

Clarity LIMSTM software

Efficient sample and
workflow management for
Illumina next-generation
sequencing (NGS) and arrays

- Expedite adoption of new workflows with ready-to-use, prepackaged workflows from Illumina
- Streamline workflow development using integrations with Illumina instruments
- Configure software without coding to easily add new fields, protocols, and workflows through an intuitive user interface
- Support compliance with e-signatures, audit trails, reagent and lot tracking, and privacy and security controls

Introduction

Many genomics labs face multiple information management challenges, such as frequently changing lab workflows, integration of rapidly evolving instruments and tools, cross-organizational collaborations, stringent regulatory compliance standards, and overloaded informatics teams. Responding to these issues can require significant investments of time and resources.

To help labs address these challenges, Illumina offers Clarity LIMS software, an innovative laboratory information management system (LIMS). Clarity LIMS software enables sample tracking and workflow management for an optimized and efficient lab. The software is easy to use, implement, and configure. It includes the following features:

- Intuitive, role-based interfaces
- End-to-end sample traceability
- Genealogy view
- Real-time status monitoring
- Illumina prepackaged workflows
- Illumina instrument integrations
- Regulatory support
- Remote collaboration via LabLink
- Automation support
- Configurability and extensibility
- Advanced search
- Read-only mode

Intuitive, role-based interfaces

Bench scientists, managers, and IT personnel all have different computer skill levels and comfort with software applications. These roles don't interact with the LIMS in the same way because each one has specific tasks they need to accomplish. Clarity LIMS software features different user interfaces for the lab manager, lab scientist, and collaborator that are tailored to the skill set and interaction of each lab role.

End-to-end sample traceability

Each sample entered into Clarity LIMS software is given a unique identifier number (LIMS ID). As lab activities are recorded in Clarity LIMS software, the resulting sample histories (genealogies) are automatically created and associated with the LIMS ID from sample quality control (QC) through data analysis (Figure 1).

Sample tracking enables you to:

- Organize samples by workflow stages in the lab
- Retrieve all metadata and results associated with any submitted sample
- Keep detailed records of sample information, including date stamps for work processed, technician information, instrument ID, container IDs, and reagent lot numbers or barcodes
- Store and search all results in a centralized secure location
- Plan operations through real-time workflow tracking
- Apply QC logic to catch poor quality samples before analyzing them

The screenshot displays the Clarity LIMS interface for sample tracking. It shows two sample records, each with a detailed protocol step history.

Sample ID	Project	Received	Cont. Name	Cont. Type	LIMS ID
MT001	Ethan's Project	Mar 01, 2020	Plate_1	96 well plate	ADMS7A1PA1
19-02-2020 Test sample...			Plate_1	96 well plate	OLS102A1PA1

Protocol Step	Status	Date
test truseq dna step	In Queue	Feb 28, 2020
Aggregate QC [DNA] 5.0		Feb 28, 2020
Qubit QC [DNA] 5.0		Feb 28, 2020
DNA Extraction	In Queue	Feb 28, 2020

Figure 1: Sample traceability in Clarity LIMS software

Genealogy view

Genealogy view is an interactive and hierarchical view of the history of an experiment processed through Clarity LIMS software. A genealogy starts with a submitted sample and progresses with nodes nested beneath it. Information is displayed in a hierarchy and shows parent-child relationships between these nodes (Figure 2). Genealogy view is particularly useful to troubleshoot the outcome and possible continuous outcomes of each step, including the indented children steps nested within their parent steps.

