QuantideX®

qPCR BCR-ABL Reporter

Software User Guide, Version 1.0
For Research Use Only
CE-IVD for US Export Only

CE IVD

Asuragen, Inc.
2150 Woodward St.
Suite 100
Austin, TX 78744-1840
USA

EC REP **Emergo Europe**
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Overview

The QuantideX® qPCR BCR-ABL Reporter is a component of Asuragen QuantideX qPCR BCR-ABL IS Kit (CE-IVD P/N 86003 and RUO P/N 49651) and QuantideX qPCR BCR-ABL minor Kit (RUO P/N 49637 and CE-IVD P/N 49640). This software runs either on a stand-alone computer or in a network environment and allows users to:

- Import raw data from the 7500 Fast Dx System with 21 CFR Part 11 Software, ABI software SDS v1.4
- Import raw data from the Roche **cobas z 480** Analyzer with Roche software UDF v2.0
- Analyze the raw data and review the results in graphical form (graph and tables)
- Update product information, such as new product or lot information
- Create standard batch reports

System Requirements (Prerequisite Installation)

The minimum hardware and software requirements for the QuantideX qPCR BCR-ABL Reporter are as follows:

- A windows based PC running (32-bit or 64-bit) Windows 7 or Windows 10
- Processor
  - Minimum 1 GHz
  - Recommended 2.4 GHz single core or greater
- RAM
  - Minimum 1 GB
  - Recommended 4 GB or greater
- Disk space
  - Minimum 1 GB available disk space
  - Recommended 4 GB available disk space
- Screen resolution
  - Minimum: 1024 x 768
- Adobe Acrobat Reader: Latest version
- .NET Framework 4.0, .NET Framework 3.5, and .NET Framework 4.5.2:
  - .NET Framework 4.0, .NET Framework 3.5, and .NET Framework 4.5.2 are included in the installer and will install on your computer during the install process if it is not already on your computer.

Note: If you are using Windows 10 and .NET Framework 3.5 fails to install, you may need to complete the following steps to install .NET Framework 3.5 manually.

1. *Open your **Local Group Policy Editor** by choosing **Edit Group Policy** from the Control Panel or by running gpedit.msc.*
2. *Double-click on Computer Configuration, next on Administrative Templates, and then select System.*
3. *Double-click the setting Specify settings for optional component installation and component repair.*
4. *Along the left side of the window, select the **Enabled** radio button and then the checkbox that indicates "Download repair content and optional features directly from Windows Server Update Services (WSUS)". Click **Apply**.*
5. *Click the **Start** menu and type "Windows Features", and choose **Turn Windows features on or off**.*
6. *Find .NET Framework 3.5 (includes .NET 2.0 and 3.0) and select the box on the left, then click **OK**.*
7. *Windows should now install .NET Framework 3.5. If prompted, allow Windows to download the needed files from Windows Update.*
8. *At this point, you may now proceed with installing QuantideX qPCR BCR-ABL Reporter. If prompted to install .NET Framework 3.5, deselect the check box.*

Download Instructions

1. Download the QuantideX® qPCR BCR-ABL Reporter from the Asuragen® website by entering the following web address into your browser: http://software.asuragen.com.
2. Select QuantideX qPCR BCR-ABL Reporter from the drop down box.
3. Enter your email address, First Name, Last Name, Company, and Account number in the fields provided. To obtain your account number, please contact your account manager.
4. Click **Submit request**.
5. Click the link sent through email and select a location on the target PC (e.g. My Documents, Desktop) to save the compressed QuantideX qPCR BCR-ABL Reporter 1.0.zip file.
6. Extract the QuantideX qPCR BCR-ABL Reporter 1.0.zip files to a location on the target PC.
7. To extract press and hold (or right-click) the folder, select **Extract All**, and then follow the instructions.

Installation Instructions

1. Browse to the extracted file location and double click QuantideX® qPCR BCR-ABL Reporter. Please note an Administrator privilege is required to perform the following instructions.
2. Follow the prompts to install the Software on the target PC.
3. Click **Next** button to continue.

Note: A .NET Framework prerequisite install screen may appear if it is not installed on your computer. Refer to the System Requirements (Prerequisite Installation) section above for details.
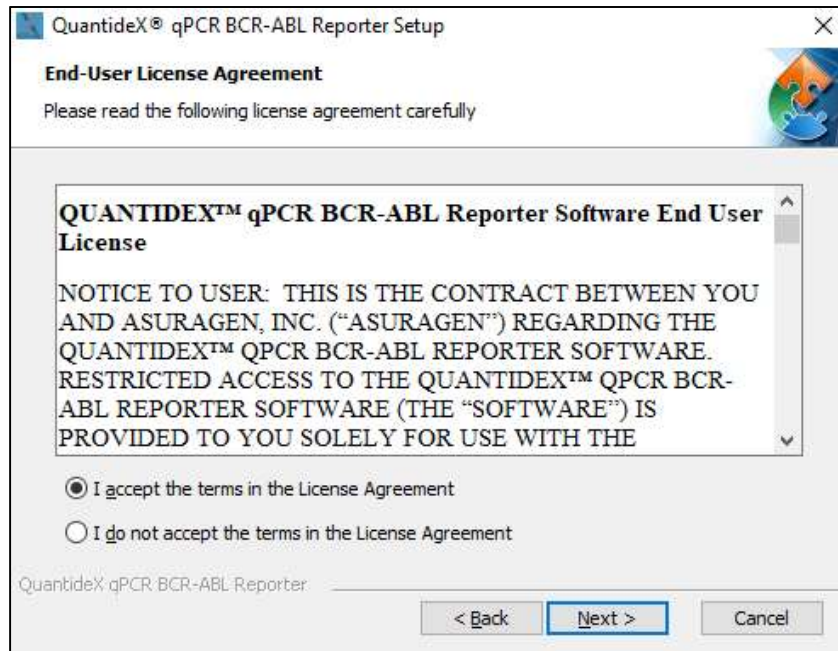
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4. Install the Software in the default location; click **Next** button to continue.

