important: Only users assigned the System Settings user privilege (typically your software administrator) can change storage locations in the System Settings window.

To specify shared folder locations

1. In each of the storage path fields, enter a file path or tap Browse to search for the folder.
2. Tap Save.
3. When the confirmation message appears, tap OK.

Software Settings

The Software Settings tab provides an option to modify the chart rendering process to improve the chart appearance.

Important: The poor rendering is associated with Intel graphics cards only. For more information, contact Bio-Rad Technical Support. Do not change the setting unless instructed to do so by Bio-Rad Technical Support.

Datafile and Template Storage | Software Settings

Chart Settings

In some cases, the software may struggle rendering charts due to a known defect with some Intel graphics cards. Limited testing has shown that modifying the anti-aliasing method may help improve performance. Please only modify this setting if instructed to do so by Bio-Rad Technical Support. A system restart is required to apply this setting.

Default

Alternate

Save

Complete the following steps if directed to do so by Bio-Rad Technical Support.

To change the graphics rendering method

1. Under Chart Settings, tap Alternate.
2. Click Save.
3. Close QX ONE Software.
4. To enable the change, restart the touch screen computer, and then reopen the software.

System Log Files

From the System tab, you can access log files for system and software events (event log), and maintenance activities (maintenance log).

Event Log

Users who are assigned the Maintenance user privilege can view the system event log, which contains timestamped information on all software activities.

Log File: QXONEStandard.History.log

Open Log... PDF Password PDF Report

Date Time	Message	Severity	User Name
11/4/2021 9:19:49 AM	System Settings Changed. Preferred Location - Datafile Storage Location Changed...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 9:14:37 AM	System Settings Changed. Preferred Location - Template Storage Location Change...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_EXIT_HOTEL_RFID_ERROR_CORR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_EXIT_HOTEL_RFID_ERROR_CORR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:52 AM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:47 AM	There was valid instrument info when comparing information acquired from the Q...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:46 AM	There was valid instrument info when comparing information read from the Calibr...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:46 AM	Connected to instrument (Try 1) - Serial Number - SIMULATOR, FW Version - 221.8...	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:38 AM	User Logged in. User Name: QX_Super, User Full Name:	Info	USPLEC0TKYF2\QX_Super
11/4/2021 8:52:24 AM	Application StartUp. Application Version: 1.2.0.200, OS Version: Microsoft Windows...	Info	USPLEC0TKYF2\QX_Super
11/2/2021 2:13:17 PM	Application Closed	Info	USPLEC0TKYF2\QX_Super
11/2/2021 2:10:47 PM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/2/2021 2:10:47 PM	Instrument Error Cleared: Code: ERROR_CHASSIS_ENTRY_HOTEL_RFID_ERROR_COR...	Error	USPLEC0TKYF2\QX_Super
11/2/2021 2:10:47 PM	Instrument Error Cleared: Code: ERROR_CHASSIS_EXIT_HOTEL_RFID_ERROR CORR...	Error	USPLEC0TKYF2\QX_Super

Selected Row Message

System Settings Changed. Preferred Location - Datafile Storage Location Changed. Old Value: C:\Users\Public\Documents\Bio-Rad\QXONEStandard\AppData\Data New Value: C:\Users\Public\Documents\Bio-Rad\QXONEStandard\AppData\

For Research Use only
Version 1.2.0

To view the Event Log

1. Select the System Utilities tab.



2. Select Event Log.
3. Tap Open Log to choose either the debug log or the history log.
4. Review the log entries.
5. (Optional) To automatically generate and display a PDF document, tap PDF Report.

Tip: To restrict access to the file, you can assign a password. Select the PDF Password check box and then enter a password in the field. The file is saved in the Log Reports folder and can be opened only by entering the password.

Maintenance Log

All users can view the maintenance log, which contains a list of maintenance records. The Maintenance Log tab is available from the instrument touch screen only. Users who are assigned the Maintenance user privilege can set up maintenance records, specify associated activities, and generate PDF reports.

Tip: This guide also contains a form on which you can document completion of maintenance activities. For information, see .

The screenshot shows the Maintenance Log interface. On the left is a navigation menu with options: System Settings, Event Log, Maintenance Log, Maintenance Reports, System Data, Instrument Calibration, and Instrument Calibration. The main area displays a table of maintenance log entries. The table has columns for Date Time, User, Product Version, Firmware Version, and Activity. One entry is visible: Date Time: 11/4/2021, User: USPLECOTRYF2/QX_Super, Product Version: 1.2.0, Firmware Version: 221.8272, Activity: System Flush. Below the table is a form for adding a new activity, with fields for Date Time (11/4/2021 12:57:32 PM), User (USPLECOTRYF2/QX_Super), Product Version (1.2.0), and Firmware Version (221.8272). The Activity field contains 'System Flush'. There are 'Cancel' and 'Save' buttons at the top right, and a 'PDF Report' button at the bottom right.

Date Time	User	Product Version	Firmware Version	Activity
11/4/2021	USPLECOTRYF2/QX_Super	1.2.0	221.8272	System Flush

To add or view an activity

1. Select the System Utilities tab.



2. Select Maintenance Log. Note that activities that are already scheduled appear in the grid, sorted by newest activity first.
3. Do one of the following:
 - Scroll to view a particular activity.

Important: You can view or add static activities; you cannot modify them.

- Add an activity; tap the + icon next to New Activity.

A line item appears in the bottom section, with all fields except Activity completed automatically.

4. In the Activity field in the bottom section, type the activity into the Activity field, and tap Save.
5. Repeat to add another activity.
6. (Optional) Tap PDF Report to create a report of the added activities.

Maintenance Reports

Reports generated from the Bio-Rad service engineer when performing maintenance on your instrument are stored on the Maintenance Reports tab. The Maintenance Reports tab is available from the instrument touch screen only.

To open a report

- ▶ Tap the list item.

