

USER MANUAL

MATRIX SOFTWARE



8003394 Rev E

For Research Use Only. Not for use in diagnostic procedures.

Matrix Software User Manual

8003394 Rev E

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Chapter 1. Overview

This chapter presents introductory concepts about the Matrix software including an understanding of various run modes, screen variations between instruments and the intended scope of information contained in this manual.

MATRIX SOFTWARE OVERVIEW

The Matrix software used to run Revvity automated cell-counting instruments is shared by multiple product families such as Cellaca MX/PLX and Cellometer K2. In addition, default assays (identified with prefixes such as MX_, PLX_ or K2_) and report templates are included for all supported instrument types. Available assays and report templates for all instruments can be viewed in the **Manage** tab > Assays and Report Templates screens.

Note: When entering setup details, only assays for your specific instrument type will be displayed for selection. After a count is complete, report templates used in the presentation of scan results will be dynamically adjusted based on instrument consumable format variations (i.e., whether running multiple samples or a single sample).

Key elements in Matrix software functionality are described below:

- Acquiring Sample Data The Acquire tab > Setup and Preview options are sequential screens used to acquire sample data. After loading samples, entering setup details, selecting at least one well and then clicking the Preview button, you can preview live channel images and adjust instrument focus/fluorescent exposure for each channel. Clicking the Count button engages the camera to acquire sample images as specified by the selected assay, which are then processed by the Matrix imaging and pattern-recognition software to decluster, identify and count individual cells according to defined cell type parameters.
- Analyzing Scan Results The Data tab > Select, Results and Recount options are sequential screens used to analyze scan results. Once a result is selected, you can vary the image displayed by clicking available channel buttons (e.g., BR, FL1, FL2, etc.) appearing across the top of the Well View tab or by choosing another well. Data associated with the well appears below the image or can be viewed as a consolidated report including data from all wells by clicking the Summary tab. To fine-tune analysis of a scan result, click the Recount button and either select a new assay or click the View button for the current assay to edit parameters as necessary. You can also view Last Used Assay parameters which are provided for your reference.
- Setting Up Auto Exports The Matrix auto export feature allows you to select the Images (e.g., Raw Images and Colorized Images), Data (e.g., Well Level CSV, Object Level CSV and Object Level ACS) and Archive (e.g., Data Set) output file types to be exported for an assay after completion of scan analysis. In addition, ACS templates can be imported into the Matrix software and assigned to an assay. On export, data will auto populate into the specified ACS template and can launch De Novo Software FCS Express if Auto Open option is also selected and the application is installed. FCS Express is pre-installed on Cellaca PLX instruments.
- Customizing Reports The Matrix custom reporting feature allows you to assign and/or modify report
 templates to be used by assays when generating scan results. You can change the report template used for
 displaying Well View tab data and manage the Reports List associated with an assay. You can also enable up to
 five additional tabs or specify output file types (e.g., CSV, Excel, PDF and Word) to be automatically exported,
 opened or printed after completion of scan analysis.

Managing Assays, Cell Types, ACS Templates and Report Templates — The Manage tab > Assays, Cell Types,
 ACS Templates and Report Templates options display lists of these entities currently loaded in your instrument
 system. From these screens you can import/export, rename, delete or show/hide an entity in its applicable list.
 For most entities you can also view, create or use locked entities as templates to create new ones.

AVAILABLE SOFTWARE RUN MODES

In scenarios where an Operating Computer cannot always remain connected to its instrument, you can run the Matrix software in multiple modes to continue your analysis of captured sample images. In addition, you can export scan results to an alternative computer (e.g., workstation or personal laptop on which the Matrix software has also been installed) and perform sample analysis in a different location.

Note: Computers used to import and analyze scan result data when *not* connected to an instrument must meet minimum requirements (i.e., *Processor*, *Memory* and *Operating System*) as noted below to run Matrix software in *Data Analysis* or *Simulated* modes. See the user manual for your instrument regarding technical specifications.

The following software Run Modes are available.

Live Mode

If the instrument and camera are physically connected to the Operating Computer via the Revvity-provided USB Connector Cable, the *Live Mode Instrument Status* icon is displayed in the right corner of the Header Bar. Clicking this icon displays a message box containing details. *Click icon again to close message box*.



Running the software in Live mode is necessary when acquiring sample data. Some **Acquire** tab functionality (such as adjusting focus and fluorescent exposure) is *not* available unless the software is being run in Live mode.

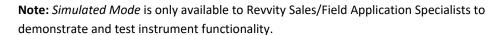
Data Analysis Mode

If the instrument and camera are *not* physically connected to the Operating Computer *or* an alternative computer is being used to continue your analysis of captured sample images, the *Data Analysis Mode* **Instrument Status** icon is displayed in the right corner of the Header Bar. Clicking this icon displays a message box containing details. *Click icon again to close message box*.



Simulated Mode

If the instrument and camera are *not* physically connected to the Operating Computer, a *Simulated Mode* uses stored/simulated images to mimic camera functionality.





MINIMUM COMPUTER REQUIREMENTS

The following *minimum* requirements apply to Operating Computers used for running the Matrix software while connected to an instrument. *Some instruments include a Revvity-provided Laptop which may be more advanced.*

For Cellaca MX and Cellometer K2

- Windows 10 PC, 64-bit
- Intel® Core i7, 2.0 GHz processor
- 16 GB RAM
- USB 3.0 Port (for MX)/USB 2.0 Port (for K2)
- GPU NVIDIA P1000 (or equivalent)
- Full HD Display Resolution: 1920 x 1080 pixels

For Cellaca PLX

- Windows 10 Professional, 64-bit
- Intel® Core i7, 2.1 GHz processor, 16 Cores
- 32 GB RAM
- USB 3.0 Port
- GPU NVIDIA A2000
- FHD+ Display Resolution: 1920 x 1200 pixels

In addition, these requirements also apply to any alternative computer (e.g., workstation or personal laptop) used to run the Matrix software in *Data Analysis* mode (i.e., while *not* connected to an instrument). *Scan results can be exported from the Operating Computer and imported onto an alternative computer for further analysis.*

MATRIX 21 CFR PART 11 MODULE OVERVIEW

The Matrix software offers a 21 CFR Part 11 module that is compliant with the Code of Federal Regulations (CFR) Title 21 Part 11 — Electronic Records: Electronic Signatures published by the U. S. Food and Drug Administration (FDA). In summary, this module ensures that an organization's use of electronic records and digital signatures in place of traditional paper-based documentation is in compliance with current FDA regulations.

Key elements in Matrix 21 CFR Part 11 module functionality are described below:

- Electronic Signatures are captured during the counting and analysis workflow using e-Sign/e-Unsign buttons and include the name of an authorized user, date/time when the signature was executed, reason for the action being performed and meaning of the signature (i.e., for the Review, Approval or Rejection of an action). If a user's assigned role does not have permissions to approve count results, a supervisor can log in to e-Sign the record on behalf of the user.
- *Electronic Records* are created as the result of linking electronic signatures to user actions ensuring that records have not been copied or falsified in any manner.
- An *Audit Trail* provides assurance regarding the integrity of an electronic record and continually monitors all users performing actions, the type of actions performed, and the date/time associated with user actions.

This module may be enabled for your instrument at time of purchase or implemented as an upgrade in the field by our Support team. See *Chapter 9. Using the 21 CFR Part 11 Module* starting on page *85* for a full description of module functionality.

UNDERSTANDING SCREEN VARIATIONS BETWEEN INSTRUMENTS

As the Matrix software is shared by multiple product families (e.g., Cellaca MX/PLX and Cellometer K2), it must account for physical differences between instruments such as:

- Display of consumable formats (i.e., multi-well plates vs. two single chambers/wells per slide)
- Load process for consumables (i.e., clickable software buttons vs. physical insertion/removal process)
- Preview focus controls (i.e., automatic internal focus vs. physical external knob)
- Default nature of assays and report templates (i.e., running and reporting on multiple samples vs. a single sample, and specifying the number of images to be captured per well)

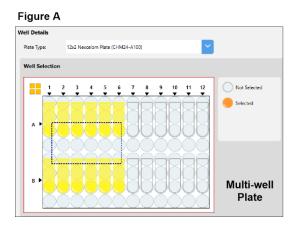
To accommodate for these differences, variations appear in the *Header Bar* and **Acquire** tab screens, in default assay file names and in the display of generated reports based on the needs of each instrument. Although the visual presentation of these differences varies, the core functionality driving these tasks remains the same.

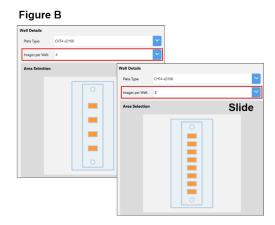
Variations in Display of Consumable Formats

The software display of consumable formats is presented in Well Details area of the Acquire tab > Setup screen.

The Cellaca MX and PLX instruments use a multi-well plate as shown in **Figure A**, below while Cellometer K2 uses a chambered slide as shown in **Figure B**. The visualization of "wells" on the slide is depicted by *Images Per Well* (i.e., 1, 4 or 8) to be captured during the scan, with each image representing a cross-section of the counting chamber. Although each slide contains two chambers, only one chamber can be inserted into the K2 instrument at a time.

As the MX and PLX allow users to select wells (i.e., a process *not* required for K2 as only one chamber can be in the instrument at a time), this feature does *not* have an impact on the preview and/or counting process other than the visual presentation of multiple scan images compared to a single scan image presented for K2.





For Cellaca PLX, the multi-well plate display shown in **Figure C** (shown on next page) varies to accommodate further instrument capabilities by allowing users to specify number of *Images Per Well* (i.e., 1 or 4) to be captured during the count. The *Images Per Well Indicator* depicts the selected number of images representing quadrants in each well. In addition, a slide holder is provided with the PLX that holds up to four low fluorescence slides as shown in **Figure D**, illustrating two wells per slide.

Well Details

Plate Type: 12x2 Nexcetom Plate (CHM24-A100)

Images per Well: 4

Well Selection

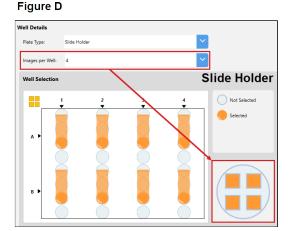
Multi-well Plate

1 2 3 4 5 6 7 8 9 10 11 12

Not Selected

Selected

Figure C



Variations in Load Process for Consumables

For instruments that have a retractable stage (e.g., Cellaca MX/PLX), the Menu Bar across the top of the screen displays an **Eject** or **Load** button based on the current position of the stage. Users will need to eject the stage in order to load or remove consumable plates. The **Eject** button becomes disabled while instrument performs a count.



No buttons are necessary for instruments that use a *Sample Slot* (e.g., Cellometer K2) as users can manually insert or remove consumable chambered slides from the slot located on the front of the instrument.



Variations in Preview Focus Controls

For instruments that use automatic internal focus (e.g., Cellaca MX/PLX), *Focus* controls are displayed while you are in the **Acquire** tab > *Preview* screen. You can use the **Auto Focus** button to perform automatic focus adjustment or the *Coarse Focus/Fine Focus* controls to move through the focal planes of sample cells. In addition, you can specify a numerical value for the vertical position of the objective lens.



For instruments that have a physical *Focus Knob* located on the right side of the instrument (e.g., Cellometer K2), users can slowly turn the knob to manually adjust sample focus. Once good focus has been achieved during initial setup, the instrument should perform most counting operations with only minor adjustments.

Variations in Default Assays/Report Templates

Default assays and report templates that were common between instruments in previous releases have been optimized to accommodate for the display needs for specific instruments (i.e., whether you are running and reporting on multiple samples vs. a single sample). Although the core nature of these assays and report templates remains the same, minor variations exist in their presentation as noted below:

- Default assay names include a prefix (e.g., "MX_" or "K2_") to identify instrument type.
- Default report templates are able to automatically adjust their presentation to display results from either multiple samples or a single sample based on your instrument type.

ABOUT THIS USER MANUAL

The intended scope of this *Matrix Software User Manual* is to provide full software-related details regarding shared functionality as it has been applied across multiple product families (e.g., Cellaca MX/PLX and Cellometer K2). This manual provides information on the following topics:

- Matrix Overview and Screen Variations
- Screen Elements and Home Tab
- Acquire Tab Functionality
- <u>Data Tab Functionality</u>
- Custom Reporting Functionality
- Managing Assays and Assays List
- Managing Cell Types and Cell Types List

- Managing ACS Templates
- Managing Report Templates and RTs List
- 21 CFR Part 11 Module Functionality
- Contacting Support and Reporting Issues
- Report Designer for WPF Reference
- Software License Details

For hardware-related details regarding the setup, safety, care and use of your instrument, refer to the specific *User Manual* and *Quick Start Guide* available for your instrument.

The following *Precaution Signifiers* are used in conjunction with the <u>A</u> symbol in this user manual:



IMPORTANT: Note indicating that to skip or move past *<content_of_note>* may result in improper functionality of the instrument.



CAUTION: Note indicating that *<content_of_note>* may damage instrument to the point where it will no longer function as expected.



WARNING: Note indicating that <content_of_note> may permanently damage instrument and cause personal injury or harm.

How Screen Variations are Identified in this Manual

As the Matrix software is shared by multiple product families, it must account for physical differences between instruments. To accommodate for these differences, screen variations are noted throughout this guide using instrument-specific sections introduced with a special statement that is *highlighted in italic font and orange text*. Be sure to choose the section containing information applicable to your instrument.

Chapter 2. Matrix Screen Elements

This chapter describes launching the software and presents basic graphical user interface (GUI) screen elements.

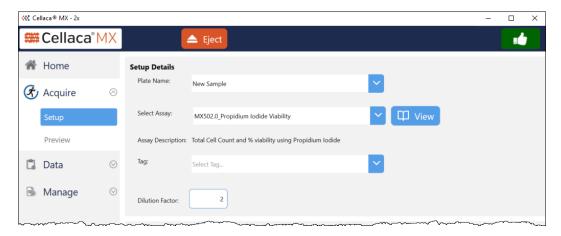
Note: Prior to launching the Matrix software, be sure to verify your system is set up as recommended in the unboxing and site preparation sections of the instrument's *User Manual*, and that the Operating Computer and instrument are both connected/powered on. In addition, follow all equipment safety protocols while using the instrument and keep the area around it clean before, during and after operation.

LAUNCHING THE MATRIX SOFTWARE

If the Operating Computer being used is a touchscreen device, you can interact directly with the software GUI by tapping gently on-screen elements (e.g., tabs, drop-downs or buttons) using a finger or stylus. If you choose to use touchscreen functionality, the term "click" as it appears in this guide may be replaced with "tap" interchangeably. A USB mouse may also be connected.

From desktop of Operating Computer, launch the Matrix software by double-clicking the **Matrix** icon. The instrument will run through a startup sequence that includes connecting it to the database and initializing the calibrations. The default screen for your instrument is displayed (e.g., the Cellaca MX **Acquire** tab > Setup screen is shown below).





Note: If the Matrix 21 CFR Part 11 module has been enabled for your system, users must log in *before* they can use the software. See Chapter 9. Using the 21 CFR Part 11 Module starting on page 85 for module functionality.

To confirm both the instrument and camera are connected to the software:

1. Click the **Instrument Status** icon (green "thumbs up") located in the upper right corner of the screen. *Text displayed indicates that the instrument and camera are connected to the Matrix software.*



2. Click the icon again to close the message box.

After initial setup of an instrument, it must be calibrated using the Matrix software prior to first-time use. You will be prompted with a message if you attempt to acquire data before calibration has been performed.

MATRIX SCREEN ELEMENTS

Upon launching the Matrix software you are presented with a default screen for your instrument (e.g., the **Acquire** tab > *Setup* screen). Basic screen elements and their display variations between instruments are described below.

Header Bar

The *Header Bar* visible across the top of the screen is always displayed. *Elements displayed in this bar may vary based on instrument type.*



Functionality of Header Bar elements is described below.





Eject/Load Buttons: Controls movement of the instrument stage (either ejects stage from instrument or retracts stage into instrument for sample loading) so the counting plate or slide holder can be placed onto or removed from the stage. The **Eject** button becomes temporarily disabled while instrument performs the count process.

Eject/Load buttons are displayed only for Cellaca MX/PLX instruments.

Instrument Status Icons: Displayed in the right corner of the *Header Bar*, indicates current instrument status. Clicking this icon displays a message box containing details. Click icon again to close the message box.







- The *Live Mode* icon (green "thumbs up") indicates that the instrument and camera are connected to the Matrix software.
- The *Data Analysis Mode* icon (red "thumbs down") indicates that the instrument and camera are *not* connected to the Matrix software.
- The *Simulated Mode* icon (blue with an "S") indicates that the instrument and camera are running in simulation mode.

Note: *Simulated Mode* is only available to Revvity Sales/Field Application Scientists to demonstrate and test instrument functionality.



Assay/Plate Names: Assay name and plate name are added to the Menu Bar when you proceed to the Preview screen in the count process.



User ID and Logout Button: If the Matrix 21 CFR Part 11 module is enabled, displays the identity of the currently logged in user and **Logout** button.

Navigation Bar

The Navigation Bar visible on the left side of the screen contains tabs/screen names and is always displayed. Functionality associated with each tab is described below. Note that options displayed in the **Acquire** and **Data** tabs represent screens marking your progression through a sequential process, while options in the **Manage** tab may be individually selected to perform distinct tasks.



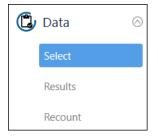
Also contains the **About Matrix** button which displays software version details and global Support hotlines, as well as the **Generate Diagnostic Report/Clear All Logs** buttons used to assist Support with troubleshooting technical issues. See *Viewing Software Version* on page 11 and *Generating Diagnostic Reports* on page 104.



Acquire Tab: Contains the two sequential screens in the *Data Acquisition* workflow. For example, in the **Acquire** tab you must first enter *Setup* details before advancing on to *Preview* the sample and confirm focus/fluorescent exposure for each channel. As you move through screens in this workflow, the *Navigation Bar* status is updated to display the current screen.

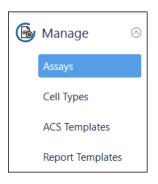
The *Setup* screen can be selected as an option if you decide to review your setup *after* previewing the sample. Once you are satisfied and proceed to performing the count, *Navigation Bar* status is updated to display the **Data** tab > *Results* screen.

See *Chapter 3. Acquiring Sample Data* starting on page *13* for more information.



Data Tab: Contains the three sequential screens in the data analysis workflow. For example, in the **Data** tab you must first *Select* a scan result before you can view its count *Results*. You can also perform a *Recount* by fine-tuning assay parameter settings to be used in the analysis to create a new scan result. As you move through screens in this workflow, the *Navigation Bar* status is updated to display the current screen.

Only the *Select* screen can be selected as an option if you decide to review other count results *after* viewing the currently selected scan. See *Chapter 4. Analyzing Scan Results* starting on page 23 for more information.



Manage Tab: Contains the various system lists of assays, cell types, ACS templates and report templates used in the *Data Acquisition* and *Data Analysis* workflows.

- In the Assays screen you can view the library of assays available in your system, import/export assays, manage the list of assays as well as create new/modify existing assay details. See Chapter 6. Managing Assays starting on page 41.
- In the Cell Types screen you can view the library of cell types available in your system, import/export cell types, manage the list of cell types as well as create new/modify existing cell type details. See Chapter 7. Managing Cell Types starting on page 61.
- In the ACS Templates screen you can view the library of ACS templates available
 in your system, import/export ACS templates and manage the list of ACS
 templates. ACS Templates cannot be created or viewed in the Matrix software.
 - ACS templates can be used for populating data into specified formats when files are generated on export. If the *Auto Open* export option is also selected, the De Novo Software FCS Express application (if installed) is launched for viewing the output file. See *Chapter 8. Managing ACS Templates* starting on page 71.
- In the *Report Templates* screen you can view the library of report templates available in your system, import/export report templates, and manage the list of report templates as well as create new/modify existing template details. See *Chapter 8. Managing Report Templates* starting on page 71.

If the Matrix 21 CFR Part 11 module has been enabled for your system, a user hierarchy must be established requiring the creation of roles that control varying levels of access to functionality available in each of these tabs. See Chapter 9. Using the 21 CFR Part 11 Module starting on page 85 for details.

VIEWING SOFTWARE VERSION

The Home tab displays the logo for the instrument to which you are connected (e.g., Cellaca MX as shown below).



This **Home** tab also contains the **About Matrix** button which displays *Product Information* (e.g., software version, instrument serial number/firmware version, and camera serial number), and *Contact Us* details.



For details on using the **Generate Diagnostic Report** and **Clear All Logs** buttons to assist the Support team with troubleshooting technical issues, see *Generating Diagnostic Reports* on page 104.



WARNING: Logs may be required to maintain a historical archive. As using the Clear All Logs button will *permanently* remove accumulated logs for the installed Matrix software version, it is recommended that you contact IT *before* clearing logs from your system.



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Chapter 3. Acquiring Sample Data

This chapter describes functionality available in the two screens used to acquire sample data – *Setup* and *Preview*. After loading samples into the instrument you must complete these screens in sequence. For example, you must first enter *Setup* details before advancing on to *Preview* the sample.

- Upon entering setup details, selecting at least one well and then clicking the **Preview** button located at the bottom of the Setup screen, the instrument engages its camera for viewing live channel images of the sample. If it is necessary to modify setup details while you are in the Preview screen, click the Setup option in the Navigation Bar to return to the Setup screen and enter new details.
- After adjusting instrument focus/fluorescent exposure for each channel, click the **Count** button at the bottom
 of the Preview screen. The instrument camera acquires sample images as specified by the selected assay which
 are then processed by the Matrix imaging and pattern-recognition software to decluster, identify and count
 individual cells according to defined cell type parameters.

Once a count has been performed, the Navigation Bar status is updated to display the **Data** tab > *Results* screen. The scan result created as a result of the count is displayed at the top of the Results List. See *Chapter 4. Analyzing Scan Results* starting on page 23 for details.

ENTERING SETUP DETAILS

As the Matrix software is shared by multiple product families, it must account for physical differences between instruments such as the format of consumables. To accommodate for these differences, a variation exists in the *Well Details* area of the Setup screen as indicated by the instrument-specific sections below. Although the visual presentation of these differences varies, the core functionality driving these tasks remains the same.

Upon launch of the Matrix software, the **Acquire** tab > *Setup* option is displayed by default. Personalize the details of your experiment by entering a plate name, selecting an assay to be used, indicating specific plate wells for which to capture images (if applicable for your instrument type) and defining how the results data are to be exported.

Note: After initial setup, an instrument must be calibrated using the Matrix software prior to first use. If you are prompted with a message that the instrument has not been calibrated, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com/contact-us or send email to: <a href="mailto:CellC-support@revvity.com/contact-us/support@revvity.com/contact-us/support@revvity.com/contact-us/support@revvity.com/contact-us/support@revvity.com/contact-us/support@revvity.com/contact-us/support@revvity.com/contact-us/support@revvity.com/

Entering Setup Details

The *Setup Details* area allows users to enter a customized plate name, select an assay and view/edit its details, select a tag and enter a dilution factor.



Users can enter the following information in the Setup Details area.

Plate Name

Customize the default plate name of "New Sample" to identify contents of the plate. If a plate name is *not* entered, a date/time stamp will be appended to the "New Sample" default (e.g., *New Sample 2023/08/25-10:58:09*).