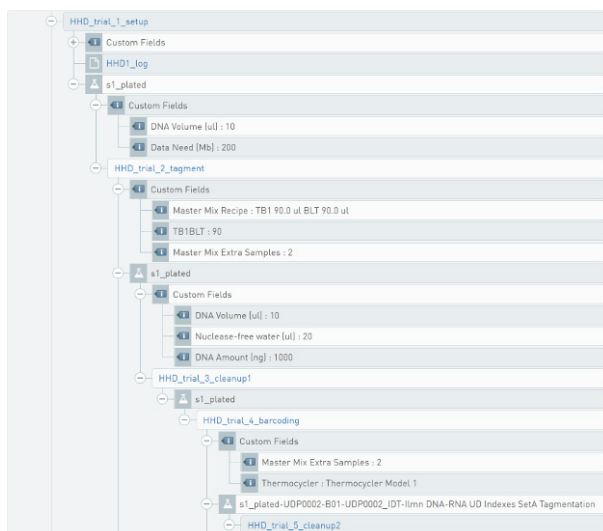


Figure 2: Genealogy view—With a click, view all steps performed on a sample and all data fields collected during the process.

Real-time status monitoring

Lab managers need to pinpoint bottlenecks in the wet lab quickly, understand project or sample progress in real-time, and resolve issues before they delay results delivery. The Lab Manager Dashboard views in Clarity LIMS software allow multitasking lab managers to use collected data within the LIMS to inform future operations. Clarity LIMS dashboards display the number of samples currently in progress throughout the lab and where the samples are in the pipeline, all without running queries or building a custom report. Lab managers can view real-time key data, such as sample or project status, completion date, and alert messages, so that stakeholders or collaborators can be updated without the need to sort through multiple data sources.


Instrument integrations

Genomics technologies are complex and many labs struggle to keep pace with integrating new technology, instruments, and methodologies. Clarity LIMS software is built specifically for genomics labs to simplify the integration process. These instrument integrations automate manual tasks, reduce errors, and enforce lab and industry best practices (Table 1).

Table 1: Clarity LIMS instrument integrations

System	Local	Cloud
iSeq™ 100 System	Manual	Manual
MiniSeq™ System	Manual	Manual
MiSeq™ Series	Automated	Automated
NextSeq™ 500/550 Systems	Automated	Automated
NextSeq 1000 and NextSeq 2000 Systems	Manual coming soon	Automated
NovaSeq™ 6000 Series	Automated	Automated
NovaSeq X Series	Manual coming soon	Automated
iScan™ System	Not available	Automated

Manual refers to a prepackaged workflow (IPP) to generate a sample sheet for manual upload to the instrument; **Automated** refers to a prepackaged workflow (IPP) to pool libraries for sequencing, setup a run, and automatically track the run status and metrics via out-of-the-box integrations.

 **Instrument integrations.** Additional configuration may be required to integrate some instruments.

Illumina prepackaged workflows

Clarity LIMS software offers > 60 prepackaged workflows for Illumina NGS and array applications (Table 2). These protocols are based on Illumina reference guides for optimal results. They allow labs to install and chain protocols together to create workflows that best suit the lab's needs and adopt Clarity LIMS software faster. Prepackaged workflows also aid lab staff in experimental planning and performing complex tasks such as assigning indexes, sample sheet generation, and calculation of dilution volumes for library normalization.

Table 2: Prepackaged workflows in Clarity LIMS (version 6.1 and higher)

