

Clarity LIMS™

Intuitive Lab Management™

Intuitive Lab Management
from **Bench to Boardroom**



Clarity LIMS' features are bundled into editions. Flags indicate the features contained within each edition.

INTRODUCTION

As a genomics or mass spec lab, you 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 IT and informatics teams. Amidst these challenges you may need to process patient samples quickly or run a research lab that has many collaborators and varied sample types.

If you operate one of these labs, consider what your lab could accomplish if you could address these challenges without spending months of staff time and resources.

What if you could easily track a sample from submission to completed result without paperwork, while still ensuring data integrity and a full documentation trail? How many more samples could your staff process in a year?

What if you could achieve and maintain CLIA/CAP compliance without adding tremendous overhead to your technical staff? How much could you save?

What if your IT and informatics teams didn't have to spend their time building and supporting inflexible systems? How many more tests could your lab introduce or develop? How else could your lab innovate because of streamlined operations? And how many patients would get important results faster?

We developed Clarity LIMS so that you no longer have to ask "what if?" Clarity LIMS helps you address these challenges so that you can run samples more quickly, track them effortlessly, and so that you can achieve or maintain regulatory compliance as efficiently as possible. Clarity LIMS is easy-to-use, implement, and configure.

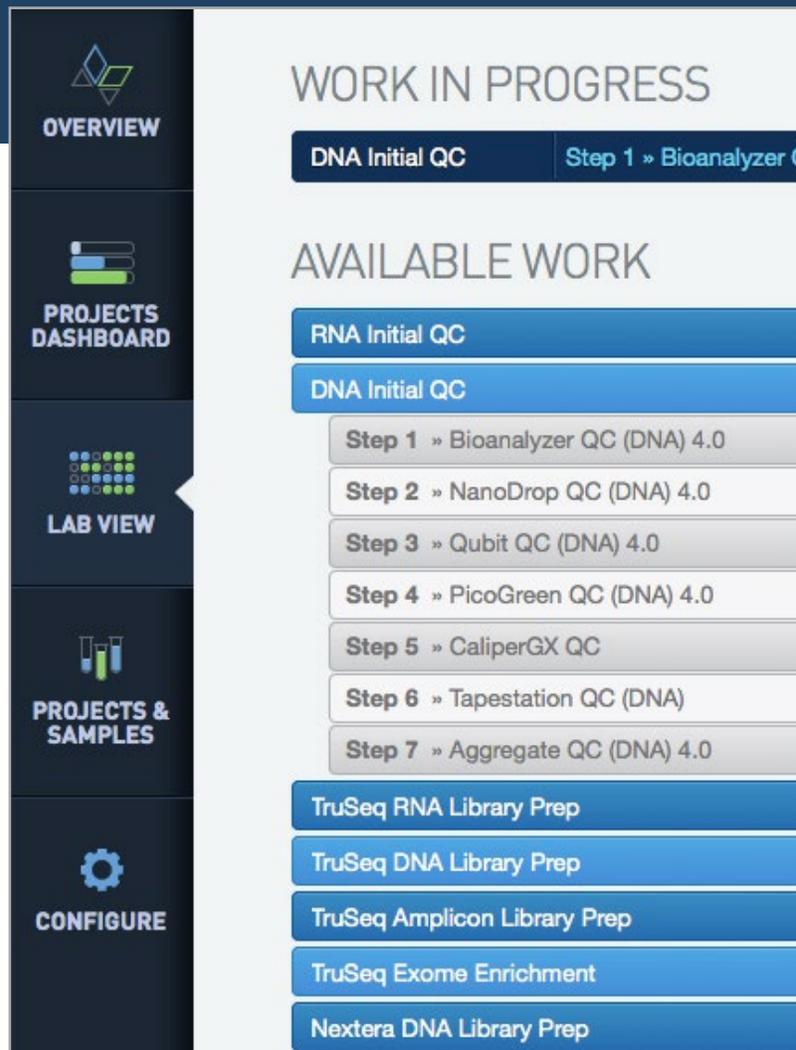


Figure 1 – Organize samples by workflow stages in the lab. All samples available for work are displayed in queues by assigned workflows. See figure 1 for an example of a work queue where five samples are ready to process in the DNA Initial QC workflow. Lab scientists can easily view work in progress and work waiting to begin.