Select Assay

Select an assay from the drop-down and verify the assay description displayed. To view and/or edit assay details, click the view button. Clicking the View button automatically updates your progression in the Navigation Bar to the Manage tab > Assays option. Click the Back or Save and Back (after making any changes) button to return to the Setup screen.

Note: If an assay is locked for editing (i.e., the **Category** field displays or *Locked* instead of *Unlocked*), users must first click **Save As** to save it as a new assay before they can edit parameters. See *Editing an Assay* on page 45 for details.

Tag

Select a tag from the drop-down or enter a new one. Tags are used to logically group scan results together for the purpose of custom reporting (e.g., Time Course Analysis). Tags have a maximum length of 32 characters and can be applied to any number of results, but can only be applied to one result derived from each scan. See *Creating a Time Course Series* on page 37 for details on how tags can be used to create custom reports.

Dilution Factor

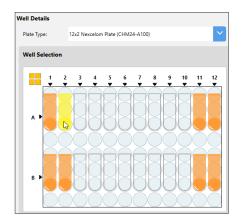
Enter the final dilution factor for the sample.

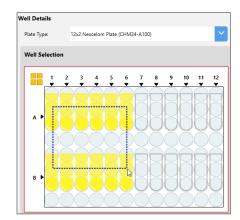
Entering Well Details (for Cellaca MX/PLX)

This section describes well selection functionality for instruments using multi-well plates such as Cellaca MX/PLX.

The *Well Details* area for the Cellaca MX identifies the **Plate Type** being used and requires you to select loaded wells in the *Well Selection* plate map.

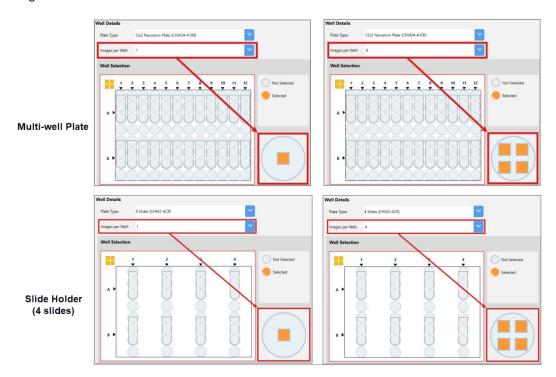
To select wells individually, click on each well to select or de-select it accordingly. To select a group of wells, click on a well at the beginning of the group and hold the mouse button down while dragging your mouse to the end of the group before releasing it. To select or de-select all wells, click the All Wells icon.





When well selection is complete, selected wells will be highlighted in orange on the plate map.

For Cellaca PLX, you can also specify number of **Images Per Well** (i.e., 1 or 4) to be captured during the count, as shown below. The *Images Per Well Indicator* for multi-well plates or PLX slide holder (provided with the instrument and holds up to four PLX slides containing two sample chambers per slide) depicts the selected number of images representing cross-sections of the area in each well.



NAMING WELLS

Once well selection is complete, you can expand the *Well Names* area below the map to see the corresponding well name fields also highlighted in blue. These fields allow you to enter well names or import them from a file to identify samples loaded into each well.



To manually enter well names, simply click on each highlighted field individually and enter a name for that well. As an alternative, you can use the following buttons to import, save and reset selected well names.

Import Button

Allows users to import a previously saved .csv file containing well names. Click the umport button, navigate to where .csv file is stored, select the file and click **Open** to load well names.

Save Button

Allows users to save the currently displayed well names as a file that can be loaded back into the system for use with another plate. Click the button and navigate to where the .csv is to be stored. Enter a name for the file and click **Save**, followed by clicking **OK** in response to the confirmation prompt. Users can open the file in a .csv compatible application (such as MS Excel) and rename the wells before importing the file again.

Reset Button

Allows users to clear the currently displayed well names. Click the button followed by clicking **Yes** in response to the confirmation prompt. Well names that have been cleared will remain highlighted in blue for your reference.

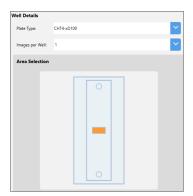
After well details have been entered, continue with your sample setup by Setting Auto Export Options on page 17.

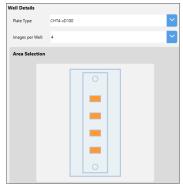
Note: If you are creating a time course series of data for use in custom reporting, it is critical that well names be consistent for all scan results in the series. See *Creating a Time Course Series* on page *37* for details.

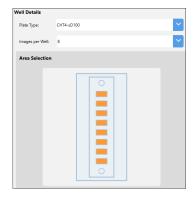
Entering Well Details (for Cellometer K2)

This section describes images per well functionality for instruments using chambered slides such as Cellometer K2.

The *Well Details* area for the Cellometer K2 identifies the **Plate Type** being used for the sample and allows you to select the number of **Images Per Well** (i.e., 1, 4 or 8) to be captured during the count, as shown below.







The visualization of *Images Per Well* for the slide depicts the selected number of images (i.e., cross-sections of the area in the counting chamber or "well") to be captured during the scan. A comparison of *Total Volume Measured* for K2 images in relation to hemocytometer quadrants is provided below.

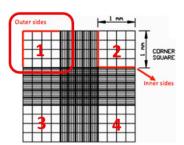
Total Volume Measured For K2 Images Per Well:

Count from 1 image per well = 0.15 μL

Count from 4 images per well = $0.6 \mu L$ (or 6 quadrants of a hemocytometer) Count from 8 images per well = $1.2 \mu L$ (or 12 quadrants of a hemocytometer)

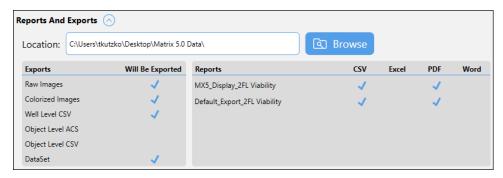
Total Volume Measured For Hemocytometer Quadrants:

Count for 1 quadrant = 0.1 μ L *Volume Per Quadrant* using an average of 4 quadrants result in 0.4 μ L *Total Volume Measured*



Setting Auto Export Location

Expand the *Reports and Exports* area to identify a **Location** for automatic exports of images/data and generated output files for reports. Click the **Browse** button and navigate to a folder on your Operating Computer or network to define the default export path. *This path will remain as the default in the software until it is manually changed.*



In addition, Exports (e.g., Raw Images, Colorized Images, Well Level CSV, Object Level ACS, Object Level CSV and Dataset) and output files for Reports (e.g., CSV, Excel, PDF and Word) defined for the current assay are displayed.

Note: To modify *Report and Export* settings displayed, click the **View** button for the selected assay in *Setup Details* area and expand the *Reports and Exports* section to update *Exports* and *Reports* file types selected. See *Managing Assay Reports and Exports* on page 57 for details.

PREVIEWING THE SAMPLE

Once you have completed entering setup details for your sample, click the Preview button located at the bottom of the Setup screen. The instrument engages its camera for viewing the sample and displays the Preview screen. Users can view live images of samples in selected wells, preview available channels for *Imaging Mode* associated with the assay, adjust instrument focus and confirm fluorescence exposure for each channel.

Note: Although the **Acquire** tab > *Preview* option appears in the Navigation Bar, you cannot access the Preview screen directly as it requires well details entered in the Setup screen. Once you click the **Preview** button at the bottom of the Setup screen, the Navigation Bar is updated to show your progression to the Preview screen.

Previewing Live Images (for Cellaca MX/PLX)

This section describes previewing live image display for instruments using multi-well plates such as Cellaca MX/PLX.

In the *Wells* area, click on highlighted wells to view live images of samples contained in the counting plate or PLX low fluorescence slide. As you move from well to well, the live image changes per selected well (i.e., indicated in the plate map by an outline surrounding the well).

To zoom in/out of an image, move the mouse to hover cursor over the viewing pane and turn the scroll wheel or, if using the touchscreen (for MX only), apply universal gestures (e.g., touch center of image with two fingers and then spread them apart to zoom in and reverse this action to zoom out). Current *Zoom* magnification is displayed in bottom right corner of viewing pane.

To move a zoomed image around, click and drag the image to a new location as needed.

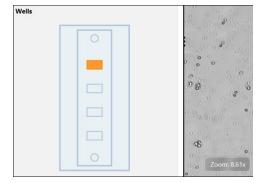
For Cellaca PLX only, if the *Images Per Well* option of 4 is selected, you can also select a specific quadrant within a well by clicking on the indicator below the Well Map. As you move from well to well (and from quadrant to quadrant), the live image changes per selected well and quadrant.

Previewing Live Images (for Cellometer K2)

This section describes previewing live image display for instruments using chambered slides such as Cellometer K2.

In the *Wells* area, click on highlighted image sections in the slide visualization (i.e., representing cross-sections of the counting chamber or "well"). As you move from section to section, the live image changes per your selection.

To zoom in/out of an image, move the mouse to hover cursor over the viewing pane and turn the scroll wheel or, if using the touchscreen, apply universal gestures (e.g., touch center of image with two fingers and then spread them apart to zoom in and reverse this action to zoom out.) Current *Zoom* magnification is displayed in bottom right corner of the viewing pane.



To move a zoomed image around, click and drag the image to a new location as needed.

Adjusting Focus (for Cellaca MX/PLX)

This section describes adjusting instrument focus using internal controls via Matrix software for Cellaca MX/PLX.

To adjust the focus of the live image being previewed, use the *Focus* controls as indicated below. Obtaining good focus is key to ensuring accurate cell counts.



Auto Focus Button Allows the instrument to determine the best focal position for the selected well.

Focus Position Allows users to enter a numerical value for the vertical (Z) position of the objective lens.

Fine Focus Manual Allows users to finely adjust the vertical (Z) position of the objective lens for optimal focus (in μ m). Click the up/down arrow to adjust focus accordingly.

-

Coarse Focus Manual Offset Buttons

Allows users to coarsely adjust the vertical (Z) position of the objective lens for optimal focus (in μ m). Click the up/down double-arrow to adjust focus accordingly.

*

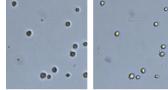
Once focus has been properly adjusted, continue by Previewing Channel Images, below.

Adjusting Focus (for Cellometer K2)

This section describes adjusting instrument focus using external Focus Knob available on Cellometer K2.

To adjust the focus of the live image being previewed, slowly turn the Focus Knob located on the right side of the instrument until cells/beads are in focus.

Obtaining good focus is key to ensuring accurate cell counts. Once good focus has been achieved, the instrument should perform most counting operations with only minor adjustments.



Unfocused

Focused

Previewing Channel Images

In the *Preview* area, channels available for viewing (e.g., *Channel 1*, *Channel 2*, etc.) are displayed based on the instrument and assay Imaging Mode. The *Channel 1*|*BR1* image is displayed by default. Clicking the **FL** button displays the *Channel 1/FL1* image.



If only one channel is available, the **Preview** field channel drop-down will be hidden. In addition, if the *BR Only* Imaging Mode is selected, the **FL** button will also be hidden.

If multiple channels are available (e.g., *Channels 1-6* for Cellaca MX/PLX or *Channels 1-2* for Cellometer K2), use the **Preview** field channel dropdown to switch between channels. For example, sample *Channel 1/FL* and *Channel 2/FL* images are shown below.

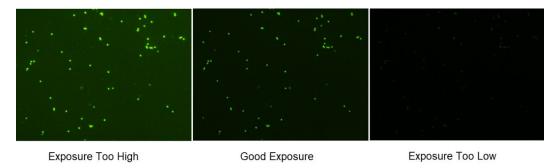




Notes:

- For BR/FL imaging modes, each channel will be associated with two images *Brightfield (BR)* and *Fluorescent (FL)*. These images are referred to in assay channel mappings as *BR1/FL1*, *BR2/FL2*, etc.
- When working with assays that have more than one channel, use the *Channel 1/BR* image to adjust focus and then select the *FL* image to confirm exposure. For *Channels 2-6*, you only need to select the *FL* images to confirm exposure since focus of their paired *BR* images is adjusted automatically when you performed the task for *Channel 1*. For K2 instruments, a slight offset may exist between *BR1* and *BR2* images due to the distance the camera must travel.

When previewing fluorescent images, confirm that FL signal is strong but has a low, dark background. Modify the **FL Exposure** default to increase (prolong) or decrease (shorten) the exposure time accordingly.



PERFORMING A COUNT

Once you have completed previewing the live image for the sample, click the bottom of the Preview screen. The instrument camera acquires sample images as specified by the selected assay which are then used by the Matrix software to calculate count results according to defined cell type parameters.

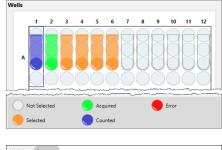
Note: Depending on the number of selected wells/images per well and defined assay parameters, the counting process can take a few seconds to up to a few minutes.

At the start of count processing, the Navigation Bar status is updated to display the **Data** tab > *Results* option.

As the system acquires sample images and calculates count results, the colors used to mark selected wells/images per well will change to indicate status (i.e., from *Selected* to *Acquired* to *Counted*) as shown in the legend appearing below the Well Map.

As soon as a well is *Counted*, you can click on it to display count results below the viewing pane. *Count results will be displayed, printed and exported based on templates defined for the assay.*

Well images displayed can be varied by toggling on/off available channel buttons (displayed across the top of the viewing area of the **Well View** tab) and enhancing the *Zoom* magnification.



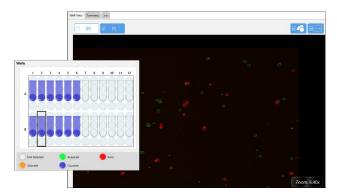


To zoom in and out of sample images, move the mouse to hover the cursor over the viewing pane and turn the scroll wheel or, if using the touchscreen, apply universal gestures (e.g., touch the center of the image with two fingers and then slowly spread them apart to zoom in and reverse this action to zoom out). Current magnification is displayed in bottom right corner of viewing pane.

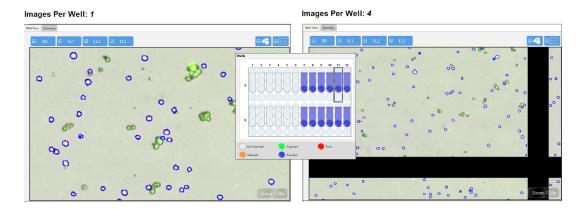
When counting of all wells is complete the scan result will be added to the top of the Results List displayed on the Select screen. In addition, *Reports and Exports* output files defined for the current assay are automatically stored in the specified location. See *Chapter 4. Analyzing Scan Results* starting on page 23 for details.

Results Display for Cellaca MX/PLX

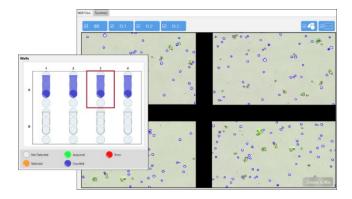
When viewing count results for plate-based instruments such as Cellaca MX, a single image is displayed representing the sample in the outlined well. Click on other highlighted wells to view their sample images.



For Cellaca PLX only, if *Images Per Well* of 1 is selected, a single image is displayed per well (as with the MX). However, if *Images Per Well* of 4 was selected, a composite image is displayed containing four separate images representing each quadrant of the well.



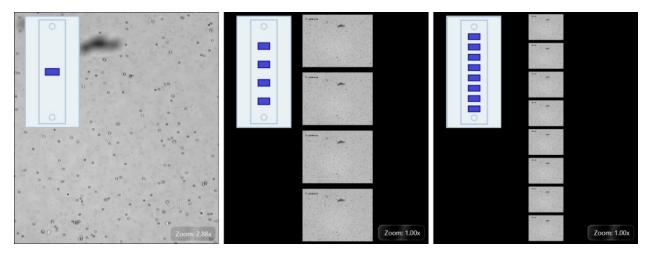
Using a PLX slide holder produces the same results – if *Images Per Well* of 1 is selected, a single image is displayed per well. However, if *Images Per Well* of 4 is selected, a composite image is displayed containing four images.



To move an image around, click once inside the viewing pane and drag the image to a new location as needed.

Results Display for Cellometer K2

When viewing count results for slide-based instruments such as Cellometer K2, the number of images displayed will vary based on your *Images Per Well* selection. Multiple images are stacked in a single viewing pane.



To move an image around, click once inside the viewing pane and drag the image to a new location as needed.

Chapter 4. Analyzing Scan Results

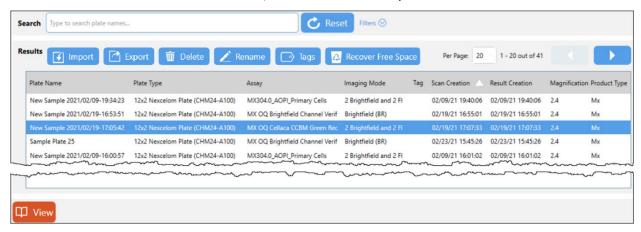
This chapter describes functionality available in the three screens used to analyze scan result data — *Select, Results* and *Recount*. When analyzing scan results you must complete these screens in sequence. For example, you must first *Select* a scan result before you can view its count *Results*. You can then perform a *Recount* by fine-tuning assay parameter settings to be used in the analysis to create a new scan result.

- To open a scan result contained in the Results List of the Select screen you can either double-click the result, or click it once (to highlight it in the list) and then click the View button. See Selecting Scan Results, below.
- Once a scan result is displayed in the Results screen you can analyze it by selecting/de-selecting channels to
 vary the image and click on highlighted wells to review the data. If you find it necessary to choose another scan
 result, click the Select option in the Navigation Bar. See Viewing a Scan Result on page 24 for details.
- To perform a *Recount* you can select either a new assay or click the **View** button for the current assay to edit its parameter settings, and then click the **Recount** button. See *Performing a Recount* on page 30 for details.

As you move through screens in this workflow, the Navigation Bar status is updated to display the current screen. After a recount is performed, the Navigation Bar returns to the **Data** tab > *Results* screen.

SELECTING SCAN RESULTS

The Select screen displays all *Scan Results* currently generated or loaded into the database for your system. From this screen you can search for, select and view scan results. In addition, scan results can be imported/exported, deleted or renamed. If scan results are deleted, users can recover free space available in the database.

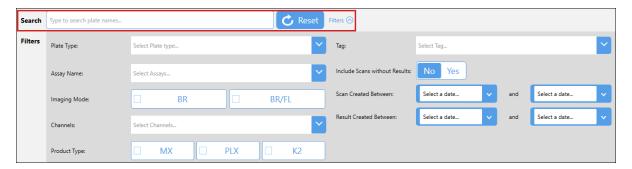


Use the **Per Page** control drop-down Per Page: 20 1-20 out of 41 (contains values from 5 to 500) located in the upper right corner of this screen to select the number of scan results to be displayed per page, and the arrows to move back and forth between list pages.

See Managing the Results List on page 25 for more information on managing scan results contained in this list.

Searching for a Scan Result

To search for a scan result you can either enter a few key characters from a plate name into the **Search** field and/ or expand the **Filters** area by clicking the down arrow Filters to specify search criteria.



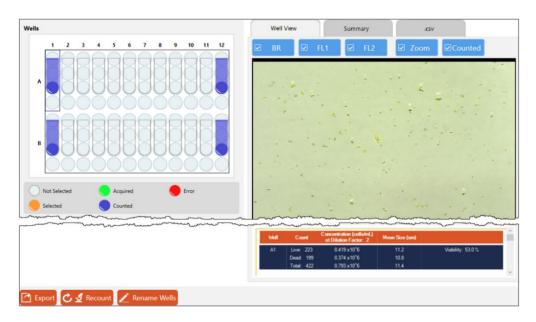
Refine your search by selecting a plate type or assay name, clicking on an imaging mode or product type, selecting a tag, indicating whether to include scans without results, or entering a range of dates between which a scan and/or result was created. As you enter search criteria, the Results List is updated with matching entries.

If you find it necessary to clear all selected filters and begin the search again, click the **Reset** button.

Note: The Matrix software is designed to support multiple product types (e.g., Cellaca MX/PLX and Cellometer K2) and displays *all* available scan results in the Results List regardless of whether the Operating Computer is physically connected to that instrument.

Viewing a Scan Result

To open a scan result contained in the *Results List* you can either double-click the result or click it once to highlight it in the list and then click the **View** button. The Results screen is displayed.



Note: As *all* available scan results are contained in the Results List, you may be able to view scan results taken by an instrument that is different from the one to which your system is currently connected.

MANAGING THE RESULTS LIST

The following functionality is available when viewing the Results List.

Import Button Allows user to import previously stored scan results (stored as .SCANRESULT files) from an

external location.

Export Button Allows users to export selected scan results (to be stored as .SCANRESULT files) to an

external location.

Delete Button Allows users to delete the selected scan result. If the Matrix 21 CFR Part 11 module is

enabled, users will be prompted to enter a reason prior to deletion.

After data has been deleted, click the Recover Free Space button (if displayed) to recover

space that the data previously occupied in the database.

Rename Button Allows users to rename the selected scan result. New plate name entered must be unique.

Tags Allows users to select a tag from the drop-down or enter a new one to apply it to the

currently selected scan result. Tags can be used to create custom reports.

Recover Free Space Button Allows users to recover free space that continues to be occupied in the database even after

scan result data previously stored in that space has been deleted.

Note: When scan results are deleted, the database does not immediately return space previously used by deleted data to the operating system. Instead, this process occurs gradually over time. The **Recover Free Space button** allows users to return unoccupied database space to the operating system at the time the operation is performed.

Users must have System Admin rights for the database for this button to be displayed. In addition, as this process requires high CPU utilization during operation it is recommended

that you not click perform other functions until this operation is complete.

View Button Allows users to open the selected scan result for viewing.

VIEWING COUNT RESULTS

Once you have opened a scan result for viewing, you can view count results presented in the Results screen.

Understanding Default Report Tabs

Report tabs initially displayed across the top of the viewing pane are associated with report templates that have been assigned to the current assay and are enabled by default to format the presentation of scan result data.



Although the **Well View** tab will always be enabled for display, you can change the report template assigned to this tab. In addition, you can disable any other default report tabs (e.g., **Summary** and **.csv** tabs for Matrix v4.0+; **All Wells** tab for Matrix v3.0), change the report templates used for display of these tabs, and/or add new tabs. See *Chapter 5. Customizing Scan Result Reports* on page *33* for details.

Note: As of the Matrix v4.0 release, users can customize report tabs displayed when viewing count results. Tabs enabled for display by default have been changed as noted below:

- The **Well View** report tab available in earlier releases will always be enabled. However, users can change the *Display* report template assigned to this tab or edit the template directly. *Any changes made to a report* template in use by other assays will also be applied to other scan results the next time a recount is performed.
- The **All Wells** tab available in earlier releases has been replaced with the **Summary** tab. In addition, a new **.csv** tab may be enabled. Users can change report templates assigned to these tabs, edit the templates directly (i.e., any changes made will also be applied to other scan results using these templates), disable them from displaying as tabs or delete them from the assay.
- Tabs enabled for display by default are identified by version numbers included in an assay name (e.g., MX405.0_AOPI_Cell Lines will include default tabs enabled in the Matrix v4.0 release).