> *Note: It is a known limitation that regardless of the folder directory that is chosen the software will install at C:\Program Files (x86)*
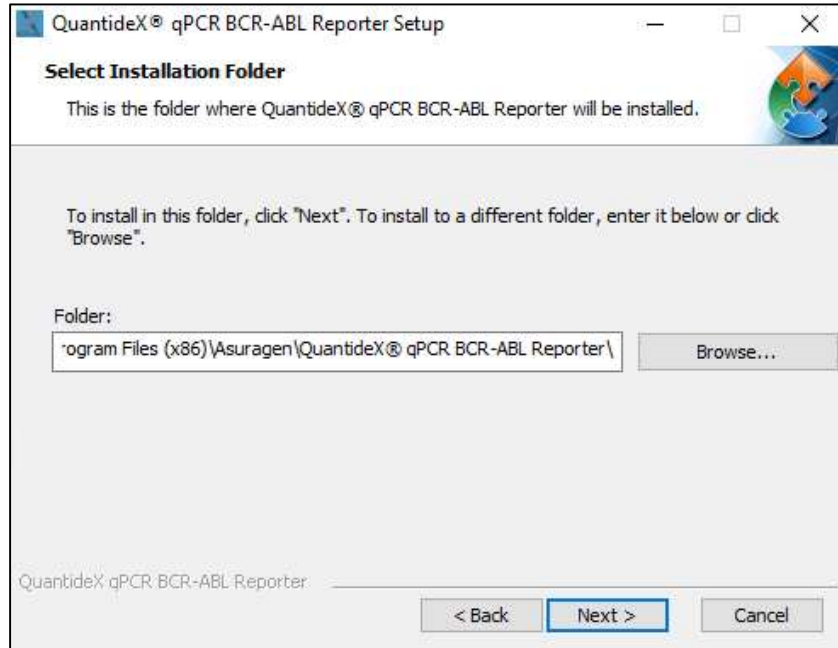

5. Review and Accept the terms in license agreement. Click **Next** to continue.

6. Click **Install** to continue. Subsequently, the installer will display several in progress screens and may take a few minutes to complete the process.

7. Click **Finish** when prompted. Leave the **Launch the program** radio button checked to launch the Software, otherwise uncheck the box. By checking the **View readme file** radio button the Release Notes for the Software will open. The installer will create a shortcut on your desktop for easy access.
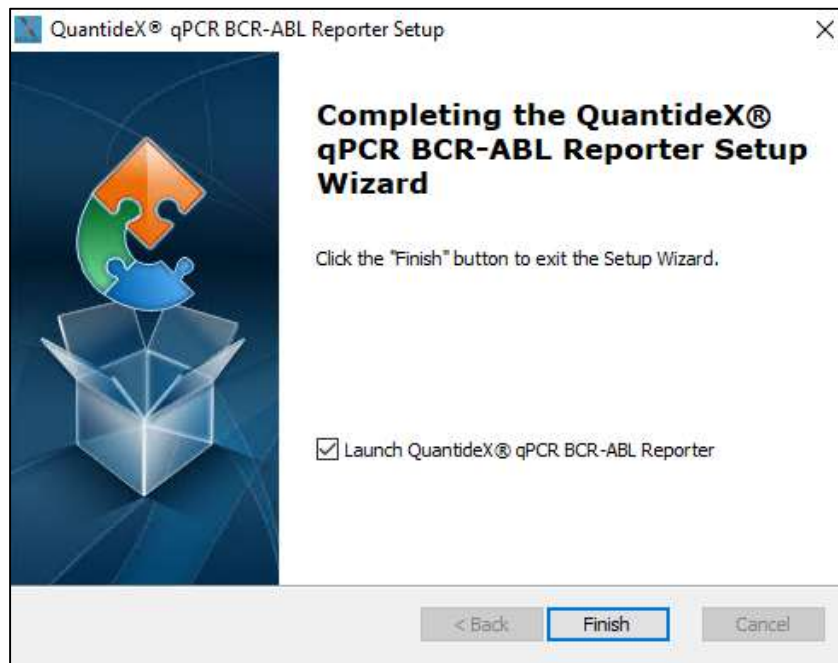
> *Note: Launching the software the very first time initiates a process requiring the user to create an Administrator account and password. This account will be initially set as an Administrator and the only user to be able to manage other user accounts and certain other functions such as Lot configuration.*

8. Complete the required fields in the following screen and click **Update Password**. The information stored in the password hint fields will be useful to retrieve your password if forgotten.

> *Note: The Password and Password Hints fields are both case sensitive.*

9. Once completed, the software will be completely installed, configured and ready to use. Select the appropriate software, enter your Username and Password to login, and to launch the software.

QuantideX® qPCR BCR-ABL IS Reporter Features

Upon successful login, the following screen will be displayed. This screen allows users to manage user accounts, configure lot information, configure file locations, view the change log, view raw data files, analyze and report/export Batch Files.

> **Note: Settings, Users, and the Change Log features are not available to users without Administrative privileges and will not appear on the screen.**
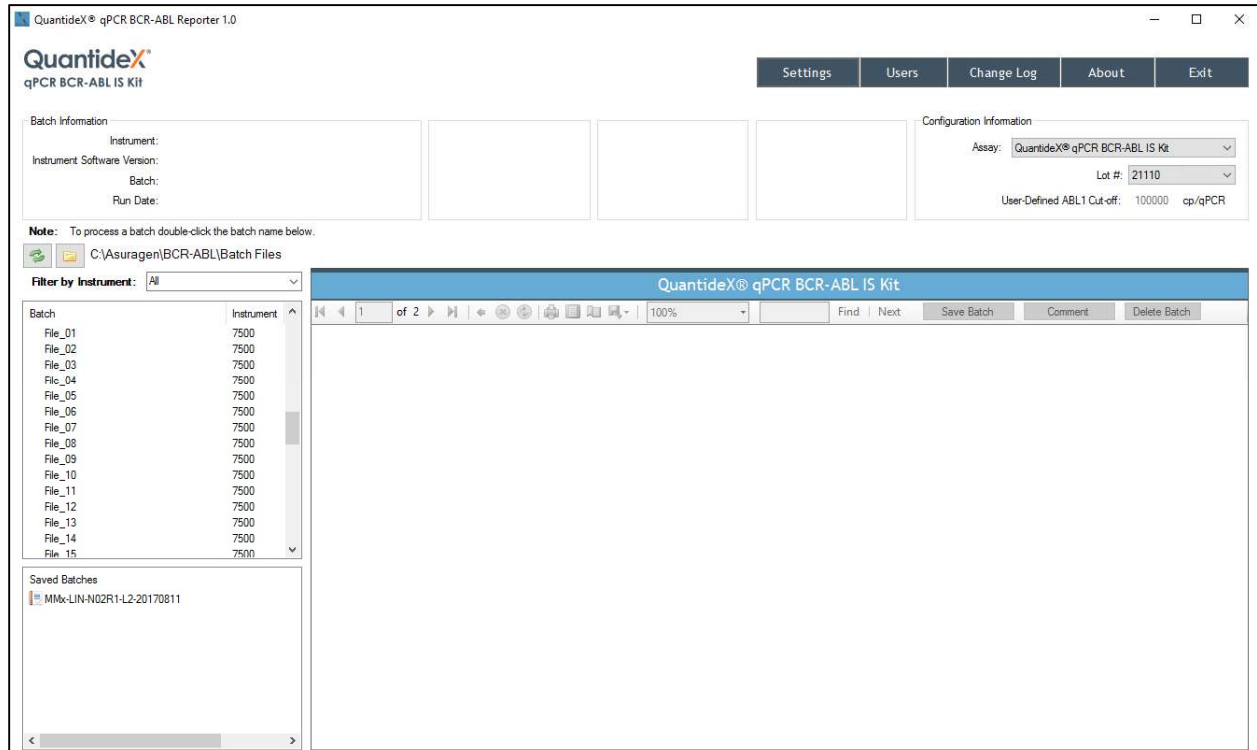
Configuration Settings