	System Settings	Color Calibration Reports
		ColorCalibrationReport_2019-07-16-10-09-23-AM
	Event Log	ColorCalibrationReport_2019-07-09-04-06-10-PM
		ColorCalibrationReport_2019-07-02-04-56-01-PM
	Maintenance Log	Volume Calibration Reports
		VolumeCalibrationReport_2019-07-16-02-41-15-PM
	Maintenance Reports	System Check Reports
		SystemCheckReport_2019-08-27-10-11-00-AM
		SystemCheckReport_2019-08-26-02-03-08-PM
		SystemCheckReport_2019-08-23-04-31-37-PM
		SystemCheckReport_2019-08-22-04-21-40-PM
	System Data	SystemCheckReport_2019-08-13-10-35-36-AM
		SystemCheckReport_2019-07-17-09-33-24-AM
	Instrument Calibration	

Following is an example of a Color Calibration report:

BIO-RAD		
Color Calibration and Carryover Report		
Username of the Person who did the Run:RRRAD		
Report Generation Date and Time:7/10/2019 09:03:29 PM		
Instrument Serial Number:CHARLIE-1		
Firmware Version:1.2790		
Software Version:1.0.774.0628		
Software:QX ONE Software Standard Edition		
Lot Information		
GC/MS Cartridge:18250		
Droplet Generation 08080208101.080208101		
Droplet Reader 08080208101.080208101		
Calibration Effective Date:7/7/2019 03:26:11 PM		
Color Calibration Results	Carryover Test Result	# of carryover events
Channel 1 (DMS)	Pass	0
Channel 2 (DMS/VE)	Pass	
Channel 3 (DMS)	Pass	
Channel 4 (DMS)	Pass	
Low Bleb	Fail	
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System Data

In the System Data window, you can

- Archive raw data
- Access troubleshooting data
- Recover data

Archiving Raw Data

When the storage space on the QX ONE instrument touch screen QX ONE Droplet Digital PCR System approaches the limit displayed under Disk Space, you can free up space by moving raw data to an archive storage folder in a different location, such as a network or USB drive.

Important: You must be assigned the System Data user privilege to archive data.

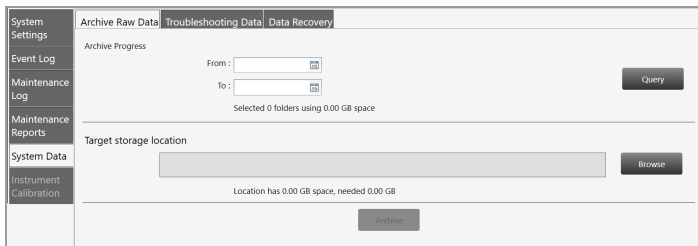
To archive raw data

1. Select the System Utilities tab.



2. Select System Data.

The Archive Raw Data tab is selected by default.



3. Under Archive Progress, tap the calendar icons and select a From date and a To date to define a date span.
4. Tap Query to search for files dated within the date span.
5. Tap Browse to search for and select the target storage location.
6. Tap Archive.

Troubleshooting Data

If issues occur with the QX ONE Software, you can access data to assist in troubleshooting the problem.

Important: You must be assigned the System Data user privilege to access troubleshooting data.

To access data for troubleshooting purposes

1. Select the System Settings tab.



2. Select System Data > Troubleshooting.

3. Tap the From and To calendar icons to select a date range.
4. Select any of the following checkboxes:
 - System Logs
 - Raw Plate Data
 - Version Data
 - Calibration Data
5. Tap Browse and navigate to the data folder in the target storage location.
6. Tap Collect Data.

Recovering Data

If a run fails on the QX ONE Droplet Digital PCR System, you can use the Data Recovery tab in System Data to recover data that has been saved to a temporary file.

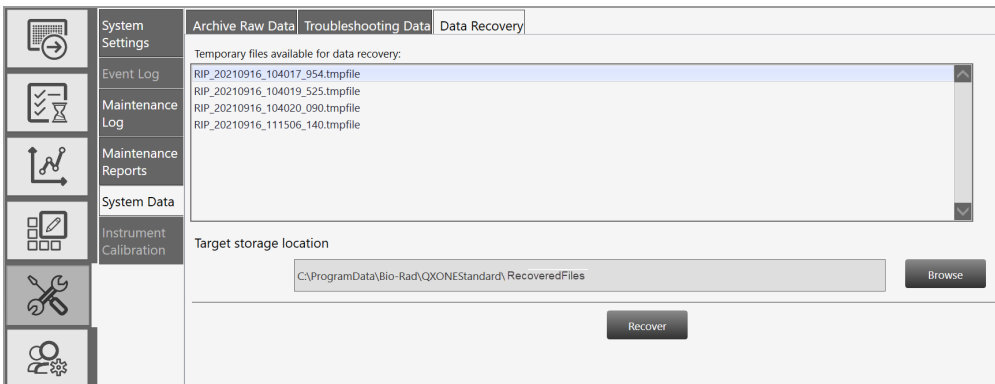
Important: You must be assigned the System Data user privilege to access the Data Recovery tab.

To create a `..ddpcrsone` file from the data in the temporary file

1. Tap the System Utilities tab.



2. Tap System Data, and then tap Data Recovery.

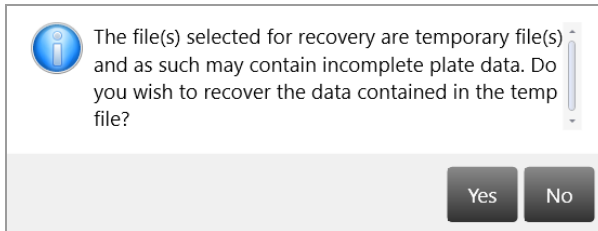


Temporary files that are available for conversion are listed in the top pane, which is scrollable.

3. Tap a file, and then tap Browse

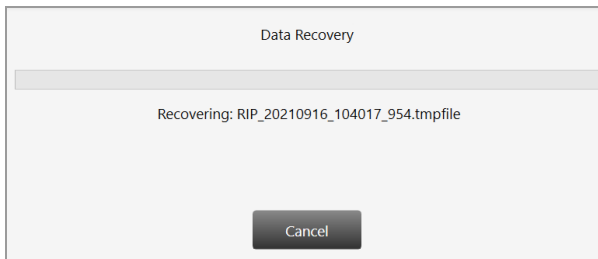
4. Navigate to the target storage location on your computer or network, and then click Recover.

The following advisory message appears.



5. Click Yes.

A dialog box appears with a progress bar, and automatically closes when the conversion is complete.



