

PiVAT™ User Manual

for ONCO/Reveal™ Dx Lung and Colon Cancer Assay

Software Version CE1.1.0

Released September 2020



For In Vitro Diagnostic Use.

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INTRODUCTION

The PiVAT™ software is for use with ONCO/Reveal Dx Lung and Colon Cancer Assay. PiVAT performs secondary analysis and report generation from sequencing runs that use the ONCO/Reveal Dx Lung and Colon Cancer Assay. See the ONCO/Reveal Dx Lung and Colon Cancer Assay User Manual (UM-0044).

PiVAT is installed on a stand-alone computer system configured with an Ubuntu operating system and a Chromium browser. The system is configured with no network connectivity.

This user manual describes how to use Pillar Bioscience's (Pillar) PiVAT software for ONCO/Reveal Dx Lung and Colon Cancer Assay. PiVAT is Pillar's genome sequence data software. This manual provides instructions on setting up user configurations and starting variant analysis.

Symbols Used in this User Manual

Symbol	Explanation
	ATTENTION: This symbol is a reminder to pay attention to details that could affect either proper installation or performance.
	CAUTION or WARNING This symbol is an indication of a critical detail not to be overlooked

INITIAL SETUP

Hardware Requirements



Caution: The PiVAT software is installed on a preconfigured system that does not require additional software or a network connection. It does require a USB storage device for data transfer. Supported formats include FAT32, ExFAT, and NTFS.

Pillar recommends using an uninterruptable power supply (UPS) with the PiVAT system to maintain data integrity.

Connect to PiVAT

Start the **PiVAT system** and login using the default account:

Username: pillaruser

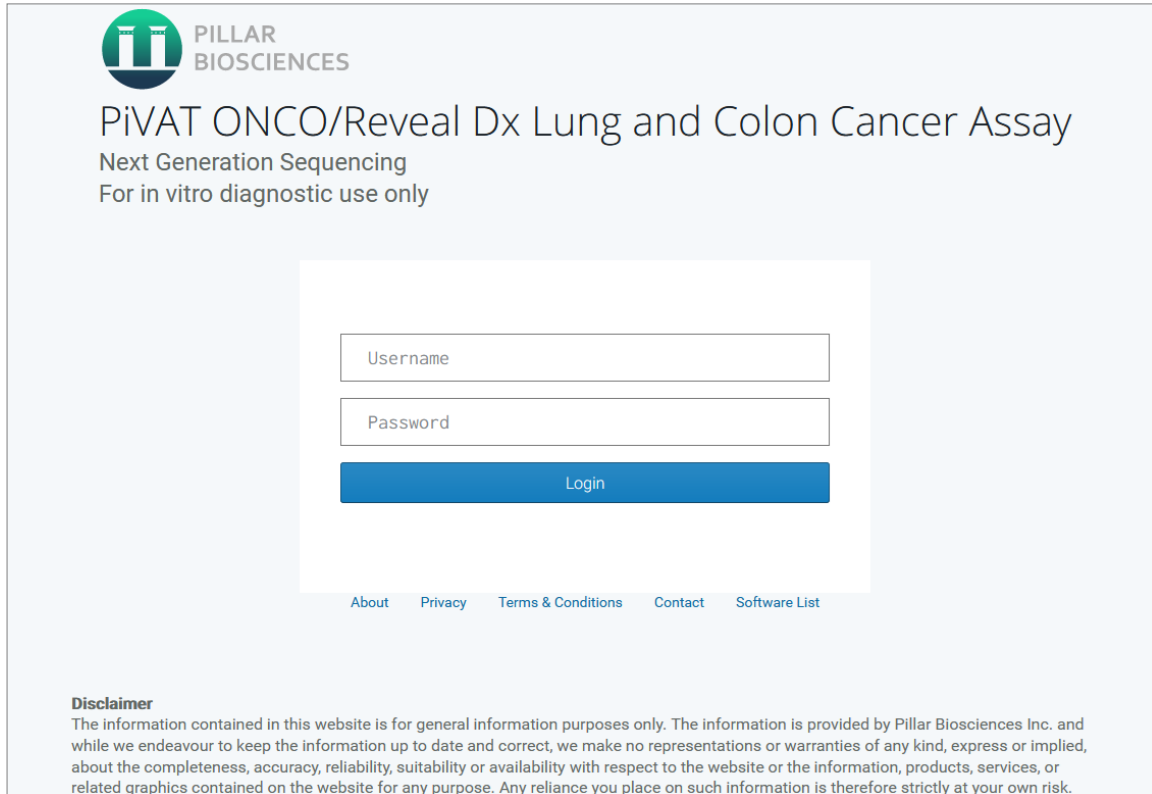
Password: pivat



If required by your organization's IT policies, change the account password.

Make sure to record the new password in accordance with your organization's IT policies.

The default browser will automatically launch and display the **PiVAT software Login page** (



PILLAR BIOSCIENCES

PiVAT ONCO/Reveal Dx Lung and Colon Cancer Assay

Next Generation Sequencing
For in vitro diagnostic use only

Username

Password

Login

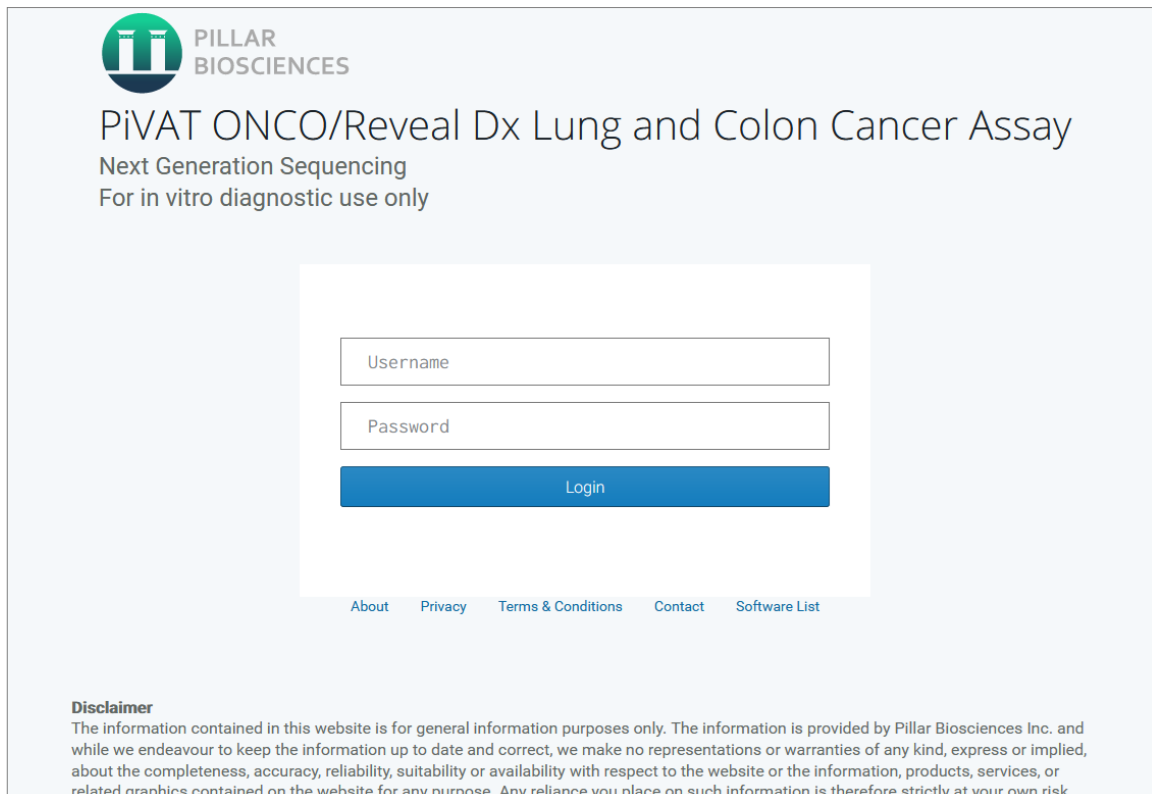
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Figure 1). Login with the default administration login:

Username: admin

Password: Install9*



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Figure 1 Login page

Accept Terms and Conditions

Upon successful admin login, the **License Agreement page** (Figure 2) displayed. Read the terms and conditions and click the [Agree](#) button to continue.