> **Note: To ensure traceable, accurate results, the lot information entered into the software must match the lot information for the kit that was used to perform the batch run. Only users with an Administrative role can perform this step.**

On the Main Screen, click **Settings** at the top-right. Confirm that the values listed match the lot information for the reagents that were used to generate the file that you wish to analyze. If so, click Cancel and the window will close returning you to the Main screen. If not, proceed with the following steps using the values stated on the certificate of analysis.

1. Click **Add New** to open a new window
2. If desired, lot information can be entered by bar code by clicking on **Input by Barcode**, scanning or entering the barcode information and clicking **Submit**.
3. Enter Lot number.

4. Enter ABL1 Copies
5. Enter ABL1 Cut-off Gap value
6. Enter Checksum value
7. Enter Calibrator 1 (CAL1) through Calibrator 4 (CAL4) values
8. Click **Save**
9. If an error message results, verify the values entered then click **Save** again. Verify that all digits were entered, including leading and trailing zeros for items 3 – 7. For example, 0.980 should be entered as 0.980 and not .980 or 0.98.

The system will allow for multiple lots to be entered and stored from which users may be able to choose by way of a drop-down on the Main screen. This is the default setting for the application. In some instances, the ability to change or choose lots that are used for processing the data may not be desirable; in this case, the Administrator may uncheck the box allowing users to select lots during analysis.

Use the **Browse** buttons within the **Data Folder Information** Section of the Configuration Settings window to change where the generated files will be stored.

Once all the information and settings have been entered, click **Save** to store the information and return to the Main screen.

Manage Users

In order for an individual to access the QuantideX® qPCR BCR-ABL Reporter, the Administrator will need to create a user account designated with one of the following roles:

Role	Description
Active (user)	Gives ability to analyze files for report generation.
Administrator	In addition to Active (user) functions, this role has the ability to update lot values.
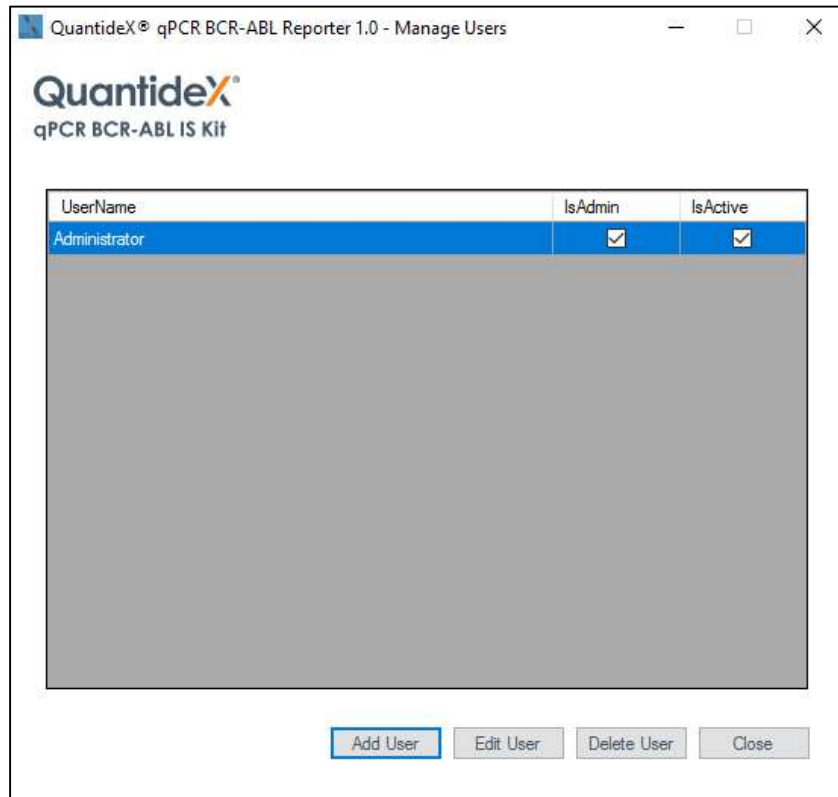
Create a New User

1. On the Main Screen, click **Users** at the top-right
2. Click on the **Add User** button to open a new window
3. Enter a Username
4. Enter a Password and confirm the Password in the subsequent box (must be greater than 6 and fewer than 55 characters)
5. Enter Password hints
6. Select whether the user will be granted Administrator rights and if the account is active

7. Click **Save** to store the information and return to the User Management window.

> *Note: It is strongly recommended that users without Administrator priviledges update their password and hints upon their first log-in. This may be done by clicking on the 'Forgot Password' link on the Log-in Screen and correctly entering the Administrator assigned hints.*

Update an Existing Account

Select the user account to be updated and click the **Edit User** button. Here the Administrator can edit the account password as well as change the Administrator privileges or the active status of the account.

Delete an Existing Account

Select the user account to delete and click on the **Delete User** button. This action will permanently delete the selected user.

