

Automating the Research Lab in the Face of a Rising Tide of COVID-19 Tests



EASING COVID-19 IMPACTS

A LIMS designed to manage COVID-19 workflows eases the pain of drastically condensed timeframes, exponentially greater sample volumes, new sample safety protocols, depletion of consumables inventory, and data integrity requirements.

The global spread of COVID-19 has created a tsunami of data that both diagnostic and research labs are having to deal with. As governments around the world deploy testing on an unprecedented scale to identify and contain SARS-CoV-2 outbreaks, and companies attempt to bring employees safely back into the workplace with testing, research labs have access to a treasure trove of COVID-19 samples. These include both SARS-CoV-2 infections and antibodies from those previously infected.

According to data from the US Centers for Disease Control, about 560,000 tests were being conducted each day in the US in early July 2020, some 100,000 more per day than a month previous. In total, an estimated 15 million tests were conducted across the US during June, about three times more than were conducted in April. Around the world, other countries lagged well behind the US in the number of tests conducted in early July, but the numbers are still massive: 10.1 million people in India, 5.7 million in Italy, and 3.7 million in Turkey.

A Tsunami of Data

With each test comes a demand on laboratories for a wide range of activities—from cataloging samples they've received, preparing the specimens for testing, recording the test data, reporting data, storing the samples for further research, and then retrieving them when needed. Each step in the process must be carefully annotated, and security must be maintained throughout.

For labs doing all that work manually, using some combination of paper records or spreadsheets, the rapidly rising demand for testing is akin to an approaching tsunami.

Like a tsunami, where a tidal surge initiates deadly inland flooding and related infrastructure destruction, the impact of a crushing wave of COVID-related tests could be a chain reaction of events. As test samples multiply, labs that still rely on manual processing could back up, bog down, and create chaos for those depending on results to slow the spread of the disease by identifying those infected, isolating them, and initiating contact tracing. In early July, it was reported that states like Texas had begun to limit tests based in part on the backlog at clinical diagnostic labs. Research labs are also affected, with requirements for new sample safety protocols, rapid depletion of consumables inventory, and demands to compress timelines for experiments and studies that lead to therapies or vaccines.

THE LABVANTAGE ADVANTAGE

Fully featured SaaS version of LabVantage's biobanking LIMS solution for COVID-19 diagnostic testing and research; also available as on-premise or cloud-hosted

- COVID-19 research and testing workflows built-in based upon CDC and other regulatory requirements; continued product investment in features to support your lab as CDC guidance continues to evolve
- LIMS will grow as your needs expand beyond COVID-19
- Product workflows can be configured based upon the specific needs of your lab
- Embedded ELN, LES, and SDMS functionality eliminates need for multiple vendor solutions and complex interfaces, reduces paperwork, and simplifies data management and ensures data integrity
- From data retrieval to lab execution to sample lifecycle management, a single system removes silos from workflows and enables collaboration across the organization

Rising demand in labs without automated systems also brings with it an increased possibility of errors as the facilities struggle to meet the need, which often entails either quickly onboarding new employees or shifting assignments for existing lab workers. Any task where data entry is done by hand is prone to human error, and the need to bring in new employees—or shift workers from their regular tasks to something more urgent—only exacerbates the problem.

For research labs, where biobanking—storing specimens for future use—is a key focus, the massive increase in the number of incoming samples presents a further logistical issue. Each specimen that enters the lab must be accurately labeled and recorded in a system that allows for easy query and fast retrieval. The pandemic has significantly increased the importance of biobanking since they hold vast promise for those seeking vaccines, treatments, and new testing modalities, but the increased inflow of samples to the repository present many unique challenges that must be overcome quickly for such research to succeed.

The Power of a Purpose-built LIMS

At the best of times, a laboratory information management system (LIMS) can help increase the speed of test processing, reducing costs by automating and streamlining lab workflows. In the current situation, LabVantage's purpose-built COVID-19 LIMS provides a powerful, flexible, and easy-to-use solution that can be quickly implemented to scale up to meet burgeoning demands for diagnostic testing and clinical research.

Built using the company's industry-leading LIMS technology, LabVantage COVID-19 LIMS is a turnkey solution that can be up and running in a matter of weeks.

LabVantage's informatics platform handles request management, next-generation sequencing workflows, consumables management, and controls the statistical process. The platform automatically captures a complete, GxP-compliant audit trail in accordance with proposed data integrity guidelines from the FDA, including changes in temporary data (entries made before saving). Because it interfaces directly with lab instrumentation, the platform replaces most manual data entry processes, reducing the risk of human error. For example, when a specimen enters the lab, the COVID-19 LIMS automatically imports data from the electronic manifest so there's no keyboarding required. A system map determines the most appropriate storage place for the sample, and the integrated Seagull Scientific Bartender® barcode labeling software generates the appropriate label, ensuring quick and error-free retrieval.

Flexible Hosting Options

While the COVID-19 LIMS can be hosted on-premise or in the cloud, the SaaS formulation helps users conserve capital budgets because they only pay for what they use, and the annual subscription fee provides access to the full LabVantage platform—which includes the LIMS, biobanking, workflows and methods, consumables management, barcode labeling software, start-up training, and ongoing support.