LICENSE AGREEMENT: TERMS AND CONDITIONS OF USE

PILLAR BIOSCIENCES, INC. ("Pillar") grants you a non-exclusive license to use the software and any associated documentation ("Software") as indicated below.

IMPORTANT NOTICE: Read this License Agreement carefully before downloading or using the Software. BY DOWNLOADING OR USING THE SOFTWARE IN ANY WAY YOU ACKNOWLEDGE THAT YOU HAVE READ, UNDERSTAND AND AGREE TO THE TERMS OF THIS LICENSE AGREEMENT. IF YOU DO NOT AGREE TO THESE TERMS, DO NOT DOWNLOAD THE SOFTWARE, DO NOT USE THE SOFTWARE IN ANY WAY, AND PROMPTLY DELETE OR DESTROY ANY COPIES OF THE SOFTWARE IN YOUR POSSESSION. YOU ARE SOLELY RESPONSIBLE FOR THE PROTECTION OF ANY PERSONALLY IDENTIFIABLE INFORMATION USED OR GENERATED AS THE RESULT OF YOUR USE OF THE SOFTWARE.

By clicking 'Agree' you agree to the Terms & Conditions

Cancel
Agree

Figure 2 License Agreement page

Configuring PiVAT Users

Create a user account:

- From the navigation menu, click the [Admin](#) button.
- Login with the default administration login when prompted.
- Under User Management/User profiles, select Add.
- Fill in the Username, Password, and Password confirmation fields.
 - Usernames can only contain lower case letters, numbers, underscores, and dashes.
 - Password rules: 8 to 32 characters, at least one uppercase letter, at least one lowercase letter, at least one number, at least one special character.
 - Allowed special characters: ~ ! @ # \$ % ^ * () _ - + = { } [] | : ; " ?
- To add another user, click the [Save and add another](#) button.
- To exit the page, click the [SAVE](#) button.

When done adding users, log out of the administrator account.



Record the new account names and passwords in accordance to your organization's IT policies.

USING THE PIVAT SOFTWARE

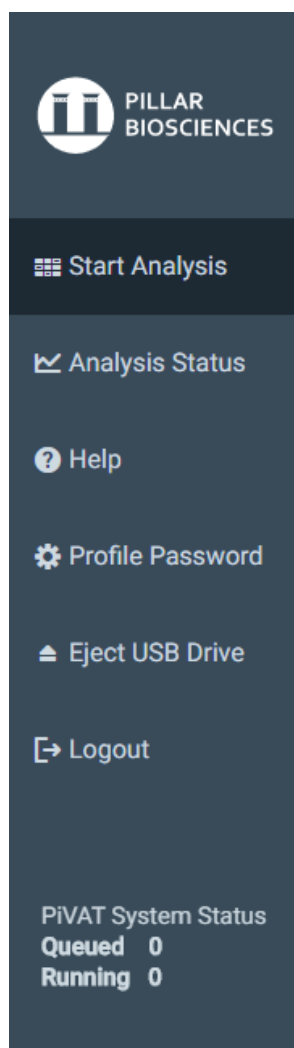
Connect to the PiVAT software via a web browser, as described in the section [Connect to PiVAT](#). Login using a user account set up in the **Configuring PiVAT Users** section.



Pillar recommends only a single instance of the PiVAT software should be running at any time.

Navigation menu

You can navigate through the software using the **Navigation Menu** (Figure 3) located on the left side of the screen.



The [Start Analysis](#) option is not available for users with administrator rights.

Note: The [Eject USB Drive](#) option is only available when a USB drive is attached.

The [PiVAT System Status](#) section displays the number of running and queued tasks for all users. An Analysis task that is entered while there are tasks in the system running and/or queued will be placed at the end of the queue.

Figure 3 Navigation Menu

Setup an Analysis

From the navigation bar at the left of the screen, select [Start Analysis](#). The **Panel Analysis page** (Figure 4) is displayed.

To configure batch applications, see Appendix B.

Before proceeding, insert your USB drive with your data.