> *Note: It is required that there is always at least one Administrator account designated within the system.*

> *Note: A user cannot be deleted if activities have been performed in the system (e.g. processing a batch or changing lot number). In this case a user account will be inactivated.*

Change Log

Clicking on the **Change Log** button will open a new window listing changes that have occurred to the Calibrators Lots stored in the system, both added and deleted.

The information presented is:

- Time stamp of when the event occurred
- Change Reason (e.g. Lot Activated, Lot Inactivated, Lot Selected)
- Lot Number
- Modified by (displays Username)

About

Clicking on the **About** button will open a new window that contains information regarding the following:
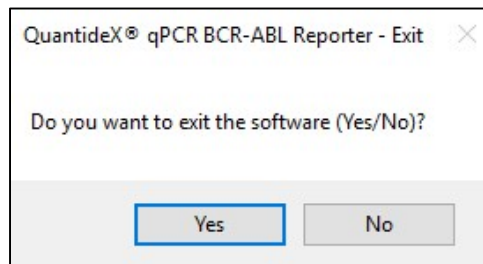
- Software Name
- Software version
- Release Date
- Operating System
- CPU Count
- Memory(GB)

- Regional Settings
- SQL Server Version
- Data Source
- Database Name

Click the **OK** button to close the window and return to the Main screen.

Exit

To exit the application click on the **Exit** button at the top of the Main screen. A confirmation window will open asking if you want to exit the software. By clicking **Yes** the application will close.

Configuration Information

The Lot Information used during analysis is displayed on the top right corner of the Main screen (if previously enabled by the Administrator). If multiple lot numbers exist in the program, then a drop down menu will be present so a user can select the correct lot to analyze the data. Once selected, the table will update to show the appropriate information stored for that lot. Once selected the User-Defined ABL1 Cut off information will be displayed.
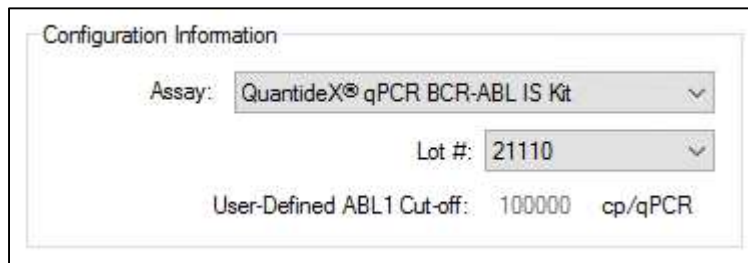
Batch Information

Batch files and the folder path on the top left side of the Main screen. This list may be filtered to show all available files or by instrument type. To choose or change the file path, click on the **File Folder** icon and a Browse For Folder window will open. Once the correct path is selected click **OK**.

To refresh the list, click on the **Refresh** icon located to the left of the File Folder icon. If the number of files to be displayed is larger than the display window, a scroll bar will appear to the right of the box that will aid in navigating up and down the list.

Single click the file of interest and the Batch Information will be displayed at the top left side of the Main Screen. The information displayed will include the Instrument, Instrument Software Version, Batch name, and Run Date.
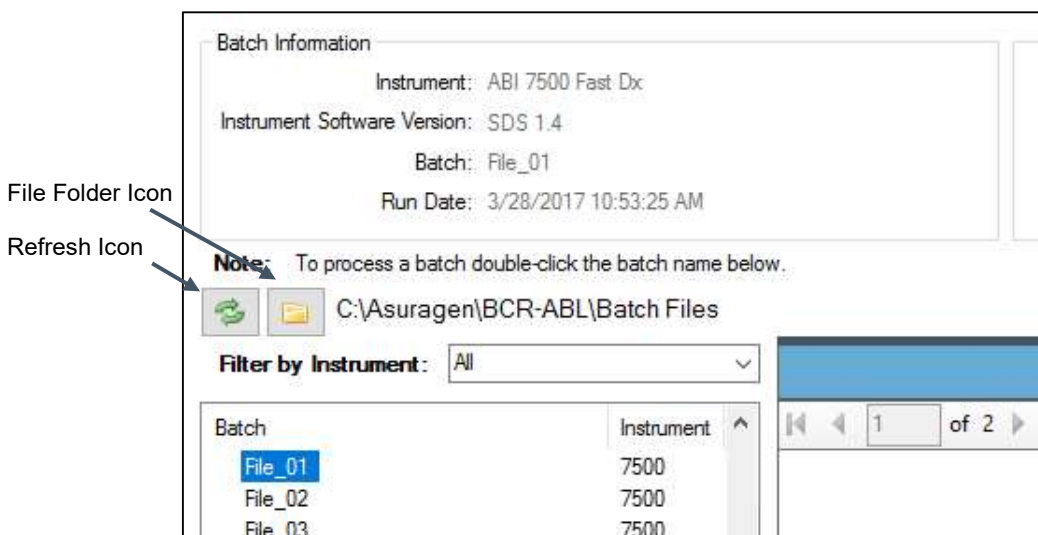
Report Generator, Viewer, and Exporter

The QuantideX® qPCR BCR-ABL Reporter will automatically generate a batch report containing Calibration Curves, MR, and %IS values for controls and clinical specimens given a valid Batch Files.

> *Note: An invalid 7500 SDS file will generate a warning message. This means you might not be using the right SDS file. Please check instrument software version.*

Follow the steps below to generate a report using the QuantideX qPCR BCR-ABL Reporter:

1. Select the desired file from the Batch List browser with a single click to display the batch information in the upper-left part of the window.
2. Double-click of the file and the Software will automatically generate Calibration Curves, Means, MR, Copies/qPCR, and %IS values for controls and clinical specimens. These are displayed in the Batch Report window.

