



Demystifying the LIS and LIMS

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Key Takeaways

- A laboratory information system (LIS) is results-driven and ideal for rapid test reporting in clinical settings. In contrast, a laboratory information management system (LIMS) is datadriven and focuses on long-term sample tracking, data management, and compliance across various industries.
- Choose a software platform that matches your laboratory needs. For example, you can select a LIS for efficient workflow and quick result delivery or a LIMS for comprehensive data organization, advanced analytics, and integration with additional digital tools.
- Integrating both LIS and LIMS or adopting a comprehensive Scientific Management Platform (SMP), including features like electronic lab notebooks (ELNs) and protocol manager, can enhance efficiency, streamline processes, and address all key challenges in laboratory operations.

Introduction

As laboratories continue to embrace cloud-based Scientific Management Platform (SMP) and AI/ML to enhance our efficiency and workflows, there is increased confusion on what to call these tools and their place within the lab ecosystem. The laboratory information system (LIS) and laboratory information management system (LIMS) are perfect examples. Even the <u>Wikipedia article on LIMS</u> attests to the confusion between the terms and their uses.

In this white paper, we'll highlight the differences between a LIS and LIMS, how each is used in the laboratory, and their integration with other software tools.

LIS vs LIMS: Matching the Right Tool and Goals

A LIS and LIMS are different tools to help labs meet different goals. Understanding the different goals of each platform is the first step in clearing up confusion about them.

LIS (Results-driven)

- Provide oversight of the same testing workflow to quickly get results to patients while minimizing the risk of inaccurate reporting.
- Workflow management is a higher priority than organization.
- Results are archived and do not affect future testing results or insights for the lab.

LIMS (Data-driven)

- Increase the efficiency of your data entry and build towards a true sample database.
- Organization is the priority over workflow management.
 Emphasis on maintaining lab operations (samples, supplies, equipment, etc.) in a compliant and error-free manner that will allow for long-term data-keeping.
- Results and other important metadata are indexed and searchable for future export and data analysis.



There are standalone LIS or LIMS platforms, but increasingly there are "all-in-one" lab software with many different functionalities besides LIS and LIMS capabilities. Even if the software you are looking at includes LIS or LIMS in the name, don't be misled, and carefully review the solutions they are providing and if they align more with a results-driven or data-driven approach.

Follow the Sample Journey

Another distinguishing factor to look out for is if sample management is designed to be a short-term or long-term journey.

For a LIS, sample tracking is a short-term experience. Most LIS focus on having a dashboard showing where samples are in the testing process (assigned, started, completed, etc.). Once testing is completed, results are reported to the provider or patient, and the tracking process is completed. Most lab personnel's connection to the sample ends as soon as the results are uploaded, and the rest of the process – namely, any billing or reimbursement tracking tied to the sample – is handled outside the lab.

For a LIMS, sample tracking is a long-term journey. Sample data and results flow into a deeper data lake of useful information, statistics, and trends. Samples that were biobanked years prior can be easily found and tested again with more advanced analyzers or test parameters. All of this stored and generated data serves to maintain compliance and provide deeper insights in advancing basic research, R&D, GMP, pharmaceutical/chemical processes, analytics, and product development.

An Overview of LIS and LIMS Features

A LIS and LIMS are designed to better laboratory operations, but they have different features that match different needs. A LIS focuses on managing sample testing workflows in clinical settings, emphasizing quick results. A LIMS is designed for comprehensive data management across life science, material science, and chemical settings. Understanding these feature differences is crucial for selecting the system that best aligns with your laboratory's goals and operational requirements.