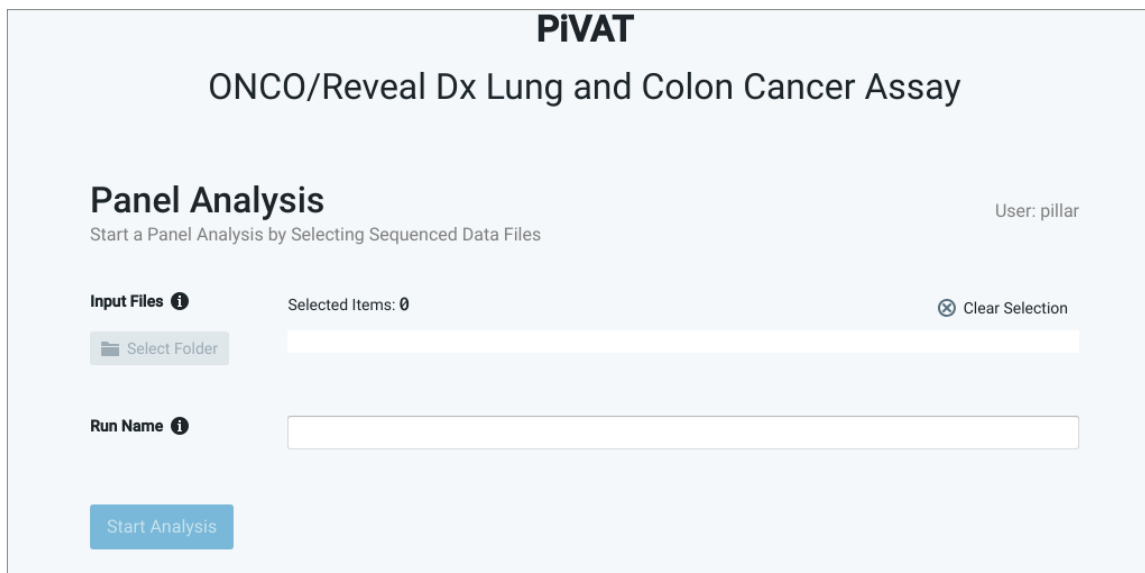


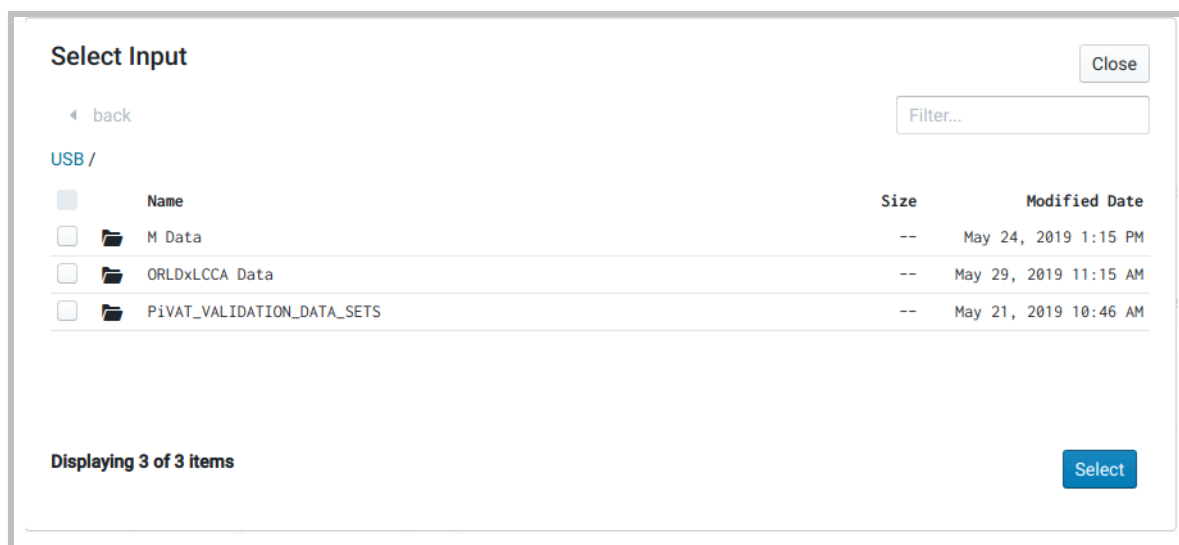
Figure 4 Panel Analysis page

Click on [Select Folder](#) to navigate to the input data. The **Select Input screen** (Figure 5) is displayed.

Navigate to the directory containing your analysis run data and select the directory. Only directories can be selected.

The directory must have all the required files, including FASTQ, SampleSheet.csv, and PBScomplete.ini.

Note: The contents of your USB drive may vary from what is displayed.



Name	Size	Modified Date
M Data	--	May 24, 2019 1:15 PM
ORLDxLCCA Data	--	May 29, 2019 11:15 AM
PiVAT_VALIDATION_DATA_SETS	--	May 21, 2019 10:46 AM

Figure 5 Select Input screen

Run Name

A run name is created based on the directory you selected in the last step. You may modify the run name after the field is automatically filled. All run names will be checked for illegal characters. Only alphabetic, numeric, dash and underscore characters are allowed in run names. The user is prevented from starting a run if there are any illegal characters.

The PiVAT software will add identifiable fields to the task name. The task name will display as:
<samplename><your-run-name><taskid><PiVAT-version><UTC-timestamp>

Start Analysis

Click the [Start Analysis](#) button to start the data analysis. A task list is displayed. The software checks the contents of the directory for required files. The analysis will not start if an error is found, or if a required file is missing.

When the analysis starts, the **Analysis Status page** (Figure 6) is displayed, and the following popup message appears:

Your files have been copied from your device. Please remember to safely eject the USB drive before removing it from the workstation.

Use the [Eject USB Drive](#) button on the **Navigation Menu** to safely eject the USB drive.



Caution: Do not remove the USB drive prior the message stating that your files have been copied. Do not remove the USB storage device without using the [Eject USB Drive](#) button.

Analysis Status				User: pillar
Check the Status of Panel Analyses				
Task Name	Date		Status	
<input type="text"/>	Start date	End date	completed x running x queued x aborted x failed x deleted x	
			Apply Filter	Reset Filter
ID	Task	Date	Status	
3029	80-181213_M70466_0009_000000000-BYKY7	Oct 3, 2019 6:03 PM	queued	
3028	Fridge-181213_M70466_0009_000000000-BYKY7_3028_1.0.0rc3-UTC20191003220229	Oct 3, 2019 6:03 PM	queued	
3027	FT2x-181213_M70466_0009_000000000-BYKY7_3027_1.0.0rc3-UTC20191003220229	Oct 3, 2019 6:03 PM	running	
3026	error_in_log_failure_test_3026_1.0.0rc3-UTC20191003204435	Oct 3, 2019 4:44 PM	failed	
3025	alt_QC_fail_q30_3025_1.0.0rc3-UTC20191003204413	Oct 3, 2019 4:44 PM	completed	
3024	HotSpot1-error_code_failure_test_3024_1.0.0rc3-UTC20191003204359	Oct 3, 2019 4:43 PM	failed	
3023	HotSpot1-exception_failure_test_3023_1.0.0rc3-UTC20191003204352	Oct 3, 2019 4:43 PM	failed	
3022	alt_qc_baseline_3022_1.0.0rc3-UTC20191003204330	Oct 3, 2019 4:43 PM	completed	
3021	HotSpot1-string_error_code_failure_test_3021_1.0.0rc3-UTC20191003204313	Oct 3, 2019 4:43 PM	failed	
3020	basic_run_3020_1.0.0rc3-UTC20191003204300	Oct 3, 2019 4:43 PM	completed	
3019	HotSpot1-SRS-106-test_3019_1.0.0rc3-UTC20191003203823	Oct 3, 2019 4:38 PM	aborted	
3018	HotSpot1-HSControl_test_selenium_5_3018_1.0.0rc3-UTC20191003203658	Oct 3, 2019 4:36 PM	aborted	

Figure 6 Analysis Status page

Analysis Details

The **Analysis Details** page (Figure 7) provides summary information including:

- **Task status** as described in Monitoring the Task Status below.
- **Task ID** is a unique identifier assigned to every analysis task initiated.
- The Username of the **User** who initiated the analysis task.
- Date and time the analysis task was **Created**, **Started** and **Completed**.
- **Duration** of the analysis task.
- **Notes** section of the page displays error and summary information
- **Inputs** displays the input files that were processed by this task.

Analysis Details

190703_M70769_0006_000000000-BYL4J

User: pillar

← Back

[Logfile](#)
[Results](#)
[Abort](#)

Status	ID	User
completed	18	pillar

Created	Started	Completed	Duration
Sep 24, 2019 3:23 PM	Sep 24, 2019 8:36 PM	Sep 24, 2019 9:48 PM	1:11:56

Notes

N/A

Inputs

```

20190703-InterStab-GSPCR-t30-NTC_S22_L001_R1_001.fastq.gz
20190703-InterStab-GSPCR-t30-NTC_S22_L001_R2_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000QL_S1_L001_R1_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000QL_S1_L001_R2_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000SX_S13_L001_R1_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000SX_S13_L001_R2_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000TQ_S17_L001_R1_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000TQ_S17_L001_R2_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000TV_S6_L001_R1_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000TV_S6_L001_R2_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000U6_S2_L001_R1_001.fastq.gz
20190703-InterStab-GSPCR-t30-PB0000U6_S2_L001_R2_001.fastq.gz

```

Figure 7 Analysis Details page

Clicking on the **Logfile** button displays logging information for every stage of this task. The logging info is unavailable if the task is in the **queued** or **deleted** state. Click the **Back** button to return to the **Analysis Details** page.

