



Amplidex[®]

PCR/CE Reporter

Software User Guide, Version 4.0

Research Use Only

REF A00573



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Overview

AmplideX® PCR/CE Reporter is a data analysis and visualization tool designed to support the interpretation of capillary electrophoresis (CE) trace files (FSA files) produced using AmplideX PCR/CE Kits. Sample analysis and reporting functionality is provided by independent Analysis Modules, which are installed separately from AmplideX PCR/CE Reporter.

Refer to the software user guide for each analysis module to review instructions for configuring analysis settings, creating and analyzing batches, and reviewing analysis results for sample FSA files produced as a byproduct of each kit assay.

System Requirements (Prerequisite Installation)

To download the AmplideX PCR/CE Reporter, go to <https://asuragen.com/myasuragen>. The minimum hardware and software requirements are as follows:

- Windows-based PC running (64-bit) Windows 10, Windows Server 2016, or Windows Server 2019

Note: Before installing the software, ensure all Windows Updates are installed for the target OS and restart the machine if required before proceeding.

- Ports 9045, 9040, 44375, and 5436 for localhost must be available
- Processor (CPU)
 - A CPU with at least 4 logical processors (2 cores) is required for all versions of Windows

Note: For most versions of Windows, you can press Windows + R, then type “msinfo32”, and finally press Enter to list the total number of logical processors, and other system information.

- Physical Memory (RAM)
 - At least 4 GB RAM is required for all versions of Windows

Note: If processing a large volume of samples and batches, using a CPU with at least 8 logical processors (4 cores) and at least 8 GB RAM is recommended.

- Minimum 10 GB available disk space
- Firefox (v96+) or Chrome (v96+) browsers

Note: An Internet connection is not required to perform analysis with the AmplideX PCR/CE Reporter. However, for certain functions (such as sending error reports or accessing the latest user guide) Internet access will be required on the PC where the software is installed.

Configuring IT Security Software (Antivirus/Anti-Malware)

The AmplideX® PCR/CE Reporter does not require any specific configuration to antivirus, anti-malware, or other IT security software for normal operation. Verify the following actions will not be blocked by the IT policies and operating environment of your organization:

- The use of four services to run the web applications that collectively comprise the software.
- The software communicates over the local network on ports 9045, 9040, 44375, and 5436.
- The use of the directory C:\Asuragen\ARCore\v4_x to read and write files.

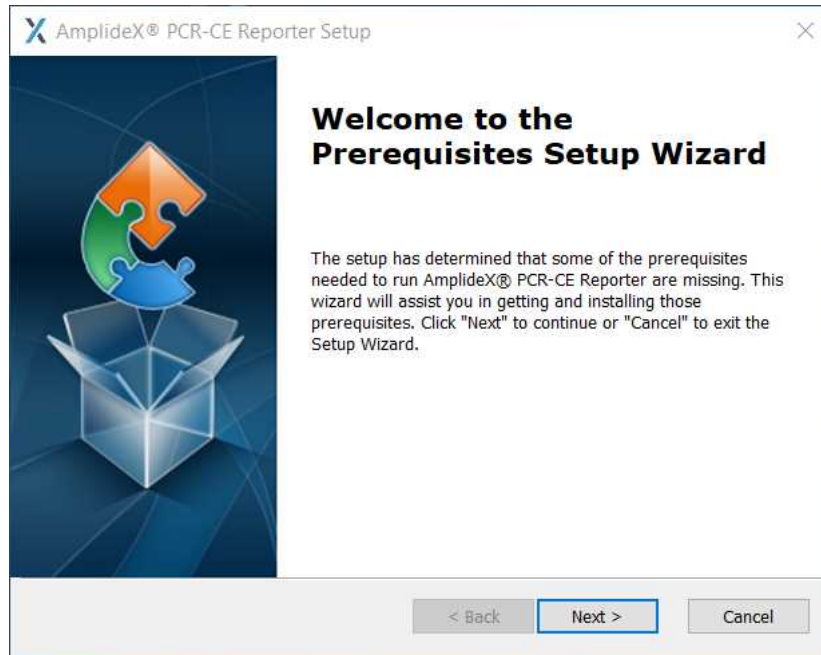
Note: Some antivirus software automatically scans new files as they are created in a process called “live scanning”. It is possible that live scanning will interfere with normal operation of the software, especially with certain analysis modules that read and write many small files in rapid succession. Check with your IT department to see if live scanning may be the cause if intermittent analysis failures are experienced.