AmpliSeq™ for Illumina	Targeted enrichment	Methylation
AmpliSeq for Illumina <i>BRCA</i> Panel	Illumina DNA Prep with Enrichment (S) Tagmentation	TruSeq ChIP-Seq
AmpliSeq for Illumina Cancer Hotspot Panel v2	Illumina RNA Prep with Enrichment (L) Tagmentation	TruSeq Methyl Capture EPIC
AmpliSeq for Illumina Childhood Cancer Panel	TruSeq DNA Exome	Quality control (QC)
AmpliSeq for Illumina Comprehensive Cancer Panel	TruSeq RNA Exome	DNA Initial QC
AmpliSeq for Illumina Comprehensive Panel v3	Nextera Rapid Capture Custom Enrichment	Library Validation QC
AmpliSeq for Illumina Custom DNA Panel	Targeted amplicon prep	RNA Initial QC
AmpliSeq for Illumina Focus Panel	TruSeq Custom Amplicon	Infinium™ portfolio
AmpliSeq for Illumina Immune Repertoire Plus, TCR beta Panel	TruSight™ portfolio	GenomeStudio™ Software
AmpliSeq for Illumina Immune Response Panel	TruSight Oncology 500 ctDNA	ILASS Infinium Genotyping Assay
AmpliSeq for Illumina Myeloid Panel	TruSight Oncology 500 High-Throughput	Infinium HD Methylation Assay Manual
AmpliSeq for Illumina TCR beta-SR Panel	TruSight Oncology 500	Infinium HTS Assay Manual
AmpliSeq for Illumina Transcriptome Human Gene Expression Panel	TruSight Tumor 170	Infinium LCG Assay Manual
DNA library prep	RNA library prep	Infinium XT Assay Manual
Illumina DNA PCR-Free Prep	Illumina Stranded mRNA Prep v1.0	Viral pathogens
Illumina DNA Prep (M) Tagmentation	Illumina Stranded Total RNA Prep Ribo-Zero™ Plus	CDC COVID-19 RT-PCR
Nextera™ Mate Pair Library Prep Kit	TruSeq Small RNA	Illumina COVIDSeq™ Assay (96 samples)
Nextera XT DNA Library Preparation Kit	TruSeq Stranded mRNA	Respiratory Virus Panel
TruSeq™ DNA PCR-Free	Illumina Genomics Architecture	
TruSeq DNA Nano	Illumina Genomics Architecture Library Prep Automated v1.0	
	Illumina Genomics Architecture NovaSeq™ Sequencing	

This is a representative, non-exhaustive list; prepackaged workflows are updated with new software releases; for more information on available prepackaged workflows, visit: support-docs.illumina.com/SW/ClarityLIMS/clarity-lims-ipp.htm.

Regulatory support

Clarity LIMS software provides a comprehensive solution for laboratories working in regulated environments, such as Clinical Laboratory Improvement Amendments (CLIA)–certified organizations, to achieve or maintain certification and compliance.

Key features for CLIA and other regulated labs include:

- Data entry enforcement
- Workflow enforcement
- Issue resolution documentation
- Precision monitoring
- Role-based permissions
- Audit trail
- Electronic signatures

Remote collaboration

Laboratories generating genomics data may be working with customers and partners across the hall or across the globe. These customers or partners need a secure mechanism for communicating with the lab on sample submission, status, and results delivery without sending multiple emails, accessing shared spreadsheets, or making phone calls.

Clarity LIMS software provides the LabLink interface (Figure 3) to enable external clients to:

- View and retrieve results securely
- View sample and project status securely
- Access self-service status updates
- Transfer information directly from the LIMS without manual data entry
- Send and receive email notifications for Sample and Project Notes updates

Automation support

Reducing the amount of manual interaction with a system supports the reporting of accurate real-time documentation, reduces errors, and speeds the turnaround time from sample receipt to data acquisition. Clarity LIMS software enables qualified staff to automate a wide variety of functions, such as:

- Assigning samples at the Step or Project level (Figure 4)
- Defining sample placement and container type
- Pooling samples
- Adding reagent labels to samples
- Assigning next steps in the workflow

Clinical and high-throughput laboratories must significantly shorten sample turnaround time and reduce the possibility of errors in sample preparation. One key method for dramatically improving performance in these areas is to introduce automation devices. Illumina Lab Automation Software Solution (ILASS) automates liquid-handling robots and other wet lab devices. When ILASS is integrated with Clarity LIMS software, users can inform liquid-handling robots on sample placement location and container types, as well as track and record any information reported by the robots.

Configurability

Typically, adding new protocols to support new technologies to a LIMS requires significant software development resources. Clarity LIMS software puts lab managers in control without the need for new software coding. Via the user interface, lab managers can easily add new protocols, fields, and workflows and control what other staff members can view or edit, all with a few clicks (Figure 5).