Figure 1

It includes all of the following features:

- » End-to-end sample traceability
- » Preconfigured workflows
- » Regulatory support
- » Real-time status and reporting
- » Configurability
- » Collaboration
- » Role-based interfaces
- » Extensibility
- » Automation
- » Instrument integration

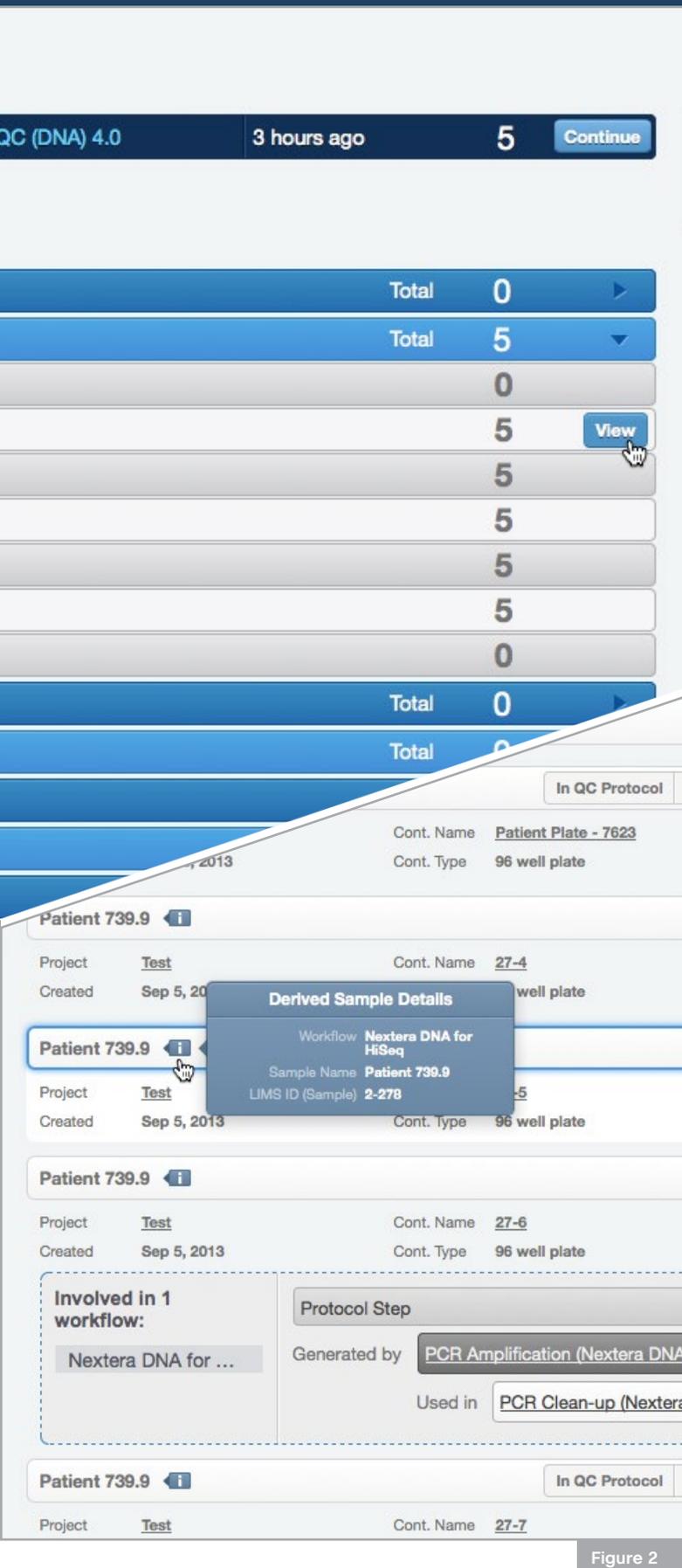


Figure 2

END-TO-END SAMPLE TRACEABILITY



What if you didn't have to search across filing cabinets and spreadsheets to find all sample information from last week or last year?

When a sample is entered into Clarity LIMS it is given a unique identifier (LIMS ID). As lab activities are recorded in Clarity LIMS, the resulting sample histories (sample genealogies) are automatically created and associated with the LIMS ID from the sample QC results through data analysis and reporting.

This sample tracking enables you to:

- » Organize samples by workflow stages in the lab
- » Easily 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
- » Catch poor quality samples before analyzing them

Figure 2 – Complete sample traceability. All sample details are tracked within Clarity LIMS, so retrieving them at any time is easy. This figure is an example of a sample search which shows the current status and all recorded details for Patient 739.9 and his or her derived samples.





