

VeriSeq™ NIPT Solution v2

Customer Release Notes

Assay Software v2.3

August 14, 2024

Introduction

These Release Notes detail the key changes to assay software components for the VeriSeq NIPT Solution v2 since the package containing assay software v2.1.

Illumina recommends that all VeriSeq NIPT Solution v2 users update their software to this latest version of the assay software.

The software package includes:

- VeriSeq NIPT Assay Software CE-IVD v2.3

I. VeriSeq NIPT Solution v2 Assay Software v2.3

NEW FEATURES:

- Hardware compatibility
 - Support new hardware variant with Broadcom 9560-8i RAID controller. This replaces the end of life RAID controller card (LSI9361-8i).
- Inputs
 - Make more fields mandatory in the user interface email configuration screen
 - Change internal Docker base subnet to avoid IP address conflicts during deployment
- Quality Control and risk mitigations
 - Perform daily checks and send e-mail notification for RAID errors
 - Reject batches that contain two samples whose ID differ only in capitalization, to reduce risk of sample mixup. (for example, "sample" and "SAMPLE" cannot both appear in the same batch)
 - Reject new batches if there already exists a batch that differs only in capitalization. This avoids a problem where clients from MS Windows PCs could only access one of the two batches.
 - Detect and automatically fail runs where plate-level contamination may have occurred.
- Cybersecurity improvements
 - Require more secure protection of passwords that are required for connecting to external system
- Updated Linux operating system
 - Oracle Linux 9.2

FIXED ISSUES:

- Analysis fails when cADAS reports FF of 0
- Clarification of the wording in the reboot/shutdown confirmation screen
- Daily and hourly backups not created on the 1st of the month or on Sundays

Release History

Revision	Release Reference	Originator	Description of Change
0	CN 1102296	Mariangela Nava	Initial Release
00.1	CN 1111710	Mariangela Nava	Header was updated with correct Customer Release Notes and date of release was updated with release to occur Q3 2024