> *Note: To ensure traceable, accurate results, the lot information entered into the software must match the lot information for the Kit that was used to perform the batch run. To verify this, ensure that the entry for "Lot #:" in the upper right-hand corner of the Batch Report window displays the lot number of the Kit used to generate the .sds file that was processed. If it does not match, use the drop-down to select the correct one or notify an Administrator who may change it to the correct Lot #. Process the .sds file again starting with step 1.*

3. Refer to the QuantideX qPCR BCR-ABL IS Kit Instructions For Use for additional information regarding the interpretation of results.
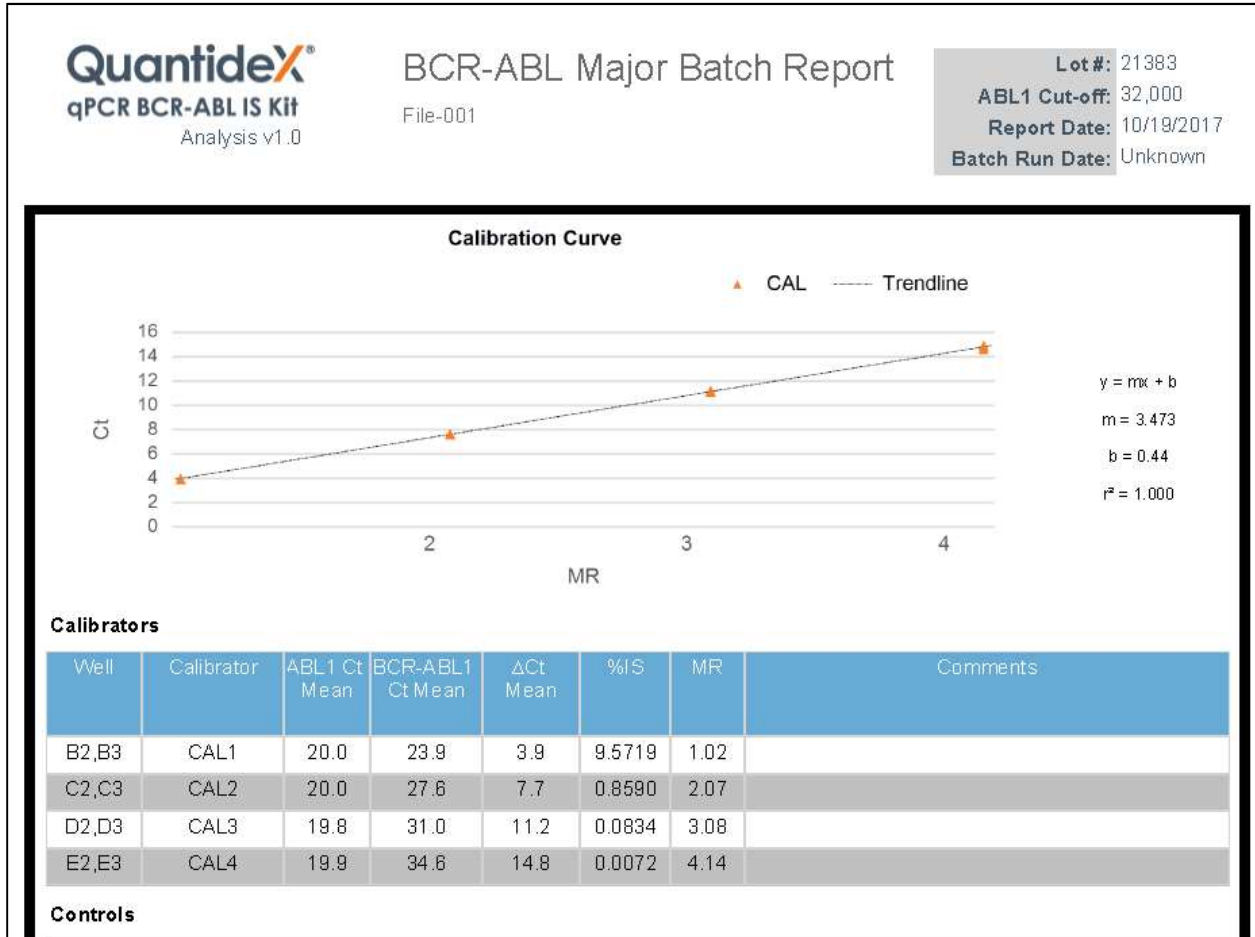
Icons available to use in navigating the reports are (from left to right in the image below):

- Return to the First Page
- Return to the Previous Page
- Current Page Number
- Total Page Numbers
- Next Page
- Last Page
- Back to the Parent Report
- Stop Rendering
- Refresh

- Print
- Print Layout
- Page Setup
- Export (PDF)
- Zoom
- Search box
- Save Batch
- Add Comment
- Delete Batch

QuantideX® qPCR BCR-ABL minor Reporter Features

Upon successful login, the following screen will be displayed. This screen allows users to manage user accounts, configure Lot Information, configure file locations, view the Audit Log, view raw data files analyze, and report/export batch files.

> *Note: Settings, Users, and the Change Log features are not available to users without Administrative privileges and will not appear on the screen.*
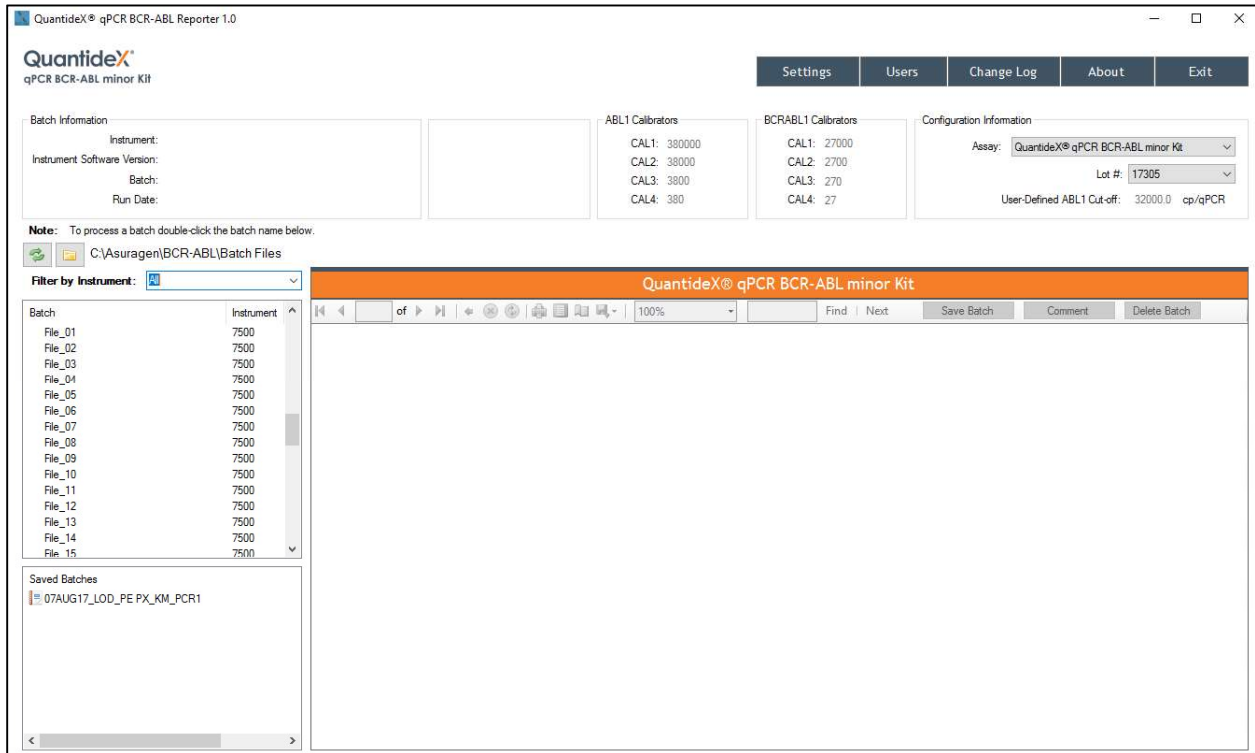
Configuration Settings

