



PART II: PiVAT® User Manual for oncoReveal® CDx Assay

PiVAT® Software for oncoReveal® CDx

P/N: SFW-2012

For In Vitro Diagnostic Use.

Caution: Federal law restricts this device to sale by or on the order of a physician

CONTENTS

INTRODUCTION	3
Symbols Used in this User Manual	3
INITIAL SETUP	4
Hardware Requirements	4
Connect to PiVAT	4
Accept Terms and Conditions	5
Configuring PiVAT Users	5
USING THE PIVAT SOFTWARE	6
Navigation menu	6
Setup an Analysis	7
Run Name	8
Exporting Data	10
Help Page	13
Change User Password	13
Monitoring the Task Status	14
Aborting an Analysis Task	14
ADMINISTERING PIVAT	15
Navigation menu	15
PiVAT Administration	16
Audit Log	17
System Settings	18
User Profiles	19
Adding a User	20
Modifying a User	20
Data Management	22
TROUBLESHOOTING	23
OTHER INFORMATION	24
Cybersecurity	24
LEGAL NOTICES	24
COMPANY INFORMATION	24
Appendices	25
Appendix A: FASTQ File Name Format	25
Appendix B: SampleSheet.csv Format	26



INTRODUCTION

The PiVAT software is for use with oncoReveal® CDx. PiVAT performs secondary analysis and report generation from sequencing runs that use the oncoReveal® CDx. See the oncoReveal® CDx User Manual (UM-0043).

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 oncoReveal® CDx. 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

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



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.

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** (Figure 1). Login with the default administration login:

Username: admin

Password: Install9*

Figure 1 Login page

ACCEPT TERMS AND CONDITIONS

Upon successful admin login, the **License Agreement page** (Figure 2) is 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 with 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.

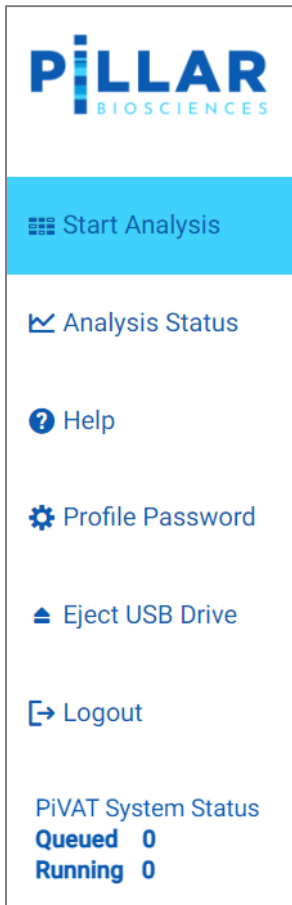


Figure 3 Navigation Menu

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.

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.

Panel Analysis
Start a Panel Analysis by Selecting Sequenced Data Files

User: pillar

Input Files ⓘ Selected Items: 0 ⊗ Clear Selection

Select Folder

Run Name ⓘ

Start Analysis

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.

Select Input Close

◀ back Filter...

USB /

<input type="checkbox"/>	Name	Size	Modified Date
<input type="checkbox"/>	M Data	--	May 24, 2019 1:15 PM
<input type="checkbox"/>	ORLDxLCCA Data	--	May 29, 2019 11:15 AM
<input type="checkbox"/>	PiVAT_VALIDATION_DATA_SETS	--	May 21, 2019 10:46 AM

Displaying 3 of 3 items Select

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.



Do not remove the USB drive prior to 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 running queued aborted failed deleted	
			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	

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

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.

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).

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

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.