Clicking on the **Results** button displays the **Analysis Results** page (Figure 8) if the task is in the complete status state.

Analysis Results

Click the [Download Report to System](#) button to obtain a PDF formatted report of the completed analysis run. This page provides information on:

- [Run Summary](#) including Run ID, date and run validation results.
 - PASS: Run is valid. A run is valid where both PosCtrl and NTC meet Quality Control metrics. A valid run may include both valid and invalid sample results.
 - FAIL: Run is invalid where it did not meet one or more Quality Control metrics. Sample results will not be available.
- [Run Control Result](#)
 - NTC must be valid to ensure absence of inadvertent contamination.
 - PosCtrl must be valid to ensure that target mutations can be detected by the assay.

[Sample Result](#) is the summary of variants detected in the samples of a valid run.

Note: All run and sample validation is performed by PiVAT software.

Exporting Data

All the individually downloadable files on this page can be downloaded. Confirm that a USB drive is properly plugged in to the system before proceeding.

Click the [Select USB Destination](#) button and choose where the file is to be downloaded to

Click the [Export data to USB](#) button.

Analysis Results

User: pillartest

View Sample Results and Positive Mutations

[← Back](#)

Output Download ⓘ

Selected directory: **None**
 Select USB Destination

 Export data to USB

 Download Report to System

Run Summary

Run ID	Variant_Detect_047-EGFR-45-1d1pct
Run Date	2020-07-09
PosCtrl PASS/FAIL*	PASS
NTC PASS/FAIL*	PASS
Run PASS/FAIL	PASS

* In the case of multiple control samples all numeric results will be shown, separated by '|' characters.

Summary of Sample Results

Sample ID ⚙	Sample QC ⚙	Result* ⚙	Gene ⚙	Exon ⚙	Nucleotide Change ⚙
047-EGFR-45-DELETION-D-55242462-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2232_2249c
047-EGFR-45-DELETION-D-55242463-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2233_2247c
047-EGFR-45-DELETION-D-55242464-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2234_2248c
047-EGFR-45-DELETION-D-55242465-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2235_2237c
047-EGFR-45-DELETION-D-55242465-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2235_2246c
047-EGFR-45-DELETION-D-55242465-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2235_2249c
047-EGFR-45-DELETION-D-55242465-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2235_2252c
047-EGFR-45-DELETION-D-55242466-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2236_2250c
047-EGFR-45-DELETION-D-55242466-55242	Valid	Mutation detected	EGFR	19	NM_005228.4:c.2236_2253c

Figure 8 Analysis Results page

Sample Result

The [Sample Result](#) table (Figure 8) can be sorted by clicking on the column headings. More detailed analysis reports are available wherever you see this icon



Clicking the icon loads a **Sample Results page** (Figure 9).

A PDF formatted copy of the report can be downloaded by pressing the [Download Sample Report](#) button. Your report can be edited using a third-party PDF reader once downloaded from the PiVAT system to add patient and medical facility data.

To return to the **Analysis Results page**, click the [Back](#) button.

Sample Results

RDvSMpLC103-629-20ng

User: pillartest

[← Back](#)

[Download Sample Report](#)

VARIANTS DETECTED FOR THERAPEUTIC USE

Indication	Gene	Exon	Nucleotide Ch...	Amino Acid C...	Variant Freque...	FDA-Approved Therapeutic ...
N/A	N/A	N/A	N/A	N/A	N/A	N/A

OTHER ALTERATIONS AND BIOMARKERS IDENTIFIED

Gene	Exon	Nucleotide Change	Amino Acid Change	Variant Frequency (%)
N/A	N/A	N/A	N/A	N/A

Figure 9 Sample Results page

Help Page

Click the [Help](#) link in the **Navigation Menu** to access the **Help Page** which contains:

- [Contact Information](#) of Pillar Biosciences Inc.
- [User Guide](#) with links to:
 - PiVAT Software User Manual
 - ONCO/Reveal Dx Lung and Colon Cancer Assay User Manual
 - PiVAT Software Release Notes
 - Pillar Sample Sheet Tool (requires Windows OS and MS-Excel)
 - FASTQ Naming Formatting
- [Software Versions](#)

To exit this page, select another option from the **Navigation Menu**.

Change User Password

You can change your password by selecting the [Profile Password](#) option on the **Navigation Menu**. The **Profile Password page** (Figure 10) is displayed:

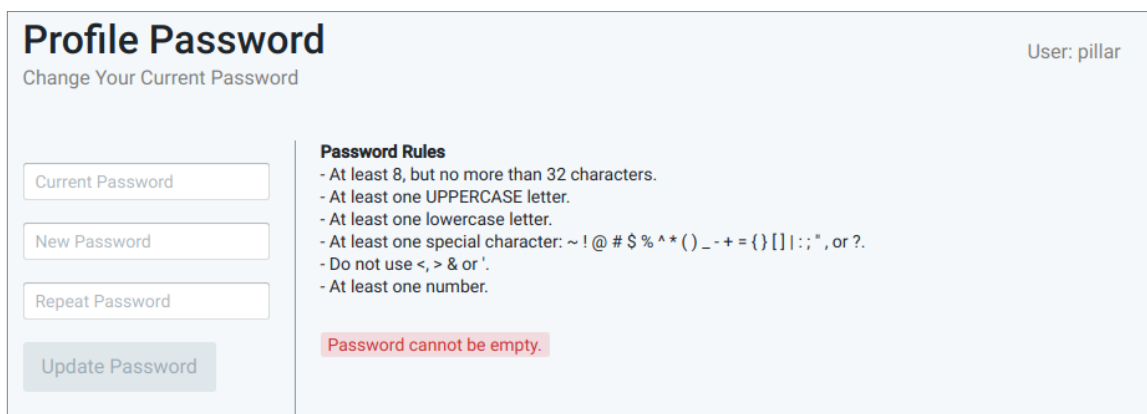


Figure 10 Profile Password page



To exit without changing your password, select another option from the **Navigation Menu**.

Record the new password in accordance to your organization's IT policies.

Monitoring the Task Status

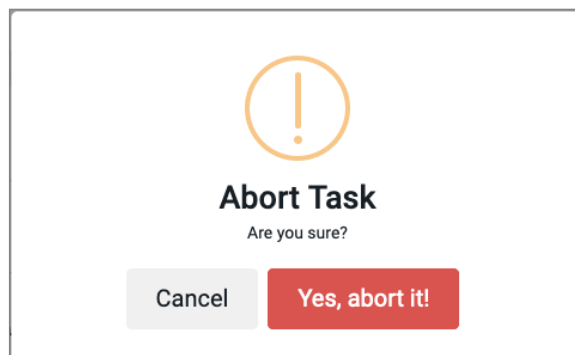
The first entry at the top of the list is the task that was started in the previous step and is displayed with its current status in the Status column at the right. Status states include:

- **queued**: There is another task running. Your present task is queued until preceding tasks are finished.
- **running**: This task is currently running.
- **completed**: The task has completed successfully.
- **failed**: An error occurred, and the analysis did not complete.
- **aborted**: This task is aborted by a user.
- **deleted**: The task data has been deleted by an administrator.

