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THE IDEAL LIMS FOR CLINICAL DIAGNOSTICS

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FOR CLINICAL DIAGNOSTICS

A PRACTICAL BUYER'S GUIDE

LabLynx, Inc. has been involved in laboratory informatics (data management) for over two decades. Our knowledge and experience are shared here to bridge that gap, enabling laboratories to make informed decisions about their own needs, how they can be met and what that process entails.

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1. Introduction

The ideal clinical laboratory (https://www.limswiki.org/index.php/Clinical_laboratory) is one that provides timely and accurate test results that lead to improved patient outcomes or practical clinical discoveries benefiting future patients. In order to meet or exceed these expectations, the ideal clinical lab requires the ideal LIMS (https://www.limswiki.org/index.php/Laboratory_information_management_system) for its workflows. This is, however, not as straightforward as it sounds. Finding and implementing the ideal LIMS requires research, planning, expertise, communication and knowledge. Given how much information the lab has to arm itself with to make the best decision on the ideal LIMS, this process can leave many labs frustrated before even getting started.

The ideal LIMS is largely the one provided by a vendor that meets all of your lab's functional, budgetary and support needs. Who is providing such a LIMS? How are they being implemented in clinical labs like yours? How should you approach the implementation process? These questions and more may cause anxiety, but they shouldn't with a practical and informed approach. This guide is intended to provide laboratories like yours with similarly practical and informative content to guide your approach to finding and implementing the ideal LIMS.

This guide first introduces the concept of the LIMS and LIS (https://www.limswiki.org/index.php/Laboratory_information_system) and how these informatics solutions should be capable of assisting your lab with its clinical workflows and goals. It then offers an approach to finding vendors who provide solutions that meet your specific niche (e.g., pathology, molecular diagnostics and COVID-19 testing), as well as the functionality those industry-specific solutions should provide. There's more to it than just the LIMS, however, and the fourth chapter acknowledges this by examining vendors, the services they provide, and how they and your lab should approach LIMS implementation. Your ideal LIMS is an investment, and the fifth chapter examines cost considerations that come with investing in a clinical LIMS. The last chapter then provides information about a clear and competitive LIMS option for your clinical laboratory.

2. Let's Talk LIMS

Computers in the laboratory are not a recent phenomenon. The mid-1960s saw clinical laboratory computerization become increasingly popular[1][2][3][4][5], though that enthusiasm was often based on the potential of the computers themselves rather than their actual capabilities.[1] Researchers imagined potentials such as automatic specimen label generation, daily log and report management, instrument interfacing and data processing, results comparisons, and time management tools. It would take time for some of those potentials to be realized.[1]

However, we've come a long way since the 1960s, to a point where the question is no longer "can a computerized system help my lab?" but rather "how do I choose and implement an informatics system to help my lab?"

Today we find the laboratory information management system (https://www.limswiki.org/index.php/Laboratory_information_management_system) (LIMS) and its related companion, the laboratory information system (https://www.limswiki.org/index.php/Laboratory_information_system) (LIS), to be the most common informatics solutions used in laboratories. In the next section, we examine what LIMS and LIS are and how they are able to streamline laboratory workflows and improve conformance to laboratory standards and regulatory requirements.

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2.1 What is a LIMS?

In many ways, a LIMS is the automated file clerk of a laboratory, responsible for storing, organizing and maintaining the laboratory's data and information. However, a LIMS is more than just a file clerk; it has evolved to automate, simplify and secure many operational aspects of a laboratory. The LIMS does this by offering functionality such as sample and specimen management, inventory tracking, workflow management, instrument management and billing management, to name a few.