PIVAT

oncoReveal® CDx

Sample Results

RDvSMpLC103-287-2x-HzMod-rep1

User: pillar

[← Back](#)

[Download Sample Report](#)

MUTATION(S) DETECTED FOR THERAPEUTIC USE

Companion Diagnostic (CDx) Associated Findings (Table 1 in Information About Assay section)

Gene ↕	Exon ↕	Nucleotide Change ↕	Amino Acid Change ↕	FDA-Approved Therapeutic O...
EGFR	Ex19 del	c.2235_2249del	p.Glu746_Ala750del	Response to EGFR Tyrosine Kinase Inhibitors approved by FDA*
EGFR	21	c.2573T>G	p.Leu858Arg	Response to EGFR Tyrosine Kinase Inhibitors approved by FDA*
EGFR	Ex19 del	c.2230_2246delinsCTT...	p.Ile744_Glu749delinsL...	Response to EGFR Tyrosine Kinase Inhibitors approved by FDA*

* see the following Table 1

MUTATION(S) WITH EVIDENCE OF CLINICAL SIGNIFICANCE

Gene ↕	Exon ↕	Nucleotide Change ↕	Amino Acid Change ↕
EGFR	18	c.2155G>A	p.Gly719Ser
EGFR	20	c.2369C>T	p.Thr790Met
BRAF	15	c.1799T>A	p.Val600Glu
EGFR	20	c.2284-5_2290dup	p.Ala763_Tyr764insPheGlnGluAla

MUTATION(S) WITH POTENTIAL CLINICAL SIGNIFICANCE

Gene ↕	Exon ↕	Nucleotide Change ↕	Amino Acid Change ↕
NRAS	3	c.181C>A	p.Gln61Lys
CTNNB1	3	c.98C>A	p.Ser33Tyr

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
- oncoReveal® CDx 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:

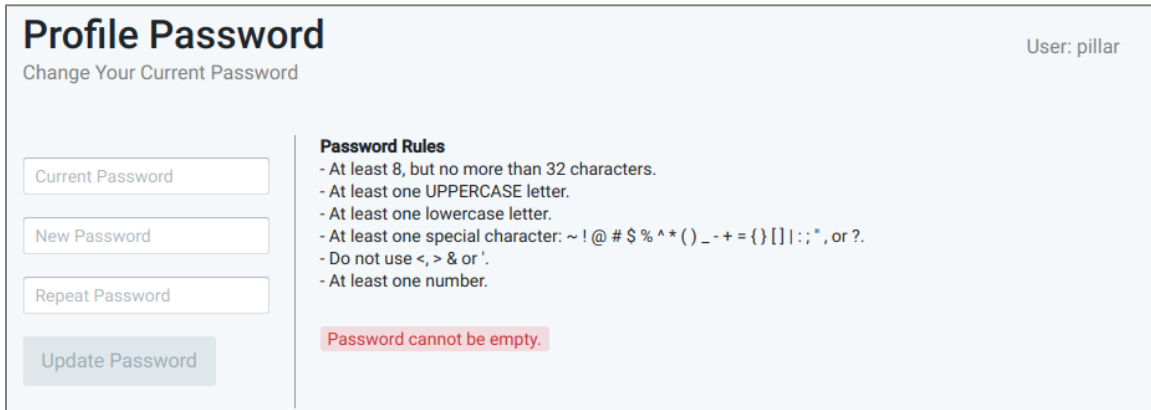


Figure 10 Profile Password page



To exit without changing your password, select another option from the **Navigation Menu**. Record the new password in accordance with your organization's IT policies.

MONITORING THE TASK STATUS

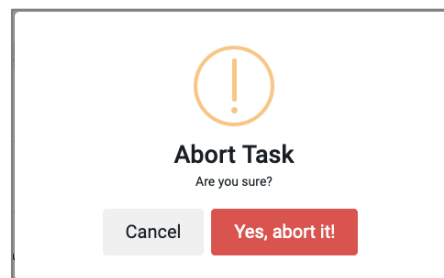
The first entry at the top of the list is the task that was started in the previous step and is displayed with its status in the Status column at the right. Status states include:

- **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 been completed successfully.
- **failed**: An error occurred, and the analysis was not complete.
- **aborted**: A user aborted this task.
- **deleted**: The task data has been deleted by an administrator.