AVAILABLE WORK

TruSeq RNA Library Prep	Total	44	▶
TruSeq DNA Library Prep	Total	58	▶
TruSeq Amplicon Library Prep	Total	96	▶
TruSeq Exome Enrichment	Total	26	▶
TruSeq Small RNA Library Prep	Total	0	▶
TruSeq Stranded Total RNA LT Sample Prep	Total	0	▶
TruSeq Stranded mRNA LT Sample Prep	Total	0	▶
Ion AmpliSeq Cancer Panel Sample Prep	Total	92	▶
Ion AmpliSeq Sample Prep	Total	104	▶
Ion TargetSeq Sample Prep (Small Region)	Total	0	▶
Ion TargetSeq Sample Prep (Large Region)	Total	14	▶
Ion Whole Transcriptome Library Prep	Total	98	▶
Ion Small RNA Library Prep	Total	96	▶
Torrent Suite Sequencing	Total	1	▶
Nextera DNA Library Prep	Total	36	▶
Nextera Enrichment Sample Prep	Total	0	▶
Epicentre ScriptSeq mRNA-Seq Library Prep (for Illumina)	Total	0	▶
SureSelect XT DNA Prep	Total	0	▶
SureSelect XT Target Enrichment	Total	0	▶
Library Validation QC	Total	72	▶
Illumina SBS (HiSeq GALbx)	Total	29	▶
Illumina SBS (MiSeq)	Total	56	▶
Taqman 7900	Total	7	▶
454 Sequencing	Total	52	▶
Agilent One Colour	Total	0	▶
LC-MS with Xcalibur	Total	36	▶
Infinium MicroArray	Total	384	▶
Microarray - Affymetrix	Total	50	▶
ViiA7	Total	0	▶
SOLID Sequencing Library Prep	Total	90	▶
SOLID Sequencing Run	Total	0	▶
Sanger Sequencing 2.0	Total	290	▶
TruSeq PCR Free Library Prep	Total	96	▶
TruSight Enrichment Library Prep	Total	88	▶
TruSeq Nano DNA Library Prep	Total	40	▶
TruSight Tumor Library Prep			
Torrent Suite Sequencing - Automated			
PacBio RS Sequencing			

Figure 3

AD003 (TTAGGC)	0
4 AD004 (TGACCA)	0
5 AD005 (ACAGTG)	0
6 AD006 (GCCAAT)	0
7 AD007 (CAGATC)	0
8 AD008 (ACTTGA)	0
9 AD009 (GATCAG)	0
10 AD010 (TAGCTT)	0
11 AD011 (GGCTAC)	0
12 AD012 (CTTGTA)	0
13 AD013 (AGTCAA)	0
14 AD014 (AGTTCC)	0
15 AD015 (ATGTCA)	0
16 AD016 (CCGTCC)	0

PRECONFIGURED WORKFLOWS



What if you could ensure quick system adoption and use of procedural best practices?

Clarity LIMS offers more than 40 production ready workflows for the most popular instruments and applications. GenoLogics employs genomics and proteomics PhD and MS scientists to work with instrument vendors to create these preconfigured workflows that follow best practices for optimal results based on vendor specifications. Preconfigured workflows allow labs to install and adopt Clarity LIMS faster.

Preconfigured 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.

Figure 3 – Preconfigured workflows. If it's a popular tool for genomics or mass spec technologies, it's likely that Clarity LIMS has a preconfigured workflow available for it. Preconfigured workflows offer a quick starting point for customizing your own configuration and getting into production fast.

Well	Sample Na...	Project Na...	Reagent N...
A:1	Saliva 244	WGS Illumina ...	
A:2	Saliva 312	WGS Illumina ...	
A:3	Saliva 261	WGS Illumina ...	
A:4	Saliva 320	WGS Illumina ...	

Figure 4

Figure 4 – Specialized tools within preconfigured workflows. Many of the preconfigured workflows within Clarity LIMS provide specialized tools designed to simplify that workflow for lab staff. For instance, indices can be easily dragged and dropped into plates to track complex index assignment.

Figure 5 – Alerts and issue resolution. Samples which do not meet organizational-specific criteria (e.g., not passing specified Bionanalyzer QC thresholds) are escalated to management review through Clarity LIMS alerts. Managers must document resolution of the alert in the system for a sample to progress.



Figure 5

Manager review requested from System Administrator on 1 sample

System Administrator
Sep 5, 2013
06:20:38 PM PDT

Sample failed initial **BioAnalyzer** QC. Sample is removed from workflow and a request for new aliquot from co

REGULATORY SUPPORT



What if you could achieve or maintain compliance for your lab without adding more paperwork?

Clarity LIMS goes beyond just ensuring that all data are collected accurately and securely. Clarity LIMS provides a complete solution for laboratories working in regulated environments, such as CLIA certified organizations or those regulated under 21 CFR Part 11, to achieve or maintain certification and compliance.

The system provides key features for CLIA and other regulated labs including:

- » Data entry enforcement
- » Workflow enforcement
- » Issue resolution documentation
- » Precision monitoring
- » Role-based permissions
- » Audit trail
- » E-signatures
- » *Optional* validation services

Figure 6 – Data entry enforcement. Required data entry fields—as many as needed for your documentation standards—can be configured and locked down by system administrators. Red exclamation points display when fields are not properly populated, and these samples are restricted from progressing to the next step.

