

# **Illumina<sup>®</sup> Lab Automation Software Solution (ILASS) Infinium<sup>™</sup> Module Release Notes**

**v.1.5**

**5/13/2024**

## Introduction

Illumina Lab Automation Software Solution (ILASS) Infinium Module provides a centralized environment to run microarray workflows and digitally track the results of each sample. Seamless connection to the Infinium Automated Pipetting System (IAPS) and Infinium Amplification System (IAS) maximizes laboratory productivity and throughput while delivering improved data, reproducibility, and quality.

Highlights include:

### EASE OF USE

Intuitive interface with visual guidance for microarray workflows allows operators of any skill level to perform their daily tasks with confidence and ease.

### DRIVES QUALITY AND COMPLIANCE

Users are guided through each automated step of a protocol. Repeatable execution of processes ensures consistency and SOP compliance.

### SEAMLESS INSTRUMENT INTEGRATION

Illumina Lab Automation Software Solution provides out of the box integration with the Infinium Automated Pipetting System (IAPS), and Infinium Amplification System (IAS).

### REAL-TIME STATUS AND REPORTING

Optional integration with Clarity LIMS™ facilitates end-to-end sample traceability. Automatically inform liquid-handling robotics on sample placement location and container types, as well as track and record information reported by robotics.

**Note: some automated functionality relies on hosted services which are not available to on-premise customers. Please see the LIMS Integration section on page 5 for more details.**

These release notes detail the key features and changes to software components for the release of Illumina Lab Automation Software Solution Infinium Module v.1.5. ILASS Infinium Module is a comprehensive solution for lab automation and integrated sample tracking, including features such as:

- Automation of Infinium workflows, including:
  - Infinium HD Methylation Assay
    - HD-8
  - Infinium EX Methylation Assay
    - EX-48
  - Infinium EX Assay
    - EX-24
    - EX-48

- Integration with liquid handling robots and wet lab devices including:
  - Infinium Automated Pipetting System
  - Infinium Amplification System
- Visual guidance for material layout and placement.
- Platform and local authentication options.
- Capability to scan, track, and validate reagents and plates.
- Ability to abort or pause automation.
- Optional integration with Clarity LIMS.
- Assay, activity, and application logs.

#### RELEASE v.1.5 HIGHLIGHTS

- Out-of-the-box automation for Infinium EX Assay
- Seamless connection to Infinium Amplification System (IAS)
- Automatic accessioning of BeadChips into Clarity LIMS at the Hyb. Step
- Support for full screen mode
- Added optional Batch DNA step on Infinium Amplification System
- Support for new EX reagent types (PMX to PM1 and IBX to IHX)

#### FEATURES IN DETAIL

- System Level
  - Compatible with Microsoft Windows 10 – 64 Bits using the PC attached to the liquid handling robot.
  - Provides levels of user access including 1) Lab Technician, 2) Administrator and 3) Service.
  - Available in English language.
- Installation
  - Modular installation process to install one or multiple workflows, product types, and protocol steps.
  - Option to install platform and/or local authentication services. Platform authentication provides integration with Clarity LIMS.
  - Option to add Clarity LIMS integration service.
- Liquid Handling Robots
  - Supports connection to the Infinium Automated Pipetting System and Infinium Amplification System.

- Automates the process for automated target prep, automated BeadChip processing and optional batch DNA.
  - Automated target prep protocol only available for Genotyping workflows
- Optional batch DNA protocol step allows easy requeue of samples.
- Displays errors in processing
- Support for automated Infinium Maintenance Procedure

Step	Infinium EX Genotyping (minimum/maximum input quantity)	Infinium EX Methylation	Infinium HD Methylation
<b>Make WGA</b>	0.5, 1-4 Plates	N/A	N/A
<b>Fragment DNA</b>	0.5, 1-6 Plates	Not Available	Not Available
<b>Precipitate DNA</b>	0.5, 1-6 Plates	Not Available	Not Available
<b>Resuspend DNA</b>	0.5, 1-6 Plates	Not Available	Not Available
<b>Hybridize DNA to the BeadChip</b>	EX-24: 0.25, 0.5, 1-3 Plates EX-48: 0.5, 1-3 Plates	EX-48: 0.5, 1-3 Plates	HD-8: 0.5, 1 Plates
<b>Extend and Stain BeadChips</b>	1-48 BeadChips	1-48 BeadChips	1-24 BeadChips

**Note:** The supported quantity of input containers for each step executed on IAPS/IAS with ILASS v1.5 is indicated in the table above. Plate quantities are in increments of 1 except as explicitly noted as 0.25 or 0.5. Barcode tracking steps conducted off instrument are not annotated above.