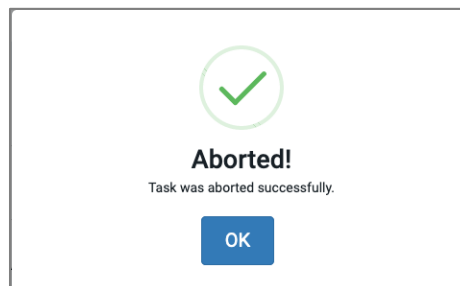
The Administrator account can see tasks from all users. A non-administrator account can only see their tasks. If your task is in the **queued** state, a task from another user is currently **running**. The **Older** and **Newer** options can be clicked to navigate through all the tasks if there are more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

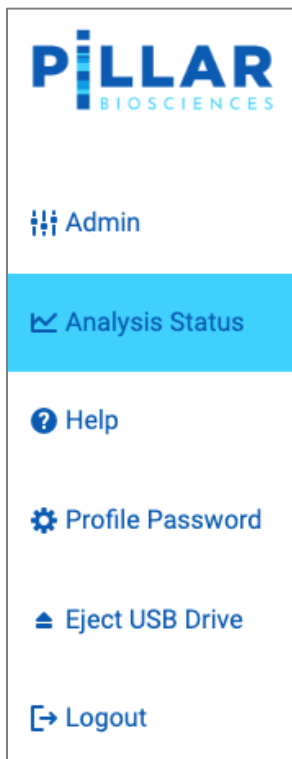
password: Install9*



Pillar Biosciences strongly recommends changing the default administrator account password. **Record the new password in accordance with 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.



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).