Download Instructions

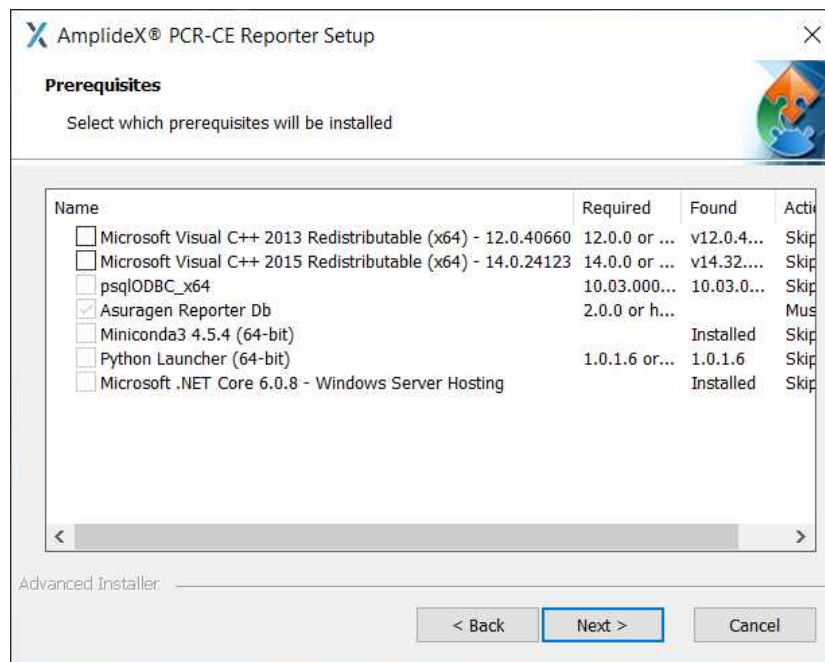
1. Download the AmplideX® PCR/CE Reporter Software from the Asuragen® website by entering the following web address into your browser: <https://asuragen.com/myasuragen>.
2. Select AmplideX PCR/CE Reporter 4.0.x Software and download.
3. Extract the AmplideX PCR/CE Reporter 4.0.x Software .zip files to a location on the target PC.
4. To extract press and hold (or right-click) the folder, select **Extract All**, and then follow the instructions.

Installation Instructions

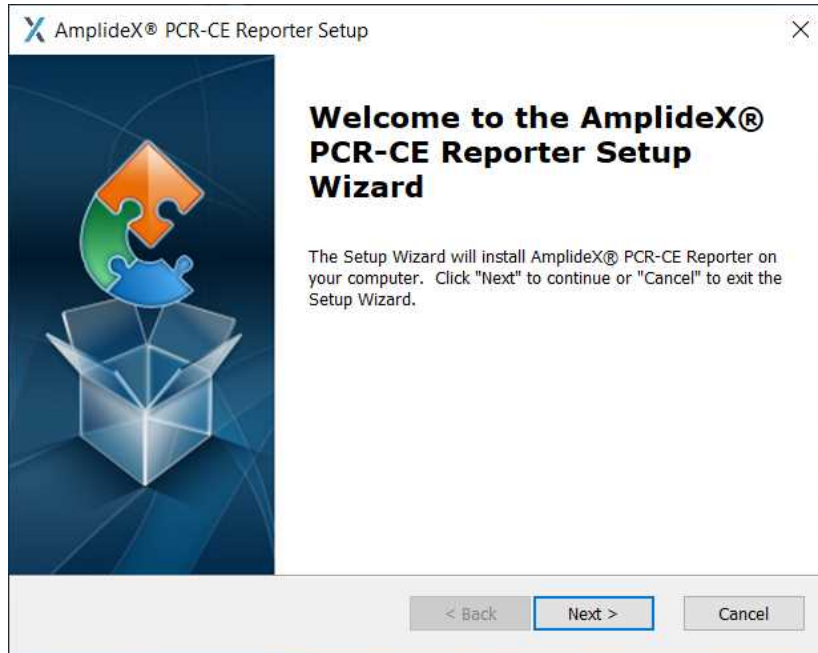
1. Save the AmplideX Reporter Installer v4.0.x.exe file to the desired location on the target PC.
2. Browse to the file location and double-click AmplideX PCR/CE Reporter Installer. Please note an Administrator privilege is required to perform the following instructions.
3. Follow the prompts to perform the Prerequisites Setup on the target PC and click **Next** to continue.



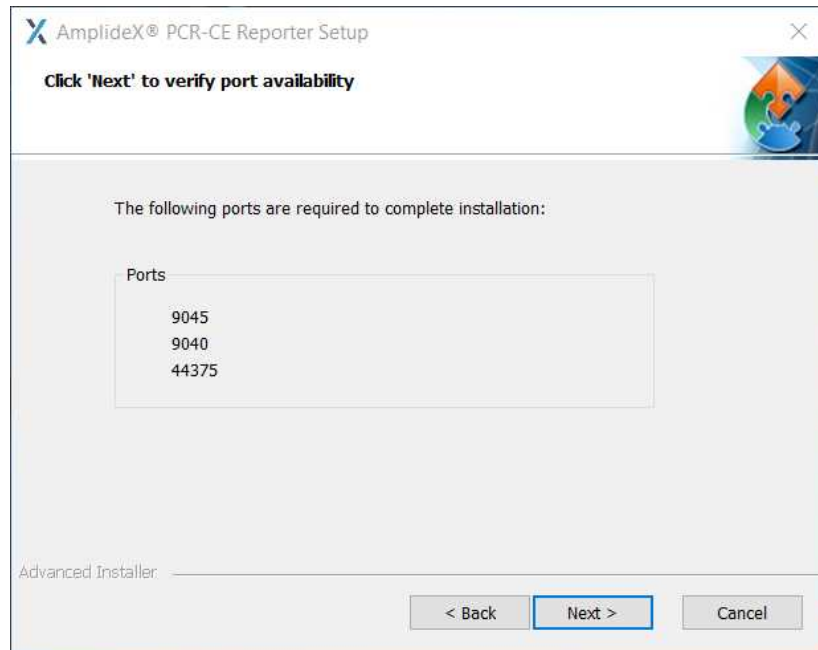
4. The installer automatically selects the required prerequisites based on the state of the machine. Using the installer defaults is recommended unless otherwise directed by your IT department or Asuragen Technical Support. Click **Next**.



