

THE CASE FOR A PURPOSE-BUILT LABORATORY INFORMATICS SYSTEM

Positioning Your Diagnostics Lab for Success



FROM THE EXPERTS

According to Michael Shanler, Analyst, Gartner, “If the situation presents itself, take the opportunity to reduce the footprint of legacy ELN and LIMS systems, consolidate them into one system that is more suitable for expansion with the enterprise, and extend it to collaborators and supply chain partners.”¹

– Gartner

WHY A PURPOSE-BUILT LIMS?

The Data Management Challenge

A successful lab is more than a scientific hub. In today’s age, it’s a digital data enterprise. An oil and gas lab managing hundreds of concurrent tests, a food and beverage lab tracking incubation in real time, a biobanking lab with a vast and complex inventory of samples – it’s all data. And it grows exponentially day by day, week by week, creating an urgent need for an integrated informatics platform where that data can be securely and efficiently stored, retrieved, and analyzed.

But should that platform be one-size-fits-all across industries? A pharma lab needs regulatory documentation, while a diagnostics lab requires advanced tracking of biospecimens. Traditionally, each would begin with the same basic building blocks: a Laboratory Information Management System (LIMS) with standalone point solutions such as an Electronic Laboratory Notebook (ELN) or a Laboratory Execution System (LES) daisy-chained together to approximate an end-to-end solution. Then, through a complex à-la-carte development and validation process, each of these labs would customize their platform in response to their divergent needs. Repeated for every organization, across every industry, this bulky deployment process represents an enormous amount of cost and effort, and a considerable degree of risk.

Until now.

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The Case for a Pre-Configured, Fully Integrated Solution

A purpose-built LIMS, with the option to embed ELN, LES, and other modules, leapfrogs the lengthy customization process. Because your industry’s best-established workflows and operating procedures determine its functionality, your platform is configured to meet your needs before you’ve even begun. The advantages of this accelerated start are numerous and notable.

1. Save Time

A pre-configured LIMS can deploy up to 75% faster than a more typical LIMS system. Its purposeful functionality reinforces a consistent, industry-standard workflow to help your lab achieve greater efficiency and productivity.

2. Save Money

Faster deployment and improved functional efficiencies translate to significant cost savings. Abandoning stand-alone ELN and LES products and other point solutions in favor of pre-packaged, fully embedded modular capabilities in one streamlined platform will help you maximize your return over time.

3. Reduce Risk

A purpose-built LIMS reflects industry best practices and the latest regulatory and compliance developments within your industry. As a result, it eliminates the need for custom code and reduces the overall configuration effort, thereby lowering the risk inherent with other LIMS projects.

4. Stay Focused

Lab managers can conceal or disable non-essential functionality in the purpose-built LIMS. The result is a user experience that's responsive not just to your industry, but also to the specific needs and use cases of your front-line staff. That means less training time, greater productivity, and better quality overall.

5. Future-Proof Your Business

Industry regulations and conditions change over time, and your lab will likely change too – you may add new service areas, new tests, or new users as you grow. A modular, purpose-built LIMS that makes use of industry-standard web technology can expand with you, from startup labs through global operations, without the prohibitive time, cost, and compliance issues of specialized coding.

Built Better for the Diagnostics Industry

Clinical and molecular diagnostics labs have their own specialized needs. What they need is to have their own specialized LIMS system.

Diagnostics labs have countless responsibilities. They're managing requests from initial intake through complex testing and reporting. They're providing physicians with the accuracy needed to have informed diagnostic and treatment discussions with patients. They're under pressure to meet the certification requirements of CLIA, CAP, and BAP. And they're doing all of that using costly instrumentation and consumables, requiring a careful balance between high-quality service and cost-effective processes.

For labs operating on outdated or insufficient data platforms, these pressures quickly multiply. What happens when a network of spreadsheets collapses? Or when an analyst drops a digit while copying data between screens? Or when a faulty instrument persists undetected?

An informatics platform that can shoulder many of these responsibilities would include a request management system, an advisor on next-generation sequencing (NGS) workflows, a consumables manager, and a statistical process control center. LabVantage Diagnostics handles all these responsibilities and much more in a single, centralized platform. And because its diagnostics-specific functionality deploys out-of-box, it's also fast to implement, intuitive to use, and responsive to the shifting and expanding needs of rapidly growing labs.

SKIP THE COST AND AWKWARDNESS OF A ONE-SIZE-FITS-ALL SOLUTION.

LabVantage Diagnostics is the result of many years developing and implementing LIMS systems in the diagnostics space. It includes ready-to-go functionality for clinical and molecular diagnostics labs, helping them handle specimens and monitor arrays in a high-throughput environment.

A few of the features pre-configured for diagnostics labs include:

- Built-in diagnostics workflows. The platform comes with common diagnostics processes built in, including NGS workflows.
- Statistical process control charting. The LIMS integrates tightly with instrumentation, helping labs identify errors and correct them the moment they appear.
- Precise inventory management across the whole lab. Reagents, collection kits, and the specimens themselves—the platform tracks it all, providing detailed traceability and tracking.

Earn and Keep Customers' Trust

The digital platform is built to improve a lab's reputation with customers in multiple ways:

- **Improved data integrity.** 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). And because it interfaces directly with lab instrumentation, the platform replaces most manual data entry processes, reducing the risk of human error.
- **Faster turnaround time.** The platform includes NGS workflows and industry-standard master data, eliminating the time-consuming customization process and accelerating overall workflow.
- **Competitive pricing.** The platform is designed to greatly lower operational costs; labs can pass these savings on to customers, giving them an advantage in a highly competitive market.