The .ddpcrsone file is stored in the folder you specified.

System Calibration

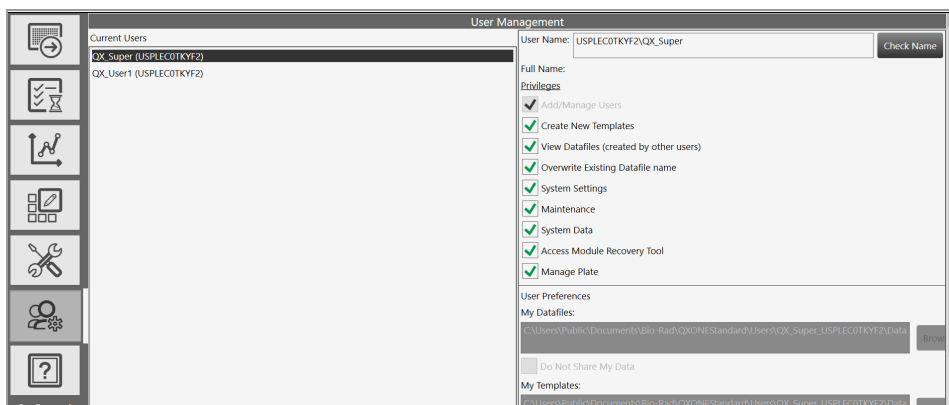
You cannot execute runs on the QX ONE Droplet Digital PCR System unless the instrument is properly calibrated. Only a Bio-Rad service engineer can calibrate your instrument and use the Instrument Calibration options in QX ONE Software. The option is available from the touch screen only, and is disabled for all other users.

If your instrument requires service, contact Bio-Rad Technical Support.

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Chapter 8 Managing Users

Use the User Management window to add, change, or remove QX ONE Software users, and set or change user privileges and preferences.



The Bio-Rad service engineer sets up an initial user with all privileges, including Add/Manage users, on the touch screen. Your software administrator can use this account to set up additional users with appropriate privileges.

You can set up local or domain accounts. If the instrument touch screen computerconnected to the QX ONE Droplet Digital PCR System

- Cannot access your company's network, your IT department or system administrator can set up user names as local Windows accounts.
- Can access your company's network, QX ONE Software can recognize the Active Directory user names.

You can create user accounts with any user name convention and password character structure, as long as it complies with your organizational requirements. The software is designed to validate each user against the name it finds in either the Active Directory or local domain, so users must log in with the proper domain and user name.

Adding Users

Before you can add users to QX ONE Software, you must be logged in with the initial superuser account, or another account that is assigned the Add/Manage Users privilege.

Important: Before you begin, ensure that all users either have local Windows user accounts on the local computer or user accounts in Active Directory (network domain).

To add a user

1. Open QX ONE Software and sign into the application.
2. Tap the User Management tab on the left



3. In the User Name field on the right, enter the user name as follows:
 - If the computer is connected to a network and you are using Active Directory accounts, enter <domain name>/<user name>. For example, **global/johnsmith**.

Important: Active Directory users must log in every time with the domain name preceding the user name.

- If the computer is not connected to a network, enter <local computer name>/<user name>. For example, **analysiscomputer/johnsmith**.

Important: To locate the computer name, right-click on the yellow folder in the lower menu bar and select File Explorer. When the dialog box appears, the computer name is located at the top of the left panel. Local users are not required to reenter the computer name after the initial login.

4. Tap Check Name.

One of the following occurs:

- If the software recognizes the network domain or computer name and the user name, the software displays a validation message.
- If the user is not recognized, an error message appears. Do one of the following:
 - For network users, ensure there is a working connection to the network and then verify your entry is accurate.
 - For local users, verify the entry is accurate. If the user is not set up locally or on the network, contact your system administrator for assistance.

5. When the This user is valid message appears, tap OK, and then tap Add at the bottom of the pane.

An Are you sure you want to add this user? message appears.

6. Tap Yes.

A confirmation message appears.

7. Tap OK.

8. Continue until all users are added.

Adding or Removing User Privileges

Only a user assigned the Add/Manage users privilege can add or remove user privileges. By default, individual users without privileges can set up and execute a run, open files, view and analyze results.

For descriptions of all user privileges, see [Viewing User Privileges on page 16](#).

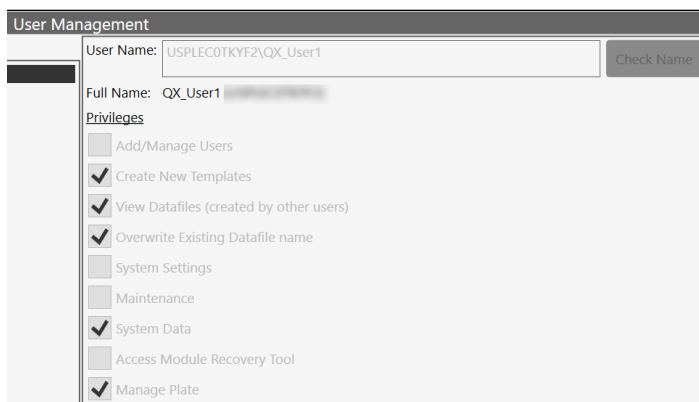


Table 28 contains a sample set of privileges assigned by user roles common to a laboratory. User roles can be defined and used in any scenario, but might be required in regulatory environments.

Table 28. Example User Roles

Privilege	Superuser	Lab Manager	Group Lead	Technician/ Student Intern
Add/manage users	✓	✓		
Create new templates	✓	✓	✓	
View data files created by other users	✓	✓	✓	✓
Override existing ddPCR file name	✓	✓	✓	
System settings	✓			
Maintenance	✓			
Archive data files	✓	✓	✓	✓

Table 28. Example User Roles, continued

Privilege	Superuser	Lab Manager	Group Lead	Technician/ Student Intern
Access the module recovery tool	✓	✓	✓	✓
Manage Plates	✓	✓	✓	

You can assign the Create new templates privilege to non-administrative roles if anyone can create and save a template. If template formats are restricted, then you should assign this permission to administrative or supervisory roles only.

Note: Bio-Rad recommends defining at least one additional superuser as a backup, as well as other administrative and standard roles based on your needs. Guest users can open shared templates, execute runs, and perform analysis but are not typically assigned other privileges.