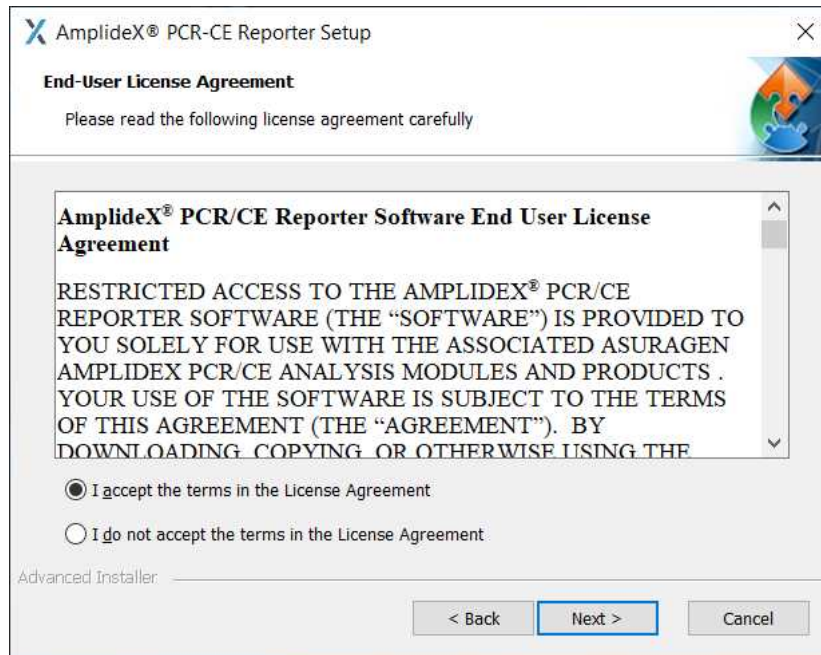
5. Follow the prompts to install the software. Click **Next** to continue.



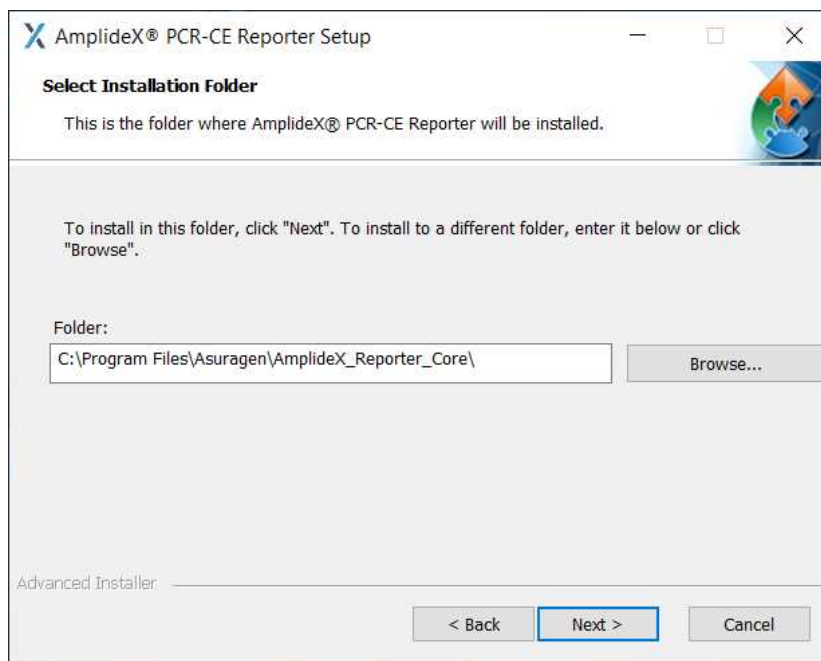
6. Click **Next** to verify port availability. If a required port is in use, the installer will notify the user and installation will stop. Contact your IT department for appropriate action.