Note: Settings, Users, and the Change Log features are not available to users without Administrative privileges and will not appear on the screen.

On the Main Screen, click Settings at the top-right to enter Data Folder Information, Lot Information, and User-Defined ABL1 Cut-Off.

Data Folder Information

Use the **Browse** buttons within the **Data Folder Information** section of the Configuration Settings window to change where the generated files will be stored. The Export Path is the location where selected .csv files are saved when exported. The Batch File Path contains a default location where files are saved; the path can be changed if desired.

Lot Information

The system will allow entry and storage of multiple lots from which users may be able to choose by way of a drop-down on the Main screen. This is the default setting for the application. In some instances, the ability to change or choose lots used for data analysis may not be desirable; in this case, the Administrator may uncheck the box allowing users to select lots during analysis.

Confirm that the values listed match the Lot Information for the reagents used to generate the Batch File that need to be analyzed. If so, click **Cancel** and the window will close returning to the Configuration screen. If not, proceed with the following steps using the values stated on the certificate of analysis.

1. Click **Add New** to open a new window
2. Enter the Lot number and click **Save**

User-Defined ABL1 Cut-Off

1. Enter User-Defined ABL1 Cut-off value. The Software will place a default value of 32,000 for the User-Defined ABL1 Cut-off. Specimens below this value are flagged for further review.
2. Click **Save**
3. If an error message is seen, verify the values entered then click **Save** again.

Once all the information and settings have been entered, click **Save** to store the information and return to the Main screen.

Manage Users

In order for other individuals to access the QuantideX® qPCR BCR-ABL Reporter, the Administrator will need to create a user account designated with one of the following roles:

Role	Description
Active (user)	Gives ability to analyze files for report generation.
Administrator	In addition to Active (user) functions, this role has the ability to update lot values.
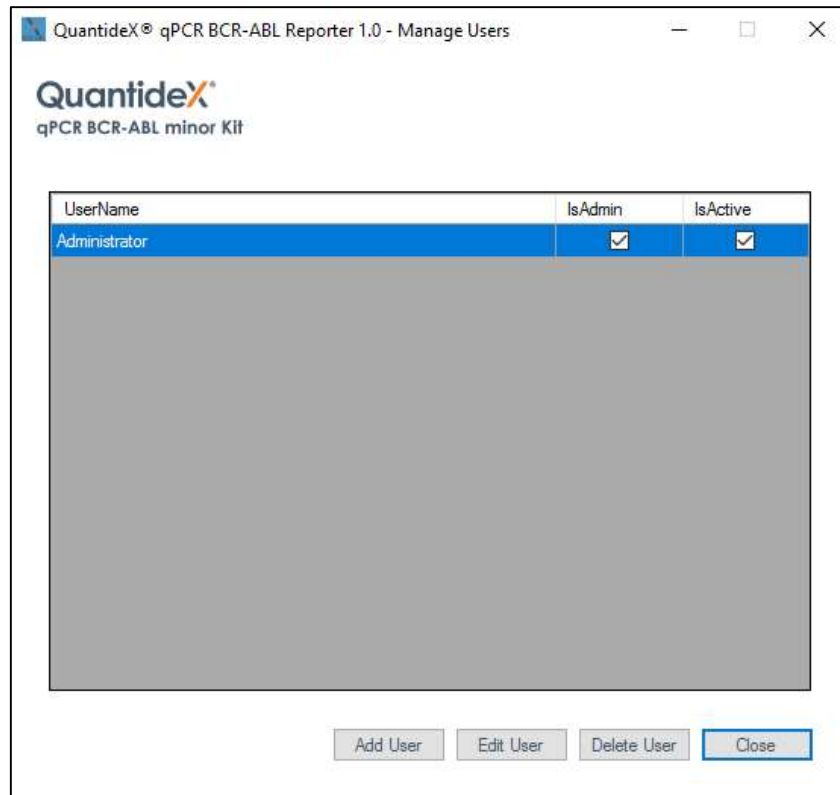
Create a New User

1. On the Main Screen, click **Users** at the top-right.
2. Click on the **Add User** button to open a new window
3. Enter a Username
4. Enter a Password and confirm the Password in the subsequent box (must be at least 6 and fewer than 55 characters)
5. Enter Password hints
6. Select whether the user will be granted Administrator rights and if the account is active
7. Click **Save** to store the information and return to the User Management window

> *Note: It is strongly recommended that users without Administrator priviledges update their password and hints upon their first log-in. This may be done by clicking on the 'Forgot Password' link on the Log-in Screen and correctly entering the Administrator assigned hints.*

Update an Existing Account

Select the user account to be updated and click the **Edit User** button. Here the Administrator can edit the account password as well as change the Administrator privileges or the active status of the account.

Delete an Existing Account

Select the user account to delete and click on the **Delete User** button. This action will permanently delete the selected user.

> *Note: It is required that there is always at least one Adminstrator account designated within the system.*

> *Note: A user cannot be deleted if activities have been performed in the system (e.g. processing a batch or changing lot number). In this case a user account will be inactivated.*

Change Log

Clicking on the **Change Log** button will open a new window listing changes that have occurred to the Calibrators Lots stored in the system, both added and deleted.