Lower the Cost of Testing

Running a test with low-quality samples wastes significant time and money. The platform protects against this loss by integrating directly with lab instruments, including liquid-handling robotics. If a sample doesn't have enough DNA to run a genetics test, for example, the LIMS system can prevent the test from moving forward, preserving inventory and avoiding re-tests.

Consistent Specimen Management from Request Through Final Reporting

The platform tracks every specimen's location and parentage precisely and in real time, helping labs manage inventory and locate specimens at any point in their lifespan.

Clear and Compliant e-Signature Functionality

Whether a medical director needs to issue a conclusion based on aggregate results or simply approve an analyst's work, the platform provides the necessary tools. Its Workflow Designer is agile enough to fulfill both internal SOPs and consistent enough to enforce U.S. and EU rules governing e-signatures (21 CFR Part 11 and Annex 11).

Maintain Compliance

The platform is designed to comply with all relevant regulation, including CLIA, CAP, 21 CFR Part 11 or Annex 11 requirements.

The Accelerated Implementation Experience

Choosing a purpose-built LIMS is like strapping a rocket booster to the implementation process. It means much of the background work is complete before you even begin, giving you a head start without sacrificing consistency, compliance, or performance.

Here's how the LabVantage implementation process compares to a typical implementation experience.

A Typical LIMS Implementation	LabVantage LIMS Implementation
<i>Minimum 12 months to deploy</i>	<i>Deploys in as few as three months</i>
<p>A massive up-front investment drives this deployment process, which begins with a detailed discovery and documentation of user needs and progresses through multiple design iterations and testing phases. Heavily customized and configured systems introduce risk and its corresponding compliance requirements, necessitating a significant investment in validation and test planning.</p> <p>Once fully customized and compliant, the system is ready for use – but only after a significant investment in training for all users and administrators. Training timelines are contingent on the complexity of customization and are often a significant factor in typical deployment costs. When updates are required after deployment, the vendor must be involved for specialized customization and/or installation, further adding to the costs and time required to maintain performance.</p>	<p>Because this system is already configured for your industry using established industry best practices, the implementation process is much more efficient. Data templates are integrated and the products and functions most commonly relied upon by industry-specific users are engaged and ready. If further configuration is required, the system's modular design is easily adaptable without code; ongoing updates and enhancements require no specialized skill or outside management.</p>

Run Your Digital Enterprise with LabVantage

Across industries, every successful laboratory functions at the nexus of talent and technology: the right people using the best, most streamlined tools. And as the market's leader in modern and efficient LIMS solutions, LabVantage is essential to that winning formula. Here's why.

The Best and Most Secure Technology in the Industry

Our feature-rich LIMS is completely web-hosted, giving networked users access to the same information from one secure, easy-to-use system – whether they are in the same lab or across the world. Hosted on-premise or in the cloud, the system also connects labs with third-party contributors outside of their firewall, like manufacturing partners or research organizations, allowing for harmonized data input through a single platform.

A System That Adapts to Your Needs – Without Code

Our purpose-built LIMS features a modular design that invites further configuration and adaptation without specialized coding skills. Users can configure their platform themselves or rely on our global professional services team to do it; both scenarios reduce the cost, effort, and complexity of additional testing and compliance.

A Fully Interoperable Experience From Start to Finish

No more siloed informatics systems for individual use cases within a product life cycle. Our system interconnects your processes within a single, central hub, meaning that documentation generated during early R&D explorations is consistent throughout manufacturing and final quality assurance testing. The result is a more efficient lab with fewer opportunities for risk, leading to a stronger business performance overall.

A Professional Support Team in Lockstep With Your Needs

From deployment through validation and ongoing monitoring, our global professional services team of solution engineers, business analysts, and project managers offer consistent and top-rated support services. We seek to become more *partner* than *vendor* through our managed services offering; for example, our team will regularly monitor, optimize, administrate, and enhance your system, giving you greater confidence and more control over your IT and labor costs.

Conclusion

LabVantage Diagnostics is designed to help labs turn first-time customers into long-time advocates through fast, high-quality service.

Enhance your diagnostics lab with the full-featured, entirely web-based informatics platform designed specifically for success in your industry.

TAKE ADVANTAGE of LabVantage Diagnostics at LabVantage.com/diagnostics

REFERENCES

¹ Gartner, "Hype Cycle for Life Sciences, 2018", Published 25 July 2018, Analyst(s): Stephen Davies, Michael Shanler, Jeff Smith



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ABOUT LABVANTAGE SOLUTIONS

LabVantage is the recognized leader of enterprise laboratory software solutions with over 35 years of experience. We deliver an integrated laboratory informatics platform including laboratory information management systems (LIMS), electronic laboratory notebooks (ELN), and laboratory execution systems (LES). We support more than 1500 customer sites in the life science, pharmaceutical, medical device, biobank, food & beverage, consumer packaged goods, oil & gas, genetics/diagnostics, and healthcare industries. Headquartered in Somerset, N.J., LabVantage offers a comprehensive portfolio of products and services that enable companies to innovate faster in the R&D cycle, improve manufactured product quality, achieve accurate record-keeping, and comply with regulatory requirements. The LabVantage integrated LIMS/ELN/LES platform is highly configurable, purpose-built, and 100% web browser-based to support hundreds of concurrent users and seamlessly interface with instruments and other enterprise systems.

For more information, visit www.labvantage.com.