7. Review and accept the End User License Agreement. Click **Next** to continue.

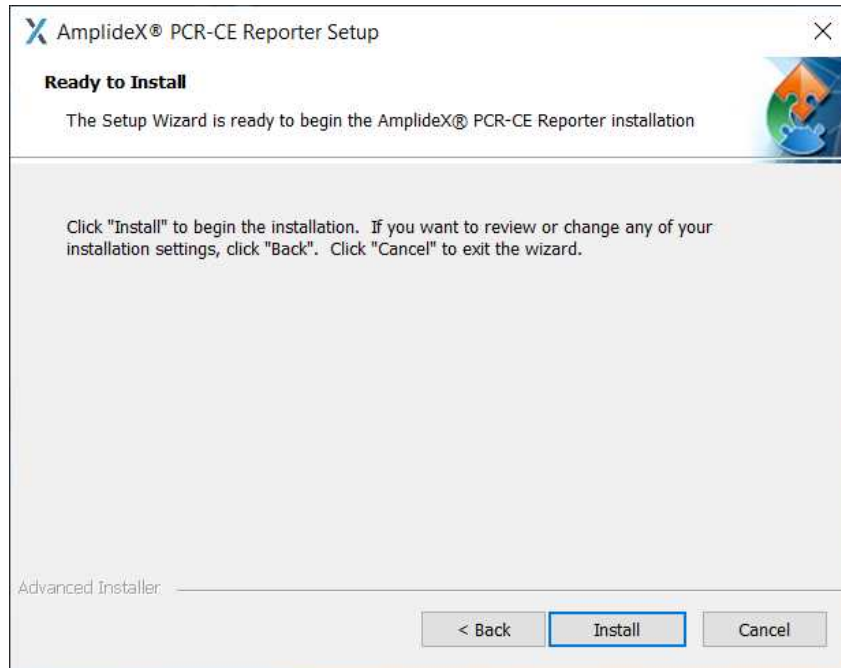


8. Select the installation folder and click **Next**.

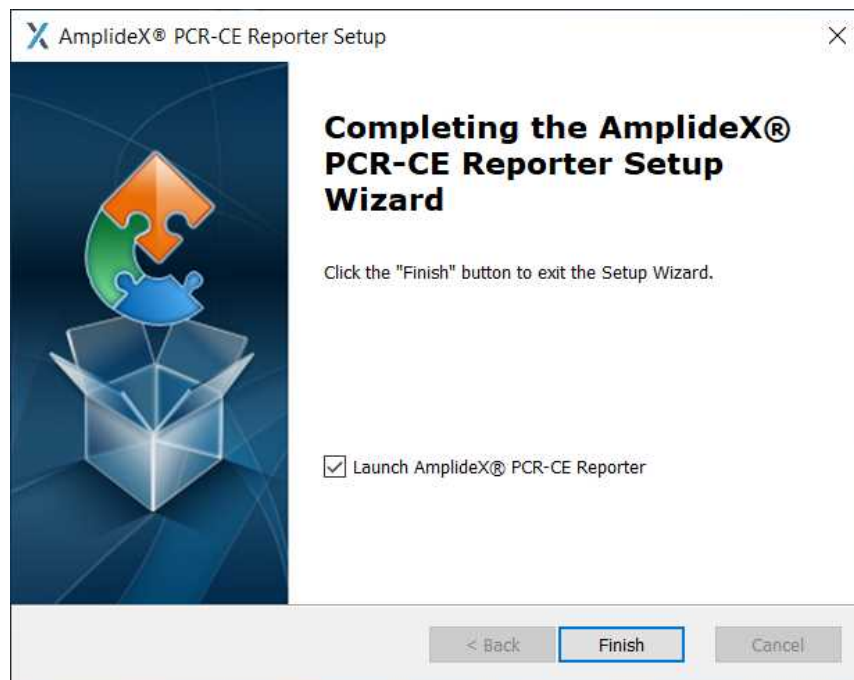


Note: Do not install the software on a network drive or use a symbolic link path. This will likely cause the application to become inaccessible or fail to start.

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



10. Click **Finish** when prompted. Leave the Launch AmplideX® PCR-CE Reporter box checked to launch the AmplideX PCR/CE Reporter, otherwise uncheck the box. The installer will create a desktop shortcut for easy access.



Accessing AmplideX PCR/CE Reporter

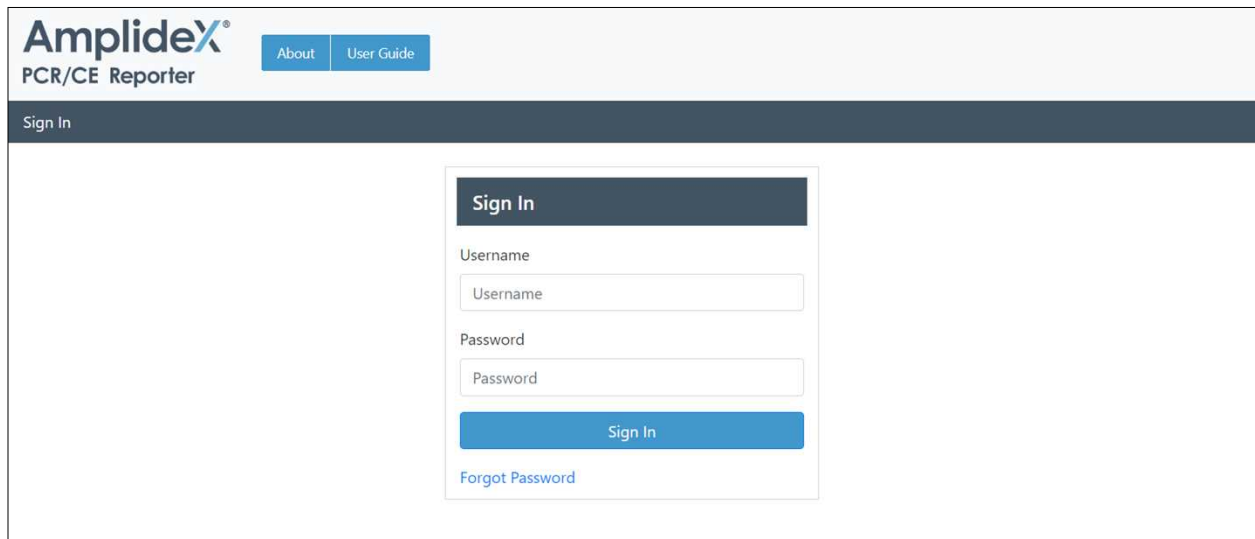
1. Double-click the AmplideX PCR/CE Reporter desktop icon to launch the software in the default web browser.
2. From other machines on the local network, navigate to `http://HostIPAddress:9045` in a web browser (replace HostIPAddress with the AmplideX PCR/CE Reporter machine IP address; 9045 is the assigned port during installation).