- Workflow Guidance
  - Provides independent execution of protocol steps for the following workflows:
    - Infinium EX Genotyping Assay
    - Infinium HD Methylation Assay
    - Infinium EX Methylation Assay
  - Based on Product Type and Container Input Quantity, the items you will need are adjusted.
  - Graphic View provides visual of deck layout as a visual guide for loading consumables and artifacts onto the deck of the liquid handling robot.

- List View provides item description and image of all consumables and artifacts to be placed on the deck.
  - Provides visual indicator of the current step of the automated workflow in progress.
  - Estimated time to completion is displayed to let users know when to return to the liquid handling robot for the next step.
  - Warnings and error messages are provided to alert users of a potential issue, including:
    - Manual intervention is needed.
    - Deck cover should be closed.
  - Abort an automation run that is currently in progress or provide emergency stop or pause should an issue occur.
  - Prompts to initiate deck clean up after protocol step completes and indicates when Maintenance is due (maintenance status).
  - Automatically runs maintenance prior to step automation run if maintenance is due.
  - Supports manual tracking of off instrument steps.
- Reagent and plate tracking
    - Liquid handling robots can scan barcodes of specific consumables.
    - Handheld scanning available for reagents to be poured into troughs or other barcodes that can't be scanned by the liquid handling robot.
    - Ability to enter reagent barcode via manual entry if reagent barcodes cannot be scanned.
      - Manual entry tracked via assay run logs.
    - All reagent, plate, and BeadChip barcodes stored in assay run logs.
    - When Clarity LIMS is in use, reagent barcodes transferred for tracking.
- LIMS integration
    - Out of the box sample tracking abilities with preset protocols available in Clarity LIMS version 6.2 and greater.

**Clarity LIMS integration requires a hosted deployment for full end to end functionality.**

- Optional integration with Clarity LIMS can be turned on or off using a toggle within the ILASS user interface.
- Illumina reagents are registered in Clarity which enables:
  - Tracking of the number of plates available for processing for each protocol in a workflow.
  - BeadChips are automatically accessioned into Clarity during the hybridization step if not yet already present.
  - Checks for expired reagents & validation that the input container matches the selected product type.
  - Tracking the utilization of single use consumables/reagents.
- Deck layout validation.
- Assay run logs visible in Clarity LIMS.
- Upon step completion, plates automatically advance to the next step in the workflow in Clarity LIMS & become available for work.
- File-based transfers using the assay run log can also be used to facilitate communication between ILASS and a third-party LIMS system.
- Troubleshooting and logging
  - Assay run log provides key user-initiated event details, such as:
    - Operator and instrument utilized.
    - Protocol step and completion status.
    - Run start and end time, plus timing of sub-step processes.
    - Consumed reagents, plates, and BeadChips with reagent barcodes.
    - Additional protocol step specific details such as water circulator temperature.
  - Application log tracks workflow and protocol steps initialized by the application.
  - Activity log tracks all user-initiated activity and permissions granted per user.
  - Configurable log storage times for troubleshooting and review.

## KNOWN ISSUES

- Local and platform authentication have separate user management systems.
- Run information is not sent to Clarity LIMS if connection to LIMS is lost at the end of a run.
- On-deck sample tracking is at plate level, not sample level.

- Moved items after deck scan on Infinium Automated Pipetting System are not re-scanned to confirm all previously validated items are present.
- ILASS shuts down when Infinium Automated Pipetting System Interface Service (ITIS) is stopped during run.

Infinium Automated Pipetting System: User cannot "Continue" (button disabled) if Maintenance is aborted due to instrument shutdown. Occurs when Infinium Automated Pipetting System Evoware and ILASS cannot detect instrument shutdown.

- Stopping Illumina Automated Pipetting Interface Service (ITIS) after Maintenance Run start results in Unexpected Error that requires ILASS restart

Infinium Amplification System door lock fails to work after a system abort. User is not notified of unlocked door. Reminder for user to keep doors closed during runs remains. Opening the door during a run results in an aborted run.

When Infinium Amplification Interface Service (IHIS) is stopped during batch setup, error is displayed and logged in the application log, but not logged in the assay run log.

- ILASS run is expected to operate under one Microsoft (MS) Windows user. An unclear error message appears when another MS Windows user tries to open ILASS, if ILASS is already open under another MS Windows user.
- During Extend and Stain, the Water Circulator is not shut down if setup is aborted (before run starts). User needs to manually put the water circulator on standby.
- When Clarity LIMS is enabled, adding a reagent barcode in ILASS that is NOT registered in Clarity LIMS results in an unclear error message in ILASS. The error does not indicate the reagent is not registered in LIMS, nor that lot number and expiry date entered in ILASS will be used to register the item in LIMS.
- When Clarity LIMS is enabled and the user is in an Off-Instrument Step on ILASS, manually entering a reagent barcode with the wrong case (lower case) causes an ILASS false error (failed to interact with LIMS) to be displayed. A subsequent success result is displayed. The wrong case is in fact ignored and the reagent does save in LIMS.