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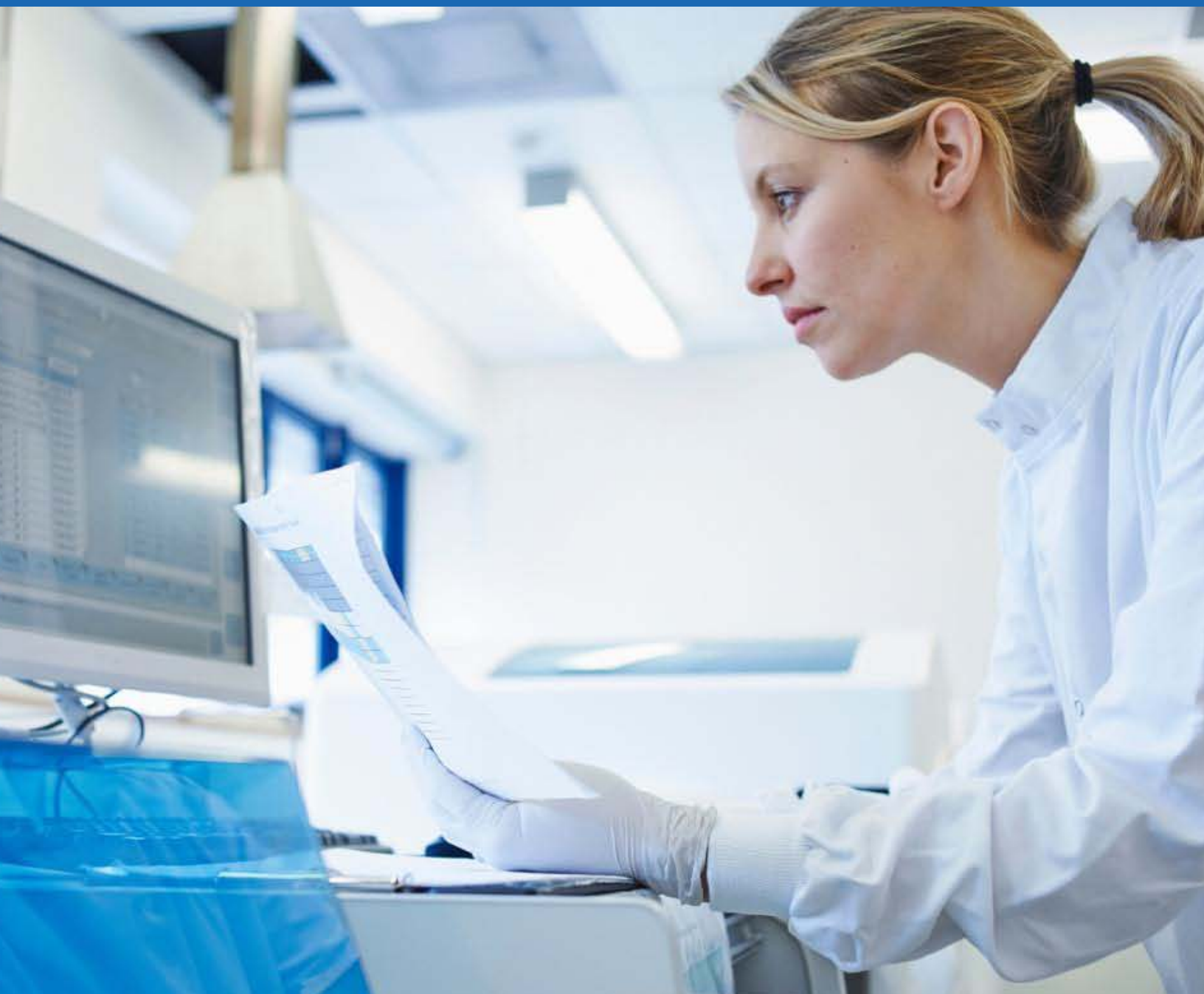
WHITE PAPER

Effective Lab Automation

How modern LIS systems increase productivity while driving down costs



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Abstract

From staffing issues to increased regulatory oversight to potential fee cuts, today's labs are facing a daunting gauntlet of challenges. A Laboratory Information System (LIS) is an essential component for effective lab automation that increases productivity while driving down costs. This white paper examines what to expect from a full-featured LIS and how to pick the best one for your organization.

Challenges for Today's Labs

Today's labs are serving a vital function in delivering improved outcomes for patients. However, labs are facing a number of challenges from staffing to cost increases to potential fee decreases. And that's just for starters. In order to address these challenges, small clinics and large hospitals alike are turning to lab automation solutions to drive efficiencies.