	LIS	LIMS
Data Entry	Typically a one-time event. It may be possible to integrate with an analyzer to automate the process.	One-time or an ongoing and repeated step. May be able to import from an Excel spreadsheet or automate if API access is provided.
Security	Varies. Avoid if you don't see mention of HIPAA compliance	e, SOC2 compliance/certification, or ISO 27001 certification.
Traceability	Focus is on the current status of the patient sample. Location data not relevant. Limited or no biobanking features.	Location, log, and audit trail are key features. Emphasis on biobanking and advanced search tools.
Audit Trail & Compliance	Typically, there is no audit trail per user. Compliance is focused on the QC of analyzers.	Audit trail for any changes made to a sample or inventory. Data entry may have options to automate or standardize to prevent human error.
Target Market	Clinical diagnostics and forensics	Utility in all life science, material science, and chemical industries.
Reporting	Primarily external. Most LIS are designed to provide test results to providers or patients.	Primarily internal. While most LIMS allow you to export data to share, the main focus is on tools to organize and manage data. Be sure to evaluate what exporting capabilities are available and who owns your data.
Equipment Management	Only focused on analyzers associated with the testing process and that need regular QC checks. Data entry can be manual or automated depending on services rendered by LIS developer.	Can include any equipment or analyzers with the possibility to automate data entry through API. Reservation system and validation/PM reminders may be available.
Unique Features	Patient/physician portal and billing tools. May also provide a marketing/sales portal for internal use.	This can vary between LIMS. Some key features to consider: • Molecular biology or chemistry-specific tools. • Advanced metadata search. • Data visualization. • Project management features.
EMR/EHR Integration	Yes, but implementation varies depending on platform.	Possible, but it will depend on API calls available. Usually not a priority.
External Integrations or Add-Ons	Varies.	LIMS could provide turn-key solutions and external integrations via an SDK or API.
Electronic Lab Notebook (ELN)	Not provided.	Not included, but many LIMS developers can include or integrate an ELN at an additional cost.
Quality Management System (QMS) or Protocol Management	Not usually provided, and if so, just as a repository for documents.	Possible integration at additional cost with the ability to "use" protocols and show changes over time.



Supply Management	Usually provided.	Usually provided and may include an audit trail.
Al/Machine Learning Features	Not provided.	Possible turn-key solutions available or external integration.
Mobile App	Very rarely provided.	Usually provided but with varying degrees of functionality compared to desktop/website interface.



To learn more about how to choose the right LIMS for your lab, read our article, <u>"How to Choose the Right Laboratory Information Management System for Your Lab"</u>

Better Together: Working with Integrated Software Platforms

Integrating multiple software platforms, such as a LIS and LIMS, can enhance lab efficiency by combining the strengths of each system. Together, these platforms and others can provide a comprehensive solution that streamlines operations, improves data management, and fosters better collaboration and communication.

Can a LIS and LIMS Work Together?

At this point, you probably have a strong idea of the platform you need.

If you are in the clinical diagnostic or forensic markets, a LIS is your priority. But that's not to say you couldn't benefit from the sample and data management that comes from having a LIMS.

To figure out if you would benefit from having both a LIS and LIMS, consider these questions:

- Is there value in the de-identified results you are collecting?
- Do you struggle with inventory management and want to implement barcode automation to make it seamless to track the usage of supplies and reagents?
- Do you have a centralized way to manage maintenance and validations for equipment and analyzers?
- Could you benefit from having a centralized repository that allows lab personnel to document notes and data related to samples or inventory, with an associated audit trail?

If the answer is "yes" to any of those, you can use a flexible LIMS that provides an ELN or SOP/protocol management. Depending on the LIMS, you can also have the LIS and LIMS connected so that data is automatically sent from one to the other.



On the other hand, if you work in the life science, material science, or chemical industry, a modern LIMS can provide the data-driven approach you need. An LIS will not be useful or worth the additional cost.

If you already have an established LIMS but do not feel you are getting the full benefits from it, the same questions above apply. You may have one piece of the puzzle but are not reaping the full benefits of lab digitization if your data, equipment, results, and protocols are not connected to those samples. A comprehensive approach means you truly increase efficiency rather than introducing another software tool the lab has to purchase, onboard, and fully implement.

I Have ERP/SCM Software Already. Is a LIMS Still Needed Then?

Your facility may have other departments using Enterprise Resource Planning (ERP) or Supply Chain Management (SCM) platforms to manage incoming inventory. And if your laboratory supplies and consumables are already being entered into that system, could lab personnel make use of the ERP/SCM software instead of a LIMS?