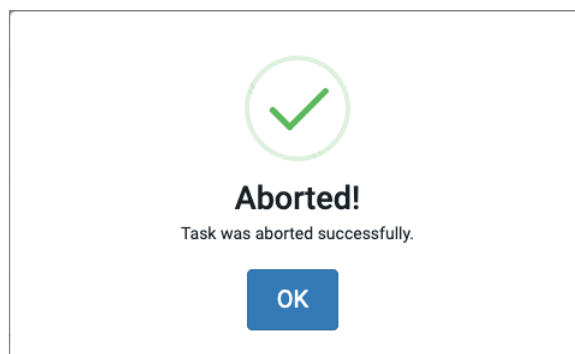
The Administrator account can see tasks from all users. A non-administrator account can only see their tasks. If your task is in the **queued** state, a task from another user is currently **running**. The **Older** and **Newer** options can be clicked to navigate through all the tasks if there are more tasks than are displayed on the page.

Aborting an Analysis Task

A task can only be aborted when its status is **running** or **queued**. To abort a task, click on the task, which takes you to the **Analysis Details page**. Click the **Abort** button. The following popup is displayed:



Clicking **Cancel** returns you to the **Analysis Details page**. Clicking **Yes, abort it!** displays the following popup:



Clicking **OK** clears the popup. You are returned to the **Analysis Details page**. The task now displays a status of **aborted**.

ADMINISTERING PIVAT

Administering PiVAT requires login with administrative privileges. Use default administrator account provided at installation:

username: admin

password: Install9*



Pillar Biosciences strongly recommends changing the default administrator account password. **Record the new password in accordance to your organization's IT policies.**

Navigation menu

The **Administrator Navigation Menu** (Figure 11) for the administration account is different than that for a non-administrator account.


 PILLAR BIOSCIENCES Admin Analysis Status Help Profile Password Logout	An administrator account cannot start an analysis run and therefore the Start Analysis option is removed.
	To perform system administration functions, click the Admin option.
	An administrator account can see all analysis runs by all users by selecting the Analysis Status option.
	Administrators can generate reports as needed. An administrator account has the additional filter field of "user".

Figure 11 Administrator Navigation Menu

PiVAT Administration

Login with the same username/password to launch the **PiVAT Administration page** (Figure 12).

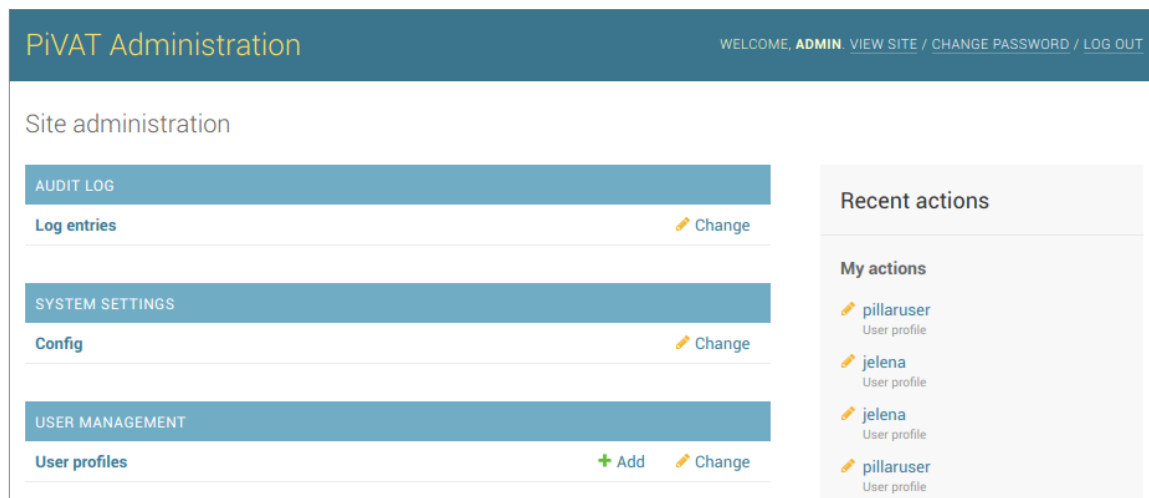


Figure 12 PiVAT Administration page

The password can be changed by the [CHANGE PASSWORD](#) link at the top right of the page.



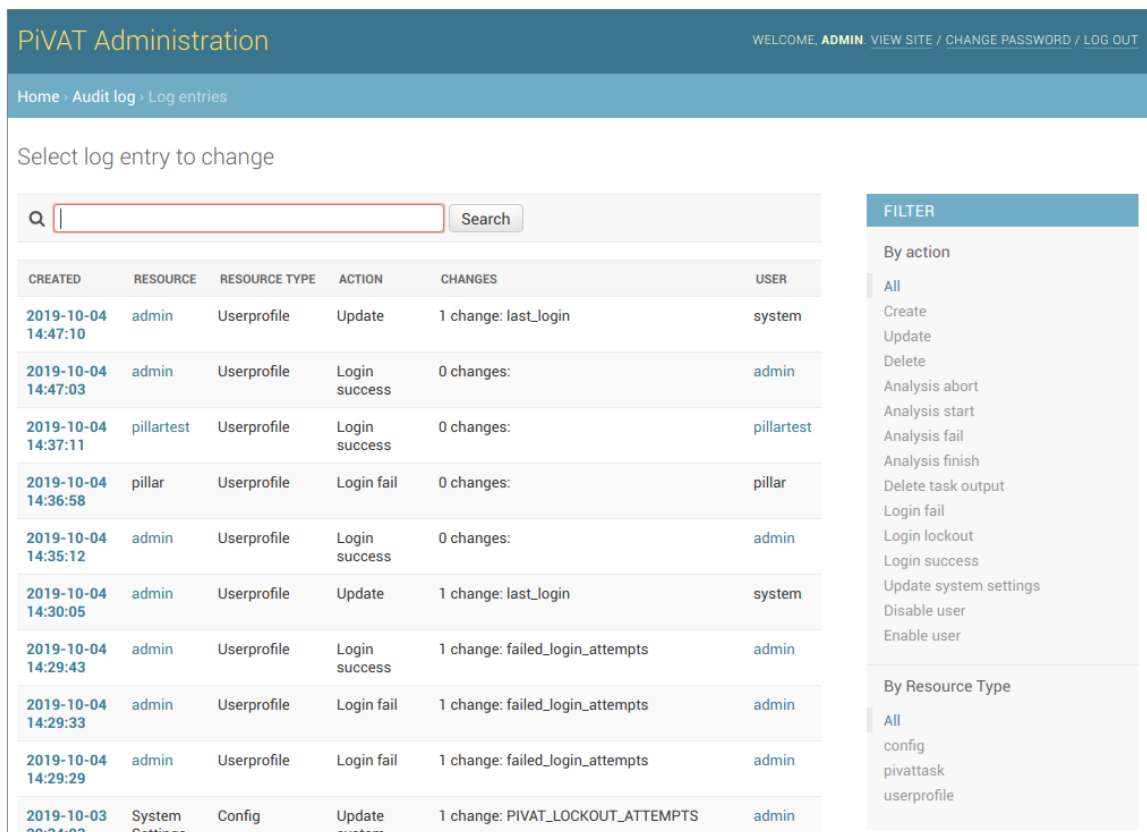
Pillar Biosciences strongly recommends changing the default administrator account password. **Record the new password in accordance to your organization's IT policies.**

Click the [LOG OUT](#) link at the top right of the page to log out at any time.

Audit Log

To view the audit log, click [Log entries](#) under the **AUDIT LOG** heading on the **PiVAT administration page** (Figure 12).