Historically, these digital solutions were developed for specific applications, such as medical billing. Over time various healthcare systems emerged, including Practice Management Systems (PMS), Healthcare Informatics Systems (HIS), Electronic Medical Records (EMR), Electronic Health Records (EHR), and Laboratory Information Systems (LIS). Some Information Technology (IT) vendors bundled all these capabilities into an all-encompassing solution, but such solutions tend to sacrifice in-depth functionality for overall system requirements.

A best-of-breed LIS can deliver a full set of features at a lower cost, integrate seamlessly with other healthcare systems, and be an essential component for increasing productivity and driving down costs.

What is an LIS?

Clinical laboratories have been able to choose from a variety of commercial LIS since the 1980s. An LIS is designed to process, store, and manage patient medical lab test records. In addition to associating the right test with the right patient, cumulative test results can be examined to investigate demographic and other statistics of importance to the medical community.

Initially, LIS were standalone solutions that handled basic medical test data from order entry to results processing. Today, LIS can accommodate a variety of medical testing needs, from inpatient to outpatient, from hematology to immunology, and now even to molecular genetics. There are specialized LIS for police crime labs that require strict Chain of Custody procedures, and there are LIS for veterinary labs that require species-specific functionality. The common denominator is the medical test record and how well the LIS organizes and manages the data.

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In a sense, the LIS is a component or module of the larger EHR solution that contains non-test related patient data, such as records of hospitalization, visits to healthcare professionals, patient insurance, etc. As such, how well the LIS interfaces with the EHR solution is a critical driver for the overall cost and efficiency of the LIS.

What to Expect from an LIS

At its core, an LIS is a highly sophisticated relational database that manages medical lab test records from requests to results. Because data is captured digitally, the LIS can reduce the time spent managing test records as well as reduce transcription errors.

Every LIS will provide a methodology for lab test management. This includes a range of features and functions that perform patient lab test ordering and tracking; interfaces to lab instruments; interfaces to PMS, HIS, EHR, EMR and billing systems; results processing; data storage; reporting; quality controls; and, statistical analyses. Within each of those areas, the LIS will have a range of capabilities designed to streamline the patient test management process.

However since every lab is unique and has different workflows and priorities, it's wise to specify the LIS attributes most important to yours. Then, when investigating different LIS solutions, you can ensure that the LIS meets your specifications, and not get sidetracked by unnecessary features and functions that add to the overall cost, but won't actually help your organization's workflows.

In essence, with any LIS the goal is to expedite test record processes, interface seamlessly with other healthcare applications and instruments, and automate data collection and reporting. This all needs to be done in compliance with state and federal regulations, which requires flexibility on the part of the LIS since these regulations often change.

How to Evaluate Commercial LIS Offerings

LIS selection should be approached using standard project management methodologies. In addition, because the final decision crosses departments, the LIS project team should involve not only the lab but also purchasing and IT. Purchasing will want the LIS to integrate with the billing system. IT may have infrastructure requirements that the LIS must accommodate. The decision is a team effort.

However the search for an LIS should start in the lab, since the lab is the primary LIS user. The Laboratory Manager will need to ensure that the LIS not only meets all the needs of the lab with regard to managing and reporting test results, but also confirm that there are user-specific capabilities for physicians and technologists alike that enable them to perform their LIS-related activities most efficiently.

User Interface

A simple and elegant user interface is vital to successful user adoption. The less complicated, the better. Easy to find, understand, and use functions make access to patient test data intuitive. For instance, test ordering, ICD-10 checking, and test result entry and verification are just a few of the items that should be no more than a glance and a keystroke away. In fact, the majority of test activity should be performed and accessible from the main screen; users should not waste time navigating through numerous folders and screens to input or retrieve data.

Functionality & Flexibility

The LIS should offer a full set of functions for applications that range from pathology to hematology to toxicology. Determine whether specialized functionality is included in the LIS or whether there are extra costs for adding application-specific "modules." Regardless of how you will use the LIS, standard functions include user-definable lists, rules, comments, and result screens; automated results entry and sample ID number generation; automated and ad hoc reporting; individual and batch request and results entry; multiple range definition based on age, sex, and species; duplicate order checking; and, easy manual entry for offline results. These are the minimums; expect to see many more functions in a robust, full-featured LIS.

You'll want to ensure that key industry standards and codes are supported, including SNOMED CT, LOINC, HL7, NDC, and ICD-10. Even if your initial needs are modest, don't ignore the LIS scalability to accommodate future growth. Functionality is driven by system flexibility. For instance, question how the LIS addresses changes such as the recently implemented ICD-10 codes. How long did it take the LIS vendor to integrate the ICD-10 code changes? Was it well ahead of the deadline? The answer will provide clues as to how responsive the LIS vendor is for delivering new functionality.