Extensibility

Changing analysis methodologies and technologies require a LIMS that can evolve with them. Clarity LIMS software provides the Application Programming Interface (API) to empower customers to integrate various analysis and third-party tools, as well as automate processes and integrate robots. The API uses technologies in other software and instrument systems; provides detailed documentation, how-to videos, example cookbooks, and packages written by other customers; and allows qualified users to:

- Automate sample tracking to ensure quality results
- Incorporate new analysis methods
- Automate the transfer of data from an instrument or other systems to the LIMS

Advanced search

Clarity LIMS advanced search enables flexible data mining and powerful search querying for users. Introduced in Clarity LIMS version 6.1, advanced search provides users with the capability to perform multivariable search queries saved to a user's profile (Figure 6). Paginated results come with optimized navigation and excel export capabilities to streamline efficiency and turnaround times for laboratories.

Read-only mode

Data security and integrity is a critical consideration for laboratories of all disciplines, including clinical users working in a highly regulated environment. Clarity LIMS software features read-only mode, a user-based permission setting, to enable secure data access. Users with admin roles can configure settings such that designated individuals may exclusively view data in read-only mode without editing capabilities. Use cases include auditing, reporting, and training.

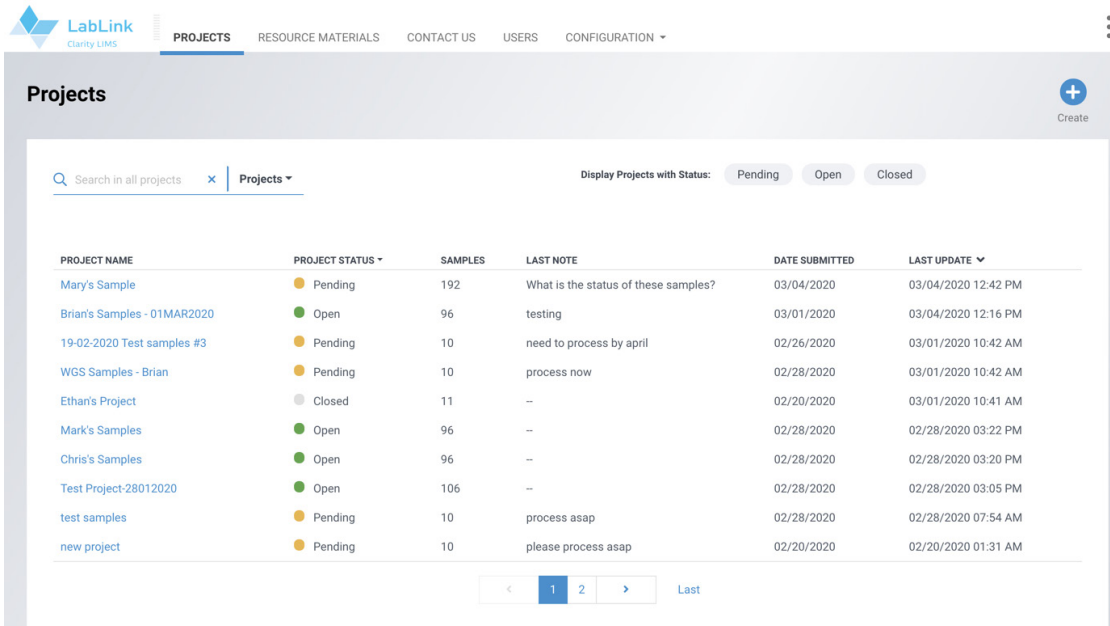


Figure 3: Clarity LIMS LabLink

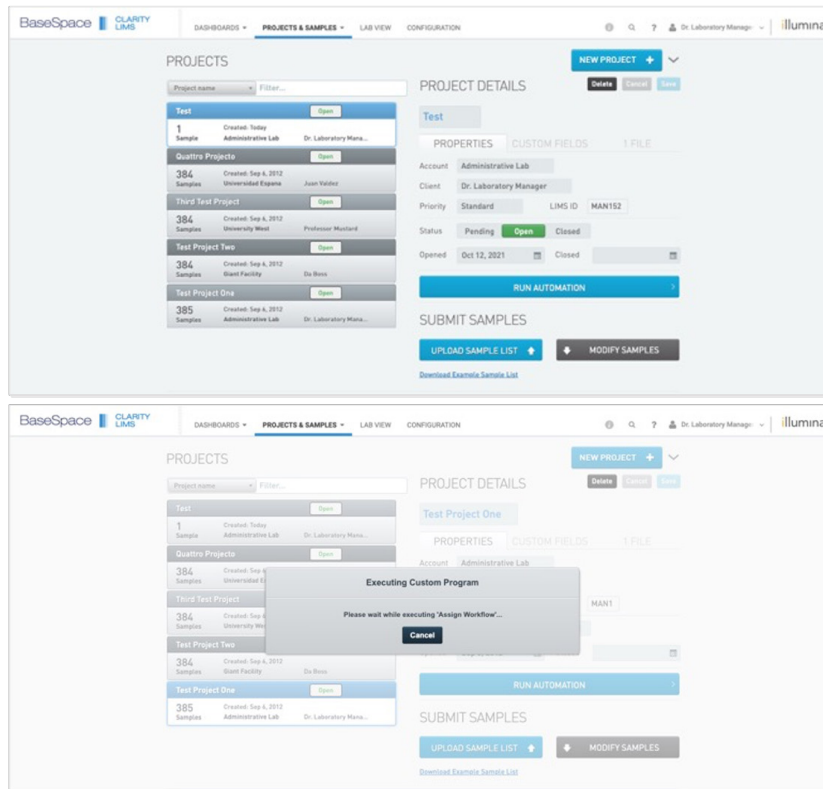


Figure 4: Assign samples to workflows at the Step and Project level— Write custom scripts and perform custom actions at the project level from the “Projects and Samples” screen. For instance, automate sample validation and assignment of samples to a given workflow. The “Run Automation” button executes the defined script and polls until the automation completes.