Using Cookies

The AmplideX PCR/CE Reporter uses cookies to store settings that enable sign in and combats fraud and malicious use. Disabling this feature in the browser renders the application inaccessible.

Log in to AmplideX PCR/CE Reporter

After launching the AmplideX® PCR/CE Reporter, the following login screen will appear:



The screenshot shows the login interface for the AmplideX PCR/CE Reporter. At the top left, the logo 'AmplideX® PCR/CE Reporter' is displayed, with 'About' and 'User Guide' links. A dark blue header bar contains the text 'Sign In'. The main content area features a white login form with a dark blue 'Sign In' button at the top, followed by 'Username' and 'Password' input fields, a blue 'Sign In' button, and a 'Forgot Password' link.

For first-time login, use the following credentials:

Username: Admin

Password: Admin123!

System Lockout

If a user fails to log in with the correct credentials 5 times, the system will automatically lock the user account. After 5 minutes, the account will reset and the user can try again.

Note: To ensure system security, avoid using the automatic login functionality of the browser.

AmplideX PCR/CE Reporter Overview

The Project Dashboard view appears after logging into the system. From this screen, the user will be able to create new projects, review the results, or edit information from previously created projects.

To create or edit a project, use the project management screen to enter a name and description for the project and select the applicable analysis type. Navigate through the tabs to import FSA files, annotate specific sample information, review the annotations, and submit samples for analysis.

After submission for analysis, the Batch view displays the status of the analysis. Once the analysis successfully completes, the user can select and review the batch.

The Project Summary view will display relevant analysis statistics as well as sample, calibrator, and/or control results. The user can review CE traces, enter any comments, and generate PDF reports or export data to a CSV file.

Note: Input fields associated with Project and Batch creation are captured as plain text. To minimize risk, follow best practices for ensuring protected health information (PHI) compliance.

AmplideX PCR/CE Reporter Features

The following screen will appear upon successful login. This screen allows users to create new projects, search and view previous projects, and manage user accounts.

The screenshot displays the AmplideX PCR/CE Reporter Project Dashboard. At the top, there is a navigation bar with the AmplideX logo and links for Project Dashboard, About, User Guide, Admin, Account, and Logout. Below the navigation bar, the Project Dashboard title is shown. The main content area features a table of projects with the following columns: Name, # Batches, Groups, Owner, and Created. The table lists projects A through J, each with a specific number of batches and a creation timestamp. The interface also includes a search bar, a 'Show 10 entries' dropdown, and pagination controls at the bottom.

Name	# Batches	Groups	Owner	Created
Project A	18	Unassigned	admin	2020-01-28T00:41:36.603437
Project B	13	Unassigned	admin	2020-01-31T21:06:29.294556
Project C	5	Unassigned	admin	2020-02-03T15:22:46.33199
Project D	9	Unassigned	admin	2020-02-03T15:33:23.855028
Project E	20	Unassigned	admin	2020-02-03T16:07:17.727357
Project F	10	Unassigned	admin	2020-02-03T16:16:21.78355
Project G	10	Unassigned	admin	2020-02-03T16:25:36.167407
Project H	14	Unassigned	admin	2020-02-03T22:17:22.91984
Project I	17	Unassigned	admin	2020-02-03T22:46:28.369653
Project J	20	Unassigned	admin	2020-02-03T23:09:50.232866

Navigation

The navigation bar is accessible from the main views of the software. It allows users to navigate the application, access administrative and account views, and log out.



Administration and User Management

In order for an individual to access the AmplideX® PCR/CE Reporter, the administrator will create a user account designated with one or more of the following roles:

Role	Description
User	Users can view, edit, and delete projects they created. Users have read access to projects within their group but cannot edit them.
Admin	Administrators can view, edit, delete all projects, and view the audit log. They can also view, edit, and disable all users and groups in the system apart from themselves and modify a user role and reset passwords.
Manager	Managers can view, edit, and delete any project within their groups.

Update Passwords

Change the first-time login password on the Admin page after the initial login.

To modify the password, perform the following the steps:

1. On the navigation bar, click **Admin**.
2. Click **Users** on the left side of the screen.
3. Select the user from User Table.
4. Click **Reset Password** from the header menu.
5. Click **Generate Code**.
6. Provide the Reset Password Code to the user account holder.
7. On the Sign In screen, the user will click **Forgot Password**, and enter the Username and Reset Password Code.
8. Complete the New Password and Confirm Password fields.

Note: Passwords must be between 8 to 32 characters, have at least one digit (0–9), have at least one upper-case letter (A–Z), and must contain at least one non-alphanumeric character from the following set: !@\$%&*?£€

9. Click **Submit**.
10. Enter the Username and new Password on the Sign In view to access the software.

Create a New User

1. On the navigation bar, click **Admin**.
2. Click **Users** on the left side of the screen.
3. Click **New**.
4. Enter the User Name, Email Address, First Name, and Last Name fields.

