

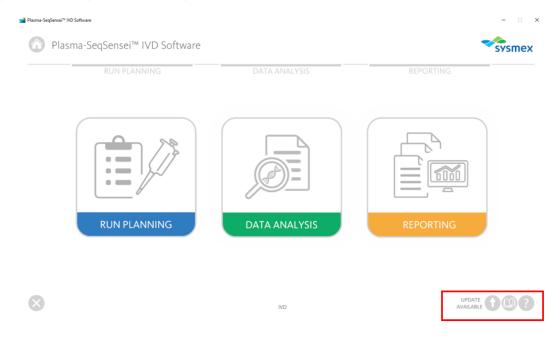
# Release Note Plasma-SeqSensei™ IVD Software

New version:	v1.3.1
Date:	2024-04-29
Issued by:	Sysmex Inostics GmbH Bioinformatics Department

## Description

This document describes new features, bug fixes and changes implemented in the new version of the Plasma-SeqSensei™ IVD software.

**Important note:** To keep your existing analysis results and run history, it is recommended to perform the update via the update button within the software.



## Added:

Reporting:

• Partially covered amino acid changes are now marked with a superscript 1). This applies to detected mutations that are located in an amino acid encoding nucleotide triplet at the border of an amplicon, which is not fully covered.



- ClinVar ID column added in "Somatic Mutations Detected" and "Potential Germline Mutations Detected" result tables.
- Table that lists all coding sequence positions of genes for that the corresponding amplicons were not covered sufficiently.

GUI:

- Warning message, if the user's display scaling setting or screen resolution is not suitable for the software.
- If the software cannot connect to the update server, an internet disconnection button appears in the bottom right corner of the GUI.
- Whenever a data analysis is started, a compliance message for confirmation of the IVD workflow is displayed.

## **Changed:**

Reporting:

- From this version on, only valid MD calls are reported.
- If the sample exceeds the upper GE limit, the sample is invalid due to quantification failure, and nothing will be reported.
- For Depth of coverage of the Positive Control (PC) the minimal detected value for the PC amplicons is displayed instead of the average value over all PC amplicons.
- If the quantification of the PC fails, no GE value is displayed in the Positive Control section. It is then stated as "not quantifiable".
- The amplicons in the coverage plot are now sorted by gene name and CDS position in alphabetic and ascending order.
- If not all amplicons in a sample achieve the minimal coverage, the sequencing depth checkmark in the sample validity section will be displayed in orange.

## Removed:

Reporting:

- Removed the "Invalid Mutations Detected" section.
- Green check marks next to detected mutations were removed.

### Fixed:

Reporting:

• Fix for genomic position for insertions detected on reverse orientated amplicons in VCF files being one base too low.