Figure 6

TruSeq DNA Library Prep
Record Details (1 sample)

System Administrator

Protocols

Step Details

- *Plate Barcode: Covaris Fragmentation Plate (CFP) [Red exclamation point]
- *Plate Barcode: DNA plate (DNA) [Red exclamation point]
- *Plate Barcode: Insert Modification Plate (IMP) [Red exclamation point]
- *Lot No.: TruSeq DNA Sample Prep Kit [Red exclamation point]
- *Lot No.: Covaris tubes [Red exclamation point]
- Covaris Duty Cycle (%) [10]
- Covaris Intensity [5]
- Covaris Bursts per Second [200]

Figure 7 – Workflow and protocol enforcement. Steps within a workflow or protocol can be locked down by system administrators. As many or as few possible next steps can be allowed depending on the standard operating procedures of your organization.

Figure 7

TruSeq DNA Library Prep » **Fragment DNA (TruSeq DNA) 4.0**

« Back Properties **Next Steps** Queue View Record Details

Configure Permitted Next Steps

Fragment DNA (TruSeq DNA) 4.0 - (current step)

- Bioanalyzer Fragmentation QC (TruSeq DNA) 4.0
- Repair Ends (TruSeq DNA) 4.0
- Adenylate ends & Ligate Adapters (TruSeq DNA) 4.0
- Purify ligation products (TruSeq DNA) 4.0
- Enrich DNA fragments (TruSeq DNA) 4.0



Intuitive Lab Management from Bench to Boardroom

REAL-TIME STATUS AND REPORTING



What if you could put your data to work for you?

Lab managers need to quickly pinpoint bottlenecks in the wet lab, understand project or sample progress in real-time, and resolve issues before they delay results delivery. Clarity LIMS includes mobile supported real-time status and reporting tools, such as Dashboards and Reports, for lab managers.

Dashboards

The Lab Manager Dashboard views in Clarity LIMS were designed to allow multi-tasking lab managers to put all the data collected within the LIMS to work for them in informing future operations.

Clarity LIMS dashboards display the information that lab managers need to know, such as how many samples are 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.

