A Lab With a One-of-a-Kind Test Configures a One-of-a-Kind Informatics Solution

For some time, physicians understood disease activity through a relatively simple test: they would pinch a patient's joints in 28 places and record their reported pain score. They called this DAS28, or Disease Activity Score 28. Some physicians improved on the subjectivity of this test by considering single biomarkers as well, but the fact remained: this was a time-consuming and imperfect method. As long as it was the best we had, it worked. Then a leading molecular diagnostic company came along and the needle moved. Suddenly, "the best we had" got a lot better.

This company offers innovative products that transform patients' lives. Their advanced blood test assesses disease activity based on a number of biomarkers, producing a score between 1 and 100 that categorizes, for example, the autoimmune disease activity of a patient as low, moderate or high. As a replacement for the largely subjective methods, this lab-generated result gives physicians and their patients the quantitative assessment they need to develop informed treatment plans.

Physicians are paying attention. The lab, whose parent company has a policy against endorsing third parties and thus requires anonymity, now processes 700 samples daily, delivering results within five to seven days. Maintaining this momentum while developing new products and services is not easy; to do that, they need an informatics solution that can not only keep up, but also help drive the company forward.

A One-of-a-Kind Lab Seeks a Pioneering LIMS

In preparing the launch of the diagnostics lab services company, the management team remembers searching for a modern, cost-effective alternative to a Laboratory Information System (LIS). While an LIS was a common tool in hospital testing labs, they knew it would be too rigid to support the innovation and discovery that they had in mind. As a new and aspiring entity, they were not interested in an informatics solution that would commit them to a fixed way forward. They needed something

more fluid, a powerful but flexible informatics platform that could help them stay on top of both their R&D objectives and their clinical diagnostics throughput. Eventually they would add manufacturing activities to that list—another reason to prioritize flexibility.

Management looked for a solution that would serve each of these requirements without draining their bottom line. For them to buy into a laboratory informatics platform, they would need to find one that could buy into them—one that they could modify to make "their own" but without costly and time-consuming customizations. With this mandate in mind, they found LabVantage.

ONE LAB, THREE LIMS INSTANCES

A high degree of configurability attracted a leading molecular diagnostics lab services company to the LabVantage solution from the start. Today, they run their operations using LabVantage LIMS configured for three different branches of their operations.

1. **Clinical LIMS:** To help manage all test requisitions, sample shipments, assay batching and laboratory communications.

2. **Development LIMS:** To manage intellectual property and support ongoing R&D activities.

3. **Manufacturing LIMS:** To support the production of reagents and kits.

"This is a product that buyers can mold to their own shape [through configuration]," explains the lab's director of software engineering. "With LabVantage, you get the tools you need to implement a solution that's right-sized for your needs. The way we work with the LabVantage platform is different from the way another lab works with it, which is its beauty. It's like a fingerprint, unique for each of its use cases."

For this lab, those fingerprints show the loops and whorls of a company defined by its drive to efficiency and to offer a fast, concierge-like customer experience. They've configured LabVantage LIMS to help them do both.

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How LabVantage Helps Staff Improve Throughput

LabVantage LIMS is integrated with the lab's Electronic Medical Records (EMR) and AutoFax delivery systems, which helps staff move samples through the pipeline with fewer headaches or time spent on manual data transfer. To further improve on this level of seamlessness, lab IT reskinned the system's front-end to better support its users, while the backend remains powered by the LabVantage engine. The software engineer says that this capability—to layer their own user interface onto a powerful and sophisticated LIMS—is a rare and significant advantage, demonstrative of just how much configurability is built into the system.

"We were able to offer staff a user experience that's configured with their needs and responsibilities in mind," he said. "From opening boxes in the shipping department to issuing final reports, our staff can rely on an end-to-end platform that they know is tailored just for them."

How LabVantage Elevates Their Customers' Experience

When thinking about a physician's customer experience, the lab wanted an unrivaled accessioning process that reduces risk and error. When staff unbox a shipment and add a new sample to the pipeline, there are opportunities for error. What if the sample is insufficient? What if the requisition form is missing key demographic information? In another lab, these problems might cause unaccountable delays (as well as irrecoverable costs), impacting the physician's experience and negatively affecting the company's brand.

Not so for this lab. They use the LabVantage LIMS to ensure that even problematic shipments are efficiently and proactively managed. The system alerts its operators when something requires attention, essentially pulling the handbrake on a futile test and thereby saving the lab from squandered time and money. This handbrake is a trigger for the lab's customer service team to take action. With the insights provided via the LIMS, they know exactly what's missing from a given requisition and can contact the physician immediately to request a new sample or chase down missing patient data.

In this scenario, everyone wins. The diagnostic lab services company can maintain a high-velocity throughput without costly do-overs. Physicians aren't stalled by a poorly managed callback system. Most of all, patients are given clear, actionable test results quickly, helping them manage their disease more effectively.

"With LabVantage powering our lab, we've built out a really nice, efficient workflow that starts with a question and ends with a clear answer," the engineer says. "The question is, how active is my patient's disease? The answer is a quantified value made possible by a lab that's doing what no other lab can do. Our LIMS is there at every step, from accessioning to final results, helping us make this all possible."

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THE ROLE OF LIMS IN PROTECTING PATIENTS

The LabVantage solution helps diagnostic labs maintain a pristine reputation for safety and data integrity in three key ways:

- **Protected data:** Labs can use a segregated instance of LabVantage LIMS that is uniquely configured to provide extra security for patients' Protected Health Information (PHI).

- **Comprehensive audit trails:** The system automatically captures and identifies data and configuration changes in accordance with 21 CFR Part 11, including user ID, date/time, reason for change, original value and new value.

- **Reduced dependence on manual data entry:** Laboratory robots interface directly with the LIMS, populating it with sample data without the potential for error or omission.

Parting Wisdom

Asked what he would advise another diagnostic lab seeking a new LIMS, this lab's software engineer doesn't hesitate.

"You can't beat LabVantage," he says. "It performs in two important categories that can be hard to find together: configurability and stability. We've used it to help scale from a relatively unknown entity to a lab that's processing 700 samples a day. LabVantage has been with us from the beginning, and I'm sure it will be with us far into the future as we continue to grow and innovate."

ABOUT LABVANTAGE LIMS

LabVantage, the most flexible LIMS in the market, is trusted by the largest companies to run their labs. Run your lab more efficiently by automating tasks and integrating with instruments and systems. With a flexible system along with an experienced professional services team, you minimize the risk of project delays or failures. Once live, the system can easily adapt to evolving business requirements. LabVantage lets you reduce your total cost of ownership through reduced maintenance and training.

TO LEARN MORE about LabVantage visit, labvantage.com

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ABOUT LABVANTAGE SOLUTIONS

LabVantage is the recognized leader of enterprise laboratory software solutions with nearly 40 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.