CHANGING WELL VIEW IMAGE DISPLAY

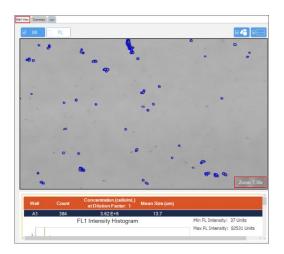
The **Well View** tab will always be displayed in the Results screen and includes both an image and the associated count results for the selected well. To change the well view image displayed, use one of the following methods based on your instrument:

- When viewing count results for plate-based (Cellaca MX/PLX) or slide holder-based (Cellaca PLX) instruments, a single image represents the sample in the outlined well. To display images for other acquired samples, select their highlighted well in the Well Map. For Cellaca PLX, if the Images Per Well option of 4 is selected, a single well image may be a composite of four separate images representing each quadrant of the well. To move the image around, click and drag the image to a new location as needed.
- When viewing count results for slide-based instruments such as Cellometer K2, the number of images displayed for the outlined well varies based on your *Images Per Well* selection. Multiple images taken are stacked into a single composite image. To move the image around, click and drag the image to a new location as needed.

You can zoom in/out of the well view image by clicking once in the viewing pane and turning the mouse scroll ball or, if using a touchscreen, by applying universal gestures (e.g., touching center of image with two fingers and then spreading them apart to zoom in and reverse this action to zoom out).

Zoom magnification is indicated in bottom right corner of the viewing pane and can be increased up to 10.00x.

At the bottom of the **Well View** tab is a report containing well-level data for the sample in the selected well.



VARYING WELL VIEW CHANNELS/COUNTED OVERLAY DISPLAY

In the **Well View** report tab displayed by default, the following buttons may be available across the top of the viewing pane based on the Imaging Mode defined in the current assay.

- Click the Brightfield (BR) or Fluorescence (e.g., FL1, FL2, FL3, etc.) buttons to select/de-select channels used in the image display. Channel views are overlaid on top of each other.
- Click the button to show/hide a graphic overlay that identifies Counted cells by surrounding them with colorcoded outlines. For 2-channel Viability assays, Green is used for counted/live cells, Red for dead cells and Yellow for cells not counted (e.g., if larger than the specified cell diameter). For Expression assays, Blue is used for outlining total cells in the masked channel.
- Click the button to enable/disable display of the current Zoom magnification in bottom right corner of viewing pane. Zoom feature will still be functional even if not displayed.

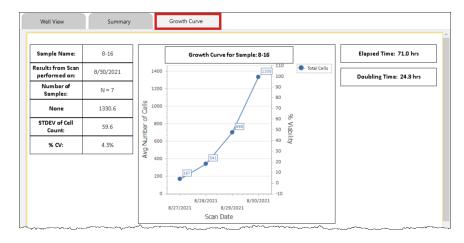


Understanding Custom Reporting

The Matrix custom reporting feature allows you to assign and/or modify report templates to be used by assays when generating scan results. You can change the report template used for display of the **Well View** report (which is always displayed) and add report templates to be enabled as tabs or output as specific file types (e.g., *CSV*, *Excel*, *PDF* and *Word*) that can be opened/printed upon report generation.

Note: Any changes made to *Reporting* options for an assay will be saved with the assay and applied to all other scan results using that assay the next time a new scan or recount is performed.

For example, a custom **Growth Curve** report tab has been enabled in the scan result shown below. Clicking this tab displays data in the format defined by the associated report template (i.e., illustrating calculation of a growth curve for a time course series of scan results).

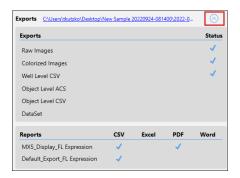


See Chapter 5. Customizing Scan Result Reports on page 33 for details on customizing Reporting options.

Verifying Auto Exports

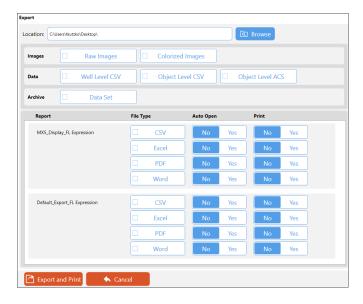
Expand the *Exports* area in the Results screen to verify that automatic exports were completed and click the location link to open folder where the exported scan result files are stored.

In addition, if you defined any output file types (e.g., *CSV*, *Excel*, *PDF* and *Word*) to be generated for assay report templates, you can verify that selected file type exports were also completed.



Exporting and Printing Scan Results (Manual Settings)

To manually select additional export options (images/data) for scan result files as well as generated output files for reports, click the **Export** button located at the bottom of the Results screen. The Export dialog is displayed.

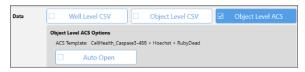


Confirm the export **Location** and if necessary update this path by clicking the **Browse** button, navigating to a folder on your Operating Computer or network, and clicking **OK**.

Select scan result **Images** (e.g., *Raw Images* or *Colorized Images*), **Data** (e.g., *Well Level CSV*, *Object Level CSV* and *Object Level ACS*) and **Archive** (e.g., *Data Set*) file options to be exported to the specified location. *Data Sets are stored as .SCANRESULT files*.

In addition, for reports associated with the scan result you can select generated output file types (e.g., CSV, Excel, PDF and Word) to be exported and indicate if files are to be opened automatically and/or printed upon export.

Note: If the *Object Level ACS* option is selected, the screen expands to display if an ACS template has been assigned to the assay and offers an *Auto Open* option after the report is generated. *If no ACS template is displayed, users can still export object level ACS data assuming they have the export privilege.* To change the ACS template assigned to an assay, users will need to edit the assay.



For report templates associated with the scan result you can select generated output file types (e.g., *CSV*, *Excel*, *PDF* and *Word*) to be exported and indicate if files are to be opened automatically and/or printed upon export.

Note: Any changes to export options are applied only when manually exporting scan results (i.e., by clicking the **Export and Print** button) and will *not* be saved with the assay or scan result.

Renaming Wells

You can rename wells as necessary for a scan by clicking the **Rename Wells** button located at the bottom of the Results screen. Wells that were selected for the scan are highlighted in blue and contain the current well names. *All remaining wells will be blank and disabled for editing.*

Note: As well names are associated with a scan and *not* individual results derived from that scan, renaming wells in a scan result will affect well names used for *ALL* results (counted or recounted) generated from that scan.

To manually enter well names, simply click on each highlighted field individually and enter a name for that well.



As an alternative, you can use the following buttons to import, save and reset selected well names.

Import Button

Allows users to import a previously saved .csv file containing well names. Click the under the file and click **Open** to load well names.

Note: Using this button when editing a scan result imports only those well names that were selected/enabled for the scan. *All other well names in the imported file will be ignored.*

Save Button

Allows users to save the currently displayed well names as a file that can be loaded back into the system for use with another plate. Click the button and navigate to where the .csv is to be stored. Enter a name for the file and click **Save**, followed by clicking **OK** in response to the confirmation prompt. Users can open the file in a .csv compatible application (such as MS Excel) and rename the wells before importing the file again.

Reset Button

Allows users to clear the currently displayed well names. Click the **C** Reset button followed by clicking **Yes** in response to the confirmation prompt. Well names that have been cleared will remain highlighted in blue for your reference.

After any changes to well names have been saved, reports enabled as tabs in the Results screen will immediately be updated to display the new well names.

Note: If you are creating a time course series of data for use in custom reporting, it is critical that well names be consistent for all scan results in the series. See *Creating a Time Course Series* on page *37* for details.

PERFORMING A RECOUNT

If you find it necessary to fine-tune assay parameters after reviewing your data results, click the **Recount** button located at the bottom of the Results screen. The Recount screen is displayed.

Once you have made any necessary changes (per the options described below), click the **Recount** button located at the bottom of the screen. After a recount is performed, the Navigation Bar returns to the Results screen.

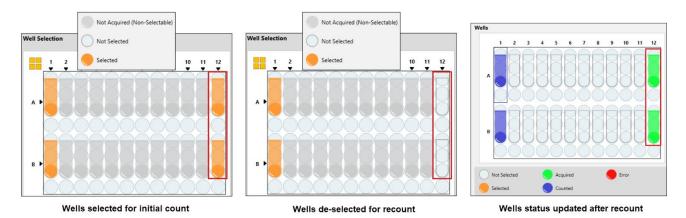
Refining Assay Details/Selecting New Assay

In the *Recount Details* area you can view parameter settings for the *Last Used* assay, select a new assay from the drop-down or view the current assay to edit parameter settings to be used in the recount. See *Editing an Assay* on page 45 for details.



De-selecting Wells

In the *Well Selection* area you can de-select wells previously highlighted to exclude them from the recount (e.g., to increase counting speed). *You cannot add wells to the recount that were not selected for the initial count.*



Managing Channel Mappings

Expand the *Channel Mappings* area to identify *Scan Channels* and *Recount Channels* for the Imaging Mode associated with the current assay. Performing a recount uses channel mappings as defined by default (i.e., *Recount Channels* will remain in same positions used for the original *Scan Channels*).

Note: With the exception of *Brightfield Only* configurations (i.e., *BR1*, *BR2*, etc.), each channel will have separate brightfield and fluorescent images as depicted in the mapping indicators (i.e., *BR1/FL1*, *BR2/FL2*, etc.).

To manage channel mappings for use in a recount, click on individual mapping indicators and drag them to a new channel. The mapping indicator in that channel will swap positions with the one you are dragging automatically.

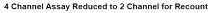




To return channel mappings to the positions they were in when you first expanded the *Channel Mappings* area, click the **Reset** button followed by **Yes** to confirm the action.



If a new assay selected for recount has fewer channels or you edit the assay previously used to reduce the number of channels, mappings displayed are updated to reflect available channels. To manage channel mappings for use in the recount, click on mapping indicators and drag them to an available position in the *Recount Channels* area.







If dragging an indicator from the *Scan Channels* to *Recount Channels* area and the *Recount Channels* postion is already populated, the indicator in *Recount Channels* will be returned to its home *Scan Channels* location.



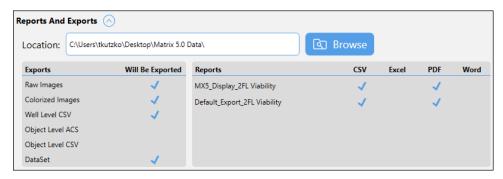


If you drag indicators from *Recount Channels* to their home *Scan Channels* locations, a red outline is used to highlight empty *Recount Channels* locations. All *Recount Channels* must contain an indicator prior to recount.



Modifying Auto Export Options

Expand the *Reports and Exports* area to identify a **Location** for automatic exports of images/data and generated output files for reports. Click the **Browse** button and navigate to a folder on your Operating Computer or network to define the default export path. *This path will remain as the default in the software until it is manually changed.*



In addition, Exports (e.g., Raw Images, Colorized Images, Well Level CSV, Object Level ACS, Object Level CSV and Dataset) and output file types for Reports (e.g., CSV, Excel, PDF and Word) defined for the assay will be indicated with a blue checkmark.

Note: To modify *Report and Export* settings displayed, click the **View** button for the selected assay in *Setup Details* area and expand the *Reports and Exports* section to update *Exports* and *Reports* file types selected. See *Managing Assay Reports and Exports* on page 57 for details.

Clicking the Recount Button

Once you have completed entering recount details for the samples, click the details button located at the bottom of the Recount screen. The Matrix software performs a recount of the scan using the modified parameters and displays the new scan result.

Chapter 5. Customizing Scan Result Reports

The Matrix custom reporting feature allows you to assign and/or modify report templates to be used by assays when generating scan results in the following ways:

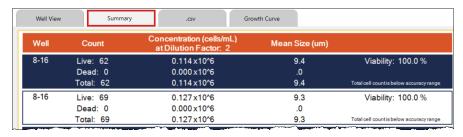
- The display template used for the **Well View** report tab may be changed. This tab will always be displayed.
- Report templates can be enabled/disabled as tabs and arranged to appear in sequence as desired.
- Report templates can be used to output specific file types (e.g., CSV, Excel, PDF and Word) and open/print upon report generation.

Note: Any changes made to *Reporting* options for an assay will be saved with the assay and applied to all other scan results using that assay the next time a new scan or recount is performed.

VIEWING CUSTOM REPORTS

Although the **Well View** tab will always be enabled for display, you can change the report template assigned to this tab. In addition, you can disable any other default report tabs (e.g., **Summary** and **.csv** tabs for Matrix v4.0+; **All Wells** tab for v3.0), change the report templates used for display of these tabs, add new tabs and/or view a report template to edit its format directly.

For example, clicking the **Summary** tab for a scan result displays a full page view containing report data for all selected wells. The **Summary** tab is enabled for Matrix v4.0+ assays by default and the assigned report template contains information similar to what was displayed in the **All Wells** tab available in earlier releases.

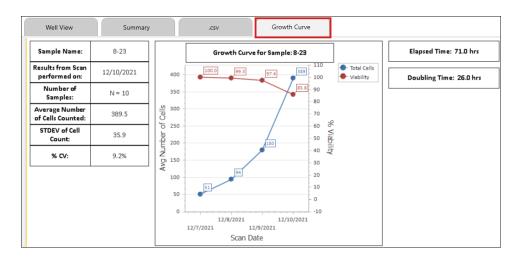


You can either change the report template used for display of this tab or view it to modify the overall format of how report objects and data selections are presented.



Note: Any changes made to report templates will be saved with the assay and applied to all other scan results using that assay the next time a new scan or recount is performed.

As another example, a custom **Growth Curve** tab has been enabled for display in the scan result shown below. Clicking this tab displays consolidated sample data and line graphs for each group of wells illustrating the calculation of a growth curve for a time course series of scan results. *This report was generated on a Cellaca MX*.



Note: The Growth Curve shown above was created by assigning the *MX5_Growth Curve* report template (included as a custom report in the Matrix Report Templates Library) to an assay that was run repeatedly on the same sample in a time course series with a single tag applied to multiple scan results. See *Creating a Time Course Series* on page *37* for details on how create this custom report.

SETTING REPORTS AND EXPORTS FOR AN ASSAY

You can manage Reports and Exports options for an assay in the following areas of the Matrix software:

- When entering *Setup Details* in preparation for a count (i.e., **Acquire** tab > **Setup** option), select an assay and click the view button to edit assay details.
- When entering *Recount Details* for a selected scan result in preparation for a recount (i.e., **Data** tab > **Recount** option), select an assay to be used for the recount and click the view button to edit assay details.
- When managing details for a selected assay (Manage tab > Assays option) in the Assays List. Double-click on an assay in the list or highlight it once and then click the view button to edit assay details.

Once you are viewing details for an assay, expand the *Reports and Exports* area by clicking the down arrow to view available options. When editing of the assay is complete, click **Save and Back** to save your changes to the assay or **Save As** to save a copy of the assay that includes your changes with a new name.

Note: As of the Matrix v4.0 release, report templates are no longer limited to the *Display, Export* or *Print* template types used in earlier releases. A report template can be created for all these purposes and multiple templates assigned to an assay as needed. In addition, report tabs enabled by default will vary based on the Matrix software version associated with an assay (e.g., **Well View**, **Summary** and **.csv** tabs are displayed for v4.0+ assays; **Well View** and **All Wells** tabs for v3.0 assays). Users can change report templates assigned to these tabs, edit the templates directly (i.e., any changes made will also be applied to other scan results using these templates), disable them from displaying as tabs or delete them from the assay.

Changing Template used in Well View Report Display

The **Well View** tab is enabled by default for all assays and cannot be disabled. However, you can change the report template used for the display of this tab or view the assigned report template and edit its format as necessary.

To change the report template currently assigned for the display of this tab, select a new template from the **Display** drop-down. Click **View** to confirm the selected template suits display needs for the report and edit it if necessary.



Editing Assay Exports

Current assay Exports for scan result Images (e.g., Raw Images or Colorized Images), Data (e.g., Well Level CSV, Object Level CSV and Object Level ACS) and Archive (e.g., Data Set) file options to be exported can be edited as necessary. Data Sets are stored as .SCANRESULT files.

If Object Level ACS is selected, the screen is expanded to display if an ACS template has been assigned and offers an Auto Open option. If no template is displayed, users can still export object level ACS data assuming they have the export privilege. To change the ACS template assigned to the assay, select a new one from the drop-down.





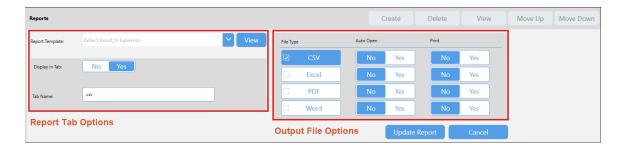
Managing the Assay Reports List

The Reports List for an assay may initially contain two report templates enabled by default used in the display of the **Summary** and **.csv** tabs. *Note that the .csv tab may not be available for assays using Expression imaging mode.*



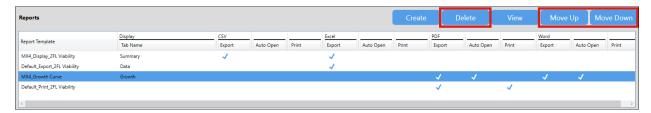
To select a report template and edit how it is being applied to this assay, you can either double-click it in this list or click on the report once to highlight it and then click the **View** button.

You can use *Report Tab Options* to disable/enable the display of report templates as tabs and edit/enter tab names. A total of five (5) custom tabs may be enabled for display at any one time. In addition, you can select *Output File Options* for report templates and indicate if files are to be opened automatically or printed upon report generation.



When you have finished defining options for a report, click the **Update Report** button to save your changes and view the updated Reports List. Repeat this process for each report template to be modified.

To delete a report template from the Reports List for an assay, click on the report once to highlight it and then click the **Delete** button. You can also add a new report template by clicking the **Create** button. See *Adding Report Templates*, below for details.



Note: If the report template deleted was from the Report Template Library provided with the Matrix software, it can be re-imported if necessary. If the report template was from a custom library or created using the Matrix software, it may be permanently deleted unless it was exported to an external location and saved prior to deletion.

As report tabs enabled for display are presented in the order in which they appear in the Reports List, you can change the sequence of tabs by highlighting a report and clicking the **Move Up** or **Move Down** buttons.

Adding Report Templates

To add a new report template, click the **Create** button. Select a template in the **Report Template** field, choose if the report should be enabled as a tab for display (i.e., *Yes*) and enter a tab name.

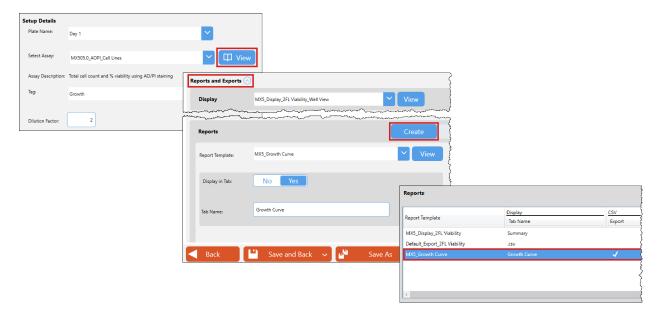


Select any output file types for the report and indicate if they are to be opened automatically (*Auto Open*) or printed upon report generation whenever the assay is used to perform a count/recount. *Output of files is independent of whether a template is also enabled as a tab.* Click **Add Report** to add the report to the Reports List.

CREATING A TIME COURSE SERIES

Creating a time course series of scan count results is useful when the intent of an experiment is to analyze the evolution of cell samples over time. The Matrix software custom reporting feature uses tags to logically group scan results in the order they are generated to identify them as part of a sequence. Tags can later be modified when viewing scan results in the Results List.

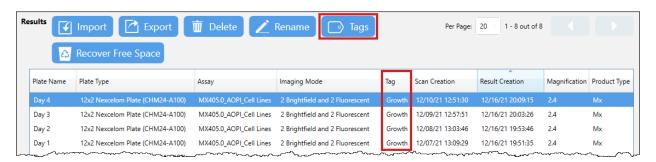
In this example, a time series of count results was acquired over the course of four days. For the first scan, a plate name of *Day 1* was entered for cell samples, an appropriate assay (e.g., *MX505.0_AOPI_Cell Lines*) was selected and the tag *Growth* added. *Once a tag is added you will be able to select it from the Tag drop-down in future scans*.



The **View** button for the assay was selected to present assay details and the *Reporting* area expanded to create a **Growth Curve** tab (i.e., by assigning the *MX5 Growth Curve* report template) enabled for display.

As the experiment progressed and subsequent counts were performed at determined intervals, new plate names were entered to reflect the stage of the experiment (e.g., Day 2, Day 3, Day 4) with users continuing to select the same tag (e.g., Growth) from the drop-down.

When the fourth day of the experiment was complete, scan results appeared in the Results List as shown below.



Once a scan result is available in the Results List, users can highlight it and click the **Tags** button to change the tag (i.e., add a new tag, edit/replace an existing tag or remove the tag by clearing the field). Scan results associated with the same tag will be used collectively to create a time series.

If users find it necessary to refine assay parameters and perform a recount for a scan result associated with a tag, they will be presented with a notification prompt that the tag is already in use by a result of the scan. Users can choose to move the tag to the new scan result (**Yes**), create the new scan result without the tag (**No**), or cancel the recount to select a new tag.

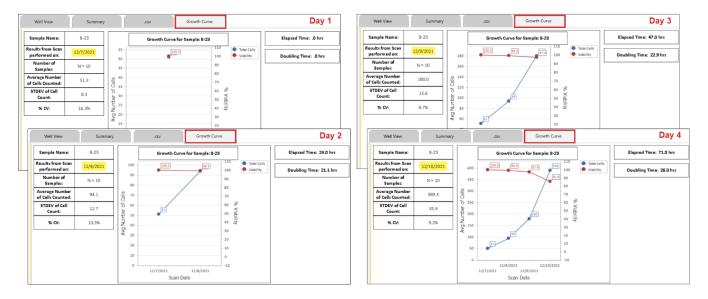




Note: Although a single tag may be applied to multiple scan results, only one result derived from each scan may be associated with the tag.

Another key concept when creating a time course series is that well names used in scan results must be consistent throughout the entire series and if multiple wells on the same plate use the same name, data from those wells will be averaged together before generation of the report. Wells can be renamed while viewing a scan result.

To create a **Growth Curve** report for this example containing all four scan results, users must select the scan result representing the *end* of the time series to include all data points (i.e., if users viewed the **Growth Curve** report generated for the scan result with plate names *Day 1*, *Day 2* or *Day 3* as shown in the series as below, only the data points available at each specific point in time for the series will be included in the line chart).



Details for creating a simple custom time course report template using the DevExpress *Report Designer for WPF* plugin are provided in *Creating a Time Course Report Template* on page 40.

For assistance with creating or editing more complex time course time course reporting templates, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com/contact-us or send email to: CellC-support@revvity.com/contact-us/ or send email to: CellC-support@revvity.com/contact-us/ or send email to: CellC-support@revvity.com/contact-us/ or CellC-support@revvity.com/contact-us/ or CellC-support@revvity.com/contact-us/ or CellC-support@revvity.com/contact-us/ or Cel

Best Practices and Workflow Tips

- Time course data is accumulated based on the well names used in scan results. If wells are *not* consistently named throughout the entire series, well data presented in the report may exceed the number of wells on the plate and/or include gaps. In addition, if the same well name applies to multiple wells on a plate, data in those wells will be averaged together before generation of the report. Wells can easily be renamed after a scan and a recount performed to update the scan result.
- When performing a recount on a scan result currently tagged to be part of a time course series, you will be prompted with a *Tag Already in Use* notification pop-up since the updated result will be derived from the same initial scan. Click **Yes** to move the tag to the updated result.
- Tags may consist of up to 32 characters in length and are displayed in a column in the Results List. *Click on the Tag column header to sort scan results in the list by tags.* In addition, tags may be used to filter the Results List to limit the display of scan results.
- If a tag is associated with a time course series, selecting the scan result with the most recent *Scan Creation* timestamp will include all data available for the report. *Selecting a scan result in the middle of the series will display only data available at that specific point in time.*
- To add a tag to be associated with multiple scan results, highlight all results before clicking the Tags button.
 Click once to highlight the first result and then hold either the Shift key (to select a block of results) or Ctrl key (to select non-contiguous results) down while clicking additional results. Any changes you make to the tag will be applied to all selected scan results.
- To change a tag associated with multiple scan results that are assigned the same tag, highlight all results
 before clicking the Tags button. Click once to highlight the first result and then hold either the Shift key (to
 select a block of results) or Ctrl key (to select non-contiguous results) down while clicking additional results.
 Any changes you make to the tag will be applied to all selected scan results.
- To delete tags associated with one or more scan results, highlight all results containing the tags to be deleted before clicking the Tags button. Click once to highlight the first result and then hold either the Shift key (to select a block of results) or Ctrl key (to select non-contiguous results) down while clicking additional results. Ensure the New Tag field is blank and click Change Tags to remove the tags from all selected scan results.