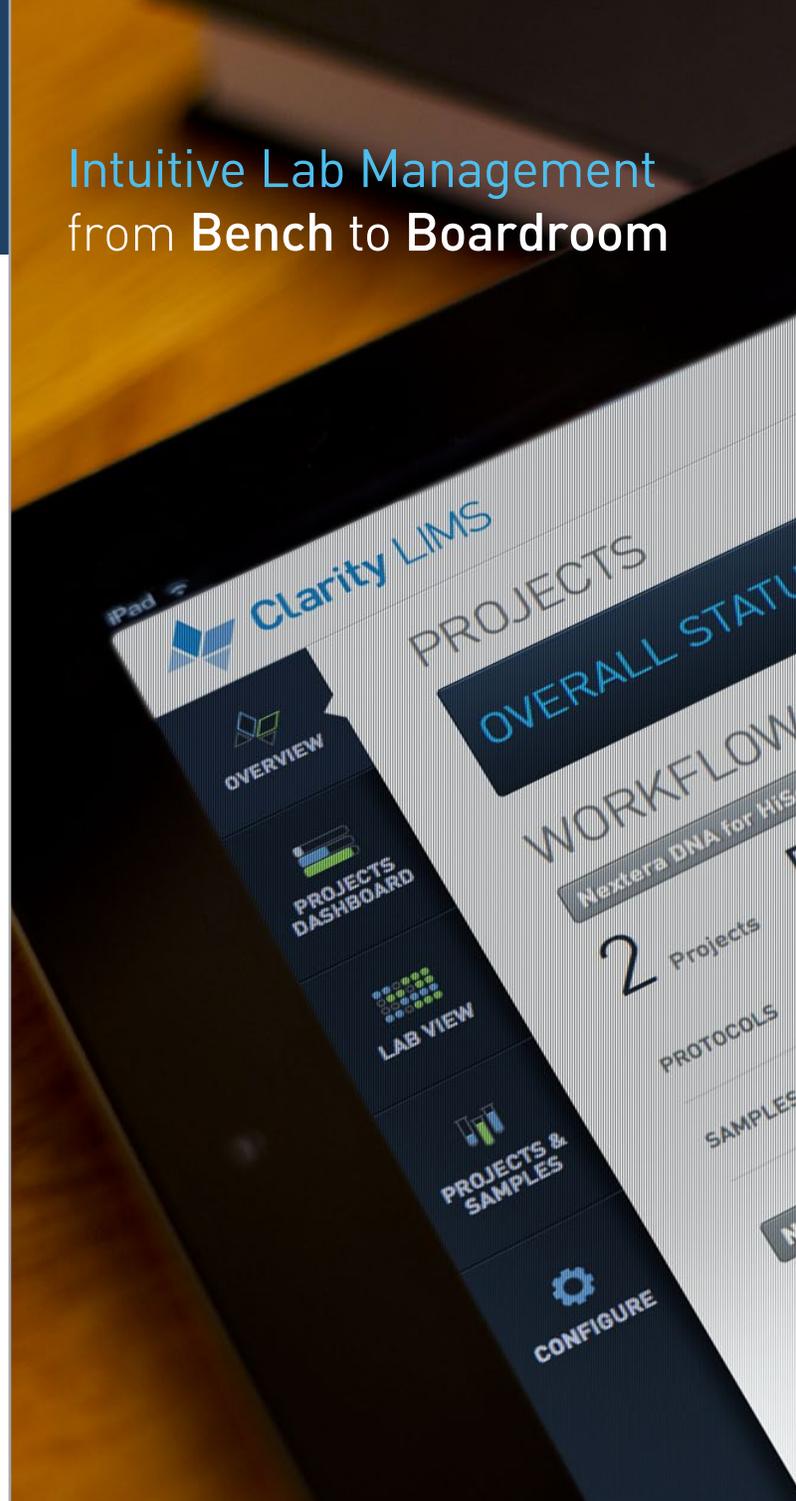




Figure 8

Figure 8 – Real-time status and reporting dashboards. No need to run time-consuming reports to see the health of your lab projects or workflows. The Overview dashboard in Clarity LIMS provides real-time status of capacity and alerts, the number of samples waiting for processing, and the number of ongoing projects.

All of our reporting dashboards can be accessed via mobile devices to ensure you have all the answers for collaborators, management, or your lab team, even when you're not in the lab.

Reports

Laboratory directors and managers require access to operational, sample/project level and instrument precision monitoring reports to ensure efficient lab operations and maintain regulatory compliance. Clarity LIMS offers preconfigured out-of-the-box reports, as well as customized reporting options.

The reporting capabilities in Clarity LIMS allow customers to:

- » Perform instrument precision monitoring on current and historical data
- » Generate reports of all lab or customer activity for accurate account billing
- » Produce data quality reports for customers
- » Pinpoint organizational bottlenecks
- » Create electronic reports to upload to institutional billing packages

“IT’S VERY VISUAL AND MAKES IT EASY TO SKIM THROUGH AND PICK OUT A PROJECT THAT IS STUCK OR IF THERE IS A PROCESS IN THE LAB THAT WE NEED TO DEVOTE MORE RESOURCES TO”

James Hadfield, Head of Genomics Core Facility, Cancer Research U.K.





“WE’VE FOUND THE SYSTEM VERY INTUITIVE TO OPERATE AND EASY TO CONFIGURE AND CUSTOMIZE”

Dr. JinChang Sun, Sr. Engineer, Olso University Hospital, Radium Hospital

CONFIGURABILITY



What if you could add new system functionality in minutes without the need for coding (or several inter-departmental meetings)?

While many LIMS vendors claim to be flexible, this flexibility often requires software development resources (yours or theirs) to add new protocols to support new technologies. Clarity LIMS 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 rather than a few committee meetings.

Figure 9



Figure 10

Figure 9 – Configuration in minutes.
With Clarity LIMS you never have to wait for a software developer to configure a new protocol or lab workflow. Users with correct permissions can easily create and modify new protocols and workflows in minutes.

Figure 10 – Detailed configuration made easy.
Configuring each detail of a protocol or workflow is easy for lab administrators to complete on their own. Here is an example of the configuration options for the properties of the Bioanalyzer step of the DNA Initial QC protocol.



COLLABORATIONS



What if you could empower customers to access sample or project updates without lab staff having to hunt down the information?

Laboratories generating genomics and mass spec 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 e-mails, accessing shared spreadsheets, or making phone calls.

Clarity LIMS provides the LabLink interface to enable external clients to:

- » View and retrieve results securely
- » Submit contextual sample information
- » View sample and project status securely
- » Access self-service status updates
- » Transfer information directly from the LIMS without manual data entry

The screenshot displays the LabLink interface for setting up a workflow. On the left, there is a list of workflows created on 'Sep 03, 2013'. The main area shows the configuration for 'Nextera DNA for MiSeq', which is currently in a 'Pending' status. The workflow consists of four steps: 1. DNA Initial QC, 2. Nextera DNA Library Prep, 3. Library Validation QC, and 4. Illumina SBS (MiSeq). There are buttons for 'Add Protocol +', 'Save Workflow', and 'Activate'. Below the workflow setup, there are navigation tabs for 'Information', 'Filters', 'Queue View', 'Step Setup', and 'Record Details', along with a 'Next »' button. At the bottom, there is a section for sorting samples in a container, with options for 'Row (A1, A2, A3)' (selected) and 'Column (A1, B1, C1)'.





Figure 11

ROLE-BASED INTERFACES



What if you could accommodate each of your users?

Bench scientists, managers, IT, and bioinformatics 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 has very specific tasks they need to accomplish.