Entries in the **Log entries page** (Figure 13) can be viewed, but not modified. The log can be filtered using the filter menu on the right-hand side of the screen.



PiVAT Administration WELCOME, **ADMIN** [VIEW SITE](#) / [CHANGE PASSWORD](#) / [LOG OUT](#)

Home > Audit log > Log entries

Select log entry to change

Q [Search](#)

CREATED	RESOURCE	RESOURCE TYPE	ACTION	CHANGES	USER
2019-10-04 14:47:10	admin	Userprofile	Update	1 change: last_login	system
2019-10-04 14:47:03	admin	Userprofile	Login success	0 changes:	admin
2019-10-04 14:37:11	pillartest	Userprofile	Login success	0 changes:	pillartest
2019-10-04 14:36:58	pillar	Userprofile	Login fail	0 changes:	pillar
2019-10-04 14:35:12	admin	Userprofile	Login success	0 changes:	admin
2019-10-04 14:30:05	admin	Userprofile	Update	1 change: last_login	system
2019-10-04 14:29:43	admin	Userprofile	Login success	1 change: failed_login_attempts	admin
2019-10-04 14:29:33	admin	Userprofile	Login fail	1 change: failed_login_attempts	admin
2019-10-04 14:29:29	admin	Userprofile	Login fail	1 change: failed_login_attempts	admin
2019-10-03 20:34:03	System Settings	Config	Update system	1 change: PIVAT_LOCKOUT_ATTEMPTS	admin

FILTER

By action

- All
- Create
- Update
- Delete
- Analysis abort
- Analysis start
- Analysis fail
- Analysis finish
- Delete task output
- Login fail
- Login lockout
- Login success
- Update system settings
- Disable user
- Enable user

By Resource Type

- All
- config
- pivattask
- userprofile

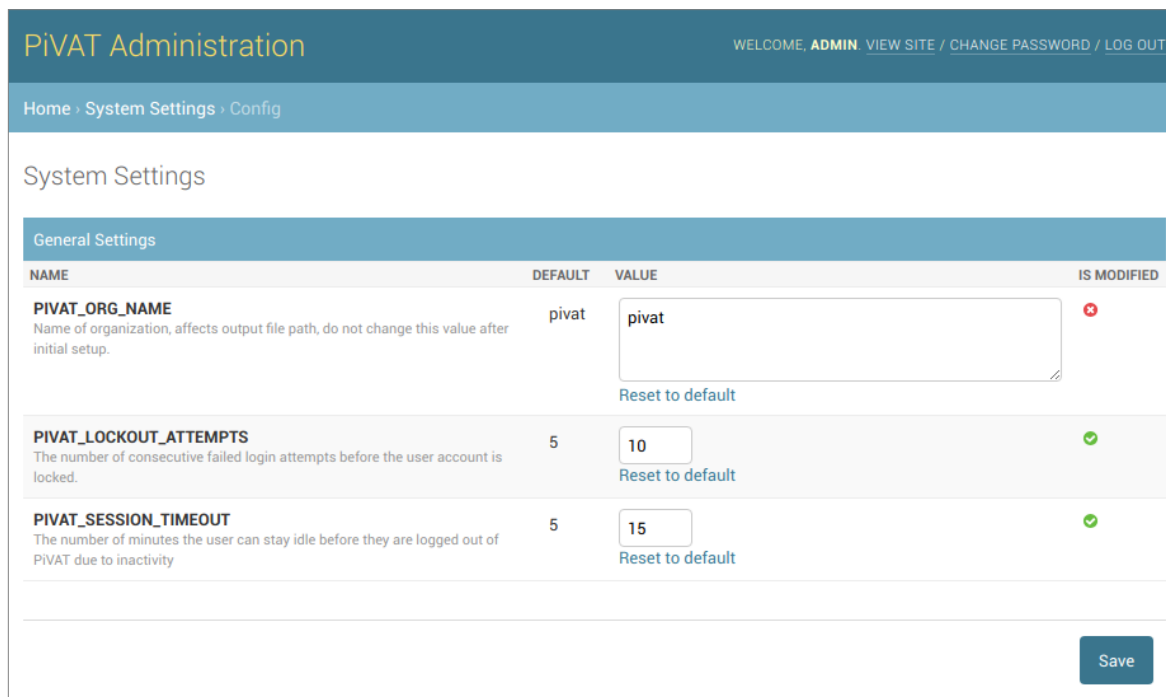
Figure 13 Log entries page

To return to the admin home, click [Home](#) > [Audit log](#) > [Log entries](#) on the navigation menu.

System Settings

To change the site configuration, click [Change](#) in the line labeled **Config** under the **SYSTEM SETTINGS** heading on the **PiVAT administration page** (Figure 12).

The **System Settings page** (Figure 14) will be displayed. Fields can be configured to user defined file paths or left at their default values.



PiVAT Administration WELCOME, **ADMIN** VIEW SITE / CHANGE PASSWORD / LOG OUT

Home > System Settings > Config

System Settings

NAME	DEFAULT	VALUE	IS MODIFIED
PIVAT_ORG_NAME Name of organization, affects output file path, do not change this value after initial setup.	pivat	<input type="text" value="pivat"/>	✖
Reset to default			
PIVAT_LOCKOUT_ATTEMPTS The number of consecutive failed login attempts before the user account is locked.	5	<input type="text" value="10"/>	✔
Reset to default			
PIVAT_SESSION_TIMEOUT The number of minutes the user can stay idle before they are logged out of PiVAT due to inactivity	5	<input type="text" value="15"/>	✔
Reset to default			

[Save](#)

Figure 14 System Settings page

General Settings:

- **PIVAT_ORG_NAME:** Once this is set, do not change this value, as it affects the output file path. The default value is “pivat”.
- **PIVAT_LOCKOUT_ATTEMPTS:** The number of consecutive failed login attempts before the user account is locked. The default is 5. The minimum value is 1 and the maximum value is 10.
- **PIVAT_SESSION_TIMEOUT:** This is the number of minutes the user can remain idle before they are logged out of PiVAT. The default is 5. The minimum value is 1 and maximum value is 15.

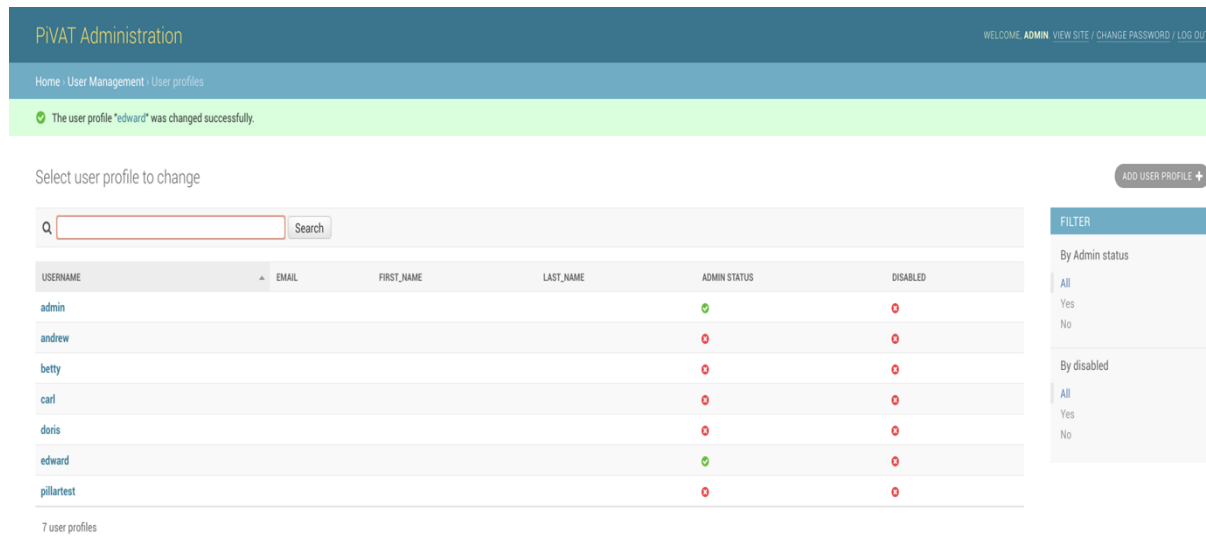
Click [Save](#) to keep any changes made.