CREATING A TIME COURSE REPORT TEMPLATE

Users can create a time course report template to illustrate data collected from a time course series by selecting the **Manage** tab > *Report Templates* option and clicking the **Create** button located at bottom of the screen. See *Editing a Report Template* on page 80 for details on using the *Report Template Designer*.

Follow these steps to create a simple time course report template containing a chart:

- 1. From the Control Toolbox displayed along the left side of viewing pane, select the **Chart** object and drag it onto the template. The *Chart Designer* window opens automatically.
- 2. Click the **Change Chart Type** icon located above the navigation panel on the left. Use the scroll bar to select the desired chart type (e.g., *Line* in the *Line Series* section).
- 3. In the navigation panel, click "Series 1" once to highlight it.
- 4. In the panel displayed on the right, click the **Data** tab. From the *objectDataSource1* list displayed, expand the *TimeCourseData* list (must be expanded for both levels).
- 5. Select and drag ScanCreationTimeStamp into the Argument cell below the list.
- 6. Select and drag *LiveCount* into the **Value** cell below the list.
- 7. Click **OK** followed by the **Select Result** button (located at bottom of the screen).
- 8. Choose a result that has a value in the *Tag* column and click **Select**. If a tag is associated with multiple results, selecting the result with the most recent Scan Creation timestamp will include all the results in the chart while selecting a scan result in the middle of the series will display only data available at that point in time.
- 9. Click the Preview tab (located in upper right corner of screen) to preview the chart with selected data.
- 10. Click **Save and Back** to enter a name for the time course report template.

Once you've created a time course report template, assign it to an assay being used for the collection of time series data and enable it for display as a report tab (e.g., **Growth Curve**). Ensure that tags have been added to scan results identifying key data points in the time course series and select a scan result associated with that tag to be used as the endpoint for the report.

To create a more complex time course report template or for assistance using *Report Template Designer*, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com

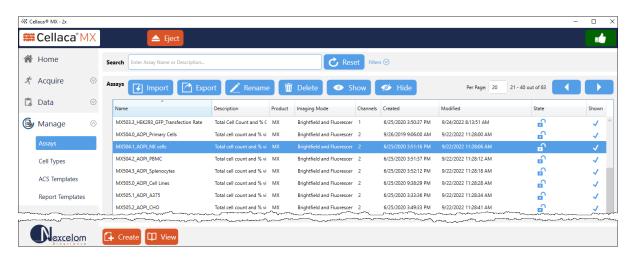
Chapter 6. Managing Assays

This chapter describes how assays are displayed in the *Assays List* and how to manage the list to keep it current. Details on how to edit and create assays are also provided. Assay parameters can be optimized before each count /recount to meet your analysis needs.

Note: When migrating to the Matrix database from an earlier version, updated assays can be imported via the software *after* migration is complete. For a list of assays provided with the Matrix software or for assistance in defining a custom assay, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com

VIEWING THE ASSAYS LIST

You can manage assays available for your instrument system by clicking the **Manage** tab > *Assays* option to view the *Assays List*. From this screen you can import/export, rename and delete assays appearing in the *Assays List*, as well as show/hide assays displayed in the *Assays* drop-down appearing in other screens.



In addition, you can select an assay from the list to view/edit its details, create a new assay by defining custom parameter settings or use a locked assay as a source for creating a new assay based on its parameter settings.

Note: If the Matrix 21 CFR Part 11 module is enabled, the **Create** button (and **Save and Back** button when viewing assay details) will only be available for users who have been granted permission to perform these functions.

Use the **Per Page** Per Page 20 21-40 out of 83 control to change the number of assays displayed per page and the arrows to move back and forth between pages in the list.

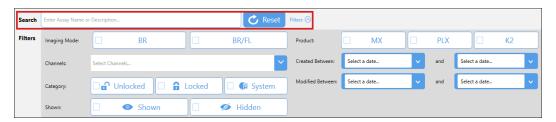
Assays can be sorted by clicking on column headings (i.e., ascending // descending // indicators will be displayed) and information presented for each assay includes name, description, the product for which it is intended, imaging mode defined for the assay and created/last modified dates.

Icons displayed in the *State* column indicate whether an assay was provided as a Revvity *System* standard, (which cannot be edited) or if an assay is currently *Locked* or *Unlocked*. When viewing *System* and *Locked* assays, a **Save As** button allows users to copy defined parameter settings as a source for creating a new assay.

A checkmark $\sqrt{\ }$ displayed in the *Shown* column indicates the assay is to be included in the *Assays* drop-down available in other screens (e.g., **Select Assay** field in the **Acquire** tab > *Setup* screen and **Assay for Recount** field in the **Acquire** tab > *Recount* screen).

SEARCHING FOR ASSAYS

To search for an assay, enter a few key characters of an assay name or description in the **Search** field and/or expand the *Filters* area by clicking the down arrow Filters to specify search criteria.



As you choose filters (e.g., by selecting *Imaging Mode*, *Category*, *Shown* and *Product* options) or enter a *Created Between/Modified Between* range of dates, the *Assays List* is updated automatically to display matching entries.

Imaging Mode Choose from the following imaging modes:

BR – Filters for assays with Brightfield

BR/FL - Filters for assays with Brightfield and Fluorescence

Channels Use the dr

Use the drop-down to select one or more channels to be included in the search, then click **OK**.



Category

Choose from the following categories:

Unlocked – Filters for assays that are unlocked and can be edited **Locked** – Filters for assays that are locked and cannot be edited

System – Filters for assays provided by Revvity (locked and cannot be edited)

System assays are no longer available in the Assay Library provided with the Matrix software but may exist on your system if imported from an earlier release.

Shown

Choose from the following *Shown* states:

Shown – Filters for assays selected to appear in the *Assays* drop-down **Hidden** – Filters for assays that do *not* appear in the *Assays* drop-down

Note: The *Assays* drop-down is available in other screens (e.g., **Select Assays** field in the Setup screen and **Assay for Recount** field in the Recount screen).

Product Choose from the following products:

MX – Filters for assays selected to be used for the Cellaca MX
 PLX – Filters for assays selected to be used for the Cellaca PLX
 K2 – Filters for assays selected to be used for the Cellometer K2

Created Between Enter a *Created Between* range by selecting start/end dates representing a time period

during which to filter for assays that were created.

Modified Between Enter a *Modified Between* range by selecting start/end dates representing a time

period during which to filter for assays that were modified.

If you find it necessary to clear all selected filters and begin the search again, click the **Reset** button.

To select an assay and view its details, double-click it in the *Assays List* or click the assay once to highlight it and then click the **View** button located at the bottom of the screen.

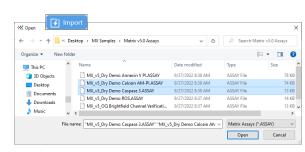
MAINTAINING THE ASSAYS LIST

When you select an assay, buttons at the top of the *Assays List* become available to perform the following functions. The *Import* button will always be available as it does not require the selection of an assay in your library.

Note: If the Matrix 21 CFR Part 11 module is enabled, buttons will only be available for users who have been granted permission to perform specific functions.

Importing Assays

- 1. While viewing the Assays List, click the **Import** button.
- 2. Navigate to a folder where an external assay library is available or an assay was previously saved.
- 3. Select one or more .ASSAY files to be imported. Keep in mind that cell types and report templates associated with selected assays will also be included in the import.
- 4. Click Open. If selected assays (or cell types and report templates associated with the assays) already exist in your database, respond to confirmation prompts by overwriting the files in your system, auto renaming the files on import or canceling import of the file.
- 5. Click **OK** to acknowledge the successful import and confirm that imported assays are displayed in the *Assays List*.





Exporting Assays

- Select one or more assays from the Assays List to be exported by clicking once to highlight the first one and then holding either the Shift key (to select a block of assays) or Ctrl key (to select non-contiguous assays) down while clicking additional assays.
- 2. Click the **Export** button.
- 3. Navigate to a folder where assays are to be saved.
- 4. Click **OK** to save .ASSAY files in the export location.

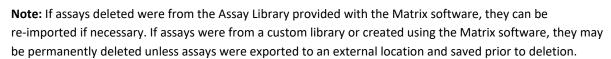
Renaming Assays

The **Rename** button will only be enabled for unlocked assays.

- 1. Select the assay to be renamed and click the **Rename** button.
- 2. Edit the assay name and click **Rename** to save your changes.

Deleting Assays

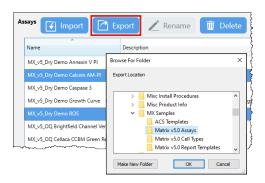
- Select one or more assays from the Assays List to be deleted by clicking once to highlight the first one and then holding either the Shift key (to select a block of assays) or Ctrl key (to select non-contiguous assays) down while clicking on additional assays.
- 2. Click the **Delete** button followed by **Yes** to confirm the action. If the Matrix 21 CFR Part 11 module is enabled, users will be prompted to enter a reason prior to deletion.



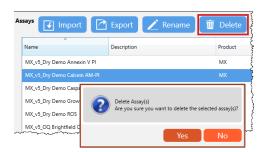
Showing/Hiding Assays in Drop-down

The Assays drop-down is available in other screens (e.g., **Select Assay** field in the **Acquire** tab > Setup screen and **Assay for Recount** field in the **Acquire** tab > Recount screen).

- Select one or more assays from the Assays List to be shown or hidden in the Assays drop-down by clicking
 once to highlight the first one and then holding either the Shift key (to select a block of assays) or Ctrl key
 (to select non-contiguous assays) down while clicking on additional assays.
- 2. Click the **Show** or **Hide** button depending on whether you want to show/hide the selected assays in the *Assays* drop-down available in other screens.





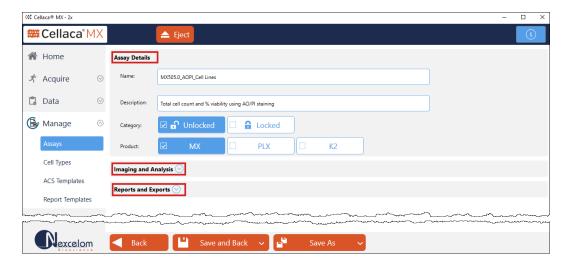




EDITING AN ASSAY

Editing an assay allows users to change basic *Assay Details* (such as name, description, category and product type), defined *Imaging and Analysis* parameter settings, and *Reporting* templates currently assigned to the assay. *Not all options shown in this section are available for all products and instrument configurations*.

To select an assay and view its details, double-click it in the *Assays List* or click the assay once to highlight it and then click the **View** button located at the bottom of the screen.



Note: The assay displayed contains many sections in which the content of each section may vary depending on the product type and the channels chosen to be associated with the assay.

Edit the assay as described in each of the sections presented below:

- Modifying Basic Assay Details on page 46
- Defining Assay Imaging and Analysis Parameters (For Cellaca MX/PLX) on page 47
- Defining Assay Imaging and Analysis Parameters (For Cellometer K2) on page 53
- Managing Assay Reports and Exports on page 57

When viewing/editing of an assay is complete, click one of the following buttons to return to the Assays List.



Back Button: Click **Back** to return to the previous screen without saving any changes. *If* assay has unsaved changes, click **OK** in response to the confirmation prompt.



Save and Back | Save Buttons: Click Save and Back to save your changes and return to the previous screen. Depending on the nature of your editing session, click to toggle the display of this button between Save (to save and continue editing) and Save and Back.

Save As | Save As and Back Buttons: Click Save As to save your changes as a copy with a new name or select another assay from the drop-down to override it and return to the previous screen. If the assay is locked, this also allows you to copy the assay to use as a source for creating a new assay. Depending on the nature of your editing session, click to toggle the display of this button between Save As (to save current version as a copy and continue editing it) and Save As and Back.

Modifying Basic Assay Details

In the Assay Details area, you can edit the assay Name, Description, Category or Product as indicated below.



Note: You can only edit an assay if the category displayed is *Unlocked*. If the category displayed is *Locked* or if the assay is a Revvity *System* default, you must first copy the assay by clicking the **Save As** button and entering a new name to save defined parameters as a source for creating a new assay. Once saved, you can edit copied parameters in the new assay as necessary.

To edit basic assay details, modify information contained in the following fields.

Name Displays the name of the assay. *Must be unique*.

Description Displays a brief description which can be used to identify the purpose of the assay or include defined parameters to help users distinguish it from others presented in the *Assays List*.

Indicates if an assay was provided as a Revvity default System (i.e., System assays cannot be edited) or if its current status is Unlocked or Locked. When viewing details for a Locked or System assay, use the Save As button to enter a new name and copy defined parameters to be used as a source for creating a new assay.

The locked state of an assay is displayed in the *State* column of the *Assays List* using the Revvity *System*, *Unlocked* or *Locked* column of the *Assays List* using the Revvity

If an assay is unlocked, you can select the **Locked** button to prevent the assay from being edited by other users.

Note: It is recommended that you do *not* select the **Locked** button until *after* editing is complete as once the assay is locked, you will no longer be able to make any changes.

Product

Indicates product type for which the assay was created (e.g., MX, PLX, K2).

Note: As the Matrix software is shared by multiple product families, it must account for physical differences between instruments. To accommodate for these differences, assay details available for editing may vary from what is presented in this guide based on the selected product.

Variations in *Imaging and Analysis Parameters* between instruments are grouped in two sections:

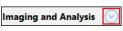
- Defining Assay Imaging and Analysis Parameters (For Cellaca MX/PLX) on page 47
- Defining Assay Imaging and Analysis Parameters (For Cellometer K2) on page 53

Defining Assay Imaging and Analysis Parameters (For Cellaca MX/PLX)

This section describes assay imaging and analysis parameters in the Matrix software available for Cellaca MX/PLX.

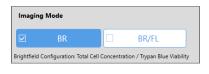
In the Imaging and Analysis area, you can edit defined assay parameter settings for Imaging Mode, Analysis Mode, Focusing Mode (if available based on product), Dilution and Channel Imaging Parameters as indicated below.

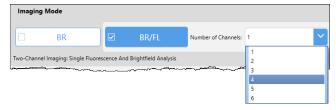
If Imaging and Analysis parameters are not displayed, expand the area by clicking the down arrow Imaging and Analysis to view available options.



IMAGING MODE OPTIONS

Edit Imaging Mode selected for the assay by clicking an imaging mode option.





- BR Brightfield Only – Indicates assay will use a brightfield image to determine Total Cell Concentration and Trypan Blue Cell Viability.
- BR/FL Brightfield/Fluorescence: Indicates assay will use single, dual or multiple channel imaging by analyzing fluorescent images in conjunction with their associated brightfield images.

Number of Channels: Drop-down lists available channels for the assay (i.e., 1-6 for Cellaca MX/PLX).

- BR/FL 1 Brightfield Image, Single Fluorescent Image Analysis
- BR/FL 2 Brightfield Image, Two Fluorescent Images Analysis
- BR/FL 3-6 Brightfield Image, Three+ Fluorescent Images Analysis

Note: If channels previously defined for assay will be lost as a result of a new imaging mode selected, you will be prompted with a confirmation message. Click **OK** to proceed or **Cancel** to retain current imaging mode.



ANALYSIS MODE OPTIONS

In the *Analysis Mode* area you can edit the analysis mode selected for the assay by clicking available options (as shown in the screens below) and entering values for any additional fields presented.

Note: Analysis modes displayed will vary based on the selected *Imaging Mode* for the assay. In addition, *Channel Imaging and Cell Type Parameters* displayed on page 51 will also vary as a result of the selected *Analysis Mode*.

FOR BR ONLY IMAGING MODE

Cell Count – Perform brightfield image analysis to determine *Total Cell Concentration*.

Trypan Viability – Perform brightfield image analysis of Trypan Blue exclusion to determine *Cell Viability*.



FOR BR/FL 1 CHANNEL IMAGING MODE

Cell Count — Count cells in brightfield/fluorescent images independently. Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images.*

Viability — Calculate cell concentration and % viability using a nuclear staining dye (single-fluorescence). Allows you to select a BR, FL or Hybrid mask to assist in finding FL positive cells. In addition, you can select FL Classification (Live or Dead).

Use a fluorescent mask if cells are difficult to detect in brightfield images OR a Hybrid mask when counting FL images to exclude corresponding cells found in BR images (e.g., dead cells with faint walls that only show up using FL).

Expression – Perform analysis using a single fluorophore (e.g., GFP, RFP, etc.). Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images.*

You can also expand (*increase Expand value*) or contract (*decrease Expand value*) the mask around objects found to accurately collect fluorescent intensity measurements.







Expression assays use a single mask for segmentation while pulling fluorescent values from the same area across all channels. By enabling the software to read FL values from cells without requiring those cells to be segmented in each FL channel using traditional methods, weaker FL intensities can be identified.

FOR BR/FL 2 CHANNEL IMAGING MODE

Viability — Calculate cell concentrations and % viability using two nuclear staining dyes (dual-fluorescence). Allows you to select either no mask (None) or a brightfield (BR) mask to assist in finding FL positive cells. You can also select a FL Classification (Total, Live or Dead populations) for each channel.

Total classification can only be assigned to one FL channel. If currently selected in one channel, selecting it in the other channel automatically swaps the first channel options.

Expression – Perform analysis using dual fluorescence for samples with two FL stains. Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images.*

You can also expand (*increase Expand value*) or contract (*decrease Expand value*) the mask around objects found to accurately collect fluorescent intensity measurements.





Expression assays use a single mask for segmentation while pulling fluorescent values from the same area across all channels. By enabling the software to read FL values from cells without requiring those cells to be segmented in each FL channel using traditional methods, weaker FL intensities can be identified.

FOR BR/FL 3+ CHANNEL IMAGING MODE

Expression – Perform multi-fluorescence analysis for samples with three or more FL stains. Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images*.

You can also expand (*increase Expand value*) or contract (*decrease Expand value*) the mask around objects found to accurately collect fluorescent intensity measurements.



Expression assays use a single mask for segmentation while pulling fluorescent values from the same area across all channels. By enabling the software to read FL values from cells without requiring those cells to be segmented in each FL channel using traditional methods, weaker FL intensities can be identified.

FOCUSING MODE OPTIONS

This section describes adjusting instrument focus using internal controls via Matrix software for Cellaca MX/PLX.

In the *Focusing Mode* area, you can edit the Focus Mode for the assay by clicking an option (e.g., *Focus Map, Auto Focus 1st Well* or *Auto Focus All Wells*) and defining settings for any additional fields presented.

Focus Map

Performs manual focusing by using the system's internal built-in plate layout to acquire images rapidly.



Auto Focus 1st Well

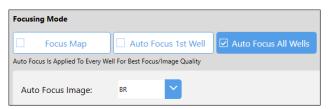
Performs automatic focusing (auto focus) on the 1^{st} well and then calculates the focus offset for all remaining wells. This option automatically uses the same set for all wells and is the fastest way to establish instrument focus.



Select the **Auto Focus Image** (e.g., *BR*, *FL1-FL6* based on number of channels in assay) to choose the image to be used during auto focus.

Auto Focus All Wells

Performs automatic focusing (auto focus) on all wells allowing the system to determine the best focus/image quality for each individual well.



Select the **Auto Focus Image** (e.g., *BR*, *FL1-FL6* based on number of channels in assay) to choose the image to be used during auto focus.

DILUTION FACTOR

In the Dilution area, you can edit the final dilution factor by clicking in the field and modifying the displayed value.

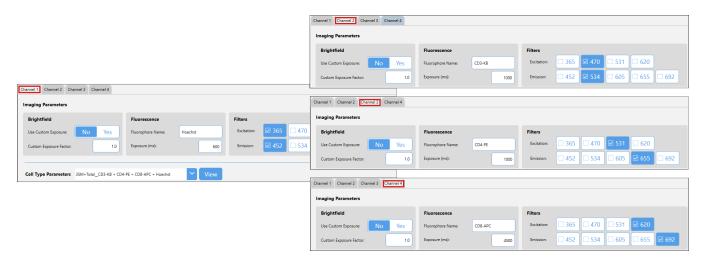


CHANNEL IMAGING AND CELL TYPE PARAMETERS

Channel Imaging Parameters are grouped using tabs and display will vary based on the selected Imaging Mode (i.e., Channel 1 tab is displayed for BR or BR/FL 1 imaging modes, and Channel 2 - Channel 6 tabs are displayed for the BR 2-6/FL 2-6).

Note: Channel 1 refers to **BR** only or **BR1|FL1** images taken by the instrument's camera during a scan through the first specified filter pair and Channels 2-6 refer to the **BR 2-6|FL 2-6** images taken through additional filter pairs.

You can edit *Channel Imaging Parameters* (e.g., *Brightfield, Fluorescence* and *Filters*) for the assay. If **Channel 1** and **Channel 2** tabs are available, toggle between the display for each channel by clicking on the applicable tab. *Channel 1 Imaging Parameters are displayed by default.*



Brightfield Use Custom Exposure – Indicates if custom exposure factors are being used for the channel.

Click Yes to edit value in the Custom Exposure Factor field (below).

Custom Exposure Factor – Value prolongs or shortens exposure time for brightfield image.

Fluorophore Name – Displays fluorophore name being used for the channel.

Exposure (ms) – Value indicates exposure time for fluorescent image.

Filters Excitation (365, 470, 531, 620) – Indicates excitation filter wavelength used for the channel.

Emission (452, 534, 605, 655, 692) – Indicates emission filter wavelength used for the

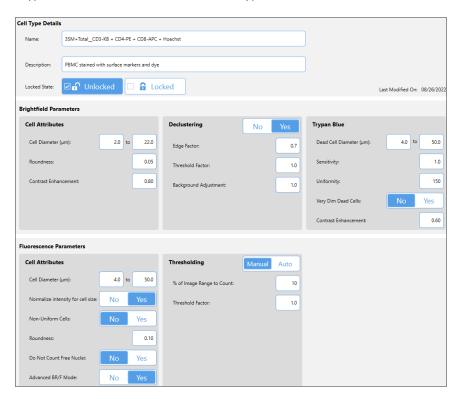
channel.

In addition, you can edit *Cell Type Parameters* used for the channel by changing the currently selected cell type (i.e., use the drop-down to choose another cell type) and clicking the **View** button to modify cell type parameters.

Note: When using the **Viability** Analysis Mode, cell type parameters can be set independently for each channel. However, when using the **Expression** Analysis Mode with more than one channel, cell type parameters are only required for *Channel 1*.