While many LIMS vendors can claim to have a simple interface that meets the needs of all these users, how many vendors have customers who rave about the usability of their system? Clarity LIMS users will tell you that the look and usability of the system in one of their favorite features because it's designed the way lab staff work and provides interfaces that are tailored to the skill set and interaction of each lab role. Clarity LIMS has the following interfaces:

- » Lab Manager
- » Lab Scientist
- » Collaboration
- » Informatics (*LIMS Gold only*)

Figure 11 – Lab Scientist Projects Dashboard. Scientists can view the overall status of lab projects, the number of workflows assigned, and projects that are in progress or complete. Scientists can also view individual project details and keep track of sample alerts all within this dashboard.

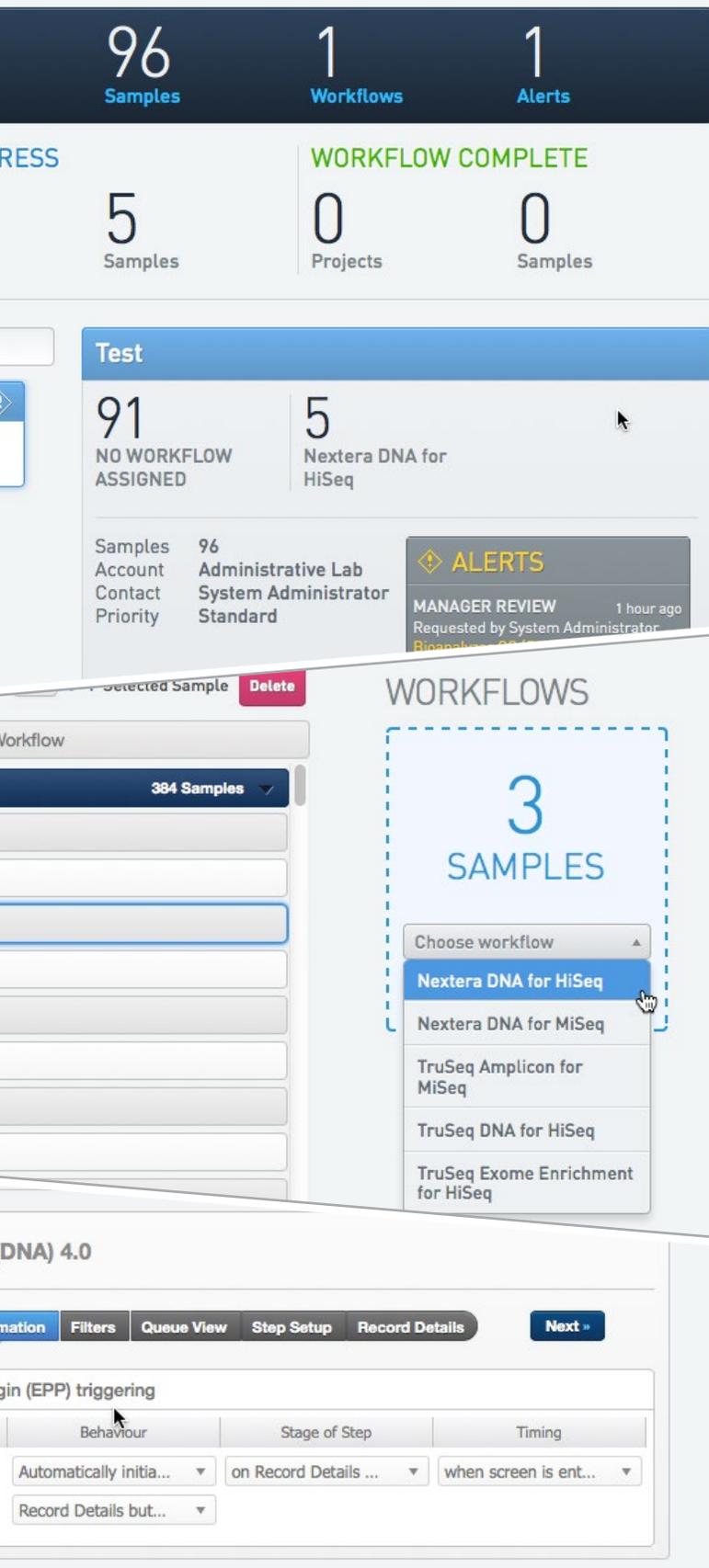


Figure 12 – Project and Sample View. Scientists can easily enter samples into the system and assign them to workflows for downstream processing. Samples are listed on the left-hand side and can simply be dragged and dropped into workflow assignments.

EXTENSIBILITY



What if you could easily integrate with third-party or in-house tools?

As with bench protocols, analysis methodologies and technologies also evolve and laboratories require a LIMS that can evolve with them. GenoLogics provides the Rapid Scripting Application Programming Interface (API) to empower customers to integrate various analysis and third-party tools, as well as, automate processes and integrate robotics.

While many LIMS may offer such software development packages, it's important to understand that not all APIs are the same. The GenoLogics Rapid Scripting API, not only makes use of widely used technologies in other software and instrument systems, but also provides detail documentation, how-to videos, example cookbooks and packages written and published by other customers.