To add or modify privileges

1. Tap the Add/Manage Users tab to open the User Management window.
2. Select a user from the Current Users list. The name appears in the User Name field. A network or computer name and backslash might appear before the user name.
3. Select or clear the checkbox for each privilege in accordance with the user's role in using the software. You can assign user privileges in any combination.
4. When the confirmation message appears, tap Yes to save the changes, and then tap OK to close the pop-up.

Removing Users

Only a user assigned the Add/Manage Users privilege can remove users. Removing a user from the software does not remove the user from other systems, such as Windows, or databases.

To remove a user

1. Tap the Add/Manage Users tab to open the User Management window.
2. In the Current Users pane, select the user and tap Remove. QX ONE Software displays a confirmation message.
3. Tap Yes to remove the user, and then tap OK to close the dialog box.

Modifying User Preferences

Users assigned the Add/Manage Users privilege can change the preferences for other users. Individual users can also change their own preferences.

To modify a user's preferences

1. Tap the Add/Manage Users tab, and then enter the user name.
2. Change any of the following preferences for the user:
 - Enter a different file path for user data files and templates, and choose to keep them private.
Important: You can also specify Preferred Locations in System Settings, to override all file paths specified in individual preferences. For information, see [System Settings Tab on page 150](#).
 - Enter a different default system timeout period.
 - Enter a different number of completed plates to show in the Status section, up to a maximum of 100.
3. Tap Save. QX ONE Software displays a confirmation message.
4. Tap Yes to save the changes, and then tap OK to close the dialog box.

Appendix A Experiment Examples

This section contains setup and analysis information for the following sample experiments:

- Direct Quantification, using the Amplitude Multiplex assay type
- Copy Number Variation, using the Probe Mix Triplex assay type
- Drop-Off, using the Basic Drop-off Assay type for genome edit detection
- Direct Quantification, using the Advanced Classification Method assay type

Direct Quantification Multiplexed

You can increase the number of targets to be evaluated by using the Amplitude Multiplex option. Optionally, to expedite plate setup you can copy and paste data from one well to another, and you can tap Undo to undo an applied well setting. You cannot change the supermix that was used during data collection.

Setting Up Experiment Parameters

To set experiment parameters

1. Open the analysis data file and select the Plate Editor tab.

The screenshot displays the software interface for setting up a Direct Quantification (DQ) experiment. On the left, the 'Plate Editor' tab is active, showing a 96-well plate grid. The grid is divided into sections A through H, with columns 1 through 12. The 'Well Data' panel on the right is open, showing the following settings:

- Experiment Type:** Direct Quantification (DQ)
- Sample Descriptions:** DNA1, DNA2, DNA1, DNA1
- Sample Type:** Unknown
- Supermix:** qPCR Supermix for Probes (No c...
- Assay Type:** Amplitude Multiplex
- Target Info:** A table with 8 rows and 6 columns: Target Name, Target Type, Signal Ch1, Signal Ch2, Signal Ch3, Signal Ch4.

Target Name	Target Type	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4
1	Unkn	FAM Lo	None	None	None
2	Unkn	FAM Hi	None	None	None
3	Unkn	None	HEX Lo	None	None
4	Unkn	None	HEX Hi	None	None
5	Unkn	None	None	Cy5 Lo	None
6	Unkn	None	None	Cy5 Hi	None
7	Unkn	None	None	None	Cy5.5 Lo
8	Unkn	None	None	None	Cy5.5 Hi

2. Select one or more wells to be assigned well analysis attributes.
3. Change the experiment type to Direct Quantification (DQ), and then tap Apply.
4. (Optional) Change the sample description identifiers.
5. (Optional) Change the sample type. The default type is Unknown.

Tip: For automatic thresholding of positive control wells, you must select Pos Ctrl.
6. Under Assay Type, select Amplitude Multiplex and tap Apply. Eight target rows appear.
7. Change the target name and type (unknown or reference) for each target in the well.

The software defaults to FAM Lo, FAM Hi, HEX Lo, HEX Hi, Cy5 Lo, Cy5 Hi, Cy5.5 Lo, and Cy5.5 Hi, respectively, for each target.

8. (Optional) Change the high and low target identifiers.

Amplitude Multiplex allows for up to two assays in each channel, indicated by Lo and Hi labels. In this multiplex mode, each target may have a signal for only one channel. You can

- Select a different dye, if the channel supports two dyes (for example change HEX to VIC or VIC to HEX)
- Select a different channel for the target (for example, change FAM to HEX)
- Change Hi to Lo or Lo to Hi

9. Tap Apply.

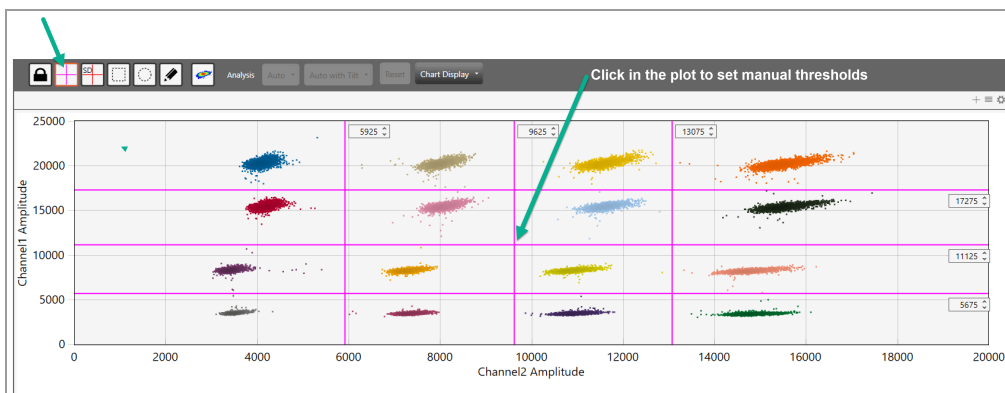
Viewing and Adjusting Results

Automatic thresholding is not available for Amplitude Multiplex experiments.

For clusters that are easily identifiable across the chart, use Threshold Lines mode to set manual thresholds. If the data is not orthogonal and the threshold lines do not adequately divide the populations of droplets, use Threshold Clusters mode to set manual thresholds.