The definition of a LIMS has changed almost as rapidly as the workflows and data management needs of labs have changed over the last several decades. However, at its core, the LIMS remains a software-based tool designed with the goal of improving efficiencies in a laboratory's workflow and supporting efforts towards standardization and compliance in the lab. When designed well, the LIMS also provides flexibility and security to a lab's operations. As laboratory informatics
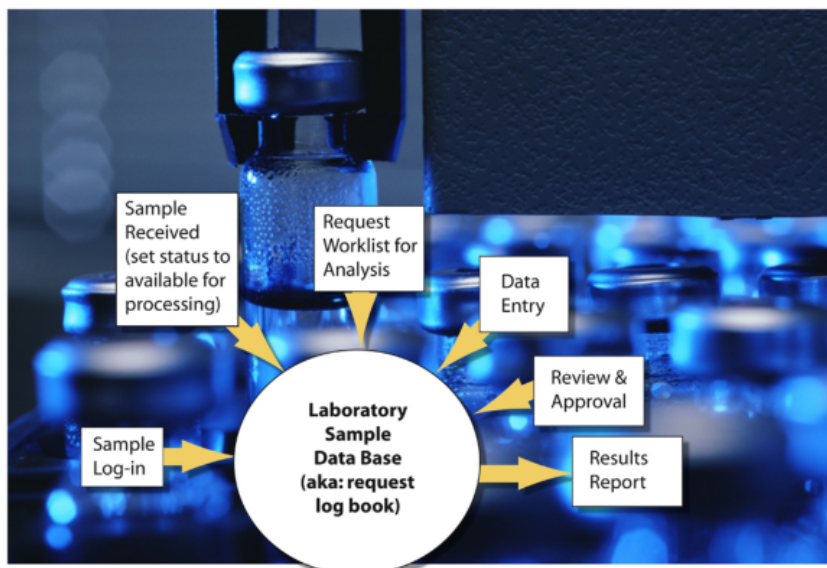
(https://www.limswiki.org/index.php/Laboratory_informatics) veteran Joe Liscouski notes in *The Application of Informatics to Scientific Work (https://www.limswiki.org/index.php/LII:The_Application_of_Informatics_to_Scientific_Work:_Laboratory_Informatics_for_Newbies)*, a LIMS is able to do these things in several ways[1]:

> Want to find a list of samples that are pending a particular test? A quality LIMS can readily display that information, including the sample numbers, priorities, and current locations, with no need to manually check work request sheets. Does a third party want to find out the status of one or more of their in-process samples? Role-based access management means a third party can receive limited access to view that status, without seeing anyone else's sensitive data. What about verifying and approving results? The LIMS can provide some level of results checking, with final verification and approval by lab management. When approved, the reports for each set of requests can be printed, emailed, or stored for portal access. And what about integrating data and systems? The LIMS can be connected to an instrument data system (IDS). Depending on the sophistication of that system, the LIMS can generate a worklist of samples that needs to be processed by that device, with the list downloaded to the IDS. When the work is completed, the results can be uploaded directly to the LIMS. This type of system interaction is one of the places where significant productivity gains can be had.

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Image   credit: Joe   Liscouski,   via   [LIMSwiki](https://www.limswiki.org/index.php/File:Fig6_Liscouski_AppInfoSciWork21.png)
(https://www.limswiki.org/index.php/File:Fig6_Liscouski_AppInfoSciWork21.png)

2.2 LIMS vs. LIS: What's the difference?

Today, many laboratorians and laboratory informatics vendors use "LIMS" and "LIS" interchangeably. Historically, however, the term "LIMS" has tended to be used to reference informatics systems targeted for environmental, research, or commercial analysis such as pharmaceutical or petrochemical work. "LIS" has tended to be used to reference laboratory informatics systems in the forensics and clinical markets, which often require special case management tools.

While the distinction between the two has faded in the last decade[1][2], a few fundamental differences remain. The LIS is largely designed to:

- Process and report specimens from patients in clinical settings.
- Handle the reporting and auditing requirements of accrediting and regulating agencies.
- Manage sensitive patient and clinical trial participant data.

The LIMS, on the other hand, is typically designed to process and report samples and sample batches from non-human sources while conforming to sampling, testing and manufacturing standards.

However, some LIMSs have evolved and broadened their service scope to address the needs of clinical diagnostic and research laboratories. The end result: more LIMS are filling the needs of labs where a LIS was traditionally used. The clinical lab seeking a laboratory informatics solution will therefore want to consider the features and functionality of a system regardless of its moniker.