To return to the admin home, click [Home](#) > **System Settings** > **config** on the navigation menu.

User Profiles

To view the User Management screen, click [User Profiles](#) under the **USER MANAGEMENT** heading on the **PiVAT administration page** (Figure 12).

The **User Profiles page** (Figure 15) displays all the user profiles. Admin status is indicated, and there are options to filter which profiles are displayed.



PiVAT Administration

WELCOME ADMIN VIEW SITE / CHANGE PASSWORD / LOG OUT

Home > User Management > User profiles

The user profile "edward" was changed successfully.

Select user profile to change

Q Search

USERNAME	EMAIL	FIRST_NAME	LAST_NAME	ADMIN STATUS	DISABLED
admin				0	0
andrew				0	0
betty				0	0
carl				0	0
doris				0	0
edward				0	0
pillartest				0	0

7 user profiles

ADD USER PROFILE +

FILTER

By Admin status

All
Yes
No

By disabled

All
Yes
No

Figure 15 User Profiles page

To return to the admin home, click [Home](#) > [System Settings](#) > [config](#) on the navigation menu.

Adding a User

Click [ADD USER PROFILE](#). The **Add user profile page** (Figure 16) will appear. Fill out the new username, password, and the password confirmation fields. Usernames must be unique. When done select one of the save options.

Selecting [SAVE](#) brings you to the **Change user profile page** (Figure 17). The following fields can be modified on this page:

- First Name
- Last Name
- Email Address
- Staff Status
- Account Locked
- Disable user

There is an account change history that can be accessed by clicking the [History](#) button.

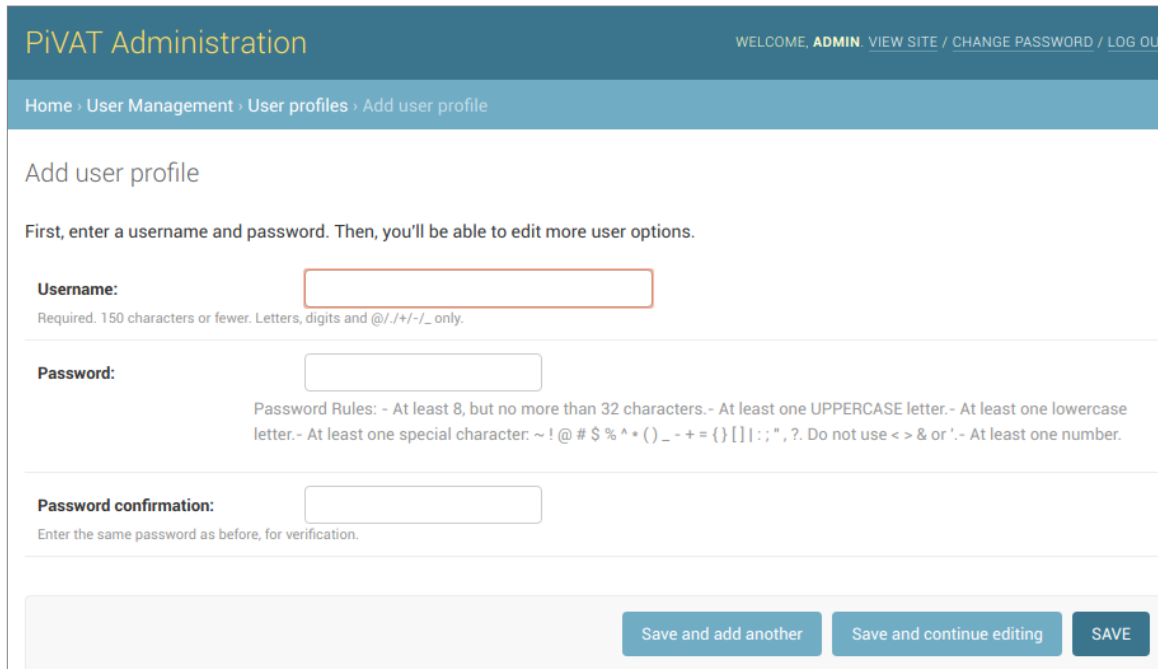


Figure 16 Add user profile page

Modifying a User

To change user profile, click [User Profiles](#) under the **USER MANAGEMENT** heading on the **PiVAT administration page** (Figure 12). Click to select one of the existing users.

This will display the **Change User Profile page** (Figure 17) described above.

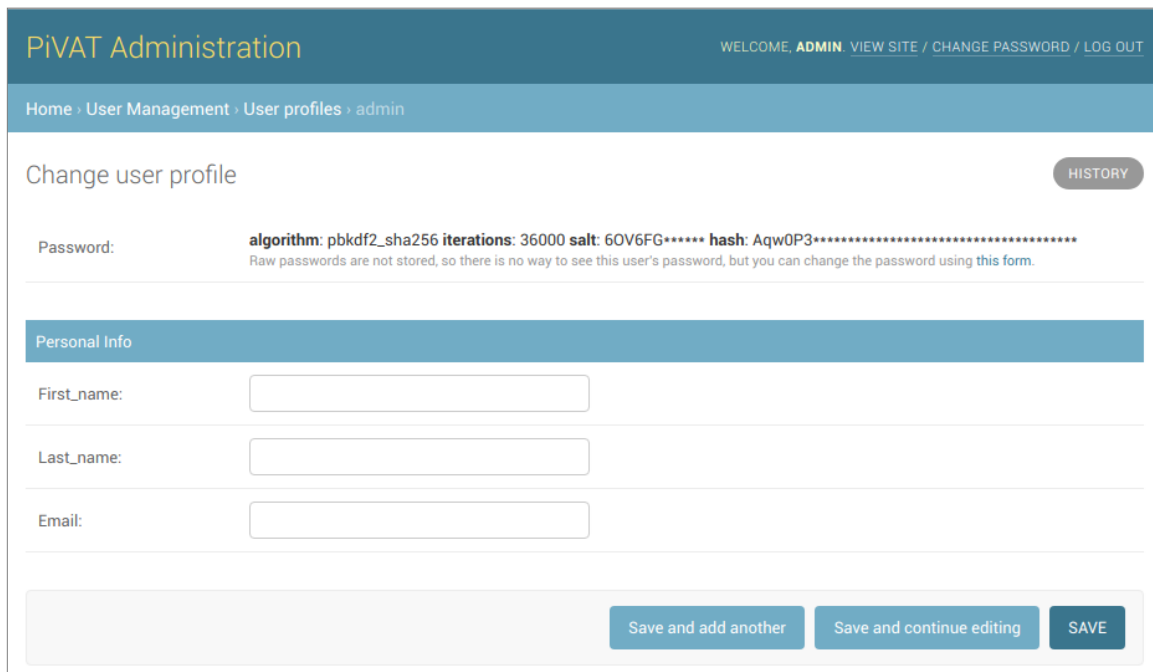


Figure 17 Change user profile page

To exit the screen without making any changes, click a previous section in the site path [Home > User Management > User profiles >](#) on the navigation menu.

