



# PiVAT® Release Notes

## for oncoReveal® CDx

PiVAT® Software  
for oncoReveal® CDx

P/N: SFW-2012

Legal Notice: For In Vitro Diagnostic Use

## PiVAT<sup>®</sup> Version 2.3.0 for oncoReveal<sup>®</sup> CDx

### Introduction

Pillar Variant Analysis Toolkit, or PiVAT<sup>®</sup>, is a software intended for use with oncoReveal<sup>®</sup> CDx assay. PiVAT<sup>®</sup> performs secondary analysis and generates test reports from next-generation sequencing (NGS) generated on a MiSeqDx<sup>®</sup> instrument. PiVAT only accepts as input the FASTQ files generated by the Pillar LRM module installed on a MiSeqDx<sup>®</sup> instrument.

### Scope

The software provides optimized NGS secondary analysis including alignments and variant calling using oncoReveal<sup>®</sup> CDx library preparation protocol and paired-end sequencing on MiSeqDx<sup>®</sup> instrument. The variants detected include Single-Nucleotide Variations (SNVs) and Insertions/Deletions up to 30 base pairs.

### Features

- Detects the target variants listed in the intended use of oncoReveal<sup>®</sup> CDx
- Reports qualitative results of the target variants for each sample.
- Provides summary and patient reports in PDF format.
- Supports multiple batched analysis runs from a single flowcell.
- Reports Run and Sample level quality control results each analysis.
- Assigns uniquely mapped reads to corresponding targeted amplicons. Non-uniquely mapped reads or reads that do not have proper amplicon structure are removed. Based on each amplicon group, variants are determined.

## Changes and upgrades

### Changes in 2.3.0

- New functionality to allow administrative users to install new release of Assay Definition files.
- Formatting updates to the About window (Login Page) and Help Page to display the current version of the Assay Definition File in addition to the PiVAT software version.
- PiVAT version numbers in task names and in the footer of PDF reports now have Assay Definition File version number appended.
- Security updates.

### Changes in 2.2.0

- Report all exonic frame-shift variants in relevant tumor-suppressor genes
- Remove COSMIC ID from reports
- Update logo and tagline to reflect change in registration status

### Changes in 2.1.0

- Updated three G12C tumor profiling mutations from Level 3 to Level 2 in non-small cell lung cancer
- Report all mutations that pass variant QC criteria
- Report amplicon that fails QC criteria AND contains no reportable mutation in Pertinent No Call table.

### Changes in 2.0.0

- Enabled tumor profiling reportable results
- Improved alignment correction for indels
- Enabled recognition of multiple tumor types

### Changes in 1.2.2

- UDI added to the About and Help pages
- Rebranding

### Changes in 1.2.1

- This version is for internal clinical validation use only.
- Therapeutic Options for KRAS changed from "Response to Erbitux<sup>®</sup>" to "Resistance to Erbitux<sup>®</sup>"

### Changes in 1.2.0

- This version is for internal clinical validation use only.
- Format of Patient and Run Summary reports have been updated

- A link to recommend FDA treatments has been added where appropriate.
- Variant Frequency column was removed
- The Sample QC Column only displays “Valid” & “ Not Valid”
- The Gene name in the Gene column is always italicized
- The format of the description field in the SampleSheetUsed.csv file has changed.
- A properly formatted SampleSheetUsed.csv is required.
- Use Version 2.6 of the SampleSheet Tool to create the file.
- The change is to the Description column which requires the following information
- Batch number
- GUID
- Tumor Type or Control indicator

## Changes in 1.1.0

- This version is for internal clinical validation use only.
- Table 2 variants removed from the intended use. Software no longer reports presence of Table 2 variants.
- Updates to the layout of the Run and Patient Report pages and PDF files.
- Enhancements to the user interface.

## Known issues and limitations

### Known Issues

- PiVAT will treat a sample sheet with a NegCtrl sample as an NSCLC patient sample.
- If a run is started using a SampleSheetUsed.csv not produced by the Pillar Module, the run may silently fail during the process of copying from the USB drive. There will be no indication that the analysis started.
- If a run is started with more than six batches defined and all tumor type data is correct, the error message displayed is “Unable to start PiVAT analysis. Tumor type entry is incomplete for one or more samples. Please refer to User Manual for instructions on defining tumor type in SampleSheet” is displayed.

### Limitations

- Pillar recommends only a single instance of the PiVAT software be running at any time. Opening multiple instances of PiVAT may cause unexpected impact on system performance.
- When starting multiple analysis tasks, do not start a new analysis until the previous analysis is in the queued or running state. Doing so may cause unexpected impact on system performance.
- Samples cannot be named Log, Common, or Report (upper or lower-case).

- Directories used with PiVAT cannot contain spaces.
- Sample file names cannot contain the underscore character.

## Known potential issues

- It is possible to enter a state where there are tasks queued but not running. This can be identified visually, by having tasks in the Queued state with no task running. Entering this state may cause delay in results.
- Restarting the workstation will clear this error state.
- In the case of a power failure or other system shutdown, there may be occurrences where a task is shown as running incorrectly.
- The task incorrectly listed as running will not affect any tasks started after the system restarts. The task incorrectly listed as running will remain in the task list.
- It is possible to lock out the default Admin account through multiple unsuccessful login attempts.
- It is recommended to create an additional account with admin privileges as a backup.

## Cybersecurity

- Systems shipped from Pillar Biosciences have the save password option disabled by default. Pillar Biosciences strongly recommends not enabling the save password option in the browser. Doing so is considered a cybersecurity risk.
- Systems shipped from Pillar Biosciences are intended for offline use only. The USB ports are only intended for use by keyboards, mice, and storage devices. Pillar Biosciences strongly recommends not connecting the PiVAT system to a network. Doing so is considered a cybersecurity risk.

## Legal notices

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