The information presented is:

- Time stamp of when the event occurred
- Audit date and time
- Change Reason (Lot Activated, Lot Inactivated, Lot Selected, or Save)
- Lot Number
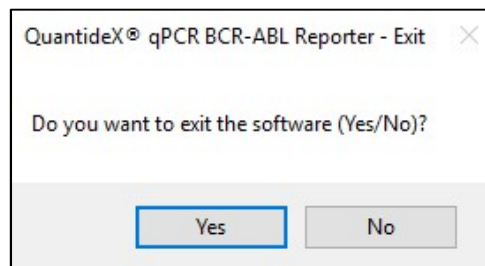- Modified by (displays Username)

About

Clicking on the **About** button will open a new window that contains information regarding the following:

- Software Name
- Software version
- Release Date
- Operating System
- CPU Count
- Memory (GB)
- Regional Settings
- SQL Server Version
- Data Source
- Database Name

Click the **OK** button to close the window and return to the Main screen.

Exit

To exit the application, click on the Exit button at the top of the Main screen. A confirmation window will open asking if you want to exit the software. By clicking Yes the application will close.

QuantideX® qPCR BCR-ABL Reporter - Exit ✕

Do you want to exit the software (Yes/No)?

Yes | No

Configuration Information

The Lot Information used during analysis is displayed on the top right corner of the Main screen (if previously enabled by the Administrator). If multiple lot numbers exist in the program, then a drop down menu will be present so a user can select the correct lot to analyze the data. Once selected, the table will update to show the appropriate information stored for that lot. Once selected the User-Defined ABL1 Cut off information will be displayed.

Configuration Information

Assay: QuantideX® qPCR BCR-ABL minor Kit

Lot #: 17305

User-Defined ABL1 Cut-off: 32000.0 cp/qPCR

Batch Information

Batch files and the folder path are displayed on the top left side of the Main screen. This list may be filtered to show all a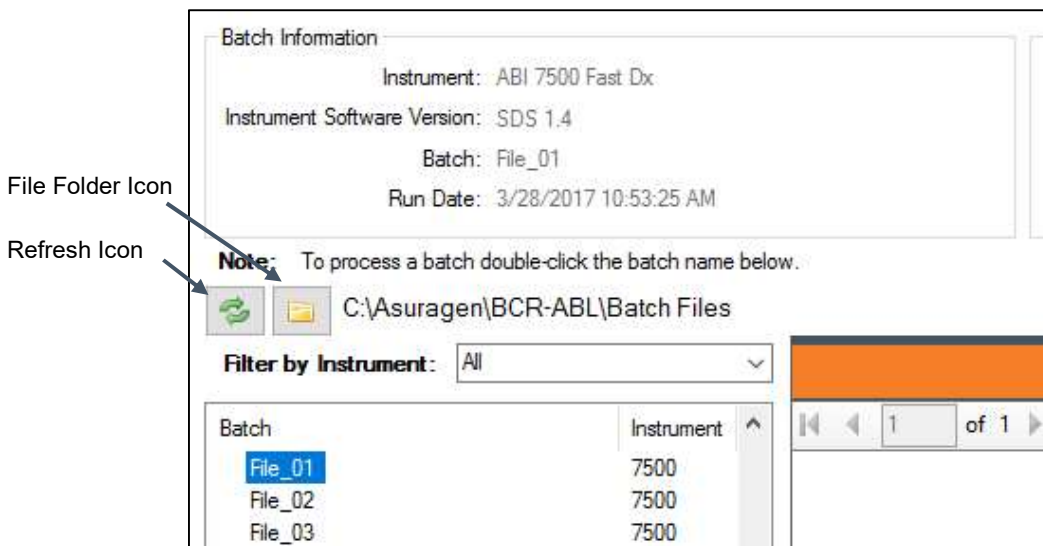vailable files or by instrument type. To choose or change the file path, click on the **File Folder** icon and a Browse For Folder window will open. Once the correct path is selected click **OK**.

To refresh the list, click on the **Refresh** icon located to the left of the File Folder icon. If the number of files to be displayed is larger than the display window, a scroll bar will appear to the right of the box that will aid in navigating up and down the list.

Single click the file of interest and the Batch Information will be displayed on the top left side of the Main Screen. The information displayed will include the Instrument, Instrument Software Version, Batch name, and Run Date.