Granting Admin Access

If the new user requires admin access to the PiVAT application, check the [Admin Status](#) checkbox.

Disabling a User

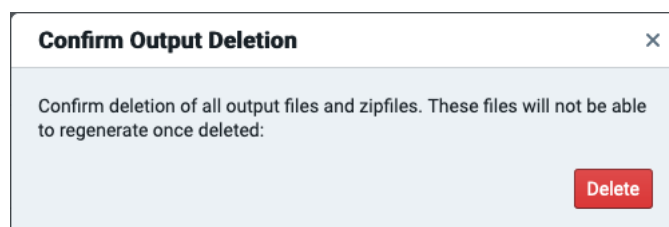
To disable a user, click on [User profiles](#), under the [USER MANAGEMENT](#) heading on the **PiVAT administration page** (Figure 12). A user can be disabled by either selecting the user name and the disable button or in bulk by selecting the user name(s) by the checkbox(es) to the left of the name(s) and selecting "Disable Selected user profiles" from the "Action" dropdown.

Data Management

Users are responsible for downloading analysis results and storing the data according to their data storage process.

Administrators can delete analysis run output directories in order to assure that there is sufficient storage space for future analysis tasks.

On the **Analysis Details Page** (Figure 7) there is a [Delete Output](#) button that is only available to Administrator accounts. Clicking this button displays the following popup:



To cancel the deletion, click the "x" close icon in the top right of the popup. Clicking the "Delete" button will delete the directory. A confirmation popup will appear.

On the **Analysis Details page** (Figure 7) the [Status](#) will change to [deleted](#). The "[Delete Output](#)" and [Abort](#)" buttons will be disabled.

On the **Analysis Status page** (Figure 6) the [Status](#) of the task will be displayed as [deleted](#).



Verify that analysis data has been downloaded and stored in accordance to your organization's IT policies before deleting data from the PiVAT system.

TROUBLESHOOTING



If the system requires a restart, the user should check that all running and queued analysis tasks have completed before restarting the system. If not, the task running at the time of the restart will be aborted when the system restarts. That task will have to be restarted using the instructions in the *Setup an Analysis* section of this manual.



If a task fails due to insufficient disk space, an administrator user can free up space on the system by following the instructions in the *Data Management* section of this manual. Once sufficient space is recovered, the failed tasks will have to be restarted using the instructions in the *Setup an Analysis* section of this manual. There must be at least 100 GB of free space on the system for a task to start.



If an inserted USB drive is not detected by the PiVAT system, check that the drive is properly formatted. Supported formats include: FAT32, exFAT, and NTFS.



If the PiVAT application is not running, click the PiVAT icon on the left side of the screen to relaunch it.



To avoid performance issues, do not run other applications on the workstation while PiVAT is running.



If the error message: “An error occurred during data transfer from the input location to PiVAT temporary directories. [errno: 5] Input/output error”, there has been a problem reading data from your USB drive. Use a different USB drive to transfer the data from the sequencer.



If the error message: “Error: Input disk files failed checksum verification” there has been a problem reading data from your USB drive. Use a different USB drive to transfer the data from the sequencer.



A PiVAT task should complete in eight hours or less from the time it started analysis, not from the time it was queued. If a task takes more than eight hours to complete, contact Pillar Biosciences at (800) 514-9307 or techsupport@pillar-biosciences.com.



If the system will not start or the PiVAT application will not load, contact Pillar Biosciences at (800) 514-9307 or techsupport@pillar-biosciences.com.

OTHER INFORMATION

Cybersecurity

The auto boot feature on the USB drives have been disabled.

The USB ports on the rear of the system have been disabled.

The Ethernet port is disabled and not intended for use.

The PiVAT workstation is a stand-alone device, and not intended to be connected to a network.

The PiVAT software will not allow users to save login information.

Software allowing editing of PDF files have been removed.

Changes to the PiVAT application configuration are recorded in the application audit log.

Login attempts, including failed attempts are recorded in the application audit log.

LEGAL NOTICES

PiVAT™ is a trademark of Pillar Biosciences, Inc., Illumina™ is a registered trademark of Illumina, Inc., Ubuntu is a registered trademark of Canonical Ltd., Chromium is a registered trademark of Google

COMPANY INFORMATION

	<p>Pillar Biosciences, Inc. 9 Strathmore Road Natick, MA 01760 (800) 514-9307 techsupport@pillar-biosciences.com https://pillar-biosciences.com/</p>
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APPENDICES

Appendix A: FASTQ File Name Format



The naming of FASTQ files MUST follow the Illumina® naming convention Example sample name:

RDvUDpL82d170101iM1-My-first-sample-name_S1_L001_R1_001.fastq.gz

Name	Description
Sample Number	Any positive integer.
Read Direction	1 (forward) or 2 (reverse)
Lane number	0001 for Miseq, 0004 for Nextseq, 0008 or 0016 for Hiseq
File Splitting	If a FASTQ file is too big and needs to be split into multiple files, this number can be used to reassemble them

A full description of the Illumina FASTQ Name Format can be found under the "Naming" section here: https://support.illumina.com/content/dam/illumina-support/help/BaseSpaceHelp_v2/Content/Vault/Informatics/Sequencing_Analysis/BS/swSEQ_mBS_FASTQFiles.htm



The following terms should be avoided as sample names: common and logs. Sample names should not vary by case only. **Do not use any patient identifiable information in any file names.**

Appendix B: Sample Batching

Batch is defined as a group of samples processed and tested together rather than individually. Batched samples must include a PosCtrl and an NTC. Sequencing on a single MiSeqDx flowcell may contain up to 6 batches of samples.

PiVAT enables independent analyses of the batches if defined in the “Description” column of SampleSheet.csv.

Pillar Biosciences provides a “Sample Sheet Tool” Excel spreadsheet. This tool is recommended for use to define batch analysis runs. It is loaded on the PiVAT system. It can be downloaded from the Help page. It can also be downloaded from the Pillar Biosciences website at:

<https://www.pillar-biosciences.com/resources/>



The Sample Sheet Tool must be run on a Windows system with Microsoft Excel installed.

If the Sample Sheet Tool is not used, the SampleSheet.csv can be edited to support batch analysis.

- Each sample in a batch must be assigned the same batch descriptor in the “Description” column.
- Each batch must have at least one PosCtrl and NTC assigned in the “Control” column.
- A maximum of 6 batches can run from a single flow cell.
- Batch names must consist of upper-case and lower-case letters, numbers, and underscores.

If there are any missing control elements, a warning will be displayed. Analysis tasks without all control elements will not run.

All of the PosCtrl and NTC entries in each batch must pass for a patient result report to be generated.



Patient identifiable information is not required for PiVAT analysis. Do not use any patient identifiable information in SampleSheet.csv or any of the control files.