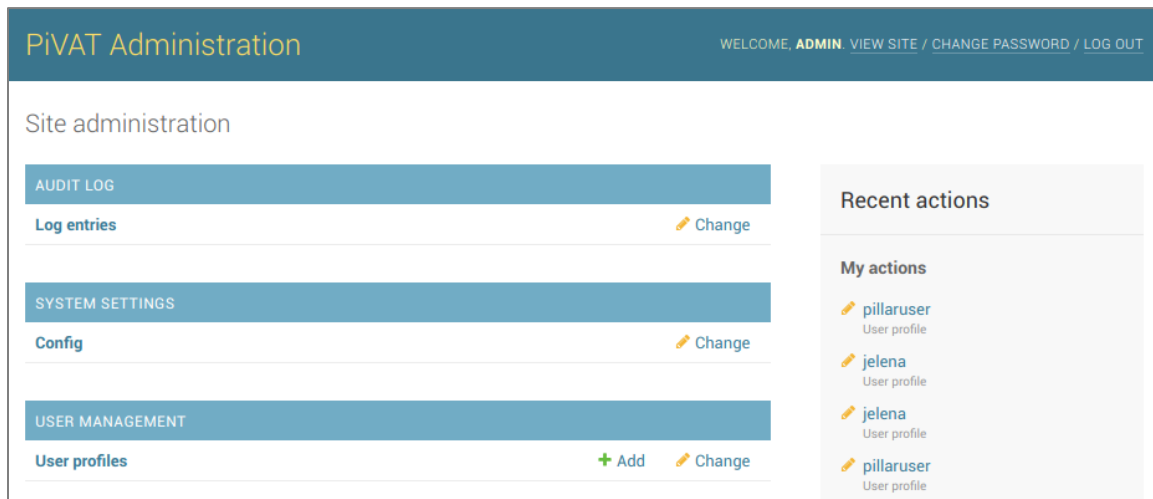


Figure 12 PiVAT Administration page

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



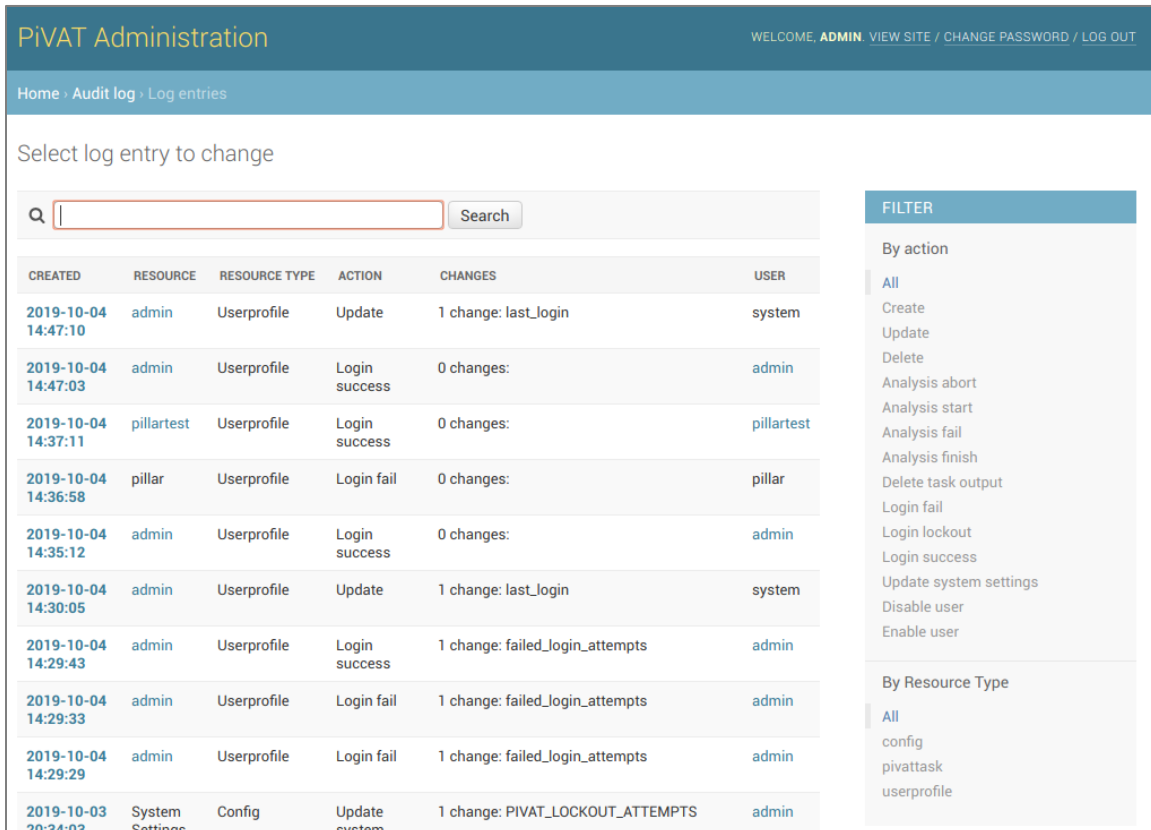
Pillar Biosciences strongly recommends changing the default administrator account password. **Record the new password in accordance with your organization's IT policies.**