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2.3 Essential features of a clinical LIMS

A LIMS can have an extravagant list of features, or it may have minimal functionality. Experienced software developers usually do well to include a collection of the essential features, as well as any industry-specific features a laboratory may need. However, not all developers get it right. A generic development approach to a clinical diagnostic or research LIMS may not suffice, given that workflows and regulatory requirements may differ across the various clinical care and research laboratory subtypes.

What follows is a list of system functionality that is considered by a variety of laboratory experts[1][2][3][4] to be vital to almost any clinical diagnostic or research laboratory. Without this functionality, end users may have to do more work, and the laboratory may have major liability issues by not complying with regulations. If the system you are evaluating doesn't contain most of the below bullet-pointed functionality, you may want to look elsewhere.

Test, experiment and patient management

- Specimen log-in and management, with support for unique IDs.
- Batching support.
- Barcode and RFID support.
- Specimen tracking.
- Clinical decision support, including test ordering tools and duplicate test checks.
- Custom test management.
- Event and instrument scheduling.
- Templates, forms and data fields that are configurable.
- Analytical tools, including data visualization, trend analysis and data mining tools.
- Data import and export.
- Robust query tools.
- Document and image management.
- Project and experiment management.
- Workflow management.
- Patient management.
- Case management.
- Physician and supplier management.

Quality, security and compliance

- Quality assurance / quality control mechanisms, including tracking of nonconformance.
- Data normalization and validation.
- Results review and approval.
- Version control.
- User qualification, performance and training management.
- Audit trails and chain of custody support.
- Configurable and granular role-based security.
- Configurable system access and use (log-in requirements, account usage rules, account locking, etc.).
- Electronic signature support.

- Configurable alarms and alerts.
- Data encryption and secure communication protocols.
- Data archiving and retention support.
- Configurable data backups.
- Environmental monitoring and control.

Operations management and reporting

- Customizable rich-text reporting, with multiple supported output formats.
- Synoptic reporting.
- Industry-compliant labeling.
- Email integration.
- Internal messaging system.
- Revenue management.
- Instrument interfacing and data management.
- Instrument calibration and maintenance tracking.
- Inventory and reagent management.
- Third-party software and database interfacing.
- Mobile device support.
- Voice recognition capability.
- Results portal for external parties.
- Integrated (or online) system help.
- Configurable language.