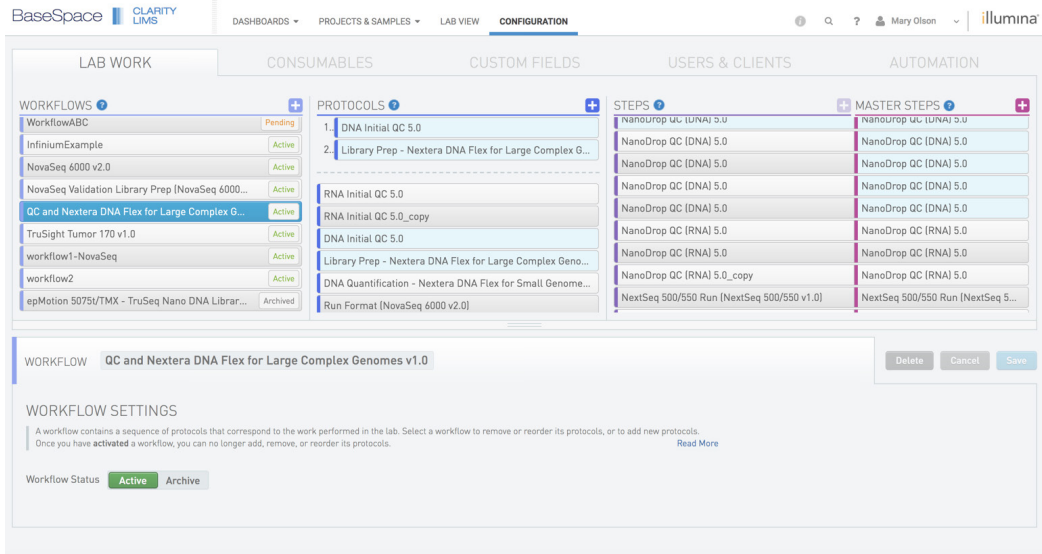


Figure 5: New workflow configuration in Clarity LIMS software

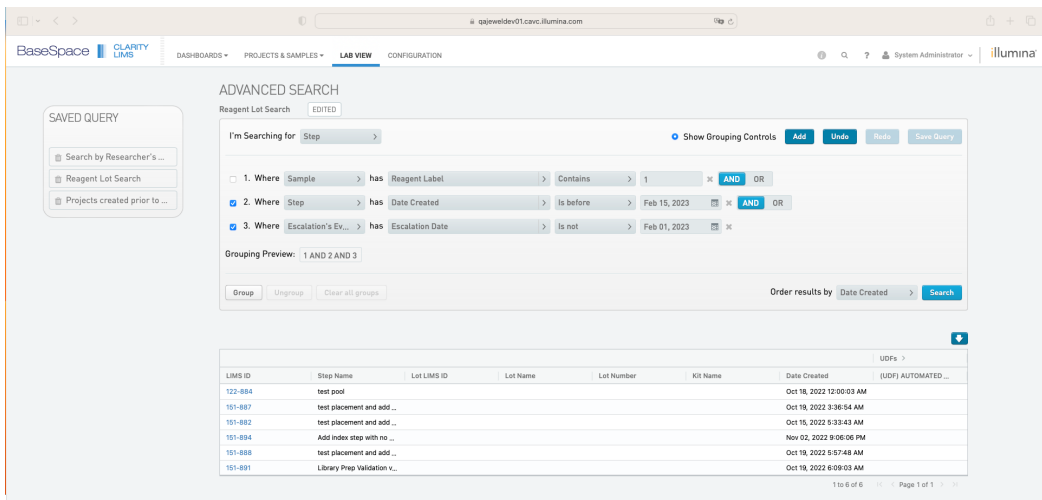


Figure 6: Clarity LIMS advanced search

Clarity LIMS subscriptions

From small, regulated institutions to large commercial or academic genomics centers, there's a Clarity LIMS package that fits the needs of every customer (Table 3). Clarity LIMS software is available in two subscription plans, renewed annually.

Learn more

[Clarity LIMS software](#)

Table 2: Clarity LIMS subscriptions (version 6.1 and higher)

Feature	Professional	Enterprise
Sample traceability	✓	✓
Illumina prepackaged workflows	✓	✓
Illumina instrument integrations	✓	✓
Dashboard reporting	✓	✓
Data and workflow enforcement	✓	✓
API access with toolkits	✓	✓
LabLink for sample submission	✓	✓
Web interface workflow configuration	✓	✓
Database read-only access	✓	✓
LDAP for single sign-on		✓
HIPAA and Business Associates Agreement (BAA) for US only		✓
ISO/IEC 27001:2013 certified	Cloud instance	Cloud instance
ISO/IEC 27701:2019 certified	Cloud instance	Cloud instance
Deployment	Local, cloud	Local, cloud
Number of instances	1	2
Number of named users	3	10

Ordering information

Product	Catalog no.
Clarity LIMS Local Professional Annual Subscription	20073857
Clarity LIMS Cloud Professional Annual Subscription	20042028
Clarity LIMS Professional One-Time Onboarding	20073861

Product	Catalog no.
Clarity LIMS Local Enterprise Annual Subscription	20073860
Clarity LIMS Cloud Enterprise Annual Subscription	20042029
Clarity LIMS Enterprise One-Time Onboarding	20042030
Add ons	
Each additional test instance local	20042032
Each additional test instance cloud	20006501
5 additional Clarity LIMS named users	20020647
10 additional Clarity LIMS named users	20020648
25 additional Clarity LIMS named users	20020649
50 additional Clarity LIMS named users	20020650
Each additional named user	20006495



1.800.809.4566 toll-free (US) | +1.858.202.4566 tel
 techsupport@illumina.com | www.illumina.com

© 2023 Illumina, Inc. All rights reserved. All trademarks are the property of Illumina, Inc. or their respective owners. For specific trademark information, see www.illumina.com/company/legal.html.
 M-GL-01069 v3.0