Based on a study¹ conducted in early 2020, a subscription-based SaaS LIMS could produce a saving of as much as 32 percent compared with the expense of an on-prem solution. A subscription-based solution can also be the ideal answer to a limited-time situation like pandemic testing, offering the advantage of scalability, flexibility, and ease of adoption.

Along with cost efficiency and flexibility, LabVantage SaaS offers several other benefits:

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Rigorous data integrity management ensures end-to-end COVID-19 diagnostic testing and research data integrity

- Comprehensive traceability and dataset management
- Audit trails of temporary data ensure compliance with 21CFR Part 11 and Annex 11, without manual intervention
- Configurable user permissions secure patient data and study integrity
- Built-in workflows and protocols ensure data records are collected according to ALCOA+ regulations

- Increased productivity with global availability
- Elimination of outdated software
- Instant scalability to meet business demand
- Less downtime
- Streamlined software licensing
- Built-in disaster recovery
- Data integrity

Utilizing a zero-footprint client, LabVantage is able to offer a LIMS platform that requires no special installation or maintenance, and needs only a web browser and address to use. All data is stored on, and served from, a long-term database server, requiring no bank of viewing software servers at the customer's end.

In addition, LabVantage's comprehensive approach to streamlining lab data integrates its LIMS with capabilities for an electronic laboratory notebook, a laboratory execution system, and a scientific data management system. Embedding those capabilities into the LIMS maintains a consistent user experience and limits the need to manage a stack of solutions from multiple vendors.

As a result, customers enjoy the benefits of robust and flexible storage options, simplified data management with fewer bottlenecks, and guaranteed data integrity.

For those organizations that have fully embraced cloud storage, the LabVantage LIMS offers the stability of being hosted through the company's partnership with Amazon Web Services and other cloud providers, along with a number of other benefits:

- No hardware purchases
- Accelerated setup and installation
- Flexible memory, disk space, number and speed of processors
- Built-in disaster recovery
- Global availability
- On-demand availability for short-term use
- Flexible server management
- Easy modification for specific, emerging requirements

Security, Not an Issue

As with any health-related information, personal privacy and the security of individuals' data is of utmost importance. The security protocols and permissions related to the COVID-19 LIMS are highly configurable, with sensitivity toward context, patient, and study anonymization, ensuring that patient data is protected to meet the requirements set out by the US Health Insurance Portability and Accountability Act and the EU's General Data Protection Regulation.

Encryption is included in multiple stages, including all data within the cloud servers and in the VPN tunnels associated with the SaaS. LabVantage is also highly proactive in terms of

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Scalable and flexible modern LIMS platform with a pre-configured solution for COVID-19 testing and research

- Platform is the result of 35+ years of experience in lab informatics with ongoing investment in product development driven by workflow best practices and technology advancements
- Modular and flexible technology easily accommodates growing and/or changing needs
- LabVantage platform, even on-premise, runs as a zero-footprint client with minimal business processing and no local storage and provides a rich intuitive user interface via HTML 5 requiring no administrative and maintenance overhead

ensuring security through penetration testing and other activities that allow users to stay out in front of any potential cyber attacks.

Built-in audit trails and workflows make all data ALCOA+ compliant and ensure data integrity.

Designed to Scale

LabVantage COVID-19 LIMS is designed to be as scalable and flexible as needs demand. The platform is the culmination of more than 35 years of experience in lab informatics, with ongoing investment in product development, driven by workflow best practices and advancements in technology. Its modular design easily accommodates growing and/or changing requirements—product workflows can be reconfigured based on your specific needs, whether related to COVID-19 or beyond.

Training and support are part of the package. The LabVantage help desk is available globally 24/7, and support personnel are available as you build up to go live. Once the LIMS is online, the LabVantage customer support group takes over, providing ongoing help and training, as required.

Quick to implement, easy to scale, LabVantage COVID-19 LIMS is designed to automate procedures, no matter what volume of testing and research comes your way.

TO LEARN MORE about how LabVantage COVID-19 LIMS can help automate tasks for greater efficiency in research labs, visit [labvantage.com/covid-19-lims](https://www.labvantage.com/covid-19-lims) or contact us today.

REFERENCES

- ¹ "LIMS Total Cost of Ownership: Cloud Hosting versus On-Premises," LabVantage Solutions, February 6, 2020, <https://www.labvantage.com/lims-total-cost-of-ownership-cloud-hosting-versus-on-premises/>.



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ABOUT LABVANTAGE SOLUTIONS

A recognized leader in enterprise laboratory software solutions, LabVantage Solutions dedicates itself to improving customer outcomes by transforming data into knowledge. The LabVantage informatics platform is highly configurable, integrated across a common architecture, and 100% browser-based to support hundreds of concurrent users. Deployed on-premise, via the cloud, or SaaS, it seamlessly interfaces with instruments and other enterprise systems – enabling true digital transformation. The platform consists of the most modern laboratory information management system (LIMS) available, integrated electronic laboratory notebook (ELN), laboratory execution system (LES), and scientific data management system (SDMS); and, for healthcare settings, a laboratory information system (LIS). We support more than 1500 global customer sites in the life sciences, pharmaceutical, medical device, biobank, food & beverage, consumer packaged goods, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, NJ., with global offices, LabVantage has, for four decades, offered its comprehensive portfolio of products and services to enable customers to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements.

For more information, visit www.labvantage.com.