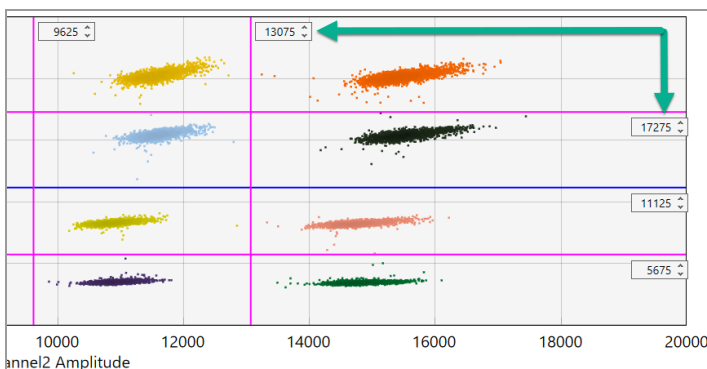
To set thresholds in the 2D Amplitude window

1. Select the 2D Amplitude tab.



2. On the toolbar, tap the Threshold Line Mode button.
3. Tap anywhere on the plot to apply “best fit” threshold lines to the data.
4. To adjust the thresholds, drag the lines horizontally or vertically in the plot area.

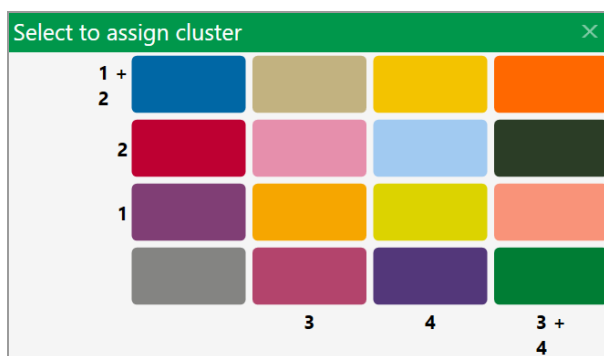
Tip: You can also enter a specific threshold value in the boxes at the end of each threshold line.



To apply and adjust manual clusters

1. Tap any of the three cluster mode buttons (square, circle, or freehand).
2. Press the left mouse button and draw the chosen shape around the cluster of droplets to be classified first.

Tip: When you release the mouse button, a pop-up tool appears to help you select the correct target combination. Target names are shown along the two axis based on the signal values assigned during plate setup.



3. To classify droplets as positive or negative for each given target, select the colored box that best represents the location of the cluster of droplets.

Copy Number Variation Triplexed

A CNV experiment with probe mix triplexing uses two targets and a reference in two groups of three to produce analysis data. Optionally, to expedite plate setup you can copy and paste data from one well to another, and you can tap Undo to undo an applied well setting.

Setting Up Experiment Parameters

To set experiment parameters

1. Open the analysis data file and select the Plate Editor tab.
2. Select one or more wells to be assigned well analysis attributes.
3. Set the experiment type to Copy Number Variation (CNV), and tap Apply.
4. (Optional) Change the sample description identifiers.
5. (Optional) Change the sample type. The default type is Unknown.

Tip: For automatic thresholding of positive control wells, you must select Pos Ctrl.

Note: You cannot change the supermix that was used during data collection.

6. Tap Apply.
7. From the Assay Type dropdown list, select Probe Mix Triplex and tap Apply.

QX ONE Software displays three targets.

Important: You cannot add or delete triplex targets.

8. Enter target names and select the target type (unknown or reference) for each target in the well.

This creates two groups of three targets each.

9. Assign the targets as follows:

Group 1

Target	Target Type	Signal Ch1	Signal Ch2	Ref Copies	Plot?
Target 1	Unknown	FAM	None	N/A	N/A
Target 2	Unknown	None	HEX/VIC	N/A	N/A
Target 3	Reference	FAM	HEX/VIC	2	Yes

Group 2

Target	Target Type	Signal Ch3	Signal Ch4	Ref Copies	Plot?
Target 4	Unknown	Cy5	None	N/A	N/A
Target 5	Unknown	None	Cy5.5	N/A	N/A
Target 6	Reference	Cy5	Cy5.5	2	Yes

10. Tap Apply.

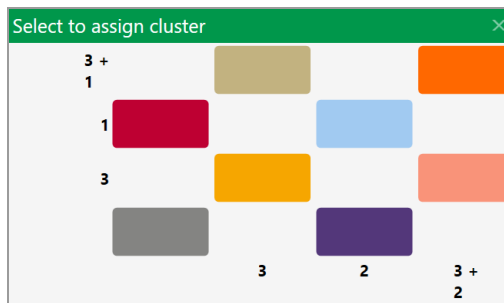
Viewing and Adjusting Results

Note: Linear thresholding is not available for Probe Mix Triplex experiments.

To see the results

1. After all wells are configured, select the 2D Amplitude tab to evaluate the data and manually set clusters.
2. Tap any of the three cluster mode buttons (square, circle, or freehand).
3. Press the left mouse button and draw the chosen shape around the cluster of droplets to be classified first.

Tip: When you release the mouse button, a pop-up tool appears to help you select the correct target combination. Target names are shown along the two axis based on the signal values assigned during plate setup.



4. To classify droplets as positive or negative for each given target, select the colored box that best represents the location of the cluster of droplets.

Drop-Off Assays for Genome Edit Detection

Optionally, to expedite plate setup you can copy and paste data from one well to another, and you can tap Undo to undo an applied well setting.

This type allows two groups of two targets per well; Group 1, shown by default, with 1 target in FAM and HEX (reference), and 1 target in FAM or HEX (unknown). You can add a second group with 1 target in Cy5 and Cy5.5 (reference) and 1 target in Cy5 or Cy5.5 (unknown).

Note: The channels within each group are not interchangeable therefore FAM is always paired with HEX/VIC and Cy5 with Cy5.5.

Setting Up Experiment Parameters

To set experiment parameters

1. Open the analysis data file and select the Plate Editor tab.
2. Select one or more wells to be assigned well analysis attributes.
3. Set the experiment type to Drop-Off (DOF) and tap Apply.