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

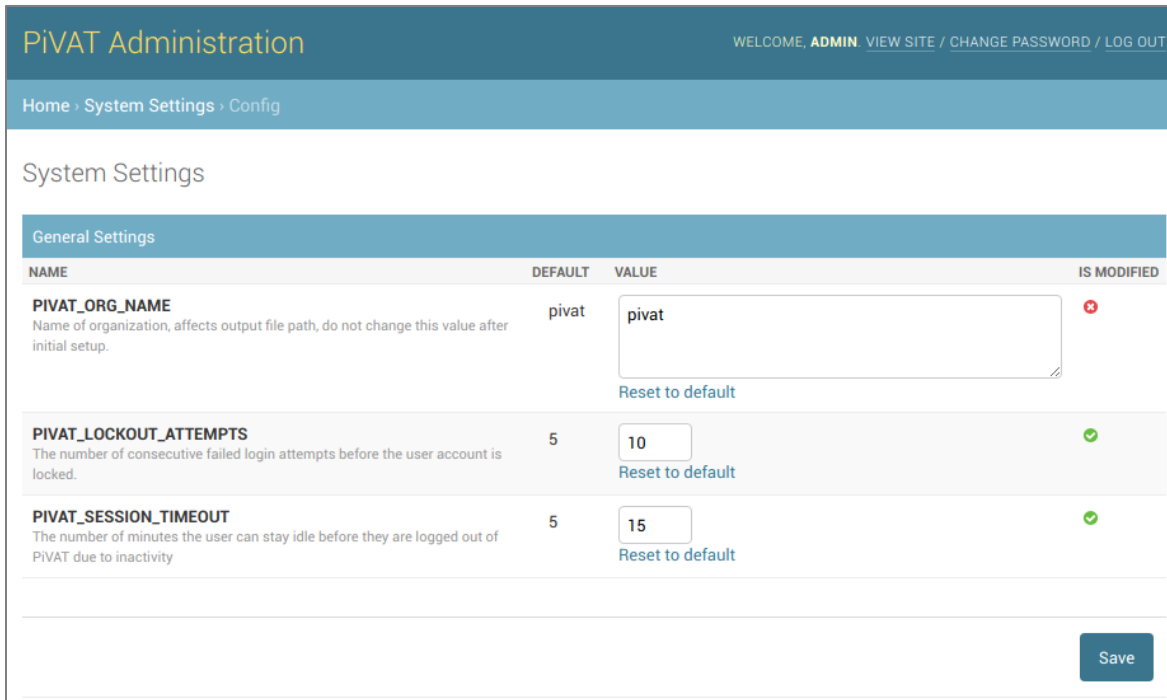
Figure 13 Log entries page

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.



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"/>	✖
PIVAT_LOCKOUT_ATTEMPTS The number of consecutive failed login attempts before the user account is locked.	5	<input type="text" value="10"/>	✔
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](#)

[Reset to default](#)

[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.

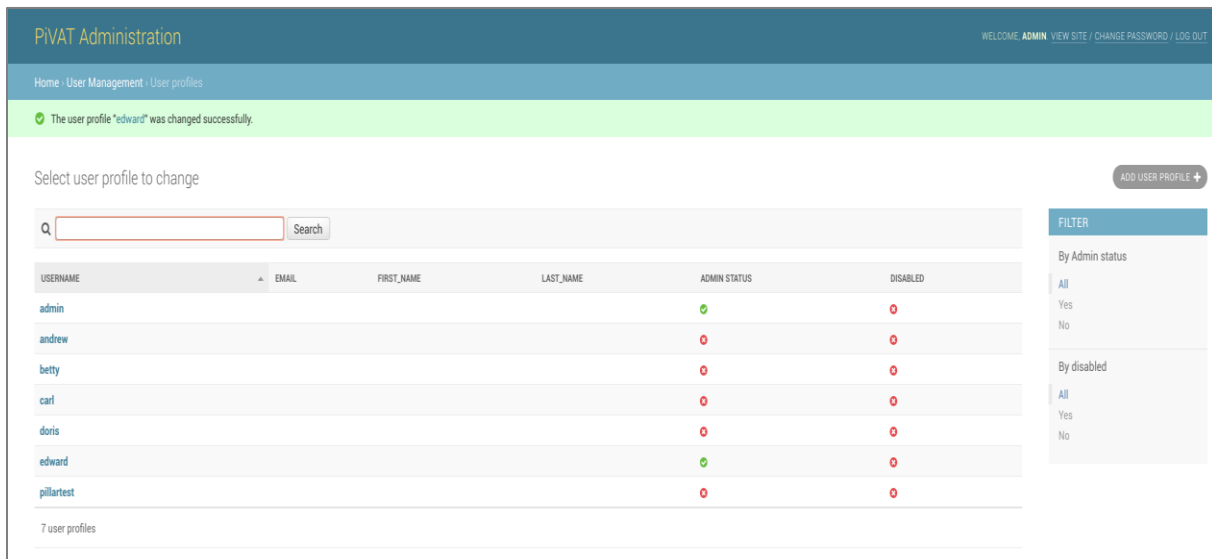
Click [Save](#) to keep any changes made.