To manage cell types available on your instrument system or to edit/create cell types, see *Chapter 7. Managing Cell Types* on starting on page *61*.

If you click the **View** button to modify cell type parameters, whether you can edit parameter settings displayed will depend on the cell type's *Locked State* indicated in the *Cell Type Details* section.



Note: You can only edit parameter settings for cell types that are *Unlocked*. However, for Revvity *System* or *Locked* cell types you can click the **Save As** button located at the bottom of the screen to save cell type parameters by entering a new name and clicking **Save**, then edit its parameter settings accordingly. When you click **Save and Back**, the cell type currently selected has been automatically updated to the cell type you just saved/modified.

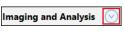
If the cell type is *Unlocked* you can edit parameter settings and then click **Save and Back** to save your changes. See *Editing a Cell Type* on page *65* for more information on editing cell type parameter settings.

Defining Assay Imaging and Analysis Parameters (For Cellometer K2)

This section describes assay imaging and analysis parameters in the Matrix software available for Cellometer K2.

In the Imaging and Analysis area, you can edit defined assay parameter settings for Imaging Mode, Analysis Mode, Focusing Mode (if available based on product), Dilution and Channel Imaging Parameters as indicated below.

If Imaging and Analysis parameters are not displayed, expand the area by clicking the down arrow Imaging and Analysis to view available options.



IMAGING MODE OPTIONS

Edit *Imaging Mode* selected for the assay by clicking an imaging mode option.





- BR Brightfield Only: Indicates assay will use a brightfield image to determine Total Cell Concentration and Trypan Blue Cell Viability.
- BR/FL Brightfield/Fluorescence: Indicates assay will use single or dual channel imaging by analyzing fluorescent images in conjunction with their associated brightfield images.

Number of Channels: Drop-down lists available channels for the assay (i.e., 1-2 for Cellometer K2).

- BR/FL 1 Brightfield Image, Single Fluorescent Image Analysis
- BR/FL 2 Brightfield Image, Two Fluorescent Image Analysis

Note: If channels previously defined for assay will be lost as a result of a new imaging mode selected, you will be prompted with a confirmation message. Click **OK** to proceed or **Cancel** to retain current imaging mode.



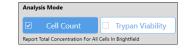
ANALYSIS MODE OPTIONS

In the Analysis Mode area you can edit the analysis mode selected for the assay by clicking available options (as shown in the screens below) and entering values for any additional fields presented.

Note: Analysis modes displayed will vary based on the selected Imaging Mode for the assay. In addition, Channel Imaging and Cell Type Parameters displayed on page 51 will also vary as a result of the selected Analysis Mode.

FOR BR ONLY IMAGING MODE

Cell Count – Perform brightfield image analysis to determine Total Cell Concentration.



Trypan Viability – Perform brightfield image analysis of Trypan Blue exclusion to determine Cell Viability.

FOR BR/FL 1 CHANNEL IMAGING MODE

Cell Count — Count cells in brightfield/fluorescent images independently. Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images.*

Viability — Calculate cell concentration and % viability using a nuclear staining dye (single-fluorescence). Allows you to select a BR, FL or Hybrid mask to assist in finding FL positive cells. In addition, you can select FL Classification (Live or Dead).

Use a fluorescent mask if cells are difficult to detect in brightfield images OR a Hybrid mask when counting FL images to exclude corresponding cells found in BR images (e.g., dead cells with faint walls that only show up using FL).

Expression – Perform analysis using a single fluorophore (e.g., GFP, RFP, etc.). Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images*.

You can also expand (*increase Expand value*) or contract (*decrease Expand value*) the mask around objects found to accurately collect fluorescent intensity measurements.







Expression assays use a single mask for segmentation while pulling fluorescent values from the same area across all channels. By enabling the software to read FL values from cells without requiring those cells to be segmented in each FL channel using traditional methods, weaker FL intensities can be identified.

FOR BR/FL 2 CHANNEL IMAGING MODE

Viability — Calculate cell concentrations and % viability using two nuclear staining dyes (dual-fluorescence). Allows you to select either no mask (None) or a brightfield (BR) mask to assist in finding FL positive cells. You can also select a FL Classification (Total, Live or Dead populations) for each channel.

Total classification can only be assigned to one FL channel. If currently selected in one channel, selecting it in the other channel automatically swaps the first channel options.



Expression – Perform analysis using dual fluorescence for samples with two FL stains. Allows you to select either a **BR** or **FL** mask to assist in finding FL positive cells. *Use a fluorescent mask if cells are difficult to detect in brightfield images.*

You can also expand (*increase Expand value*) or contract (*decrease Expand value*) the mask around objects found to accurately collect fluorescent intensity measurements.



Expression assays use a single mask for segmentation while pulling fluorescent values from the same area across all channels. By enabling the software to read FL values from cells without requiring those cells to be segmented in each FL channel using traditional methods, weaker FL intensities can be identified.

DILUTION FACTOR

In the Dilution area, you can edit the final dilution factor by clicking in the field and modifying the displayed value.

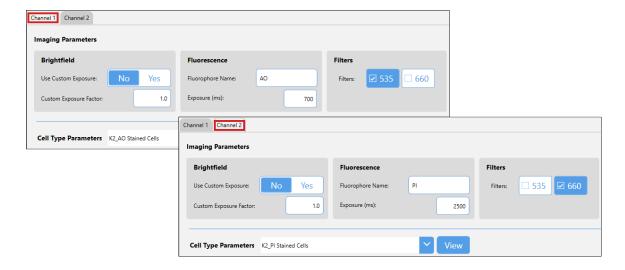


CHANNEL IMAGING AND CELL TYPE PARAMETERS

Channel Imaging Parameters are grouped using tabs and display will vary based on the selected Imaging Mode (i.e., Channel 1 tab is displayed for BR or BR/FL 1 imaging modes, and Channel 2 tab is displayed for BR/FL 2).

Note: Channel 1 refers to **BR** only or **BR1|FL1** images taken by the instrument's camera during a scan through the first filter set and Channel 2 refers to the **BR2|FL2** images taken through the second filter set.

You can edit *Channel Imaging Parameters* (e.g., *Brightfield, Fluorescence* and *Filters*) for the assay. If **Channel 1** and **Channel 2** tabs are available, toggle between the display for each channel by clicking on the applicable tab. *Channel 1 Imaging Parameters are displayed by default.*



Brightfield Use Custom Exposure – Indicates if custom exposure factors are being used for the channel.

Click Yes to edit value in the Custom Exposure Factor field (below).

Custom Exposure Factor – Value prolongs or shortens exposure time for brightfield image.

Fluorescence Fluorophore Name – Displays fluorophore name being used for the channel.

Exposure (ms) – Value indicates exposure time for fluorescent image.

Filters 535 – Excitation 470 nm/Emission 535 nm

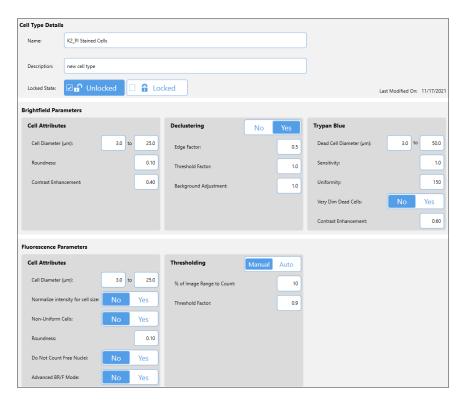
660 – Excitation 540 nm/Emission 660 nm

In addition, you can edit *Cell Type Parameters* used for the channel by changing the currently selected cell type (i.e., use the drop-down to choose another cell type) and clicking the **View** button to modify cell type parameters.

Note: When using the **Viability** Analysis Mode, cell type parameters can be set independently for each channel. However, when using the **Expression** Analysis Mode with more than one channel, cell type parameters are only required for *Channel 1*.

To manage cell types available on your instrument system or to edit/create cell types, see *Chapter 7. Managing Cell Types* on starting on page *61*.

If you click the **View** button to modify cell type parameters, whether you can edit parameter settings displayed will depend on the cell type's *Locked State* indicated in the *Cell Type Details* section.



Note: You can only edit parameter settings for cell types that are *Unlocked*. However, for Revvity *System* or *Locked* cell types you can click the **Save As** button located at the bottom of the screen to save cell type parameters by entering a new name and clicking **Save**, then edit its parameter settings accordingly. When you click **Save and Back**, the cell type currently selected has been automatically updated to the cell type you just saved/modified.

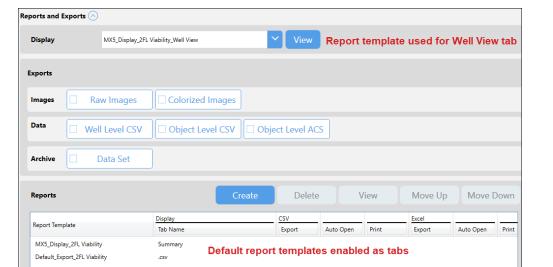
If the cell type is *Unlocked* you can edit parameter settings and then click **Save and Back** to save your changes. See *Editing a Cell Type* on page *65* for more information on editing cell type parameter settings.

Managing Assay Reports and Exports

In the *Reports and Exports* area you can assign report templates to control how data is displayed, exported and printed. In addition to the **Well View** tab which will always be displayed, a total of five (5) custom reporting tabs may be enabled for display at any one time.

Note: As of the Matrix v4.0 release, report templates are no longer limited to the *Display, Export* or *Print* template types used in earlier releases. A report template can be created for all these purposes and multiple templates assigned to an assay as needed. In addition, report tabs enabled by default will vary based on the Matrix software version associated with an assay (e.g., **Well View, Summary** and **.csv** tabs are displayed for v4.0 assays; **Well View** and **All Wells** tabs for v3.0 assays). Users can change report templates assigned to these tabs, edit the templates directly (i.e., any changes made will also be applied to other scan results using these templates), disable them from displaying as tabs or delete them from the assay.

If *Imaging and Analysis* parameters are not displayed, expand the area by clicking the down arrow to view available options.



To change the report template currently assigned to the **Well View** tab, use the **Display** drop-down to select a new template. Click **View** to confirm the selected template suits your display needs and edit it if necessary.

To define assay *Exports* such as *Images*, *Data* and *Archive* output files (i.e., exported automatically after analysis is complete), select any of the following options.

Raw Images Represents *Black and White* high-resolution PNG images.

Colorized Images Represents *Fluoresced* high-resolution PNG images.

Well Level CSV Represents well-level data including well name, calculation run, channel, count, mean size,

etc. for each selected well in Comma Separated Values (CSV) format.

Object Level CSV Represents object-level data including type, classification, size, circularity, area, perimeter,

etc. in Comma Separated Values (CSV) format.

Object Level ACS Represents object-level data including type, classification, size, circularity, area, perimeter,

etc. in Image Cytometry Experiment (ICE) format. Data may be associated with an ACS template for import into the De Novo Software FCS Express application. See Chapter 8.

Managing ACS Templates starting on page 71.

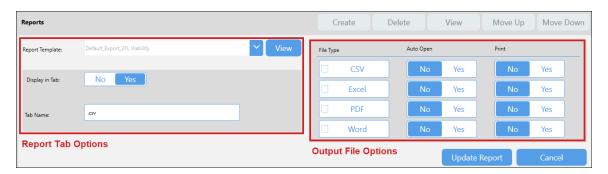
Data Set Represents a database file containing all images, results, assays, cell types and report

templates associated with the scan result.

To select a report template and edit how it is being applied to an assay, double-click it in the *Reports* area, or click on a report in the list once to highlight it and then click the **View** button.



You can use report tab options to disable/enable the display of report templates as tabs and edit/enter tab names. A total of five (5) custom tabs may be enabled for display at any one time. In addition, you can select output file types for report templates and indicate if files are to be opened automatically or printed upon report generation. Click the **Update Report** button to save your changes and view the updated Reports List.



To manage this list for an assay, select a template and click the Create/Delete or Move Up/Move Down buttons.



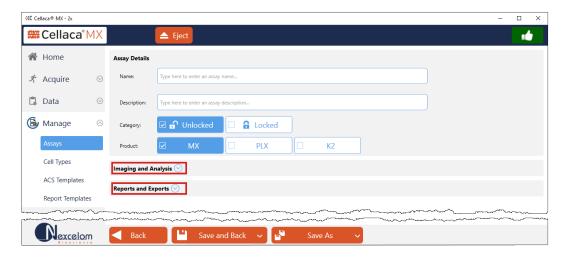
- Add a report template by clicking the Create button. Select a template in the Report Template field, choose if the report should be enabled as a tab for display (i.e., Yes) and enter a tab name. Select any output file types for the report and indicate if they are to be opened automatically (Auto Open) or printed upon generation whenever the assay is used to perform a count/recount. Output of files is independent of whether a template is also enabled as a tab. Click the Add Report button to add the report to the Reports List.
- Delete a template by clicking on the report once to highlight it and then clicking the **Delete** button.
 If report template deleted was from the Report Template Library provided with the Matrix software, it can be re-imported if necessary. If report template was from a custom library or created using the Matrix software, it may be permanently deleted unless it was exported to an external location and saved prior to deletion.
- Change the order in which report tabs are displayed by changing the sequence of templates in the Report List. Highlight a report template to select it and click the **Move Up** or **Move Down** buttons accordingly.

For complete step-by-step instructions on setting reporting options for an assay such as changing the display template in the **Well View** report, managing an assay Report List or adding report templates, see *Chapter 5*. *Customizing Scan Result Reports* starting on page *33* for details.

CREATING A NEW ASSAY

You can create a new assay by clicking the **Manage** tab > *Assays* option to display the *Assays List* and then clicking the **Create** button located at the bottom of the screen.

Enter basic Assay Details (such as name, description, category and product type), Imaging and Analysis parameter settings and Reporting options, and then click the Save and Back button to add the assay to the Assays List.



To copy defined parameter settings for an existing assay to be used as a source for creating a new assay, select an assay and view its details by double-clicking it in the *Assays List* or clicking it once to highlight it and then clicking the **View** button located at the bottom of the screen. Click the **Save As** button and enter a new name to save a copy of the assay, and then click the **Save** button.

Edit assay parameters as described in *Editing an Assay* on page 45 and click the **Save and Back** button to confirm that the new assay has been saved to the *Assays List*.

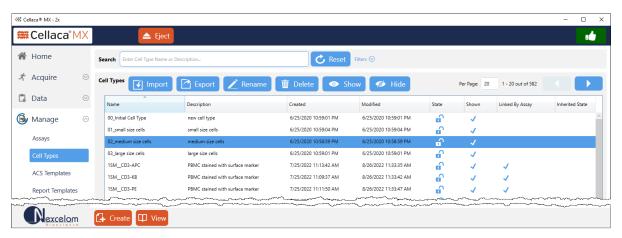
Chapter 7. Managing Cell Types

This chapter describes how cell types are displayed in the *Cell Types List* and how to manage the list to keep it current. Details on how to edit and create cell types are also provided. Cell type parameters can be optimized to meet your data acquisition needs.

Note: When migrating to the Matrix database from an earlier version, updated cell types can be imported via the software *after* migration is complete. For a list of cell types provided with the Matrix software or for assistance in defining a custom cell type, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com

VIEWING THE CELL TYPES LIST

You can manage cell types for your instrument system by clicking the **Manage** tab > *Cell Types* option to view the *Cell Types List*. From this screen you can import/export, rename and delete cell types appearing in the *Cell Types List*, as well as show/hide cell types displayed in the *Cell Types* drop-down appearing in other screens.



In addition, you can select a cell type from the list to view/edit its details, create a new cell type by defining custom parameter settings or use a locked cell type as a source for creating a new cell type based on its parameter settings.

Note: If the Matrix 21 CFR Part 11 module is enabled, the **Create** button (and **Save and Back** button when viewing cell type details) will only be available for users who have been granted permission to perform these functions.

Use the **Per Page** Per Page control to change the number of cell types displayed per page and the arrows to move back and forth between pages in the list.

Cell types can be sorted by clicking on column headings (i.e., ascending // descending indicators will be displayed), and information presented for each cell type includes name, description and created/last modified dates.

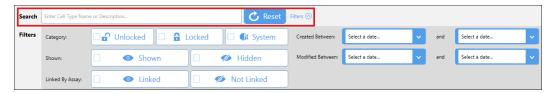
Icons displayed in the *State* column indicate whether a cell type was provided as a Revvity *System* standard (which cannot be edited) or if a cell type is currently *Locked* or *Unlocked*. When viewing *System* and *Locked* cell types, a **Save As** button allows users to copy defined parameter settings as a source for creating a new cell type.

The remaining columns display checkmarks $\sqrt{}$ for the cell type based on the conditions noted below:

- A checkmark displayed in the *Shown* column indicates the cell type is to be included in the *Cell Type* drop-down available in other screens (e.g., **Cell Type Parameters** field in the **Manage** tab > Assay Details screen).
- A checkmark displayed in the Linked by Assay column indicates the cell type is associated with an assay. Cell
 types must be unlinked from all assays before they can be deleted.
- A checkmark displayed in the *Inherited State* column indicates the cell type was locked prior to importing it into your instrument library (i.e., its *Locked State* was inherited during import). *Keep in mind that cell types may be imported directly via the Manage* tab > *Cell Types screen or as components when importing assays/datasets.*

SEARCHING FOR CELL TYPES

To search for a cell type, enter a few key characters of a cell type name or description in the **Search** field and/or expand the *Filters* area by clicking the down arrow filters to specify search criteria.



As you choose filters (e.g., by selecting *Category, Shown* or *Linked By Assay* options) or enter a *Created Between/Modified Between* range of dates, the *Cell Types List* is updated automatically to display matching entries.

Category Choose from the following categories:

Unlocked – Filters for cell types that are unlocked and can be edited

Locked – Filters for cell types that are locked and cannot be edited

System – Filters for cell types provided by Revvity (locked and cannot be edited)

System cell types are no longer available in the Cell Type Library provided with the Matrix software but may exist on your system if imported from an earlier release.

Shown Choose from the following *Shown* states:

Shown – Filters for cell types selected to appear in the *Cell Types* drop-down

Hidden – Filters for cell types that do not appear in the Cell Types drop-down

Note: The Cell Types drop-down is available in other screens (e.g., Cell Type

Parameters field in the Assay Details screen).

Linked By Assay Choose from the following *Linked by Assay* states:

Linked – Filters for cell types that are currently associated with an assay

Not Linked – Filters for cell types that are not currently associated with an assay

Cell types must be unlinked from all assays before they can be deleted.

Created Between Enter a *Created Between* range indicating the start/end dates between which to filter

for cell types created in that time frame.

Modified Between Enter a Modified Between range indicating the start/end dates between which to filter

for cell types modified in that time frame.

If you find it necessary to clear all selected filters and begin the search again, click the **Reset** button.

To select a cell type and view its details, double-click it in the *Cell Types List* or click the cell type once to highlight it and then click the **View** button located at the bottom of the screen.

MAINTAINING THE CELL TYPES LIST

When you select a cell type, buttons at the top of the *Cell Types List* become available to perform the following functions. The *Import* button will always be enabled as it does not require the selection of a cell type in your library.

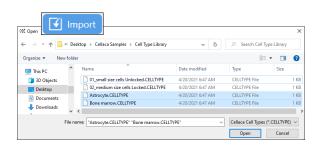
Note: If the Matrix 21 CFR Part 11 module is enabled, buttons will only be available for users who have been granted permission to perform specific functions.

Importing Cell Types

- 1. While viewing the *Cell Types List*, click the **Import** button.
- 2. Navigate to a folder where an external cell type library is available or a cell type was previously saved.
- 3. Select one or more .CELLTYPE files to be imported.
- 4. Click Open. If selected cell types already exist in your database, respond to the confirmation prompt by clicking Yes to overwrite the file in your system or No to abort the import. If you choose No you will be prompted to enter a new name under which to import the cell type (and then click Rename) or click Cancel to abort the import.

Note: When importing a *System* or *Locked* cell type, you will be prompted to import it under a different name. Click **Yes**, enter a new name and click **Rename** to complete the import.

Click **OK** to acknowledge the successful import and confirm that imported cell types are displayed in the *Cell Types List*.





Exporting Cell Types

- Select one or more cell types from the Cell Types List
 to be exported by clicking once to highlight the first one
 and then holding either the Shift key (to select a block of
 cell types) or Ctrl key (to select non-contiguous cell
 types) down while clicking additional cell types.
- 2. Click the **Export** button.
- 3. Navigate to a folder where cell types are to be saved.
- 4. Click **OK** to save .*CELLTYPE* files in the export location.

Cell Types Export **√** Import m Delete Rename Export Location 1SM CD4-PE Misc Install Procedures Misc Product Info MX Samples ACS Templates 1SM+Viab_CD3-APC + F 7/25/2022 1:2 Matrix v5.0 Assays Matrix v5.0 Cell Types Matrix v5.0 Report Template OK Cancel Make New Folder

Renaming Cell Types

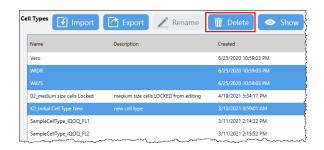
The **Rename** button will only be available for unlocked cell types.

- Select the cell type to be renamed and click the Rename button.
- 2. Edit the cell type name and click **Rename** to save your changes.

Rename Cell Type New Name: ISM_CD8-APC New Rename Cancel

Deleting Cell Types

- Select one or more cell types from the Cell Types List
 to be deleted by clicking once to highlight the first one
 and then holding either the Shift key (to select a block
 of cell types) or Ctrl key (to select non-contiguous cell
 types) down while clicking on additional cell types.
- 2. Click the **Delete** button. *If the Matrix 21 CFR Part 11* module is enabled, users will be prompted to enter a reason prior to deletion.



Note: If cell types to be deleted were from the Cell Type Library provided with the Matrix software, they can be re-imported if necessary. If cell types were from a custom library or created using the Matrix software, they may be permanently deleted unless cell types were exported to an external location and saved prior to deletion.

Cell types must be unlinked from all assays before they can be deleted.

Showing/Hiding Cell Types in Drop-down

The Cell Types drop-down is available in other screens (e.g., Cell Type Parameters field in the Assay Details screen).

Select one or more cell types from the Cell Types List to be shown or hidden in the Cell Types drop-down by
clicking once to highlight the first one and then holding either the Shift key (to select a block of cell types) or
Ctrl key (to select non-contiguous cell types) down while clicking on additional cell types.

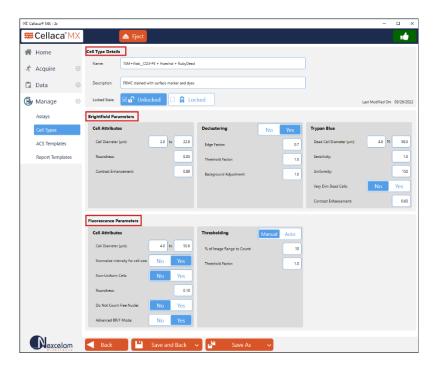
2. Click the **Show** or **Hide** button depending on whether you want to show/hide the selected cell types in the *Cell Types* drop-down available in other screens.



EDITING A CELL TYPE

Editing a cell type allows users to change basic *Cell Type Details* (such as name, description and locked state), defined *Brightfield Parameters* settings and *Fluorescence Parameters* settings.

To select a cell type and view its details, double-click it in the *Cell Types List* or click the cell type once to highlight it and then click the **View** button located at the bottom of the screen.