Target Name	Target Type	Signal Ch1	Signal Ch2	Signal Ch3	Signal Ch4	Ref Copies
1	Ref	FAM	HEX	None	None	2
2	Unkn	FAM	None	None	None	
3	Ref	None	None	Cy5	Cy5.5	2
4	Unkn	None	None	Cy5	None	

4. (Optional) Change the sample description identifiers.
5. (Optional) Change the sample type. The default type is Unknown.

Tip: For automatic thresholding of positive control wells, you must select Pos Ctrl.

Note: You cannot change the supermix that was used during data collection.

6. Tap Apply.

QX ONE Software automatically assigns the assay method as Basic Drop-Off.

7. Enter the target names, and then designate one target as Reference and the other as Unknown.

The Reference target enables ratio calculation of results.

8. Tap Apply.

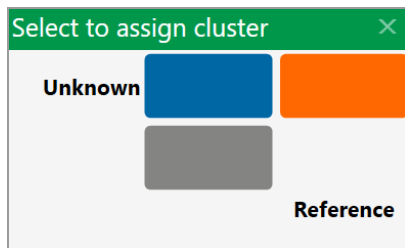
Viewing and Adjusting Results

Thresholding is not available for Drop Off experiments.

To apply and adjust clusters

1. After all wells are configured, select the 2D Amplitude tab to evaluate the data and manually set clusters.
2. Tap any of the three cluster mode buttons (square, circle, or freehand).
3. Press the left mouse button and draw the chosen shape around the cluster of droplets to be classified first.

Tip: When you release the mouse button, a pop-up tool appears to help you select the available cluster assignments. Target names are shown along the two axis based on the signal values assigned during plate setup.



4. To classify droplets as positive or negative for each given target, select the colored box that best represents the location of the cluster of droplets.

Direct Quantification with the Advanced Classification Method

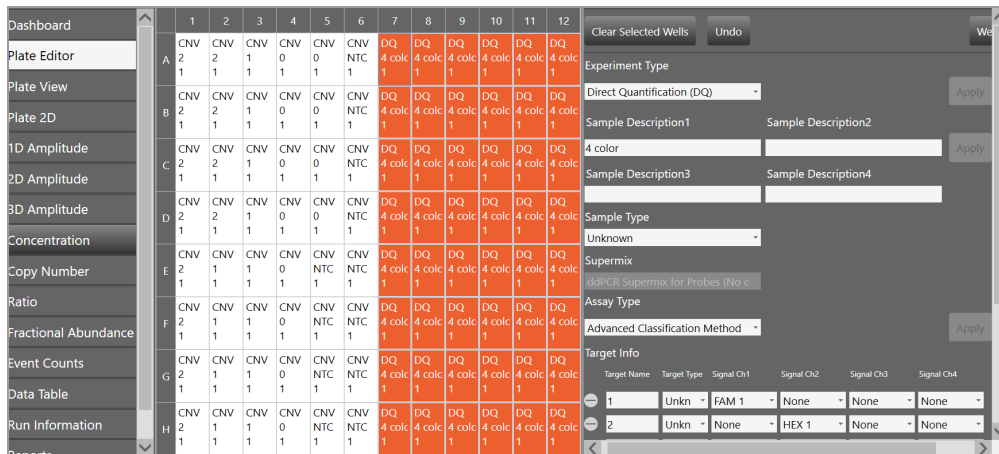
The Advanced Classification Method analysis mode allows the user complete control of droplet identification, and does not force or preassign any clusters. This allows a higher degree of multiplexing through radial dye mixing. Optionally, to expedite plate setup you can copy and paste data from one well to another, and you can tap Undo to undo an applied well setting.

Important: This mode is intended for experienced users of Droplet Digital PCR.

Setting Up Experiment Parameters

To use the advanced classification method

1. Open the analysis file and select the Plate Editor tab.



2. Select one or more wells to be assigned well analysis attributes.
3. Set the experiment type to Direct Quantification (DQ) or RED and tap Apply.
4. (Optional) Change the sample description identifiers.
5. (Optional) Change the sample type. The default type is Unknown.

Tip: For automatic thresholding of positive control wells, you must select Pos Ctrl.

Note: You cannot change the supermix that was used during data collection.
6. Tap Apply.
7. Under Assay Type, select Advanced Classification Method and tap Apply.
8. Use the + icon to add up to ten targets.

9. Enter the target name and type (unknown or reference) for each target in the well.
 10. (Optional) If you select Reference, you can change the number of reference copies. The default is 2.
 - If no reference is selected, the target with the highest dye concentration in the highest channel is used as the reference. For example, if there are targets in all four channels, the target in Channel 4 is used; however if there are targets only in the first three channels, then Channel 3 is the reference target.
 - If more than one reference is selected in the well, checkboxes appear to the right for using the reference in the plot.
- Note:** Each Reference target enables ratio calculations in the results.
11. Assign the first target an expected signal in a channel.
 12. Assign your last target a signal in a channel that was not selected for your first target.

Each target in between will be assigned a signal depending on mixture ratio of the target.
 13. Tap Apply to confirm all well settings.

Viewing and Adjusting Results

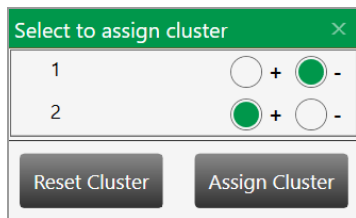
To view and adjust results

1. Tap the 2D Amplitude tab.

All droplets are unclassified by default and are colored red. Only the Threshold Cluster mode is available for setting thresholds in Advanced Classification experiments in the 2D plot.

2. Use one of the Threshold Cluster mode tools (box, circle or freehand) to assign droplet clusters to targets.

When you select a droplet cluster, a cluster assignment box appears.



3. Select a radio button to identify the composition of the cluster.

For example, if the cluster is composed of positive droplets for Target-2, select the positive radio button for Target-2 and the negative radio buttons for the remainder.

Important: For calculations to occur, you must have at least one positive cluster for each target, as well as the assigned negative cluster.

Note: The software sets aside unassigned for calculation purposes. If you are unsure of droplet/cluster composition, leave it unassigned (red).

You can view the concentration results in the data table and in the Concentration tab.

If one of your samples was identified as a Reference under AssayType, you can view a ratio of concentration for unknown versus reference in the Ratio tab.