Note: Usernames must be unique, are case insensitive, must contain between 1 and 64 characters, cannot start or end with a space, cannot start with a number, and cannot contain the following characters: !@#\$\$%^&*,.<>;`?_{}[]'"`

5. Click **Create User**.
6. To activate and select the appropriate user roles, select the new user in the Manage Users view and edit the account by:
 - a. Using the header menu to make the appropriate selections.
 - b. Double-clicking the new user to open the Edit User window, make the appropriate selections, and click **Update user**.
7. Provide the new user with the Reset Password Code as described in the Update Passwords section.

Note: Usernames cannot be changed. If a user needs to log in with a different username, create a new account with the desired username and disable the original account. Once disabled, the user will not be able to log in with the old username nor see any projects or batches created with that account; however, administrators will still be able to review and manage these batches.

Update an Existing Account

Select the user account requiring updating and click **Edit** or double-click the user in the User Table. Here the administrator can edit the user's account email, role, and disable the user account. **Note:** The user will not be able to access the system until the administrator reactivates it.

Create a New Group

1. On the navigation bar, click **Admin**.
2. Click **Groups** on the left side of the screen.
3. On the Manage Groups view, click **New**.
4. Enter the Group Name and Description (optional).

Note: The Group Name must be unique and contain between 1 and 64 characters and must not include the following characters: \:;*?"<>|. The Description field is optional and can contain between 0 and 140 characters.

5. Open the Manage Membership view by double-clicking on the desired group or click **Members** from the Groups Table header menu.
6. Drag-and-drop to add or remove users from the group.

Note: Only users who are active and have logged into the system are present in the All Users column.

Update an Existing Group

1. To update the Group Name and Description perform the following steps:
 - a. Select the group requiring updating.
 - b. Click **Edit**.
 - c. Click **Update**.
2. To update the group membership perform the following steps:
 - a. Double-click the group requiring updating.
 - b. Drag-and-drop to add or remove users from the group.

Delete a Group

1. Select the group to be deleted and click **Delete Group**. A Delete Group pop-up will appear.
2. Select **Yes**. Deleting a group is a permanent action.

Manage Analysis Types

1. Update analysis settings (for select analysis modules only):
 - a. On the navigation bar, click **Admin**.
 - b. Click **Settings** for the appropriate Analysis Type.
 - c. Adjust the settings as needed.
 - d. To revert to default values, click **Reset Defaults**.
 - e. Click **Save and Close**.
2. View license key information (status, expiration date, or to enter a license key):
 - a. On the navigation bar, click **Admin**.
 - b. Click **License** for the appropriate Analysis Type.
 - c. Click **Close** when finished viewing the information.
3. Deactivate the analysis type:
 - a. On the navigation bar, click **Admin**.
 - b. Click **Deactivate** for the appropriate Analysis Type.

Audit Logs

1. User Activity Log
 - a. On the navigation bar, click **Admin**.
 - b. Click **Users** on the left side of the screen.
 - c. Click **Activity Log**.
 - d. A CSV file will download listing the date and time of event and action details (user management activities and accessibility information).
2. System Activity Log
 - a. On the navigation bar, click **Admin**.
 - b. Click **Activity Log** on the left side of the screen.
 - c. A CSV file will download containing the date and time of event and action details (user actions and change details).
3. System Logs (for Asuragen troubleshooting use only)
 - a. On the navigation bar, click **Admin**.
 - b. Click **System Logs** on the left side of the screen.
 - c. A zip file will download containing Activity Logs, Start Logs, and System Logs.
 - d. Provide the ZIP file to Technical Support if experiencing technical difficulties.

Project Dashboard

Create a New Project

1. On the Project Dashboard screen, click **New**.
2. On the New Project window, enter the Project Name, Description, and select the appropriate Groups.
3. Click **Create**.

Note: The Project Name must be unique, is case sensitive, must contain between 1 to 64 characters, cannot start or end with a space, cannot start with a number, and cannot contain the following characters: V:*?"<>|. The Description field is optional and can contain between 0 and 140 characters.

New Project [Close]