The GenoLogics Rapid Scripting (API) 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

Figure 12

Figure 13

Figure 13 – Flexible APIs. External Program Integration Plugins (EPPs) can be integrated into protocols to automate processes or to interface with robotics and instruments. This figure is an example of the configuration of an EPP used to automate a Bioanalyzer step.



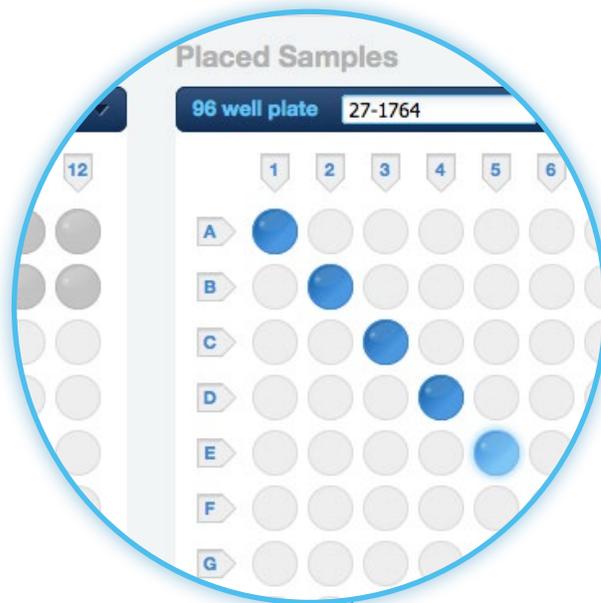


AUTOMATION

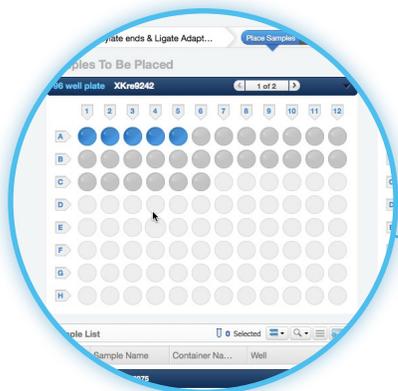


If you could save just 20 minutes per sample, how many more samples could you process this year?

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. Clarity LIMS includes support for liquid-handling robotics and enables the automation of many LIMS functions based on the business logic of your organization.



Automatically or manually place samples in Clarity.



Samples automatically placed by robotics, all placement tracked in LIMS.



LIQUID HANDLING ROBOTICS

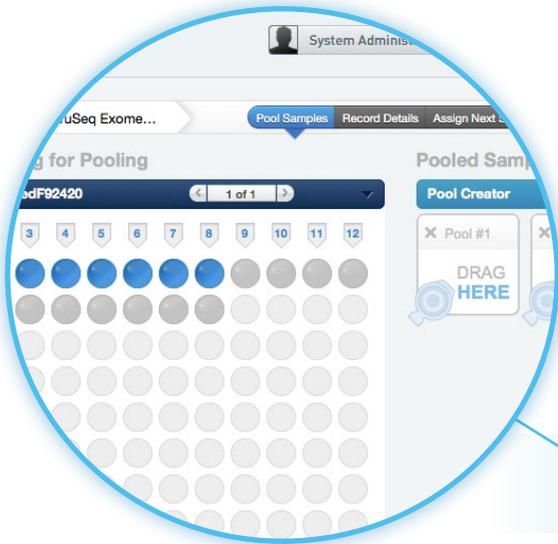
Lab scientists can use Clarity LIMS to automatically inform liquid-handling robotics on sample placement location and container types, as well as track and record any information reported by robotics. Specifically, the liquid handling robotics support in Clarity LIMS enables you to automate sample placement and output sample creation and track instrument logs.



LIMS Automation

Reducing the amount of manual interaction with a system not only supports the reporting of accurate real-time documentation, but it reduces errors and speeds the turnaround time from sample receipt to data acquisition. Clarity LIMS enables qualified staff to automate a wide variety of functions such as:

- » Assigning samples to workflows
- » Defining sample placement and container type
- » Pooling samples
- » Adding reagent labels to samples
- » Assigning next steps in the workflow

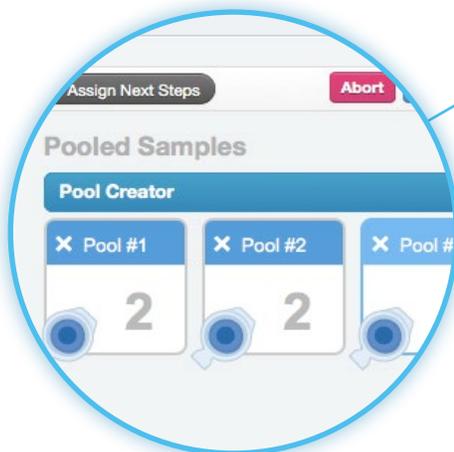


Lab scientists no longer have to spend precious time manually entering data into the LIMS. These important resources are freed up to accomplish other tasks.