Report Generator, Viewer, and Exporter

The QuantideX® qPCR BCR-ABL Reporter will automatically generate a batch report containing Calibration Curves, Means, and Copies/qPCR for controls and specimens given a valid Batch Files.
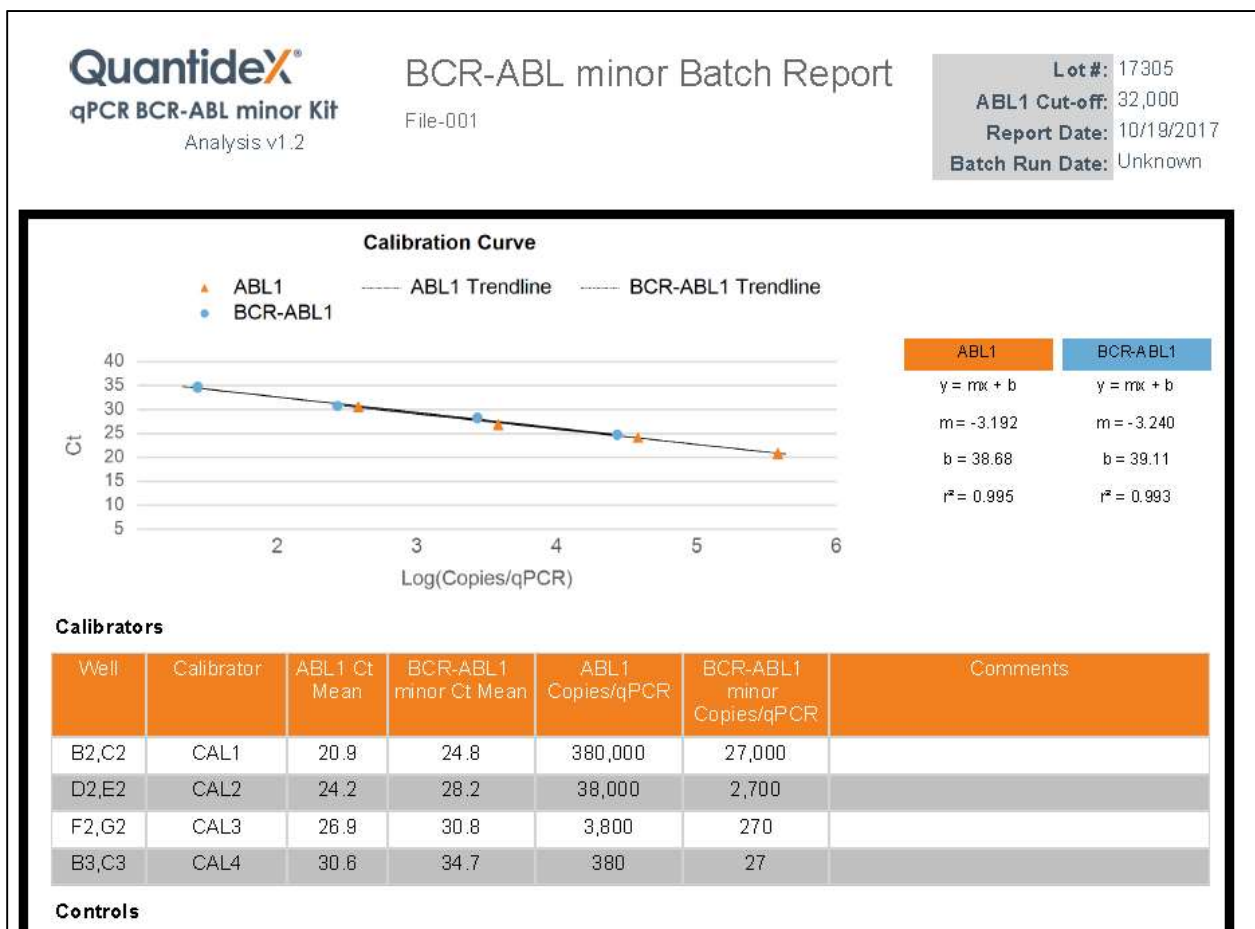
> *Note: If an invalid 7500 SDS file generates a warning message, you might not be using the right SDS file. Please check instrument software version.*

Follow the steps below to generate a report using the QuantideX® qPCR BCR-ABL Reporter.

1. Select the desired file from the Batch List browser with a single click to display the batch information in the upper-left part of the window.
2. Double-click the file and the Software will automatically generate Calibration Curves, Means, and Copies/qPCR for controls and specimens. These are displayed in the Batch Report window.

> *Note: Trendlines may not appear to extend through all calculated points of the Calibration Curve chart.*

3. Refer to the QuantideX qPCR BCR-ABL minor Kit Instructions for Use for additional information regarding the interpretation of results.

BCR-ABL minor Batch Report
File-001

Lot #: 17305
ABL1 Cut-off: 32,000
Report Date: 10/19/2017
Batch Run Date: Unknown

QuantideX®
qPCR BCR-ABL minor Kit
Analysis v1.2

Calibration Curve

	ABL1	BCR-ABL1
	$y = mx + b$	$y = mx + b$
	$m = -3.192$	$m = -3.240$
	$b = 38.68$	$b = 39.11$
	$r^2 = 0.995$	$r^2 = 0.993$

Calibrators

Well	Calibrator	ABL1 Ct Mean	BCR-ABL1 minor Ct Mean	ABL1 Copies/qPCR	BCR-ABL1 minor Copies/qPCR	Comments
B2,C2	CAL1	20.9	24.8	380,000	27,000	
D2,E2	CAL2	24.2	28.2	38,000	2,700	
F2,G2	CAL3	26.9	30.8	3,800	270	
B3,C3	CAL4	30.6	34.7	380	27	

Controls

Icons available to use in navigating the reports are (from left to right in the image below).

- Return to the First Page
- Return to the Previous Page
- Current Page Number
- Total Page Numbers
- Next Page
- Last Page
- Back to the Parent Report
- Stop Rendering
- Refresh

- Print
- Print Layout
- Page Setup
- Export (PDF)
- Zoom
- Search box
- Save Batch
- Add Comment
- Delete Batch

Uninstallation Instructions

1. Open Programs and Features by clicking the **Start** button, clicking **Control Panel**, clicking **Programs and Features**.
2. Select QuantideX® qPCR BCR-ABL Reporter, and then click **Uninstall**.

> *Note: Uninstallation of QuantideX qPCR BCR-ABL Reporter will not remove the database instance and associated files. To uninstall the database instance and associated files follow the instructions below.*

Follow the steps below to uninstall MS SQL Server 2014 BCABL instance:

1. Open Programs and Features by clicking the **Start** button, clicking **Control Panel**, clicking **Programs and Features**.
2. Select Microsoft SQL Server 2014, and then click **Uninstall**
3. Click **Remove**
4. Select **BCRABL** instance from drop down
5. Select **Database Engine Services** check box, leaving all other items unchecked.
6. Click **Next**
7. Click **Remove**

To completely remove the database files from the system, follow the steps below:

1. Browse to: C:\Program Files (x86)\Microsoft SQL Server\MSSQL12.BCRABL\MSSQL\DATA directory
2. Locate and delete the following files:
- BCRABLDB.mdf
- BCRABLDB_log.ldf

Disclaimers

1. This Product is intended to be Research Use Only in non-European markets and CE-IVD for US Export only.
2. This Product may not be resold, modified for resale, or used to manufacture commercial products without the written approval of Asuragen.
3. Asuragen® and QuantideX® are trademarks of Asuragen Inc.
4. All instrumentation must be maintained and operated according to manufacturer's instructions.
5. TO THE EXTENT PERMITTED BY APPLICABLE LAW, IN NO EVENT SHALL ASURAGEN BE LIABLE IN ANY WAY (WHETHER IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE) FOR ANY CLAIM ARISING IN CONNECTION WITH OR FROM THE USE OF THIS PRODUCT.

Asuragen, Inc.
2150 Woodward St.
Suite 100
Austin, TX 78744-1840

USA
+1.512.681.5200
+1.877.777.1874

| EC | REP |

Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

www.asuragen.com

Technical Support: 1.877.777.1874
Email: techservicedx@asuragen.com

Change History

Revision	Change Description	Effective Date
01	Initial Release	2017-12-21