Interfacing & Integration

All LIS will enable interfacing with a variety of other healthcare applications and lab analyzers and instruments. The challenge of interfacing goes beyond this basic premise and into the realm of seamless integration. Virtually any comprehensive LIS should be easily integrated to any other clinical information system via a standard HL7 or ASTM interface. Integration also includes enabling access to the LIS by remote clinics or other satellite healthcare stations. Thus web-enabled features for remote access are important in busy, dispersed medical environments.

Reporting

Reporting is a critical attribute, thus the LIS should enable an unlimited number of user-definable report formats. Custom reports should not incur extra costs. Standard report templates that should be included with the LIS include patient cumulative summary reports with graphing; workload reports by category, doctor, and department; charge code reports with CPT and ICD-10 codes; interim patient reports; laboratory report of records, patient chartable reports, and more.

Quality Controls

Quality Control (QC) features ensure regulatory compliance. Look for a fully auditable LIS in which all results are stored, not just summaries. The ability to perform Levy-Jennings plots and charts, cross control level checking, and a range of reporting from daily to monthly to history to summary reports by date ranges should all be accommodated by the LIS. The LIS should comply with CLIA, JCAHO, HIPAA, HITECH, and state and federal regulations.

Data Storage

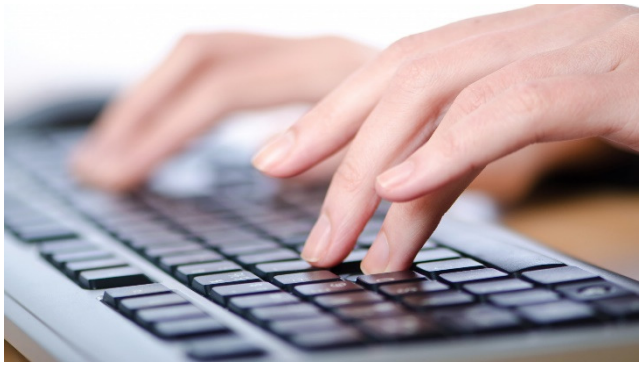
How patient data is stored can dramatically impact system efficiency and responsiveness. Understand the LIS system configuration. Are multiple redundant databases supporting the LIS to ensure zero downtime or does the LIS vendor provide statistics for average system downtime? Question the LIS data ownership and access to it. The majority of Software-as-a-Solution (SaaS)

system vendors own all the data, including yours. Ask if data can be exported to a standard format such as CSV for use in spreadsheet programs. Many LIS make it very difficult if not impossible to retrieve and export patient data, yet this capability is the hallmark of a flexible system.

Statistics & Analytics

Beyond reporting, medical laboratories should have sophisticated statistical and data mining tools at their fingertips to perform real-time data analytics on patient test data. Look for an LIS with population normal range data mining tools. Examine how the LIS performs different statistical reports, such as population studies. The LIS should perform workload accounting automatically, including the ability to set accounting weights for customized reporting capabilities.

System Demonstration



An online demonstration of the LIS should be done early in the process to determine how flexible the system is for meeting your organization's specific requirements and to weed out the systems that don't meet those requirements. Ask to see certain features. Watch how easy it is for the LIS vendor to show how these features work. Can the system perform specific tasks on your requirements list? Are regulatory requirements embedded in the system, such as ICD-10 code screening that automatically confirm accuracy or flag tests if the code does not match?

How long has the LIS vendor been in business? A seasoned LIS vendor will have greater knowledge of industry challenges and deliver the ability to consistently offer a compliant LIS solution over time. Ask about customer support. Does the LIS vendor provide direct live support from system engineers or will you be routed through a phone tree? Are remote support capabilities available via the Internet? How is the LIS vendor organized; e.g., is it focused on system development or are there more sales people than system engineers? An LIS vendor that is weighted toward increasing their bottom line at the expense of product development is not focused on customer satisfaction.

There are many criteria to weigh and discuss before determining the best LIS for your organization. Once you are close to a final decision, it's also important to evaluate the costs associated with the LIS.

Calculating the True Cost of an LIS

LIS have been proven to increase workflow efficiency and cut lab costs, however there are a number of factors besides system price that affect the overall cost before a return on investment (ROI) can be achieved. Bear in mind that an LIS is not shrink-wrapped off-the-shelf software. It is custom software designed to streamline the workflows in your unique lab set-up.

Before you talk to any LIS vendor, create a Functional Requirements Specification (FRS). Your FRS should include equipment, systems and capabilities. Start by creating a list of all analyzers, reference labs, and any systems the LIS needs to connect with to determine hard costs. Determine if you need to replace or add any equipment when you implement the LIS or if you can use existing equipment. Include not just computers that will be used for the LIS, but also printers, bar code printers, modems, etc. Add these hardware costs to the system cost. Consider your wants versus your needs carefully. The accuracy of your list will enable you to accurately estimate project costs.