Appendix B End User License Agreement

For research use only.

The Bio-Rad Droplet Digital PCR system is composed of a droplet generator, thermal cycler, droplet reader, and related components, in a single instrument (of the Droplet Generator and Droplet Reader and related components (collectively “Hardware”) and Bio-Rad’s proprietary QX Software and related files (collectively “Software”). The Hardware and Software are collectively referred to herein as the “System”.

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4. Ownership. As between Bio-Rad and End User, Bio-Rad owns all rights, title, interest and ownership in the Software and Documentation and all proprietary rights in the System and any subsequent releases, versions or modifications to the System. Bio-Rad's rights include, but are not limited to, all copies of the Software and Documentation and any patent rights (including but not limited to patent applications and disclosures), copyrights, trademark rights, trade secret rights, and any other intellectual property right recognized in any country or jurisdiction in the world as well as the content and related services and any suggestions, ideas, enhancement requests, feedback, recommendations or other information provided by End User or any other party relating to the System or any component thereof. Under the terms of this Agreement, End User receives only a limited right to use the Software and Documentation. The Software is protected both by United States laws and international treaty provisions. The System may include third party products. Please read our accompanying documentation help files for further information. By using the System, End User represents and warrants that it has complied and will continue to comply with the terms of use of any third party products that are covered by the System.

5. End User Responsibilities. End User is responsible for maintaining the security of End User's login information including any user names and passwords for End User's use of the System. Your computer systems must be selected, maintained, and controlled solely by You.

6. Term and Termination. This Agreement will become effective upon the first date on which End User accesses the Software and will continue perpetually unless terminated by either party in accordance with this Section 6 or, in the case of trials, as may be otherwise provided by Bio-Rad in applicable terms. Bio-Rad may terminate this Agreement immediately if End User fails to comply with any provision of this Agreement. Upon termination of this Agreement, all of End User's rights and licenses to use the Software shall cease immediately without any further action by Bio-Rad. End User shall cease all use of the Software, and shall (i) return to Bio-Rad all existing copies of the Software, or (ii) furnish Bio-Rad evidence satisfactory to Bio-Rad that the original and all copies of the Software have been destroyed. The following provisions shall survive termination of this Agreement: Section 4, and Sections 6 – 11.

7. Confidentiality. "Confidential Information" means Bio-Rad's non-public information relating to the Software, the Documentation, the System or any component thereof that may be disclosed to, or accessed by, End User through use of the System, Software and/or Documentation. End User agrees not to disclose or use any Confidential Information except as permitted in this Agreement. Access to the Confidential Information shall be restricted to the End User's employees and agents, who, in each case, need to have access to carry out a permitted use and are bound to maintain the confidentiality of such Confidential Information. The Confidential Information, and all copies of part or all thereof, shall be and

remain the exclusive property of Bio-Rad, and End User shall acquire only such rights as are expressly set forth in this Agreement and only for as long as such rights are in effect. Upon Bio-Rad's request or upon termination of this Agreement, End User shall return to Bio-Rad or destroy all copies of Confidential Information in End User's possession.

8. Indemnification. End User agrees to indemnify and hold Bio-Rad and its officers, agents, employees, partnering agencies and/or associations harmless from any claim or demand or fines or fees, including reasonable attorneys' fees, due to or arising out of End User's breach of this Agreement or violation of any applicable laws.

9. Warranty Disclaimers. Bio-Rad makes no warranties or representations concerning the Software or system or any results to be achieved through use of the software or system. Bio-Rad disclaims all warranties, express or implied, including the warranties of merchantability and fitness for a particular purpose, and all implied warranties arising from a course of dealing, usage, or trade practice. Bio-Rad does not warrant that the System will be uninterrupted or error-free.

10. LIMITATION OF LIABILITY. IN NO EVENT SHALL BIO-RAD BE LIABLE FOR ANY LOST REVENUE, PROFIT, OR DATA, OR FOR SPECIAL, INDIRECT, CONSEQUENTIAL, INCIDENTAL, OR PUNITIVE DAMAGES HOWEVER CAUSED AND REGARDLESS OF THE THEORY OF LIABILITY, ARISING OUT OF THE USE OF OR INABILITY TO USE THE SOFTWARE OR SYSTEM, INCLUDING LOSSES RESULTING FROM LOSS, MISAPPROPRIATION OR UNAUTHORIZED ACCESS TO OR MODIFICATION OF ANY END USER DATA, OR FROM MISTAKES, OMISSIONS, OR DELAYS IN ANY TRANSMISSION OF INFORMATION, OR FROM INTERRUPTIONS IN ANY TELECOMMUNICATIONS CONNECTIONS TO THE SOFTWARE OR SYSTEM, VIRUSES OR FAILURES OF PERFORMANCE, OR FROM THE IMPACT OF THE SOFTWARE OR SYSTEM ON ANY SYSTEM, EVEN IF BIO-RAD HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL BIO-RAD'S TOTAL LIABILITY TO YOU, WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EXCEED THE AMOUNT OF ANY LICENSE FEE PAID BY YOU TO BIO-RAD FOR THE SOFTWARE OR SYSTEM. The foregoing limitations shall apply even if the remedy fails of its essential purpose. Because some states or jurisdictions do not allow limitation or exclusion of consequential damages, the above limitation may not apply to End User.

11. General.

1. Compliance with Laws. You agree to comply fully with all relevant export laws, regulations, treaties, and orders ("Export Laws") to assure that neither the System nor any components thereof are (i) exported, directly or indirectly, in violation of Export Laws; or (ii) are intended to be used or are used for any purposes prohibited by the Export Laws.

2. Assignment. End User may not assign this Agreement in whole or in part without the prior written consent of Bio-Rad, except that End Users who have purchased the System may assign this Agreement (along with a transfer of the System) without such consent upon written notice to Bio-Rad in connection with a merger, acquisition, corporate reorganization or sale of all or substantially all of its assets, unless

such transaction would result in an assignment to an entity reasonably deemed to be a direct competitor of Bio-Rad. This Agreement will inure to the benefit of, and will be binding upon, the parties and their successors and permitted assigns.

