

The Need for Advanced Laboratory Informatics in a Public Health Crisis



“WHEN A PUBLIC HEALTH CRISIS STRIKES, laboratories need to get mechanisms in place fast to test for the new pathogen. But, without the technical infrastructure in place to send and receive data... any response effort would be futile.”¹

As the most widespread public health crisis of the past century, SARS-CoV-2 has challenged every part of the world, and every stratum of society. In the US—which, with 8.5 million cases of COVID-19 by mid-October, was the country with the most individuals affected out of the 40.9 million cases reported around the world—the pandemic has stretched all elements of the national, state, and municipal healthcare system.

Facing a parallel economic crisis, with demands to return employees to work and students to school, the US has placed enormous pressure on both diagnostic and research laboratories in an effort to process samples from tens of millions of individual COVID tests. A significant portion of that load has fallen on both established public health labs (PHLs) and other labs that have been contracted to take on testing by public health authorities. The increased flow of tests, most of which require molecular assays to complete, has underlined a key fact about PHLs, as outlined by the Association of Public Health Laboratories (APHL): “When a public health crisis strikes, laboratories need to get mechanisms in place fast to test for the new pathogen. But, without the technical infrastructure in place to send and receive data... any response effort would be futile.”¹

Accessioning—the ordering and documenting of samples as they are received by the lab—has presented a particular challenge, highlighting the reality that many PHLs lack digital informatics systems to handle the volume or that are incapable of managing molecular testing. At the other end of the process, PHLs face an additional challenge related to meeting the reporting protocols set out by the Centers for Disease Control (CDC), while, throughout testing procedures, the reliance on manual data handling has strained resources.

With COVID-19 cases surging to new records across the US, Europe, Canada, and elsewhere, there is a clear need for PHLs and those labs handling public health-related testing to quickly adopt an advanced informatics system that can meet the challenges of both today and tomorrow.

The Public Health Challenge in Numbers

To set things in perspective, an overview of national laboratory testing released by the CDC in early October indicated that slightly more than two million specimens were tested in one week (of a total of almost 132 million specimens reported since COVID testing began). Of those two million, 296,000 were processed in US PHLs, 216,000 in

clinical labs, and 1.6 million in commercial labs. (No information is available regarding how many public health-related tests were conducted outside of PHLs.) Of the 100,000 positive tests reported that week, more than 14,000 were reported by PHLs, slightly less by clinical labs, and 72,000 by commercial labs.

That is, of course, just a snapshot of national testing activity, and the CDC notes that “as the outbreak progresses, it is possible that different types of laboratories will take on different roles,” meaning that public health authorities may well contract out a different level of testing to clinical or commercial facilities.

Even at just under 300,000 tests per week, the volume of samples has stretched the capacity of PHLs, especially considering those in the national network remain responsible for ongoing testing and other procedures related to natural disasters, chemical spills, foodborne diseases, post-natal health, and various health emergencies. Although CDC surveys indicate 91 percent of PHLs were able to meet the testing demand, there were other numbers that raise cause for concern, such as the fact that 19 percent reported they would run out of reagents or other testing supplies within a week—an increase of four percent over the previous week.

Besides supplies, testing infrastructure also presents an issue for PHLs. The APHL reports that 39 percent of PHLs have no high-throughput platforms, which allow labs to test many specimens at a time, while minimizing the hands-on time required by lab staff. Add to that the paucity of electronic informatics systems designed to handle the type of molecular testing demanded by the pandemic and it becomes clear that PHLs must take action to head off more serious bottlenecks.

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. In October, Modern Health Care reported anecdotal cases of senior management being pressed into service in labs that were operating up to 18 hours a day to process the heightened volume of COVID tests.²

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 as a SaaS, cloud-based, or on-premise system.

The Power of Informatics

At the best of times, a laboratory information management system (LIMS) can reduce costs and increase the speed of test processing by automating and streamlining lab workflows. 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 in PHLs, along with the adaptability to manage workflows for other types of testing.

Built using the company's industry-leading LIMS technology, the COVID-19 LIMS is a turnkey solution that can be up and running in a matter of weeks as a SaaS, cloud-based, or on-premise system.