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				✔	○
andrew				○	○
betty				○	○
carl				○	○
doris				○	○
edward				✔	○
pillartest				○	○

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.

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

Figure 16 Add user profile page

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

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.

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

Home > User Management > User profiles > admin

Change user profile HISTORY

Password: **algorithm:** pbkdf2_sha256 **iterations:** 36000 **salt:** 6OV6FG***** **hash:** Aqw0P3*****
Raw passwords are not stored, so there is no way to see this user's password, but you can change the password using [this form](#).

Personal Info

First_name:
Last_name:
Email:

Save and add another Save and continue editing SAVE

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

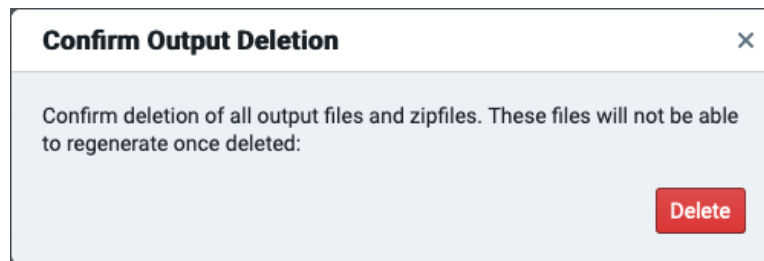
To disable a user, click on [User profiles](#), under the [USER MANAGEMENT](#) heading on the **PiVAT administration page** (Figure 12). A user can be disabled by either selecting the username and the disable button or in bulk by selecting the username(s) by the checkbox(es) to the left of the name(s) 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 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 with 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 been 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 be completed 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 support@pillarbiosci.com.
- If the system will not start or the PiVAT application will not load, contact Pillar Biosciences at (800) 514-9307 or support@pillarbiosci.com.
- If the system loses power, all tasks that were running at the time of the power failure will be listed as 'failed.' New tasks will have to be restarted using the same data set.

OTHER INFORMATION

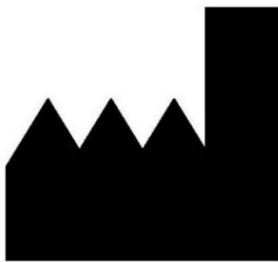
CYBERSECURITY

- 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 has 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®, Pillar®, oncoReveal® are trademarks 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



Pillar Biosciences, Inc.
9 Strathmore Rd
Natick, MA 01760
(800) 514-9307
support@pillarbiosci.com
<https://pillarbiosci.com/>

APPENDICES

APPENDIX A: FASTQ FILE NAME FORMAT



The naming of FASTQ files **MUST** follow the Illumina naming convention. For example: **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: SAMPLESHEET.CSV FORMAT

The Description column of this file contains information required by PiVAT to start. These include the sample type (either a Control or a specific tumor type), batch number, and a GUID (Global Unique ID).

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 when defined properly in the “Description” column of SampeSheet.csv.

Pillar Biosciences provides a “Sample Sheet Tool” Excel spreadsheet. This tool is required for use to define batch analysis runs and to assure the correct tumor type is identified for each sample. 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. <https://www.pillarbiosci.com/>



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

- 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 are assigned by the Sample Sheet Tool.
- Each sample must be either a control (NTC or PosCtrl) or a supported Tumor Type.
- The Sample Sheet Tool generates a required 15 digit GUID for each sample. Do not modify this field.

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

All 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.