3. Notices. Notices shall be given by personally delivering or mailing same by first class U.S. mail, if to Bio-Rad to: Bio-Rad Laboratories, 5731 West Las Positas Blvd., Pleasanton, CA 94588 or other address as Bio-Rad may specify in writing; and if to End User to End User at the address provided by End User during the respective purchase order, sign-up or registration process. Notice shall be deemed to have been given three (3) days after deposit in first class U.S. Mail, or if personally delivered, upon delivery.

4. Governing Law and Venue. This Agreement will be construed in accordance with and governed by the laws of the State of California, USA, without giving effect to any choice of law rule that would cause the application of the laws of any other jurisdiction. The exclusive venue for actions relating to this Agreement is the federal and/or state courts in Alameda County, California.

5. Audit Rights. Bio-Rad or a Bio-Rad agent may examine End User's System, desktop computers, laptops, servers, books and records for the purposes of verifying End User's compliance with the terms of this Agreement, upon reasonable notice and during normal business hours at End User's place of business. End User shall have the right to request that the agent acting on behalf of Bio-Rad sign an appropriate non-disclosure agreement with respect to any End User confidential information that may be viewed during an audit.

6. Relationship of the Parties. Nothing contained in this Agreement creates a joint venture, partnership, agency or similar endeavor between the parties. Each party is acting solely as an independent contractor and neither party has any power or authority to direct or indirectly bind or act on behalf of the other.

7. Agreement Construction. This Agreement (including accompanying purchase orders, if any) sets forth the entire agreement between the parties and supersedes all prior agreements, understandings and discussions regarding the subject matter hereof. No purported amendment or modification of any provision of this Agreement will be binding unless set forth in a written document agreed upon by the parties. No waiver by either party of any default of the other party will be held to be a waiver of any other or subsequent default. No waiver shall be effective unless it is in writing and is signed by the party against which it is asserted. If a provision contained or referred to in this Agreement is determined to be legally invalid or unenforceable, that provision will be ineffective to the extent of the invalidity or unenforceability without affecting the remaining provisions of the Agreement, which will continue to be valid and enforceable to the fullest extent permitted by law.

Appendix B Ordering Information

This appendix contains descriptions and catalog numbers for new or replacement items.

QX ONE Droplet Digital PCR System

Table 29 contains information on the QX ONE Droplet Digital PCR System components.

Table 29. QX ONE Droplet Digital PCR System

Product	Description	Catalog number
QX ONE Droplet Digital PCR System	<p>Instrument used for droplet generation, PCR, droplet reading, and data analysis</p> <p>This purchase includes the QX ONE Accessory Kit (formerly catalog number 12011478), which contains the following:</p> <ul style="list-style-type: none">■ PX1 GCR Sealer Support Block■ QX ONE Droplet Digital PCR System ddPCR System Waste bottles■ Keyboard■ Power cord, compatible within North America■ Warranty card	12006536
QX ONE Software	Connects to the QX ONE Droplet Digital PCR System for instrument control, assay setup, and data collection and analysis	Standard Edition, N/A Regulatory Edition, 12012078
Plate Sealer	PX1 PCR Plate Sealer	1814000

ddPCR Materials and Consumables

Table 30 contains information on additional items for performing ddPCR.

Table 30. Additional ddPCR materials and consumables

Product	Description	Catalog Number
Reagents for Probe Detection		
PCR Supermix	■ ddPCR Supermix for Probes (No dUTP)	1863023
		1863024
		1863025
	■ ddPCR Supermix for Probes	1863026
		1863010
		1863027
		1863028
	■ ddPCR Multiplex Supermix	12005909
		12005910
		12005911
	■ ddPCR Supermix for Residual DNA Quantification	1864037
1864038		
1864039		
1864040		
■ One-Step RT-ddPCR Advanced Kit for Probes	1864021	
	1864022	
DTT (dithiothreitol)	2 ml DTT	12012171
Control	ddPCR Buffer Control for Probes	1863052
QX ONE Droplet Digital PCR System Droplet Generation Oil	QX ONE Droplet Generation Oil for Probes, 15 plates	12006058
QX ONE Droplet Digital PCR System Droplet Reader Oil	QX ONE Droplet Reader Oil, 10 plates	12006057
Consumables		

Table 30. Additional ddPCR materials and consumables, continued

Product	Description	Catalog Number
Cartridge	■ GCR96 Cartridge, pk of 1	12006858
	■ GCR96 Cartridges, pk of 10	12006859
Foil plate seal	GCR96 Foil Heat Seal	12006843
Waste bottle	QX ONE Droplet Digital PCR System ddPCR System Waste bottle	12006060
Materials from Other Suppliers		
Pipets (Rainin)	■ 8-channel multichannel pipet, 2–20 µl	L8-20 XLS
	■ Single channel pipet, 2-20 µl	L-20 XLS
	■ Single channel pipet, 100–1,000 µl	L-1000 XLS
Pipet tips (Rainin)	■ 20 µl filter tips	GP-LTS-A-10µL-/F-960/10
	■ 1,000 µl filter tips	GP-LTS-A-1000µL-/F-768/8
Reagent trough	Matrix Reagent Reservoirs (Thermo Fisher Scientific)	8093
Vortexer	Any	N/A
Centrifuge	Centrifuge with plate rotor capable of at least 1,150 rcf	N/A
50 ml BD Luer-Lok Tip Syringe	Syringe for removing liquid from the overflow reservoir	309653
Services		
Bio-Rad service	QX ONE Droplet Digital PCR System IQ/OQ/PQ service	IQ 12012331 OQ 12012333 PQ 12012332

Appendix B Ordering Information



**Bio-Rad
Laboratories, Inc.**

Life Science
Group

Website bio-rad.com **USA** 1 800 424 6723 **Australia** 61 2 9914 2800 **Austria** 00 800 00 24 67 23 **Belgium** 00 800 00 24 67 23 **Brazil** 4003 0399
Canada 1 905 364 3435 **China** 86 21 6169 8500 **Czech Republic** 00 800 00 24 67 23 **Denmark** 00 800 00 24 67 23 **Finland** 00 800 00 24 67 23
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Switzerland 00 800 00 24 67 23 **Taiwan** 886 2 2578 7189 **Thailand** 66 2 651 8311 **United Arab Emirates** 36 1 459 6150 **United Kingdom** 00 800 00 24 67 23