Edit the cell type as described in each of the sections presented below:

- Basic Cell Type Details on page 66
- Brightfield Parameters on page 67
- Fluorescence Parameters on page 69

When viewing/editing of a cell type is complete, click one of the following buttons to return to the Cell Types List.



Back Button: Click **Back** to return to the previous screen without saving any changes. *If cell type has unsaved changes, click* **OK** *in response to the confirmation prompt.*



Save and Back | Save Buttons: Click Save and Back to save your changes and return to the previous screen. Depending on the nature of your editing session, click to toggle the display of this button between Save (to save and continue editing) and Save and Back.



Save As | Save As and Back Buttons: Click Save As to save your changes as a copy with a new name or select another cell type from the drop-down to override it and return to the previous screen. If the cell type is locked, this also allows you to copy the cell type to use as a source for creating a new cell type. Depending on the nature of your editing session, click to toggle the display of this button between Save As (to save current version as a copy and continue editing it) and Save As and Back.

Basic Cell Type Details

Locked State

In the Cell Type Details area, you can edit the cell type Name, Description and Locked State as indicated below.



Note: You can only edit a cell type if the category displayed is *Unlocked*. If the category displayed is *Locked* or if the cell type is a Revvity *System* default, you must first copy the cell type by clicking the **Save As** button and entering a new name to save defined parameters as a source for creating a new cell type. Once saved, you can edit copied parameters for the new cell type as necessary.

To edit basic cell type details, modify information contained in the following fields.

Name Displays the name of the cell type. *Must be unique*.

DescriptionDisplays a brief description which can be used to identify the cell type or include defined

parameters to help users distinguish it from others presented in the Cell Types List.

Indicates if a cell type was provided as a Revvity default (i.e., *System* cell types cannot be edited) or if its current status is *Unlocked* or *Locked*. When viewing details for a *Locked* or *System* cell type, use the **Save As** button to copy defined parameters as a source to be used for creating a new cell type.

The locked state of a cell type is displayed in the *State* column of the *Cell Types List* using the Revvity *System* , *Unlocked* or *Locked* icons.

If a cell type is unlocked, you can select the **Locked** \square **a** Locked button to prevent the cell type from being edited by other users.

Note: It is recommended that you do *not* select the **Locked** button until *after* editing is complete as once the cell type is locked, you will no longer be able to make any changes.

Brightfield Parameters

In the Brightfield Parameters area, you can edit defined settings for Cell Attributes, Declustering and Trypan Blue parameters as indicated below.

Cell Attributes

Defines basic brightfield parameter attributes for cells to be counted.

Cell Diameter (µm) Indicates range of cell diameter minimum to maximum

values to be counted. Cells with diameters that fall

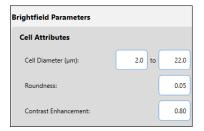
outside of this range will not be counted.

Roundness Indicates minimum cell shape roundness factor to be

> counted. Values range from 0.00 (includes all cell shapes) to 1.00 (includes only perfectly round cells).

Contrast Defines contrast enhancement value for cells in relation **Enhancement**

to the background. Values range from 0.00 (cells with high contrast to background) to 0.80 (cells with low contrast to background); recommended value is 0.4.



Declustering

Defines whether individual cells within a clump are to be counted. Turning this feature off allows clumps to be counted as one unit if its diameter falls within the minimum/maximum cell diameter range. The Yes button indicates declustering parameters are to be used (enabled by default). Click **No** to turn OFF declustering.

Edge Factor Indicates degree to which cell edges must be enhanced

> for optimal declustering. Values range from 0.0 (clearly defined edges) to 1.0 (edges difficult to distinguish from

the background).

Threshold Factor Indicates threshold ratio between cell signal and

background. Values range from 0.0 (cell signal to

background is very low) to 1.0 (cell signal to background is high). Lower values help to normalize 'noise' from

fluorescent signals.

Background Indicates the adjustment ratio between cell signal and Adjustment

background. Values range from 0.0 (cell signal to

background is very low) to 1.0 (cell signal to background is high). Lower values help to normalize 'noise' from

brightfield signals.



Trypan Blue

Defines trypan blue viability cell detection parameter settings for cells to be counted.

Dead Cell Diameter

(µm)

Indicates range of dead cell diameter minimum to maximum values to be counted. Dead cells with diameters that fall outside of this range will not be

counted.

Sensitivity Adjusts sensitivity of the camera to darkness level of

trypan blue stained cells to be counted. Values range from 0.00 (detects very dark stained cells) to 10.0

(detects more mixed staining populations).

Uniformity Indicates trypan blue staining uniformity to be counted.

Values range from 100 (stained cells are all uniform in color) to 255 (stained cells have non-uniform dark and

light areas).

Very Dim Dead Cells When feature is enabled (*Yes*), helps to detect very dim

stained dead cells.

Contrast Enhancement Very Dim Dead Cells feature must be selected for this field to be enabled. Refines the division between the background and cells with low contrast (i.e., no defined edges). Suggested enhancement value is 0.60; values range from 0.00 (stained cells have medium contrast to background) to 0.80 (stained cells have very low

contrast to background).



Fluorescence Parameters

Defines fluorescent parameter attributes for cells to be counted.

Cell Diameter (µm)

Indicates range of cell diameter minimum to maximum values to be counted. Cells with diameters that fall outside of this range will not be counted.

Normalize Intensity for Cell Size

When feature is enabled (*Yes*), adjusts fluorescent intensity to the size of the cell. For example, if cells don't uptake the staining all at once and both light and dark areas exist within cells, enabling this feature normalizes FL intensity throughout the entire cell rather than having multiple intensity readings.

Non-Uniform Cells

When feature is enabled (*Yes*), identifies a cell as positive even if only a portion of the cell has fluorescence intensity above the defined threshold. Enabling this feature is useful if cells in the sample have a mixed staining population that contains both light and dark areas.

Roundness

Indicates minimum cell shape roundness factor to be counted. Values range from 0.00 (includes all cell shapes) to 1.0 (includes only perfectly round cells).

Do Not Count Free

Nuclei

When feature is enabled (Yes), uses a proprietary image analysis algorithm that excludes free floating nuclei

from being counted as cells.

Advanced BR/F

Mode

When feature is enabled (*Yes*), uses a proprietary counting method combining brightfield and fluorescence imaging to perform enhanced

declustering.

Thresholding

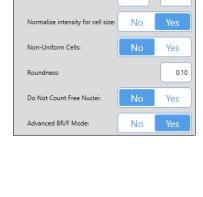
Indicates fluorescence intensity required for cells to be counted.

% of Image Range to Count

Defines percentage of FL threshold to be counted.

For *Manual* thresholding, entering a value in this field defines the percentage of pixels to be counted thus excluding cells that fall below that value. *Values range*

from 1-100.



4.0 to

50.0

luorescence Parameters

Cell Attributes

Cell Diameter (um):



For *Auto* thresholding, this feature establishes maximum intensity of all images taken for the sample to be 100%. Entering a value in this field defines a percentage of that maximum (e.g., 10 %) thus excluding cells with an intensity that fall below that value.

A general rule is to lower the threshold value to include dim cells or increase threshold value to exclude cells.

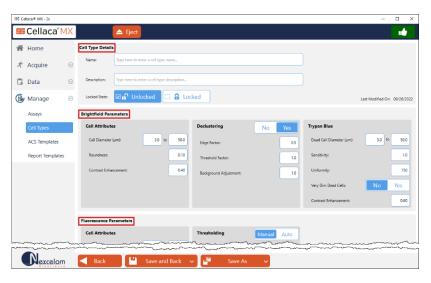
Threshold Factor

Indicates threshold ratio between cell signal and background. Values range from 0.0 (cell signal to background is very low) to 1.0 (cell signal to background is high). Lower values help to normalize 'noise' from fluorescent signals.

CREATING A NEW CELL TYPE

You can create a new cell type by clicking the **Manage** tab > *Cell Types* option to display the *Cell Types List* and then clicking the **Create** button located at the bottom of the screen.

Enter basic *Cell Type Details* (such as name, description and locked state), define *Brightfield Parameters* settings and *Fluorescence Parameters* settings, and then click the **Save and Back** button to add the cell type to the *Cell Types List*.



To copy defined parameter settings for an existing cell type to be used as a source for creating a new cell type, select a cell type and view its details by double-clicking it in the *Cell Types List* or clicking it once to highlight it and then clicking the **View** button located at the bottom of the screen. Click the **Save As** button and enter a new name to save a copy of the cell type, and then click the **Save** button.

Edit cell type parameters as described in *Editing a Cell Type* on page 65 and click the **Save and Back** button to confirm that the new cell type has been saved to the *Cell Types List*.

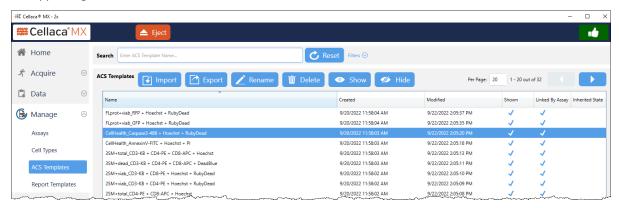
Chapter 8. Managing ACS Templates

This chapter describes how ACS templates are displayed in the ACS Templates List and how to manage the list to keep it current. ACS templates can be assigned to assays if the Object Level ACS export option is selected.

ACS templates can be assigned to assays as an output file type when exported data in Image Cytometry Experiment (ICE) format is to be imported into the De Novo Software FCS Express application.

VIEWING THE ACS TEMPLATES LIST

You can manage ACS templates available to your instrument system by clicking the **Manage** tab > ACS Templates option to view the ACS Templates List. From this screen you can import/export, rename and delete ACS templates appearing in the ACS Templates List, as well as show/hide ACS templates displayed in the ACS Templates drop-down appearing in other screens.



Note: ACS templates can only be created, edited and viewed in the De Novo Software FCS Express application and then imported via the Matrix software for your instrument system. In addition, no verification is performed on ACS templates other than checking for the .FEY file extension.

Use the **Per Page**| Per Page | 20 | 1 - 20 out of 32 | control to change the number of ACS templates displayed per page and the arrows to move back and forth between pages in the list.

ACS Templates can be sorted by clicking on column headings (i.e., ascending // descending indicators will be displayed), and information presented for each template includes name and created/last modified dates.

The remaining columns display checkmarks $\sqrt{}$ for the ACS template based on the conditions noted below:

- A checkmark displayed in the *Shown* column indicates the ACS template is to be included in the *ACS Templates* drop-down available in other screens (e.g., in *Reports and Exports/Data* section of Assay Details screen).
- A checkmark displayed in the Linked by Assay column indicates the ACS template is associated with an assay.
 ACS templates must be unlinked from all assays before they can be deleted.

A checkmark displayed in the Inherited State column indicates the ACS template was locked prior to importing
it into your instrument library (i.e., its Locked State was inherited during import). Keep in mind that ACS
templates may be imported directly via the Manage tab > ACS Templates screen or as components when
importing assays/datasets.

SEARCHING FOR ACS TEMPLATES

To search for an ACS template, enter a few key characters of an ACS template name or description in the **Search** field and/or expand the *Filters* area by clicking the down arrow Filters to specify search criteria.



As you choose filters (e.g., by selecting *Category*, *Shown* or *Linked By Assay* options) or enter a *Created Between/Modified Between* range of dates, the *ACS Templates List* is updated automatically to display matching entries.

Category Choose from the following categories:

Unlocked – Filters for ACS templates that are unlocked and can be edited

Locked – Filters for ACS templates that are locked and cannot be edited

System – Filters for ACS templates provided by Revvity (locked and cannot be edited)

System ACS templates may not be included in a release.

Shown Choose from the following *Shown* states:

Shown – Filters for ACS templates selected to appear in ACS Templates drop-down

Hidden – Filters for ACS templates that do not appear in ACS Templates drop-down

The ACS Templates drop-down is available in other screens (e.g., in Reports and Exports/

Data section of the Assay Details screen).

Linked By Assay Choose from the following *Linked by Assay* states:

Linked – Filters for ACS templates that are currently associated with an assay

Not Linked – Filters for ACS templates that are *not* currently associated with an assay

ACS Templates must be unlinked from all assays before they can be deleted.

Created Between Enter a *Created Between* range indicating the start/end dates between which to filter

for ACS templates created in that time frame.

Modified Between Enter a *Modified Between* range indicating the start/end dates between which to filter for

ACS templates modified in that time frame. As ACS Templates cannot be modified in the Matrix software, modification dates for templates file are updated only when you overwrite an

existing file on import.

If you find it necessary to clear all selected filters and begin the search again, click the Reset button.

MAINTAINING THE ACS TEMPLATES LIST

When you select an ACS template, buttons at the top of the ACS Templates List become available to perform the following functions. The **Import** button will always be enabled as it does not require selection of an ACS template in your library.

Note: If the Matrix 21 CFR Part 11 module is enabled, buttons will only be available for users who have been granted permission to perform specific functions.

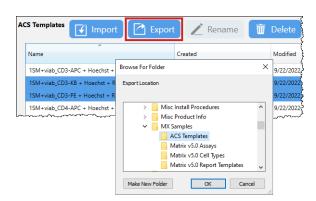
Importing ACS Templates

- While viewing the ACS Templates List, click the Import button.
- 2. Navigate to a folder where an ACS template library is available or an ACS template was previously saved.
- 3. Select one or more .FEY files to be imported.
- 4. Click Open. If selected ACS templates already exist in your database, respond to the confirmation prompt by clicking Overwrite to overwrite the file in your system, Auto-Rename to automatically add "(#)" to the end of the file name indicating the imported file is a copy (where # represents a value of 1, 2, 3, etc.) or Cancel to abort the import.
- 5. Click **OK** to acknowledge the successful import and confirm that imported ACS templates are displayed in the *ACS Templates List*.



Exporting ACS Templates

- Select one or more ACS templates from the
 ACS Templates List to be exported by clicking once to
 highlight the first one and then holding either the
 Shift key (to select a block of templates) or Ctrl key
 (to select non-contiguous templates) down while
 clicking additional ACS templates.
- 2. Click the **Export** button.
- 3. Navigate to a folder where ACS templates are to be saved.
- 4. Click **OK** to save .FEY files in the export location.



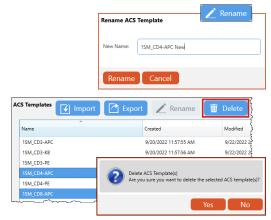
Renaming ACS Templates

- Select the ACS template to be renamed and click the Rename button.
- 1. Edit the ACS template name and click **Rename** to save your changes.

Deleting ACS Templates

Select one or more ACS templates from the ACS Template
 List to be deleted by clicking once to highlight the first one
 and then holding either the Shift key (to select a block of
 templates) or Ctrl key (to select non-contiguous templates)
 down while clicking on additional ACS templates.

Click the **Delete** button followed by **Yes** to confirm the action.



If the Matrix 21 CFR Part 11 module is enabled, users will be prompted to enter a reason prior to deletion.

Note: If ACS template deleted was from the ACS Template Library provided with the Matrix software, it can be re-imported if necessary. If ACS template was from a custom library, it may be permanently deleted unless ACS template was exported to an external location and saved prior to deletion.

ACS Templates must be unlinked from all assays before they can be deleted.

Showing/Hiding ACS Templates in Drop-down

The ACS Templates drop-down is available in other screens (e.g., in Reports and Exports/Data section of Assay Details screen).

- Select one or more ACS templates from the ACS Templates List to be shown or hidden in the ACS Templates
 drop-down by clicking once to highlight the first one and then holding either the Shift key (to select a block of
 templates) or Ctrl key (to select non-contiguous templates) down while clicking on additional ACS templates.
- 2. Click the **Show** or **Hide** button depending on whether you want to show/hide the selected ACS templates in the *ACS Templates* drop-down available in other screens.



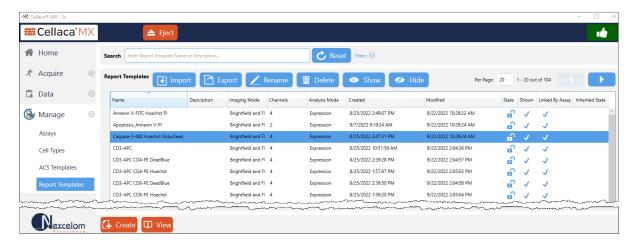
Chapter 9. Managing Report Templates

This chapter describes how report templates are displayed in the *Report Templates List* and how to manage the list to keep it current. An overview on how to edit and create report templates is also provided. Report templates are used to display, export and print data, and can be customized to meet your reporting needs.

Note: When migrating to the Matrix database from an earlier version, updated report templates can be imported via the software *after* migration is complete. For list of report templates provided with Matrix software or for assistance in defining a custom report template, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com

VIEWING THE REPORT TEMPLATES LIST

You can manage report templates for your instrument system by clicking the **Manage** tab > *Report Templates* option to view the *Report Templates List*. From this screen you can import/export, rename and delete report templates appearing in the *Report Templates List*, as well as show/hide report templates displayed in the *Report Templates* drop-down appearing in other screens.



In addition, you can select a report template from the list to view/edit its details, create a new report template by adding custom report elements/defining parameter settings, or use a locked report template as a source for creating a new report template based on its elements/parameter settings.

Note: If the Matrix 21 CFR Part 11 module is enabled, the **Create** button (and **Save and Back** button when viewing report templates) will only be available for users who have been granted permission to perform these functions.

Use the **Per Page** Per Page control to change the number of report templates displayed per page and the arrows to move back and forth between pages in the list.

Report Templates can be sorted by clicking on column headings (i.e., ascending // descending // indicators will be displayed), and information presented for each report template includes name, description, imaging mode/ number of channels, analysis mode defined for the report template and created/last modified dates.

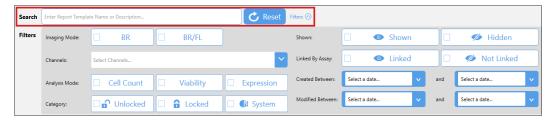
Icons displayed in the *State* column indicate whether a report template was provided as a Revvity *System* standard (which cannot be edited) or if a report template is currently *Locked* or *Unlocked*. When viewing *System* and *Locked* report templates, a **Save As** button allows users to copy report elements and defined parameter settings as a source for creating a new report template.

The remaining columns display checkmarks \checkmark for the report template based on the conditions noted below:

- A checkmark displayed in the Shown column indicates the report template is to be included in the Templates
 drop-downs available in other screens (e.g., Display Template, Print Template and Export Template fields in
 the Assay Details screen).
- A checkmark displayed in the *Linked by Assay* column indicates the report template is associated with an assay. *Report templates must be unlinked from all assays before they can be deleted.*
- A checkmark displayed in the Inherited State column indicates the report template was locked prior to
 importing it into your instrument library (i.e., its Locked State was inherited during import). Keep in mind that
 report templates may be imported directly via the Manage tab > Report Templates screen or as components
 when importing assays/datasets.

SEARCHING FOR REPORT TEMPLATES

To search for a report template, enter a few key characters of a report template name or description in the **Search** field and/or expand the *Filters* area by clicking the down arrow filters to specify search criteria.



As you choose filters (e.g., by selecting *Imaging Mode, Channels, Analysis Mode, Category, Shown* or *Linked By Assay* options) or enter a *Created Between/Modified Between* range of dates, the *Report Templates List* is updated automatically to display matching entries.

Imaging Mode Choose from the following imaging modes:

BR – Filters for report templates with Brightfield

BR/FL – Filters for report templates with Brightfield and Fluorescence

Channels

Use the drop-down to select one or more channels to be included in the search, then click **OK**.

Report templates may include up to six fluorescent channels as defined by the associated assay.



Analysis Mode Choose from analysis modes that can be associated with a template (e.g., Cell Count,

Viability, Expression). Analysis modes available for a report template will vary based on

the imaging mode selected for the template.

Category Choose from the following categories:

Unlocked – Filters for report templates that are unlocked and can be edited **Locked** – Filters for report templates that are locked and cannot be edited

System – Filters for report templates provided by Revvity (locked and cannot

be edited)

System report templates are no longer available in the Report Template Library provided with the Matrix software but may exist on your system if imported from an

earlier release.

Shown Choose from the following *Shown* states:

Shown – Filters for report templates selected to appear in *Templates* drop-downs

Hidden – Filters for report templates that do *not* appear in *Templates* drop-downs

The Templates drop-downs are available in other screens (e.g., Display Template,

Export Template and **Print Template** fields in the Assay Details screen).

Linked By Assay Choose from the following *Linked by Assay* states:

Linked – Filters for report templates that are currently associated with an assay

Not Linked – Filters for report templates that are not currently associated with an assay

When saving changes made to a report template linked by other assays, you will be prompted with a message indicating that all linked assays will also be updated.

Report Templates must be unlinked from all assays before they can be deleted.

Created Between Enter a *Created Between* range indicating the start/end dates between which to filter

for report templates created in that time frame.

Modified Between Enter a Modified Between range indicating the start/end dates between which to filter

for report templates modified in that time frame.

If you find it necessary to clear all selected filters and begin the search again, click the **Reset** button.

To select a report template and view its details, double-click it in the *Report Templates List* or click the report template once to highlight it and then click the **View** button located at the bottom of the screen.

MAINTAINING THE REPORT TEMPLATES LIST

When you select a report template, buttons at the top of the *Report Templates List* become available to perform the following functions. *The Import button will always be enabled as it does not require the selection of a report template in your library.*

Note: If the Matrix 21 CFR Part 11 module is enabled, buttons will only be available for users who have been granted permission to perform specific functions.

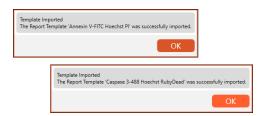
Importing Report Templates

- 1. While viewing the *Report Templates List*, click the **Import** button.
- Navigate to a folder where an external report template library is available or a report template was previously saved.
- 3. Select one or more .NEXRPT files to be imported.
- 4. Click Open. If selected report templates already exist in your database, respond to the confirmation prompt by clicking Yes to overwrite the file in your system or No to abort the import. If you choose No you will be prompted to enter a new name under which to import the report template (and then click Rename) or click Cancel to abort the import.

Note: When importing a *System* or *Locked* report template, you will be prompted to import it under a different name. Click **Yes**, enter a new name and click **Rename** to complete the import.

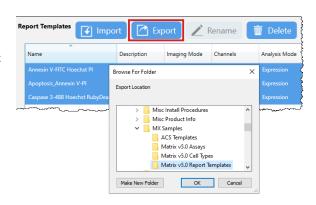
5. Click **OK** to acknowledge the successful import and confirm that imported report templates are displayed in the *Report Templates List*.

W Open W Open W Desktop > MX Samples > Matrix v5.0 Report Templates ∨ O Search Matrix v5.0 Report Templa



Exporting Report Templates

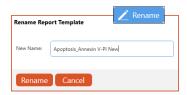
- Select one or more report templates from the Report
 Templates List to be exported by clicking once to
 highlight the first one and then holding either the Shift
 key (to select a block of templates) or Ctrl key (to
 select non-contiguous templates) down while clicking
 additional report templates.
- 2. Click the **Export** button.
- Navigate to a folder where report templates are to be saved.
- 4. Click **OK** to save .NEXRPT files in the export location.



Renaming Report Templates

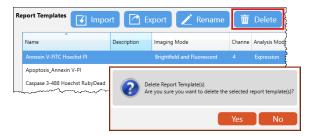
The **Rename** button will only be available for unlocked report templates.