Remove the manual set up burden from lab scientists. Set up business logic to automatically create pools.

Clarity LIMS automatically creates correct pools without any required manual interaction by users.





INSTRUMENT INTEGRATIONS



What if you could integrate with common instruments without the need for software resources?

Genomics and mass spec technologies are complex and many labs struggle to keep pace with new technology, instruments, and methodologies. Clarity LIMS is built specifically for genomics and mass spec labs to simplify the integration process.

Instrument integrations are available for many common quality control, sample preparation and assay instruments, such as:

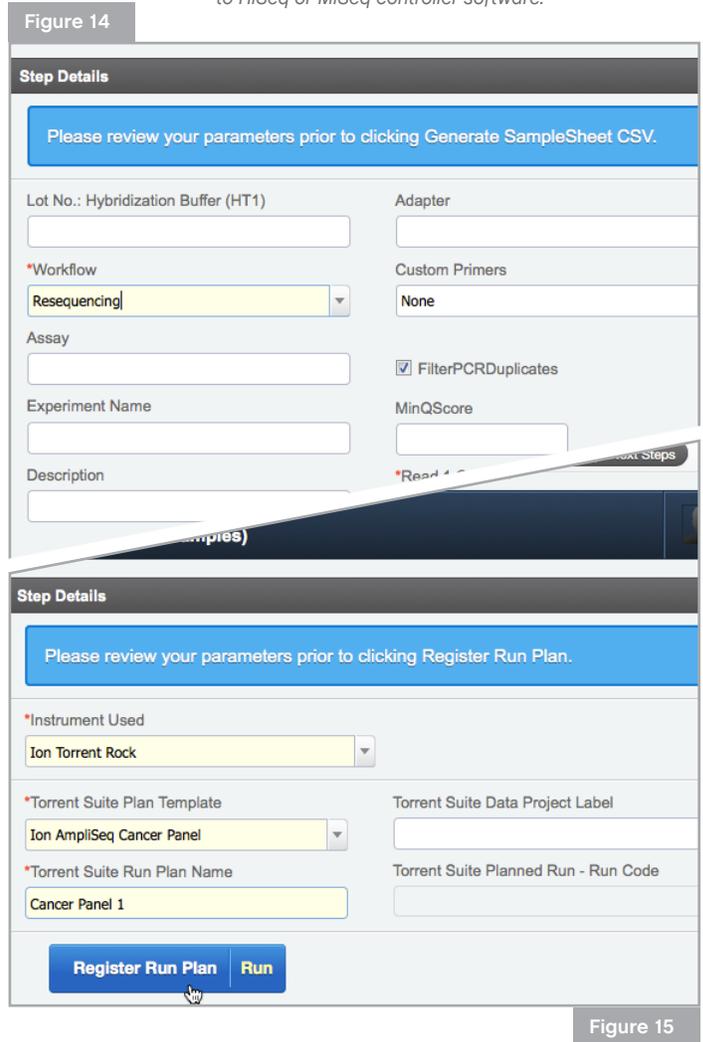
- » Next-generation sequencing
- » Sanger sequencing (capillary electrophoresis instruments)
- » Microarrays
- » Mass spectrometry
- » RT-PCR

These instrument integrations automate manual tasks, reduce errors and enforce lab and industry best practices.

Figure 15 – Instrument interoperability and integration.

GenoLogics works with instrument vendors to build instrument integrations that automate data transfer tasks between Clarity LIMS and instruments. This figure depicts the fields entered by the user to automatically create run plan on the Torrent Suite™ Software for a Ion Torrent™ or Ion Proton™ run.

Figure 14 – Automatic creation of Illumina® sample sheet. Clarity LIMS uses sample tracking data entered throughout the sample preparation process to automatically generate and submit sample sheets to HiSeq or MiSeq controller software.



“CLARITY DOES AN AWFUL LOT OF THE HEAVY LIFTING FOR US...CAPTURING MANY OF THE METRICS THAT ARE BEING GENERATED BY EACH ONE OF THE HISEQ MACHINES”

Dr. Warren Kaplan, Chief of Informatics, Garvan Institute



CLARITY LIMS EDITIONS

What if you could grow your LIMS as your business needs grow?

From small, regulated institutions to large commercial or academic genomics and mass spec centers, there's a Clarity LIMS that fits your needs.

For more information on specific editions or for pricing, visit www.genologics.com

FUNCTIONALITY	CLARITY LIMS	
	Silver	Gold
Sample Traceability	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Preconfigured Workflows	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Configurable Workflows	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dashboard Reporting	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Data and Workflow Enforcement	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Collaboration	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Extensibility Through APIs	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Automation and Robotics Integrations	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Instrument Integration	<input type="checkbox"/>	<input checked="" type="checkbox"/>





Clarity LIMS™
Intuitive Lab Management™

For more information visit:
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