Name
Project name

Description
Enter a project description

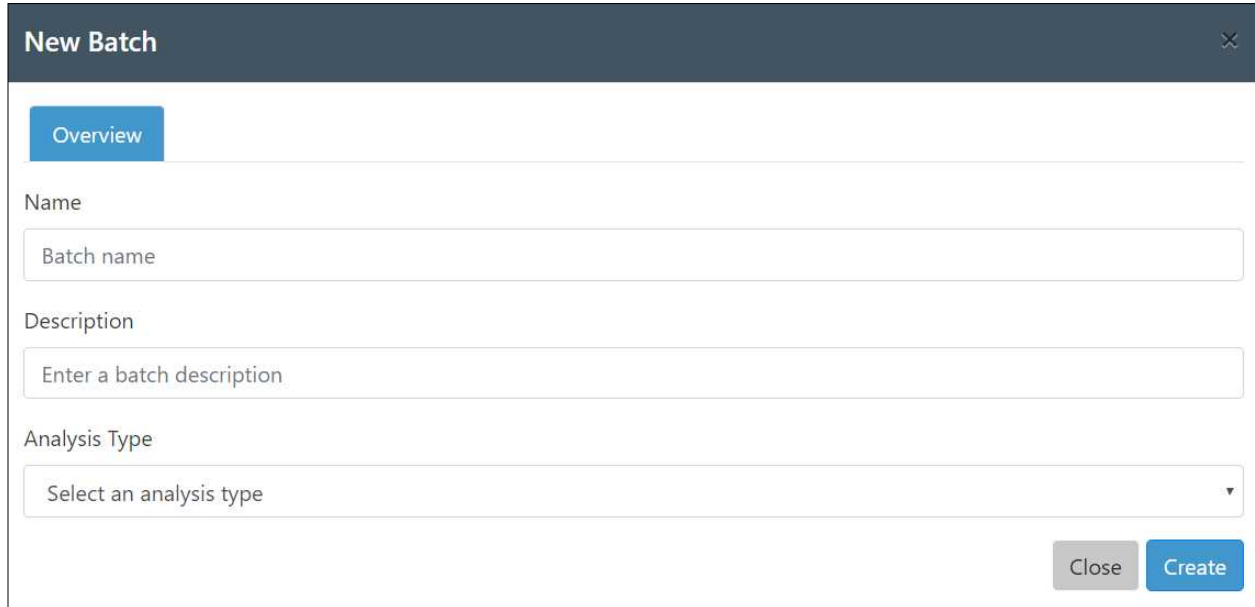
Groups
Demo Group 1

Hold CTRL and click to select multiple values.

Cancel Create

Create a New Batch

1. On the Project view screen, click **New**.
2. On the Overview tab of the New Batch window, enter the Name, Description, and select the appropriate Analysis Type.
3. Click **Create**.



The screenshot shows a window titled "New Batch" with a close button in the top right corner. Below the title bar is a tab labeled "Overview". The form contains three input fields: "Name" with a placeholder "Batch name", "Description" with a placeholder "Enter a batch description", and "Analysis Type" with a dropdown menu showing "Select an analysis type". At the bottom right, there are two buttons: "Close" (disabled) and "Create" (active).

4. On the Upload tab, click on **Choose Files** and browse to file location. To select multiple files hold down the SHIFT or CTRL keys.

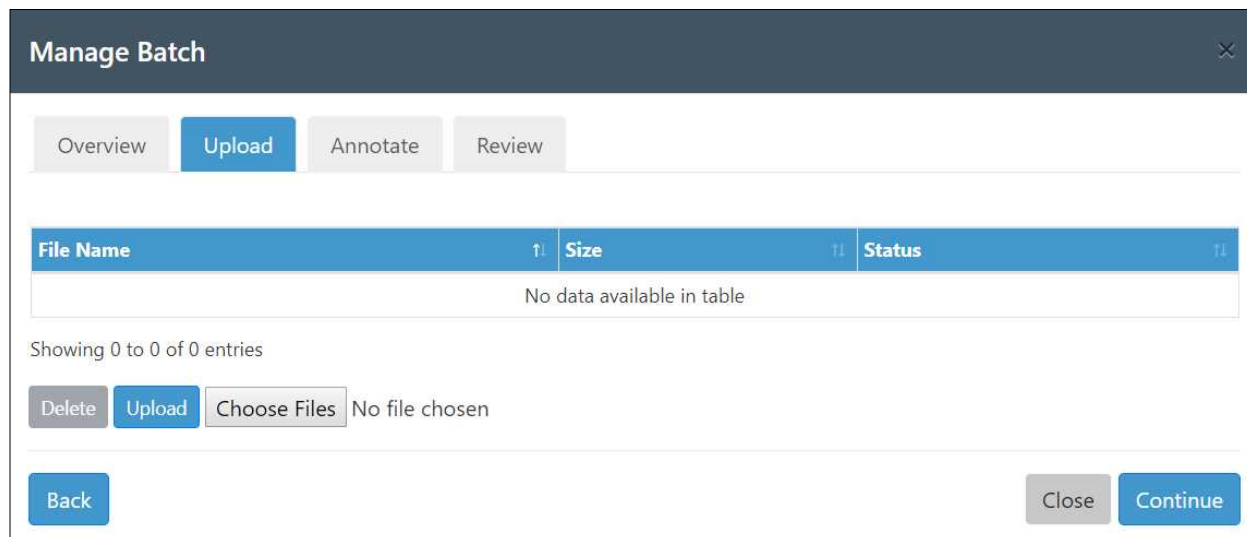
Note: To avoid manually entering information for each sample in the Annotate tab, a CSV file containing the information specific to the analysis module may be uploaded at this time. Refer to the Analysis Module User Guide for additional details.

5. Click **Upload**. Once files have uploaded successfully, the status will update to Imported. FSA files that are corrupt or incomplete will have the status of Failed. The software will adopt the naming convention used for the samples.

Note: Delete damaged FSA files in order to proceed to the Annotate or Review tabs.

Note: The software will accept samples with file names of any length, but sample names longer than 60 characters may not appear correctly on exported reports (e.g., PDF reports).

- Once the selected files have been imported, click **Continue**.