It's possible, but there are a few questions to consider:

- Is your sole focus on tracking laboratory supplies and consumables and nothing else?
- Would your organization or the other department allow a user from the lab to be in the ERP/SCM?
- If so, does the ERP/SCM have an audit trail to document when changes are made and by whom?
- Does the ERP/SCM have roles and permissions to prevent lab personnel from being able to change or have access to other processes like finances, accounting, human resources, etc.
- Is the software accessible from a laboratory computer?
- Can the ERP/SCM be modified to include the metadata lab personnel would want to keep track of regarding their supplies and consumables?

The last consideration is arguably the most important: Is the ERP/SCM easy to learn and make sense to use for a laboratory-focused workflow? Even if the previous considerations are all a "yes," the ERP/SCM may not be a wise long-term solution.





A LIMS is designed foremost for a laboratory workflow and, when done correctly, is intuitive and easy to learn. This is essential to account for personnel's primary skillset being their research/diagnostic experience and not bookkeeping or administrative software. It's especially important should that specifically-trained laboratorian leave the lab and someone new needs to be trained on the software. In that situation, the implementation of a laboratory-dedicated LIMS would also prevent the need from the key ERP/SCM user outside the department from needing to retrain someone else.

What's Next?

With both ERP/SCM and LIMS available, you can greatly minimize the time spent on data entry and automate entire processes.

This could be as simple as copying and pasting an inventory list from the ERP/SCM into the LIMS. However, this would require the ERP/SCM to export in a format the LIMS can receive. Excel spreadsheets or CSV files are commonly exportable file types, but the format the LIMS accepts is ultimately determined by what formats it can import. This approach doesn't truly automate, but it can be a significant time-saving step.

A step towards true automation would be using APIs (Application Programming Interface) to automatically make changes between systems.

Here is what you need to check to see if an automated, cloud-based approach is possible:

- Does your existing ERP/SCM and LIMS provide API access?
- Do you have an IT department or personnel who can make the API connections?

From there, you'll want to determine what data and changes are transferred between systems and if the communication is uni-directional or bi-directional. That is, does data and updates flow only from the ERP/SCM into the LIMS, or does a change in either system affect the other?

Since the steps of how an ERP/SCM and LIMS can interact with each other are outside the scope of this white paper, we won't discuss the technicalities in further detail.

Thinking Beyond a LIS or LIMS

In the conversation comparing LIS vs. LIMS, there is often a larger, overarching question we are really trying to answer:

Am I addressing all of the key challenges to streamlining my laboratory processes and documentation?

While a LIMS can be part of the solution, it may not be the complete path to addressing laboratory challenges and gaps in documentation. Often, a larger-scale digitalization of lab operations and SOPs can help. Here's how.



SOPs

Every lab has binders filled with their SOPs and protocols that show how their samples are processed. Lab personnel understand the importance of establishing a "protocol binder," but managing the paper trail becomes daunting over time. Who is responsible for updating it? Are all changes documented clearly? How do you establish version control and document updates as protocols change over time? Are changes being made in a GLP-compliant manner?

A digital approach to protocol management clearly shows how protocols have evolved and what impact that had on your results. Having your SOPs interconnected to your samples paints a more complete picture of how your laboratory operates.

ELNs

Meticulous documentation has served as a cornerstone of scientific progress since its inception.

However, as we need to work more efficiently and process more data metrics than ever before, physical lab notebooks become snapshots in time rather than living documents of improvement.

An ELN provides a lab-focused collaborative space where you can take notes and generate reports that connect your SOP and the samples involved. You can also create custom workflows for projects and templatize training for new hires. All of this happens in a space where everyone has visibility to the latest changes, and everything is audit-controlled and backed up to the cloud.

Addressing all of your laboratory needs may require a more holistic approach, such as a Scientific Management Platform (SMP), rather than a singular LIS or LIMS.

Conclusion

If you've decided on the direction you need to go, you still need to narrow down your choices. It's easy to get caught in analysis paralysis, so decide beforehand what the key solutions you need are and the obstacles you want to overcome.

Once you have determined what you need, the user experience and ease of use of the platform will still be left. Booking a demo will give you the insight to assess how your team will adapt to a Scientific Management Platform and see how it all works in action. Going through this step will help you narrow down to 1-2 platforms.

Lastly, you can use the knowledge you gained from a demo to start a free trial. Make sure your team is fully onboard to stress-test the platform.



If you're interested in how to choose the right software platform for your lab, <u>contact us today</u>.