The LIS will need to interface with other clinical systems and equipment. Some LIS include direct bidirectional interfacing but others require third-party interfaces to connect to other systems or instruments. What is the cost of those third-party interfaces? Will the LIS interface to all the systems it needs to integrate with, including patient management systems, billing, reference labs, etc.? Remember that if the LIS uses third-party middleware for the instrument interfaces, both the LIS and the middleware need to be updated whenever there is a change, which complicates any update process and might incur hidden costs downstream that you need to consider in your budget.

In addition to hardware and interfacing requirements, examine your workflows and procedures. For instance, do you schedule all non-emergency tests (such as thyroid tests) for a specific day each week and batch all requests for that day? If so, can the LIS perform batch processing, or are you expected to change your workflows to accommodate the LIS infrastructure? Batch processing is a standard function, but not all LIS offer it. If you need to implement a new workflow, this will change your processes and that often incurs additional labor costs.

Once your FRS is determined, the various LIS offerings should be reviewed against those requirements, and a short list of LIS vendors created. Get specific details from those LIS vendors on what costs are included and what costs are extra. For instance, if you need to import existing patient data into the new LIS, determine what's involved with performing this activity and whether it incurs additional costs. Most LIS roughly follow the 80-20 rule: 80% of the functions you need will be standard, but 20% will need to be customized to your organization. Discover whether those functions are user-configurable or if you will need to pay extra to the LIS vendor to have those functions implemented. Vendor consulting fees to create functionality can add up quickly, and affect the overall cost of the system.

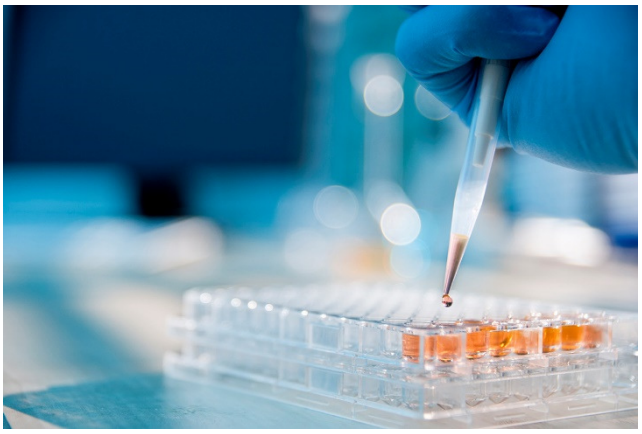
Is the price of the LIS based on the number of users, concurrent users, or the number of seats (workstations)? Each scenario will generate a different cost. How much does it cost if you want to add more users or seats in the future? If you choose a bare-bones solution, are you also eliminating required capabilities from your FRS that will cost extra to add later?

How does the LIS vendor handle upgrades to the system; e.g., are they included in the initial cost of the LIS or will you need to pay to upgrade and what is the cost? How often are upgrades released? For that matter, how does the LIS vendor differentiate between updates and upgrades? Will you be charged for either while under warranty or a service agreement? For instance, the LIS might require software modifications to comply with government regulations such as changes to meaningful use requirements. Does the LIS vendor consider this an upgrade or an update, and what is the cost to you?

Many LIS vendors promote consulting as an add-on to the LIS support contract. Even if the functions are user-configurable, changing a workflow in many of the LIS is so complicated that users often pay hundreds of dollars in consulting fees to have the LIS vendor perform the task after the contract is signed, causing scope creep and budget overruns. How can you determine if this will be the case up front? Ask the LIS vendor what their process is for assisting customers with workflow configurations and the associated costs. An easy to use LIS is exactly

that, and the LIS vendor can readily walk you through the configuration steps as part of the support contract.

Asking tough questions up front helps ensure that you select an LIS that isn't subject to scope creep and that you aren't surprised with hidden costs downstream.



Summary

Today's lab environments rely on cutting-edge tools to supplement previously manual processes associated with patient lab test management. Full-featured LIS have become a mission-critical tool in supporting those activities, particularly in an era of increased regulatory scrutiny and oversight.

An LIS that is installed and operational in a variety of clinical settings, has proven flexible enough to accommodate a variety of functions as well as different disciplines from hematology to toxicology.

Most LIS realize a rapid ROI if the lab is ordering at least 50-75 tests per day. However, if there have been transcription errors, lost lab charges, or you plan to grow lab revenue streams with new service offerings, an LIS can dramatically improve any lab's operations.

A full-featured LIS is one tool in the organization's arsenal that has proven to increase laboratory and organizational productivity and profitability.

About Comp Pro Med

Comp Pro Med has been providing clinical laboratory information solutions since 1983. Our Polytech LIS allows clinical laboratories to expedite patient record management processes, interface seamlessly with any application or instrument, and automate data collection and reporting - all with zero downtime, and all in compliance with state and federal regulations.

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