- Select the report template to be renamed and click the Rename button.
- 2. Edit the report template name and click **Rename** to save your changes.



Deleting Report Templates

 Select one or more report templates from the Report Template List to be deleted by clicking once to highlight the first one and then holding either the Shift key (to select a block of templates) or Ctrl key (to select non-contiguous templates) down while clicking on additional report templates.



Click the **Delete** button followed by **Yes** to confirm the action. *If the Matrix 21 CFR Part 11 module is enabled, users will be prompted to enter a reason prior to deletion.*

Note: If report template deleted was from the Report Template Library provided with the Matrix software, it can be re-imported if necessary. If report template was from a custom library or created using the Matrix software, it may be permanently deleted unless report template was exported to an external location and saved prior to deletion.

Report templates must be unlinked from all assays before they can be deleted.

Showing/Hiding Report Templates in Drop-down

The Templates drop-down is available in other screens (e.g., Display Template, Export Template and Print Template fields in the Assay Details screen).

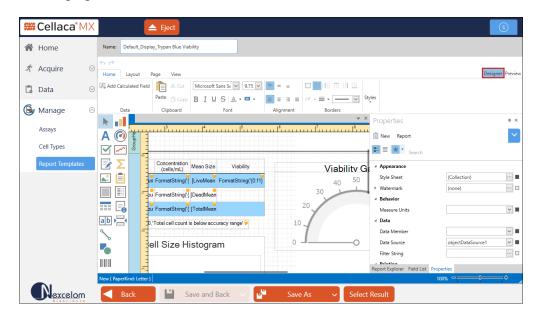
- 1. Select one or more report templates from the *Report Templates List* to be shown or hidden in the *Templates* drop-down by clicking once to highlight the first one and then holding either the **Shift** key (to select a block of templates) or **Ctrl** key (to select non-contiguous templates) down while clicking on additional templates.
- 2. Click the **Show** or **Hide** button depending on whether you want to show/hide the selected report templates in the *Templates* drop-down available in other screens.



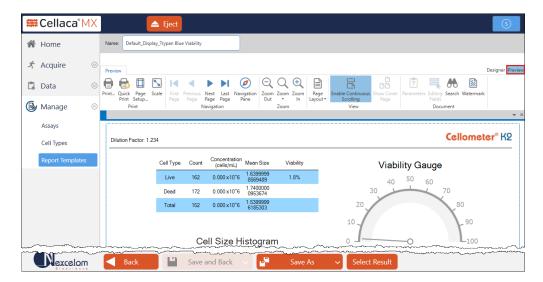
EDITING A REPORT TEMPLATE

Editing a report template allows users to customize the overall structure and individual elements used to comprise the report, as well as to modify basic *Report Template Details* (e.g., name, description, imaging mode/number of channels, analysis mode and locked state) available on the Save Report Template As screen.

To select a report template and view its details, double-click it in the *Report Templates List* or click the report template once to highlight it and then click the **View** button located at the bottom of the screen.



Report templates can be viewed in two modes – *Designer* (shown in sample screen above) and *Preview* (shown in sample screen below). *Designer* mode is displayed by default and allows you to edit template report elements while *Preview* mode displays the final layout of the template and allows you to populate it with sample data.



While viewing a report template, you can identify if it is locked (representing either a *System* or *Locked* template) based on whether the **Save and Back** button is available.

Edit the report template as described in each of the sections presented below:

- Editing Basic Report Template Details, below
- Editing Report Elements on page 83

When viewing/editing of a report template is complete, click one of the following buttons to return to the *Report Templates List*, edit defined parameters for the report template or view the template using a selected dataset.



Back Button: Click **Back** to return to the previous screen without saving any changes. *If* report template has unsaved changes, click **OK** in response to the confirmation prompt.



Save | Save and Back Buttons: Click to choose between Save (save changes and continue editing) or Save and Back (save changes and return to previous screen) and toggle the

display of buttons. Once desired button is displayed, click it to perform the action.

If a report template is linked by an assay, you will be prompted to click **Continue** as changes saved will update all linked assays.





Save As | Save As and Back Buttons: Click to choose between Save As (save template with any changes as a copy and continue editing) or Save As and Back (save template with changes and return to previous screen) and toggle the display of buttons. Once desired button is displayed, click it to perform the action.

If the report template is locked, this also allows you to copy the template to use as a source for creating a new report template.

See *Editing Basic Report Template Details*, below for details regarding the Save Template As screen.

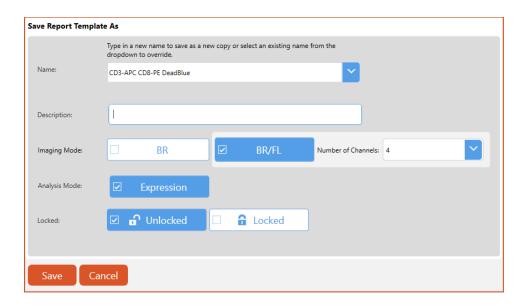


Select Result: Click **Select Result** to view the report template using a selected dataset. Choose a dataset from the displayed list and click **Select**. Click **Preview** to view the report with the selected data.

Editing Basic Report Template Details

When saving a report template (by clicking either the **Save and Back** or **Save As | Save As and Back** buttons), you can edit the *Name*, *Description*, *Imaging Mode/Number of Channels*, *Analysis Mode* and *Locked* state of the template.

Note: You can only edit a report template if it is unlocked. If the report template is locked or if the report template is a Revvity System default, you must first copy the template by clicking the **Save As** button and entering a new name. You can then edit defined parameters for the report template as necessary and click **Save** to save them as a source for a new report template.



To edit basic report template details, modify information contained in the following fields.

Name Displays the name of the report template. Enter a new name or use the drop-down to select a

template to override. Must be unique.

Description Displays a brief description which can be used to identify the purpose of the report template.

Imaging Mode Indicates if Imaging Mode to be associated with the template is Brightfield Only (BR) or

Brightfield/Fluorescence (BR/FL) including the number of channels. Note that Cellaca MX/ PLX

instruments support up to 6 channels; Cellometer K2 supports up to 2 channels.

You can change the number of channels regardless of the previous value. In addition, the

Imaging Mode selected will populate **Analysis Mode** field, below with available options.

Analysis Mode Indicates Analysis Mode to be used for the template. Analysis modes displayed will vary based

on the selected Imaging Mode.

See Defining Assay Imaging and Analysis Parameters (For Cellaca MX/PLX) on page 47 or Defining Assay Imaging and Analysis Parameters (For Cellometer K2) on page 53 for options.

Locked Indicates if template is to be *Unlocked* (to allow editing) or *Locked* (to prevent editing).

Click **Save** to create the new report template and then edit its structure and elements accordingly. *Templates can only be edited if the Unlocked option was selected for the Locked field.*

Editing Report Elements

Report elements can be edited using the *Report Designer for WPF* application (a third-party plugin by *DevExpress*). See *Appendix A. Report Designer for WPF Reference* on page 104 for more information about using this application.

Key report elements are indicated below.

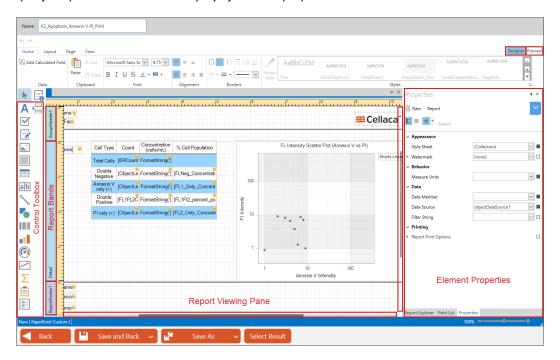
• The **Designer Tab** allows you to customize report elements using *Designer* mode. Features include:

Report Viewing Pane – Displays layout of elements in the report. Use the horizontal and vertical scroll bars to move around in the viewing pane.

Element Properties – Lists properties of elements that appear in the Report Viewing Pane. *Click on an element in the viewing page to show its properties*.

Control Toolbox — Allows you to add report controls to the template (e.g., text labels, check boxes, tables, etc. as indicated by toolbox icons). *Located on the left side of the screen*.

Report Bands – Allows you to customize the report element controlled by the band (i.e., colored boxes displayed on the left of the screen such as *GroupHeader1*, *Detail* and *ReportFooter1* as shown in the sample below) by editing its element properties (displayed on the right of the screen). *Clicking on a specific report band varies the display of element properties*.



• The **Preview Tab** allows you to view final layout of the report template using *Preview* mode.

To add report elements to a template, click on an element in the *Control Toolbox* and drag it into the viewing pane or, click on an element in the viewing pane to reposition it and/or press **Delete** to remove it from the template.

To populate a report template with sample data, click the **Select Result** button located at the bottom of the screen to choose a scan result containing appropriate data for the template (i.e., click on the *Imaging Mode* column to sort data and choose a result using the imaging mode for which the template was designed) and click **Select**.

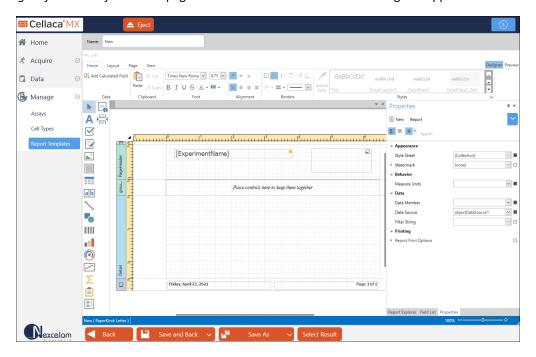
Note: Once scan result data is selected, you may need to toggle between the **Designer** and **Preview** tabs to refresh the screen and view the data.

CREATING A NEW REPORT TEMPLATE

You can create a new report template by clicking the **Manage** tab > *Report Templates* option to display the *Report Templates* List and then clicking the **Create** button located at the bottom of the screen.

Add report elements and then click the **Save and Back** button to enter basic *Report Template Details* such as the *Name, Description, Imaging Mode/Number of Channels, Analysis Mode* and *Locked* state of the report template.

Note: Report elements are added using the *Report Designer for WPF* application by *DevExpress*. See *Appendix A. Report Designer for WPF Reference* on page 104 for more information about using this application.



To copy existing report elements to be used as a source for creating a new report template, select a report template and view its details by double-clicking it in the *Report Templates List* or clicking it once to highlight it and then clicking the **View** button located at the bottom of the screen. Click the **Save As** button and enter a new name to save a copy of the report template, and then click the **Save** button.

Edit report elements as described in *Editing a Report Template* on page 80 and click the **Save and Back** button to confirm that the new report template has been saved to the *Report Template List*.

Chapter 10. Using the 21 CFR Part 11 Module

Functionality described in this chapter is available for users who have purchased a Matrix 21 CFR Part 11 module license and had the module enabled by Support. For more information about enabling this module, contact Support by visiting https://www.revvity.com/contact-us or send email to: CellC-support@revvity.com

FUNCTIONALITY OVERVIEW

The Matrix 21 CFR Part 11 module is compliant with the Code of Federal Regulations (CFR) Title 21 Part 11 — Electronic Records: Electronic Signatures published by the U. S. Food and Drug Administration (FDA). In summary, this module ensures that an organization's use of electronic records and digital signatures in place of traditional paper-based documentation is in compliance with current FDA regulations.

Key elements in Matrix 21 CFR Part 11 module functionality are described below.

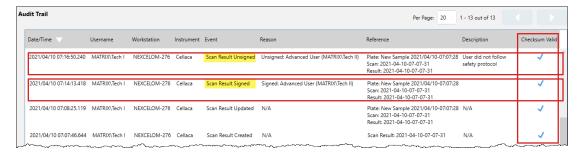
• Electronic Signatures are captured during the counting and analysis workflow using e-Sign/e-Unsign buttons and include the name of an authorized user, the date/time when the signature was executed, a reason for the action being performed and meaning of the signature (i.e., for the Review, Approval or Rejection of an action). If a user's assigned role does not have permissions to approve count results, a supervisor can log in to e-Sign the record on behalf of the user.



• *Electronic Records* are created as the result of linking electronic signatures to user actions ensuring that records have not been copied or falsified in any manner.



• An *Audit Trail* provides assurance regarding the integrity of an electronic record and continually monitors all users performing actions, the type of actions performed, and the date/time associated with user actions.



Audit trails can be retained either *Locally* on an instrument's Operating Computer or on a *Windows Network* (i.e., using administrator-controlled access via user roles and privileges).

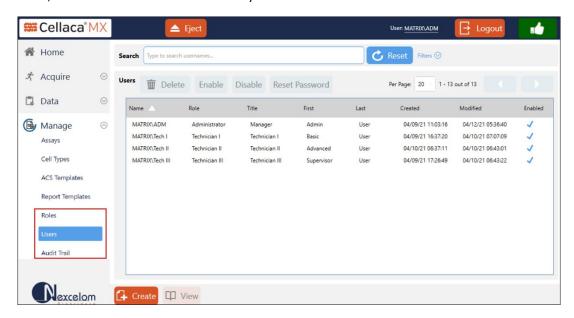
ESTABLISHING YOUR USER HIERARCHY

The Matrix 21 CFR Part 11 module requires that you establish a hierarchy of Users within your organization consisting of Administrator Users associated with full access to module functionality and other users with varying levels of access controlled through the assignment of Roles (i.e., sets of privileges that can be grouped and applied to multiple users sharing similar job responsibilities).

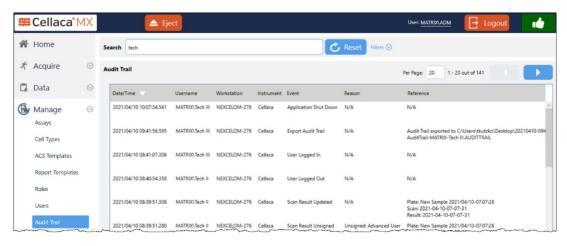
Monitoring User Actions

To create users and monitor their actions, options are added to the **Manage** tab for use by Administrator Users – *Roles, Users* and *Audit Trail* – when the Matrix *21 CFR Part 11* module is enabled.

As users are created, they are added to the *Users List* which displays a summary of account details including role, personal information (*Title* and *First Name/Last Name*), date/time stamp for when the account was created and last modified, and whether the account is currently enabled.

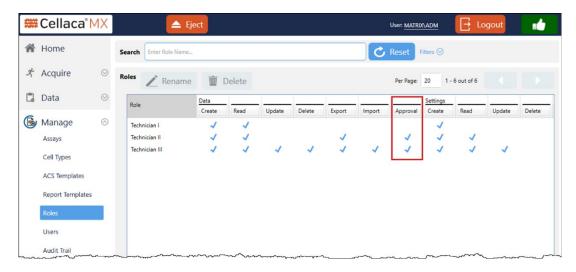


When users log in to the Matrix software to perform daily tasks, the system automatically generates an *Audit Trail* capturing user actions and validates them against the database to ensure integrity of the data is maintained.



Controlling User Access via Roles

Roles allow you to control varying levels of Matrix functionality to which specific groups of users will have access. When creating a role, select subsets of privileges that apply to users performing common tasks.



For example, you can create a basic *Technician I* role that is able to *Create* and *Read* count results but does *not* have access to add an electronic signature to approve those results. To support this basic role, you can create advanced roles (*Technicians II* and *III*) with the *Approval* privilege that are able to log in at technician workstations using the **e-Sign/e-Unsign** buttons to approve or reject displayed count results.

Understanding Role Privileges

Roles are used in the Matrix 21 CFR Part 11 module to control the following areas of responsibility:

- **Data** Controls whether users can create, manage (i.e., read, update and delete), export/import and approve/reject data during the counting and analysis workflow.
- **Settings** Controls whether users can access the **Manage** tab > *Assays, Cell Types and Report Templates* options allowing them to create, manage (i.e., read, update and delete) and export/import these entitities.
- Users, Roles or Audits Controls whether users can access the Manage tab > Users, Roles or Audits options
 (displayed only if the 21 CFR Part 11 module is enabled) allowing them to create or manage (i.e., read, update
 and delete) Matrix software users and roles. In addition, controls whether users can monitor (i.e., read and
 export) the audit trail automatically generated by the system.



DATA PRIVILEGES

The following privileges control whether users can create, manage (i.e., read, update and delete), export/import and approve/reject data during the counting and analysis workflow.

Note: The *Data: Read* privilege must be selected for the **Data** tab to be accessible to a user regardless of any other *Data* privileges assigned to that user.



Create Allows users to *create* a new scan result (i.e., Count and Recount buttons are enabled in the Acquire tab > Setup screen) and count results will be displayed under the Data tab. Users must have the Data:

Read privilege to view scan results in the **Data** tab > Select screen.

Read Allows users to *view* all scan results available under the **Data** tab and to select a specific scan result

(i.e., **View** button is enabled) to be displayed. *This privilege must be granted to all users needing to*

view the **Data** tab > Select screen regardless of any other Data privileges assigned.

Update Feature not yet implemented.

Delete Allows users to select a scan result available under the **Data** tab and delete it (i.e., **Delete** button is enabled) as necessary. *Users will be prompted to enter a reason prior to deletion.* In addition, this

privilege enables the **Recover Free Space** button if users also have sys_admin rights to perform this

action on the database server.

Export Allows users to select one or more scan results available under the **Data** tab and export them (i.e.,

Export button is enabled) to a user-defined location such as the Operating Computer desktop.

Import Allows users to select one or more scan results stored outside the Matrix software database and

import them (i.e., Import button is enabled) to be displayed under the Data tab.

Approval Allows users to add an e-signature (i.e., use of **e-Sign** and **e-Unsign** buttons is authorized) for count results data currently displayed. If the logged-in user role performing the count does not include this

privilege, another user with the privilege in their role can log in to e-Sign the record on their behalf.

SETTINGS PRIVILEGES

The following privileges control whether users can access the **Manage** tab > *Assays, Cell Types, ACS Templates* and *Report Templates* options allowing them to create, manage (i.e., read, update and delete) and export/import these entitities.

Note: The *Settings: Read* privilege must be selected for the **Manage** tab to be accessible to a user regardless of any other *Settings* privileges assigned to that user.



Create Allows users to *create* a new assay, cell type or report template (i.e., Create button is enabled in the respective *Assays*, *Cell Types* and *Report Templates* options available under the Manage tab) and save the entity (i.e., Save and Back and Save As buttons are enabled).

Allows users to *view* all assays, cell types or report templates in the respective screens for these options available under the **Manage** tab and to select a specific entity (i.e., **View** button is enabled) to be displayed. This privilege must be granted to all users needing to view the **Manage** tab > Assays, Cell Types and Report Templates screens regardless of any other Settings privileges assigned.

Update Allows users to *modify* an assay, cell type or report template in the respective screens for these options available under the Manage tab and save their changes (i.e., Save and Back and Save As buttons are enabled). *The selected entity must be unlocked to allow for editing.* Also enables the Rename, Show and Hide buttons in the Assays, Cell Types and Report Templates screens.

Delete Allows users to select an assay, cell type, ACS template or report template in the respective screens for these options available under the **Manage** tab and delete it (i.e., **Delete** button is enabled) as necessary. *Users will be prompted to enter a reason prior to deletion*.

ExportAllows users to select one or more assays, cell types, ACS templates or report templates in the respective screens for these options available under the **Manage** tab and export them (i.e., **Export** button is enabled) to a user-defined location such as the Operating Computer desktop.

Import Allows users to select one or more assays, cell types, ACS templates or report templates stored outside the Matrix software database and import them (i.e., Import button is enabled) to be displayed in the respective screens for these options to be available under the Manage tab.

USERS PRIVILEGES

The following privileges control whether users can access the **Manage** tab > *Users* option allowing them to create and manage Matrix software users.

Note: The *Users: Read* privilege must be selected for the **Manage** tab > *Users* option to be accessible to a user regardless of any other *Users* privileges assigned to that user.



Create Allows users to *create* a new account (i.e., Create button is enabled) to be displayed in the Users List and save the account (i.e., Save and Back and Save As buttons are enabled).

Allows users to *view* all accounts available in the Users List including their assigned roles and to select a user (i.e., **View** button is enabled) to display account details. Passwords will *never* be displayed.

This privilege must be granted to all users needing to view the **Manage** tab > Users screen regardless of any other Users privileges assigned.

Allows users to modify an account by assigning a different role, disabling/enabling the account, editing personal information (*First Name*, *Last Name* and *Title*) and to save their changes (i.e., **Save** and **Back** button is enabled). Although the username for an account cannot be changed, users with the User: Create, Delete privileges can easily delete accounts and create new ones as necessary. Also enables the **Enable**, **Disable** and **Reset Password** buttons in the *Manage* tab > Users screen.

Delete Allows users to select an account available in the Users List and delete it (i.e., **Delete** button is enabled) as necessary.

ROLES PRIVILEGES

The following privileges control whether users can access the **Manage** tab > *Roles* option allowing them to create and manage Matrix software roles.

Note: The *Roles: Read* privilege must be selected for the **Manage** tab > *Roles* option to be accessible to a user regardless of any other *Roles* privileges assigned to that user.



Create Allows users to *create* a new role (i.e., Create button is enabled) to be displayed in the Roles List and save the role (i.e., Save and Back and Save As buttons are enabled).

Read Allows users to *view* all roles available in the Roles List. *This privilege must be granted to all users* needing to view the **Manage** tab > Roles screen regardless of any other Roles privileges assigned.

Allows users to modify a role by editing the role name, changing privileges selected and to save their changes (i.e., **Save and Back** and **Save As** buttons are enabled). *Renaming a role automatically updates the name of the role for all users to which the role has been assigned.* Also enables the **Rename** and **View** buttons in the **Manage** tab > *Roles* screen.

Delete Allows users to select roles available in the Roles List and delete them (i.e., **Delete** button is enabled) as necessary.

AUDITS PRIVILEGES

The following privileges control whether users can access the **Manage** tab > Audit Trail option allowing them to search for and monitor the actions of user accounts, and to confirm the Checksum Valid column contains a checkmark (\checkmark) for all actions indicating records have not been copied or falsified in any manner.

Note: The *Audits: Read* privilege must be selected for the **Manage** tab > *Audit Trail* option to be accessible to a user regardless of any other *Audits* privileges assigned to that user.



Read Allows users to *view* the automatically generated audit log captured by the system and displayed for the *Audit Trail* option under the **Manage** tab. *This privilege must be granted to all users needing to view the Manage tab > Audit Trail screen regardless of any other Audits privileges assigned.*

Export Allows users to highlight one or more lines in the audit log and export them (i.e., Export button is enabled) to a user-defined location such as the Operating Computer desktop. You must use the Validator application that comes with the Matrix software to view the captured data.

FIRST-TIME LOGIN AS DEFAULT ADMIN USER

When logging in to Matrix software for the first-time *after* the 21 CFR Part 11 module has been enabled, you must log in using Default Administrator User credentials to create an Administrator User. Follow the steps listed below.

Note: If first-time login has already occurred on your system, you will need access to Administrator User credentials to create a *new* Admin User. Skip to *Creating an Administrator User* on page *93*.

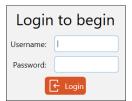
- 1. From the desktop of the Operating Computer, double-click the **Matrix** icon to launch the software.
- Log in as the Default Administrator User by entering the username admin and password admin, then click the Login button. You will immediately be prompted to create a new Administrator User.
- 3. Respond to the *Create New User* dialog by accepting the Matrix user type option selected by default (i.e., creates an Administrator User to reside locally on Operating Computer where Matrix software is installed) and click the **Continue** button.