From the diagnostic perspective, LabVantage's informatics platform handles request management, next-generation sequencing workflows, consumables management, and the statistical process. The platform automatically captures a complete, GxP-compliant audit trail in accordance with 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

IF YOU NEED A LIS

LabVantage also has the solution if your testing facility is part of a hospital or reference lab, where data is more patient-centric and a laboratory information system (LIS) is more traditionally suited to your needs. Our LabVantage Medical Suite has built-in and configurable multidisciplinary workflows and powerful business intelligence tools to seamlessly address your needs—chemistry, hematology, pathology, genomics, molecular, microbiology, and other general lab functions—all on one platform. Our common database across all lab disciplines allows for total information access without interfaces or logging in to multiple systems. Spending less time searching for patient data, along with fewer interfaces to manage, simplifies lab functions and reduces costs.

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.

Essential Flexibility

While the COVID-19 testing LIMS can be hosted on-prem 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.

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

- 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 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.

Security Prioritized

As in any health-related issue, 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, employee, or student 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 ensuring security through penetration testing and other activities that allow users to stay out in front of any potential cyberattacks.

For COVID-19 testing, the LIMS offers complete electronic patient record tracking, with pre-configured templates and forms, including eConsent support. This helps ensure that CDC-mandated patient metadata can be easily tracked, along with risk and symptom indicators, physician prescription and record, an electronic case record, and other forms.

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

THE LABVANTAGE ADVANTAGE

With 40 years of experience providing digital informatics solutions, LabVantage has the processing expertise and insight to help you develop what you require to meet your specific needs. Our highly configurable, web-based LIMS/ELN/LES/SDMS powers hundreds of labs globally, large and small. Built on a platform widely recognized as the best in the industry, LabVantage can support hundreds of concurrent users as well as interface with instruments and other enterprise systems. LabVantage domain experts advise customers on best practices and maximize their ROIs by optimizing LIMS implementation with a rapid and successful deployment.

| LabVantage LIMS Features | Benefits |
|--|--|
| Pre-configured COVID-19 extracting and testing workflows with fully featured biospecimen management, including molecular assays | Quickly ramp up testing and/or research abilities with built-in OMICS workflows, CDC test methods, and pre-populated master data specific to COVID-19 |
| Complete electronic patient record tracking for COVID-19 testing with pre-configured templates and forms, including eConsent support | Easily track CDC-mandated patient metadata with pre-built patient intake, risk, and symptom tracking, physician prescription and record, electronic case report, scheduling, and other forms |
| Comprehensive sample data traceability for COVID-19 research | Increase research velocity and accuracy with robust patient metadata query capabilities, full-life genealogy tracing, and pool testing and tracking |
| Built-in audit trails and workflows for making all data ALCOA+ | Ensure data integrity and comply with 21 CFR Part 11 and Annex 11, without manual intervention |
| Highly configurable security and permissions, sensitive to context, patient, and study anonymization | Protect private data and study integrity, in compliance with HIPAA, GDPR, etc. |
| Scalable consumables inventory management and Seagull Scientific Bartender® barcode labeling software | Start small or scale to manage many samples, related to COVID or other tests, including automation such as thresholds for supply reorders |
| Robust reporting and communications framework based on web services architecture | Reduce reporting administration time, and meet state and CDC reporting requirements, report on patient health, and adjust as needed with ad-hoc reporting |
| Integration with instruments and systems, including EMR/HER via pre-built instrument drivers and interfaces (e.g., HL7 and XML) | Accelerate testing and research processes, and reduce errors via seamless communication with instruments and downstream systems |

Scalability for Today and Beyond

LabVantage's COVID-19 LIMS is designed to be as scalable and flexible as needs demand. The platform is the culmination of 40 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 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, the LabVantage COVID-19 LIMS is designed to automate procedures, no matter what volume of testing comes your way. And, while the COVID-19 LIMS is purpose built, the software can be easily adapted to address all your public health workflow challenges, including environmental testing, ensuring your lab will be equipped to function more efficiently for whatever types of processes are being undertaken.

Whatever your specific needs, your best solution for managing public health data in challenging times is close at hand.

LEARN MORE about our advanced informatics solutions for the COVID-19 public health crisis – and beyond – at labvantage.com/PHL.

REFERENCES

- ¹ "COVID-19 Informatics Resources." Association of Public Health Laboratories. aphl.org/programs/informatics/Pages/COVID-19-resources.aspx
- ² "Labs scramble to fill new information systems needs during COVID." Modern Health, October 5, 2020. modernhealthcare.com/information-technology/labs-scramble-fill-new-information-systems-needs-during-covid



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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.