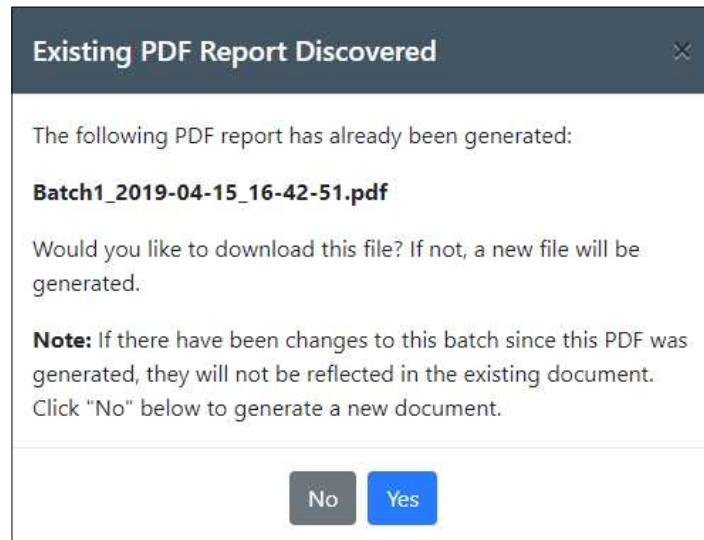


- On the Annotate tab, label each sample appropriately using the dropdown menu.
- Click **Save and continue**.
- After making the appropriate selections, click **Save and continue**. Some AmplideX[®] PCR/CE Kits contain Asuragen controls. If controls are not used, click **Yes** on the Proceed without Optional Types pop-up.
- On the Review tab, the Well and Instrument are imported directly from the FSA file. Perform a final review of the sample information and click **Submit Analysis**.
- After the analysis submission, the user returns to the Project view. The Status column tracks the project analysis progress. When complete, the status will change to Analysis Complete. The system saves the analyzed projects.
- To view the results, double-click on the desired batch or click **Results** in the header menu.
- See the specific Analysis Module User Guide for analysis instructions.

Project Export

- Open the batch by double-clicking on the desired batch or click **Results** in the header menu.
- Select either the CSV or the PDF format from the Export button in the header menu.
 - The CSV export will open containing all analysis information in an Excel file. This file can be saved or used for integration into laboratory information management systems (LIMS). Refer to the Analysis Module User Guide for analysis related information contained in the CSV file.
 - The PDF export generates a file, which parses all sample information onto a single page, including sample annotations and the associated electropherogram. The print view may take several minutes to generate, depending on the size of the batch.

Note: When downloading a previously generated PDF batch report, the following dialog box appears showing the file name containing the date and time the report was created.



Click Yes to download the initial PDF report.

Click No to generate a new report (i.e., select No if changes to the batch occurred after the initial PDF report creation).

Note: Export, archive, and delete projects after analysis from the Project Dashboard on a regular basis to preserve data in long-term storage. To delete projects, first delete all batches within a project, then delete the project.

Uninstallation Instructions

Note: Before proceeding with uninstallation of AmplideX[®] PCR/CE Reporter, it is important to uninstall any Analysis Modules. Analysis Modules are not intended to run independent of the AmplideX PCR/CE Reporter software. Refer to the Software User Guide for each module to review instructions for uninstallation.

1. Click the Start button, click **Control Panel**, and select **Programs and Features**.
2. Select AmplideX PCR/CE Reporter, and then click **Uninstall**.

Note: Application removal on windows may vary slightly for each operating system.

Note: After uninstalling the software, any exported PDF reports will remain in subfolders within the directory C:\Asuragen\ARCORE\lv4_x\Export. If you reinstall the software on the same machine again, these PDF reports will be available and may appear when exporting a batch for the first time. Always review the file name of a PDF document when downloading an existing report, which includes both the name of the batch and the date the PDF was generated.

Troubleshooting

Observation	Action
Installation	
"Service failed to start. Verify that you have sufficient privileges to start system services." error message	<ol style="list-style-type: none"> 1. Click Retry. 2. Did the installer complete successfully? If not, proceed to Step 3. 3. Click Cancel. The installation should stop and roll back any changes to the system. 4. Verify that the operating system contains the latest updates, security patches, and drivers. 5. Reboot the machine. 6. Perform the steps listed in the Installation section. 7. If the issue persists contact Asuragen Technical Support.
AmplideX® PCR/CE Reporter software cannot be launched	The software is dependent on the WinHTTP Web Proxy Auto-Discovery Service. If this service cannot be started for any reason, the AmplideX PCR/CE Reporter cannot be launched.
Application	
Software Does Not Load or Unresponsive	<p>Restart the services. There are many ways to restart the services. Recommended:</p> <ol style="list-style-type: none"> 1. Open a PowerShell command prompt as an administrator. 2. Type the following: <pre>Restart-Service -Name AsuragenReporterIS -Force</pre> 3. The Services will restart and the application will be available within 5 minutes. <p>Note: If the command does not work verify you have the correct permissions.</p>

Third Party Applications and Software Licenses

A list of open source Third Party applications and related licenses used by this software can be reviewed by clicking the About button within the AmplideX® PCR/CE Reporter.

Disclaimers

1. This Product is intended to be Research Use Only in the US.
2. This software is intended For Research Use Only, not for use in diagnostic procedures, when used with Research Use Only labeled kits.
3. This product may not be resold, modified for resale, or used to manufacture commercial products without the written approval of Asuragen®.
4. Asuragen® and AmplideX® are trademarks of Asuragen, Inc.
5. All instrumentation must be maintained and operated according to manufacturer's instructions.
6. 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.



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