Note: If your system is connected to a network, you can create a *Windows* Administrator User by clicking the **Windows** user type and selecting a user account in your domain to be assigned the *Administrator* role.

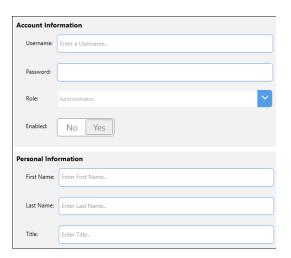
- 4. In the Account Information area, enter a username and password for the new user. The Administrator role and enabled value of **Yes** will be pre-selected by default. For Windows users, this area populates with existing username/password.
- 5. In the *Personal Information* area, enter a first name, last name and title for your user. *For Windows users, this area populates with existing First Name/Last Name.*
- Click Save and Back to create the user. You will automatically be logged out of the software upon creation of the new user.
- 7. To confirm the Default Administrator User was disabled upon creation of your new Administrator User, attempt to log in again by entering username of **admin** and password of **admin**, then clicking **Login**. An error message should be displayed.
- 8. Log in as your new Administrator User.

Continue with Managing Roles on page 94.











CREATING AN ADMINISTRATOR USER

If first-time login has already occurred on your system, you must log in using Administrator User credentials (i.e., user with *Administrator* role assigned) to create a *new* Administrator User. Follow the steps listed below.

Note: If you have just created an Administrator User using the *First-Time Login as Default Admin User* section, skip to *Managing Roles* on page *94*.

- 1. From the desktop of the Operating Computer, double-click the **Matrix** icon to launch the software.
- Enter the username and password for an Administrator
 User already created by your organization, then click the
 Login button.
- 3. Click the **Manage** tab in the Navigation Bar on left side of the screen and select the *Users* option.
- 4. Click the **Create** button located at bottom of the screen.
- 5. Respond to the *Create New User* dialog by accepting the Matrix user type option selected by default (i.e., creates an Administrator User to reside locally on the Operating Computer where Matrix software is installed) and click the **Continue** button.

Note: If your system is connected to a network, you can create a *Windows* Administrator User by clicking the **Windows** user type and selecting a user account in your domain to be assigned the *Administrator* role.

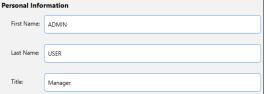
- 6. In the Account Information area, enter a username and password for the user. Select the Administrator role from the drop-down and the enabled value of Yes (default value). For Windows users, this area populates with existing Username/Password.
- 7. In the *Personal Information* area, enter a first name, last name and title for the user. *For Windows users, this area populates with existing First Name/Last Name.*
- 8. Click Save and Back to create the Administrator User.
- 9. Confirm the new user created appears in the *Users List*.













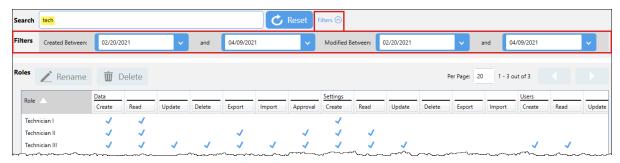
10. Click the **Logout** button and then log in again as your new Administrator User.

MANAGING ROLES

Roles allow you to control varying levels of Matrix functionality to which specific groups of users will have access. As roles are created, they are added to the *Roles List* which displays a summary of privileges assigned to the role.

If your user account is associated with *Roles* privileges (i.e., *Roles*: *Create*, *Read*, *Update* and *Delete*), you can create, maintain and delete roles containing subsets of functionality to be assigned to users accordingly. *Keep in mind that the 'Administrator' role is a reserved role including full privileges and will not be displayed in the Roles List.*

To search for a role, enter a few key characters of a role name in the **Search** field and/or expand the *Filters* area to specify search criteria (e.g., *Created Between* or *Modified Between* start/end dates). As you enter criteria, the *Roles List* will automatically be updated to display matching entries.



To select a role and view its details, double-click a role entry in the *Roles List*, or click the role once to highlight it and then click the **View** button located at the bottom of the screen.

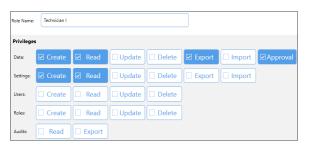
Creating a Role

- Click the Manage tab in the Navigation Bar on left side of the screen and select the Roles option.
- 2. Click the **Create** button located at bottom of the screen.
- Enter a role name (e.g., Technician I) and select privileges to be associated with the role (e.g., Data: Create, Read; Settings: Read).
- 4. Click the **Save and Back** button and verify that the created role appears in the *Roles List*.

Note: When a role is selected in the *Roles List*, the **Rename**, **Delete** and **View** buttons become enabled for that role.

Copying a Role

- To create a role based on an existing role, double-click the role just created in the *Roles List*, or click the role once to highlight it and then click the **View** button.
- 2. Add and/or remove privileges, as necessary.
- 3. Click the Save As button.



4. In the dialog box displayed, you can either enter a new role name (e.g., *Technician II*) or select a name from the drop-down to override an existing role and click the **Save** button. Verify that the new role appears in the *Roles List*.

Renaming a Role

1. To rename a role, click the role once to highlight it and then click the **Rename** button.

Note: If you rename a role currently assigned to a user, the role name will be automatically updated.

Enter a new role name in the dialog and click Rename.
 Verify that role name has been modified in the Roles List.

Deleting a Role

1. To delete a role, click the role once to highlight it and then click the **Delete** button.

Note: You cannot delete a role currently assigned to a user.

2. Verify that the role name has been removed from the *Roles List*.

Guidelines for Managing Roles

The following guidelines apply when managing 21 CFR Part 11 module roles.

- The Administrator role (i.e., containing all privileges) is not displayed in the Roles List as it cannot be modified. In addition, you cannot create a role with the name "administrator" as it represents a locked role.
- If a user is granted access to create/update roles (i.e., *Roles: Create, Read* and/or *Update*), they will have access to assigning *ALL* privileges regardless of those assigned to their own role.
- If a user is granted access to create/update users (*Users: Create, Read* and/or *Update*), they will have access to assigning *ALL* roles to those users regardless of the role assigned to their own user account. *Roles will be displayed in the Roles drop-down even if the user does not have Roles: Create, Read and/or Update privileges.*
- You cannot delete a role currently assigned to a user. You must reassign another role to the user before you can delete the role.
- If you rename a role while it is currently assigned to a user, the role name will automatically be updated for all users to which the role is assigned.
- If a role has the *Update* privilege (i.e., *Settings*: *Update*) for assays, cell types and report templates, users assigned to this role will only be able to update these entities if the selected assay, cell type or report template is unlocked (i.e., the unlocked icon is displayed for the entity).





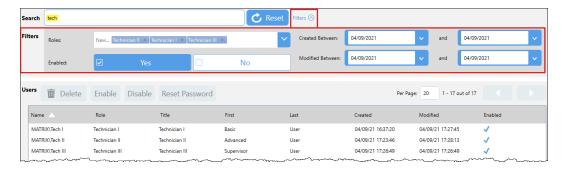
MANAGING USERS

Users are validated upon login and their actions are tracked as they move through the system via an *Audit Trail* log. As users are created, they are added to the *Users List* which displays a summary of account details including their assigned role, personal information (*Title* and *First Name/Last Name*), date/time stamp for when the account was created and last modified, and whether the account is currently enabled.

Note: Only one user may be logged into the Matrix database at a time. However, users can export scan results and upload them as files onto an alternate computer for re-analysis of captured images via *Data Analysis* mode. See *Data Analysis Mode* on page 2 for details.

If your user account is associated with *Users* privileges (i.e., *Users*: *Create*, *Read*, *Update* and *Delete*), you can create, maintain and delete users whose access to Matrix functionality will be controlled by their assigned roles. *Keep in mind that you must always have at least one active Administrator User for the 21 CFR Part 11 module.*

To search for a user, enter a few key characters of a user name in the **Search** field and/or expand the *Filters* area to specify search criteria (e.g., *Roles, Enabled* status, or *Created Between* or *Modified Between* start/end dates). As you enter criteria, the *Users List* is updated to display matching entries.

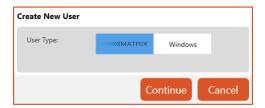


To select a user and view its details, double-click a user entry in the *Users List*, or click the user once to highlight it and then click the **View** button located at the bottom of the screen.

Creating a User

- Create a new user by selecting the Manage tab > Users option.
- 2. Click the **Create** button located at the bottom of the screen.
- 3. Respond to the *Create New User* dialog by accepting the Matrix user type option selected by default (i.e., creates a user to reside locally on the Operating Computer where Matrix software is installed) and click the Continue button.

Note: If your system is connected to a network, you can create a *Windows* user by clicking the **Windows** user type and selecting a user account in your domain.



4. In the Account Information area, enter a username and password for the user. For Windows users, this area populates with existing Username/Password.

Note: Usernames must consist of at least one character and passwords are case sensitive. Once a user account is created, usernames and passwords cannot be changed (i.e., use the **Reset Password** button for *Matrix* users).

- 5. Select a role from the **Role** drop-down and ensure that the **Enabled** field is set to *Yes*.
- 6. In the *Personal Information* area, enter a first name, last name and title for the user. *For Windows users, this area populates with existing First Name/Last Name.*
- 7. Click the **Save and Back** button to create the user.
- 8. Confirm the new user appears in the *Users List*.

Note: When a user is selected in the *Users List*, the **Delete**, **Enable/Disable** (based on user status as displayed in the *Enabled* column), **Reset Password** and **View** buttons become enabled for that user.

9. Click the **Logout** button and then log in again as the new user.

Disabling/Enabling a User

- 1. To disable a user, click the user once in the *Users List* to highlight it and then click the **Disable** button.
- Click Yes in response to the confirmation prompt, followed by
 OK to acknowledge the user was disabled. Verify the checkmark
 in the Enabled column is no longer displayed for the user.

Note: Once a user is disabled, they will *not* be able to log in.

- 3. To enable a user, click the user once in the *Users List* to highlight it and then click the **Enable** button.
- 4. Click **Yes** in response to the confirmation prompt, followed by **OK** to acknowledge the user was enabled. Verify the checkmark in the *Enabled* column is displayed for the user.

Resetting a User Password

Resetting a user password via an *Administrative Password Reset* is temporary and must be manually relayed to that user. Upon the user's next login with the temporary password, they will immediately be prompted to personally reset their password.

Note: You cannot reset the password for a *Windows* user as this functionality is controlled by mechanisms available in the network.





- 1. To reset a user password, click the user entry once in the *Users List* to highlight it and then click the **Reset Password** button.
- 2. Click **Yes** in response to the confirmation prompt.
- 3. In the *Administrative Password Reset* dialog, enter a new password for the user and confirm the password by entering it again. Click the **Reset Password** button.

Administrative Password Reset		
New Password:		
Re-type New Password:		
	Reset Password	Cancel

Deleting a User

- 1. To delete a user, click the user entry once to highlight it and then click the **Delete** button.
- 2. Click **OK** to acknowledge the user was deleted. Verify the user has been removed from the *Users List*.

Guidelines for Managing Users

The following guidelines apply when managing 21 CFR Part 11 module users.

- Your first-time login to Matrix software after this module has been enabled will be as Default Administrator
 using credentials provided. Upon login, you will be prompted to create a secure Administrator User and as
 part of its creation you will be logged out of the default account. Default Administrator credentials will be
 deactivated at this time. Log in as your newly created Administrator User to establish your user hierarchy.
- Administrator usernames cannot include "admin" or "administrator" as these represent reserved accounts.
- You must always have at least one active Administrator User for the 21 CFR Part 11 module.
- You cannot edit or delete the user account in which you are currently logged in to the system. If you disable
 an account while you are currently logged into it, you will not be able to log in using that account again. An
 exception to this rule exists if you are logged in as the only remaining Administrator User; in this case, you will
 NOT be allowed to disable the account.
- When clicking the Reset Password button for a user, you are performing an administrative password reset
 which results in the creation of a temporary password that must be manually relayed to the user. Upon the
 user's next login with the temporary password, they will immediately be prompted to reset the password.
- For network users, the **Reset Password** button cannot be selected as this functionality is controlled by mechanisms available in the domain.

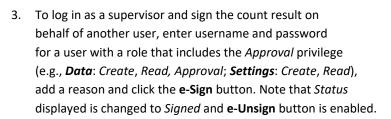
Note: Only one user may be logged into the Matrix database at a time. However, users can export scan results and upload them as files onto an alternate computer for re-analysis of captured images via *Data Analysis* mode. See *Data Analysis Mode* on page 2 for details.

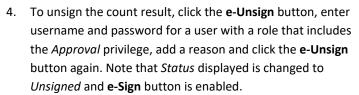
E-SIGNING COUNT RESULTS

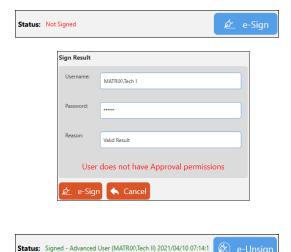
Electronic Signatures capture the name of authorized users, the date/time when the signature was executed, and meaning of the signature (i.e., indicating it was for the *Review*, *Approval* or *Rejection* of an action). Only users with the *Approval* privilege can electronically sign and unsign count results.

- Log in as a user with a basic role (e.g., *Data*: *Create*, *Read*; *Settings*: *Read*) and use the *Acquire* tab to enter setup details and perform a count. Note that *Status* for count result is *Not Signed* and e-Sign button is enabled.
- Click the e-Sign button. Confirm username displayed, enter a password and reason for the action, and click the e-Sign button again.

Note: If the user performing a count does *not* have the *Approval* privilege in their assigned role, the *User does not have Approval permissions* message is displayed.









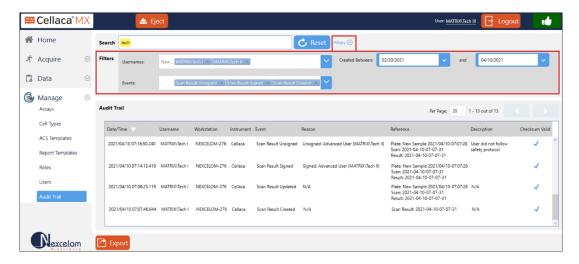


VIEWING AUDIT TRAIL

The *Audit Trail Log* provide assurance regarding the integrity of records and must capture the identity of all users performing an action, the type of action, and the date/time associated with the action. Audit trails can be retained locally on the Operating Computer or on a network.

Searching the Log

- 1. Click the Manage tab > Audit Trail option.
- To search for the actions of specific users, enter a few characters of a user name in the Search field and/or expand the Filters area to specify search criteria (e.g., Usernames, Events or Created Between start/end dates).
 As you enter criteria, the Audit Trail is updated to display matching entries.



3. Review matching entries and ensure that a checkmark appears in the Checksum Valid column for each entry.

Exporting Log Details

Click the Export button, navigate to an export location on the desktop and click OK to save the audit trail log. A
 YYYYMMDD-HHMMSS-AuditTrail-MATRIX-<user>.AUDITTRAIL file is created, where *YYYYMMDD* represents
 the current date, *HHMMSS* is a time stamp (hours, minutes, seconds) and *<user>* is your username.

Note: When exporting audit log details, it may be useful to record the total number of action entries in the log prior to export (e.g., 1354 as shown in the example below).

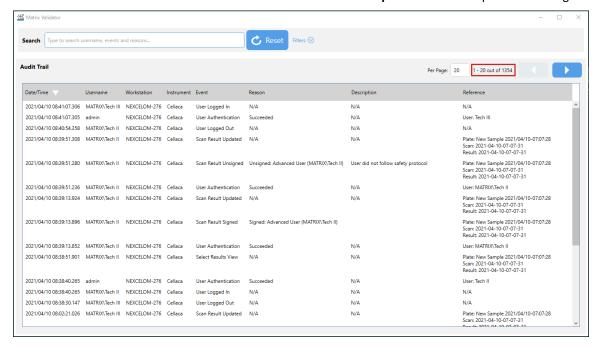


2. From the Windows Applications Menu expand the **Nexcelom Bioscience** folder and launch the *Matrix Validator* application.

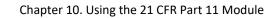
3. Click the **Browse** button to navigate to the exported YYYYMMDD-HHMMSS-AuditTrail-MATRIX-<user>.AUDITTRAIL file in the saved location.



4. Double-click the file or click the file once to select it and then click **Open** to view the exported audit log.



- 5. Validate that the total number of action entries currently logged for your system (i.e., 1354 as highlighted in the sample screen shown above) matches what you recorded before the export.
- 6. To search for the actions of specific users, enter a few characters of a user name in the **Search** field and/or expand the *Filters* area to specify search criteria (e.g., *Usernames, Events* or *Created Between* start/end dates). As you enter criteria, the *Audit Trail* is updated to display matching entries.



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Chapter 11. Contacting Support

This chapter presents the scope of Support services and contact methods. In addition, it contains instructions on how to report issues to Support and generate diagnostic reports to assist with troubleshooting.

SCOPE OF SUPPORT SERVICES

Revvity is dedicated to providing our customers with outstanding support including the following services:

- Online and in-lab customer training
- Creation of new cell types
- · Optimization of counting parameters
- Creation of new report templates
- Troubleshooting via telephone
- · Periodic safety checks and functional evaluations (offered as part of a separate maintenance contract)

To inquire about training, visit our website at https://www.revvity.com/contact-us/customer-training and choose the Cell Counting and Image Cytometry product. Enter your contact details and any training comments/questions.

CONTACT METHODS

If there is a technical issue with your instrument or software, contact Support using the following methods:

- Visit https://www.revvity.com/contact-us/instrument-support-and-service and choose the Cell Counting and Image Cytometry product for support. Enter instrument serial number, name and model, your contact details, and a detailed description to report the issue to Support.
- Visit https://www.revvity.com/contact-us-by-phone to find the global phone number for your area.
- Send email to <u>CellC-support@revvity.com</u>

REPORTING AN ISSUE TO SUPPORT

If a technical issue encountered cannot be resolved using troubleshooting steps provided in your instrument's user manual or the issue persists after rebooting the instrument, perform the following steps *before* contacting Support to report the issue:

- 1. Record the error message.
- 2. Record the sequence of events leading up to the error, if possible.
- 3. If necessary, close the error message window.
- 4. Record the Serial Number located on the Device Label for your instrument.

Gathering these details prior to contacting Support will be helpful as they troubleshoot the technical issue.

GENERATING DIAGNOSTIC REPORTS

To generate a diagnostic report that can be emailed to Support when experiencing a technical issue:

- 1. Click the **Home** tab and then the **About Matrix** button.
- Click the Generate Diagnostic Report button followed by OK in response to the confirmation prompt.
- From the desktop, click the generated *Diagnostic_YYYYMMDD.zip* folder (where *YYYYMMDD* represents the date on which file was generated) to display files in the folder.





Files in the zipped folder include logs (located in *C:\logs\Matrix\vNNN* where *NNN* represents installed version) and configuration files (located in *C:\ProgramData\Nexcelom Bioscience\Matrix\vNNN\Configurations*).

4. Attach the zipped folder to an email, include the *Support Ticket ID* (if assigned) in the Subject line and send to: CellC-support@revvity.com

It may be helpful to clear all logs before reproducing the sequence of steps leading up to an issue and/or to reduce the size of the diagnostic report to be sent to Support. Logs are generated automatically by your system on a daily basis. Keep in mind that clearing all logs will remove accumulated files to date for the version.



WARNING: Logs may be required to maintain a historical archive. As using the Clear All Logs button will *permanently* remove accumulated logs for the installed Matrix software version, it is recommended that you contact IT *before* clearing logs from your system.

To clear all logs:

1. Click the Clear All Logs button.

Note: It is *not* recommended to clear all logs unless you are confident that they are not being archived by your organization.

- 2. When prompted, click Yes to confirm you want to clear all logs.
- 3. Click **OK** to acknowledge that all logs have been cleared.



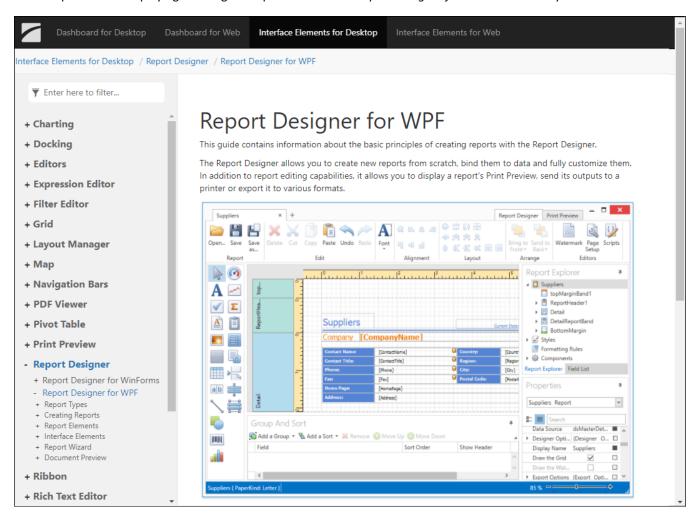
Appendix A. Report Designer for WPF Reference

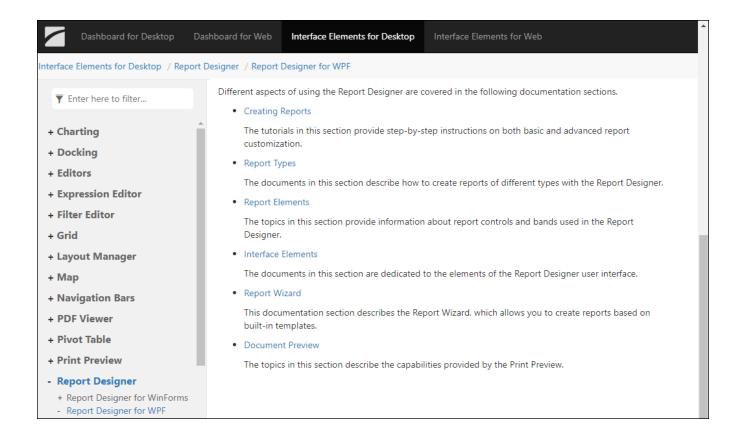
Revvity uses DevExpress as a third-party plugin for Matrix software reporting capabilities.

Visit the following page on the DevExpress website for more information about creating Matrix software report templates using *Report Designer for WPF*.

https://devexpress.github.io/dotnet-eud/interface-elements-for-desktop/articles/report-designer/report-designer-for-wpf.html

Sample screens displaying the range of topics available for Report Designer for WPF functionality are shown below.





Appendix B. Software License Details

This appendix presents Revvity's *Terms and Conditions* related to the use of the Matrix software. In addition, it includes a definition of *Revvity Proprietary Information*.

TERMS AND CONDITIONS

The *Revvity, Inc. – Terms and Conditions of Sale* license agreement states the terms and conditions upon which Revvity offers to license to you the software together with all related documentation. The Matrix software is licensed to you for use only in conjunction with Revvity's family of products.

In addition, the original Matrix software and any subsequent software upgrades installed for your Revvity instrument system is protected. You may not tamper with this software (including unauthorized upgrades), disclose it to third parties or use it for any purpose other than running your Revvity instrument system.

Revvity, Inc. does not grant you any other rights to use or disclose the original Matrix software or its upgrades, and any further uses will be prosecuted by Revvity to the maximum extent possible by law. Any other use of Matrix software or its upgrades is explicitly prohibited. In addition, you may not disclose Matrix software, upgrades, or any of its features and benefits to a third party.

Revvity Proprietary Information

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