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3. Finding the LIMS that Fits Your Lab Industry
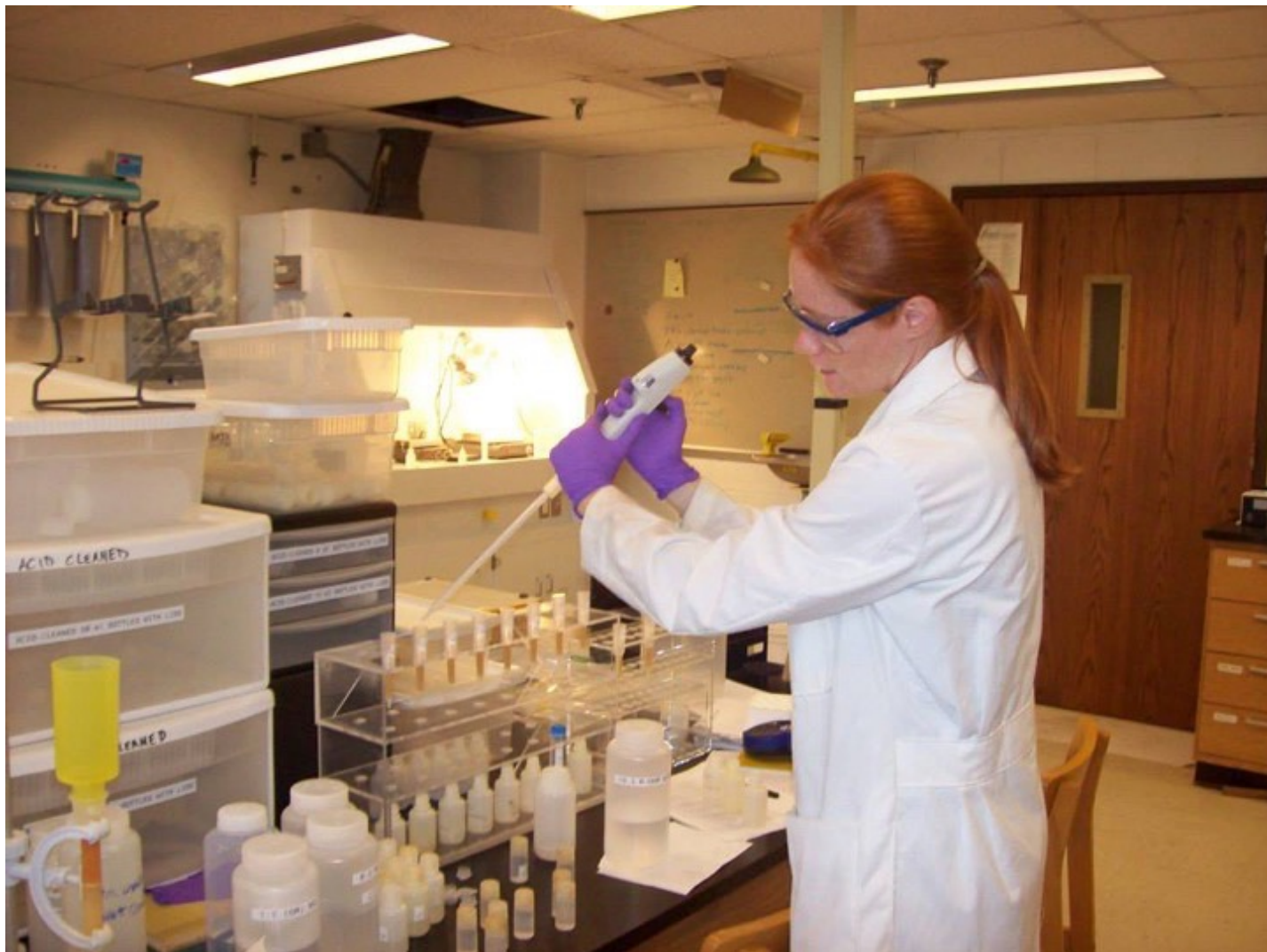
(https://www.limswiki.org/index.php/File:Dr._Wendy_Bohon_in_the_lab.jpg)

Before arriving on the LIMS that fits your laboratory's needs, you'll need to conduct some planning and research. The planning phase involves assessing the lab's goals, regulations, capabilities, workflows and budget, while also ensuring strong buy-in from management. The research phase involves determining what solutions are available, who is developing and supporting them, and what their reputation and experience is.

You may bring to this research a high set of expectations based upon your lab's initial planning. However, reality may prove slightly different. You research may turn up an ideal LIMS, but you discover you're not enamored with the vendor of the LIMS, or vice versa. From this initial research your lab may realize it needs to make a few compromises regarding the vendor, the ideal solution or both. That's not to say you won't be able to find a best-in-class solution offered by a developer with competitive rates and a strong track record of success in your industry. Rather, understand that your lab's wish list of features, extensibility, pricing and excellent service across both a vendor and their solution may not necessarily be fulfilled with every LIMS option you examine. It may take some effort to find the right combination of the two; however, when you do, it will surely be worth the effort!

Image credit: Jzeli, via [Wikimedia Commons](https://commons.wikimedia.org/wiki/File:Dr._Wendy_Bohon_in_the_lab.jpg) (https://commons.wikimedia.org/wiki/File:Dr._Wendy_Bohon_in_the_lab.jpg)

3.1 Finding vendors

There are hundreds of software vendors offering LIMS and LIS solutions making for a daunting challenge of narrowing down your laboratory's options. However, there are a few tools available to you. Chief among them is [LIMSwiki](https://www.limswiki.org/index.php/Main_Page) (https://www.limswiki.org/index.php/Main_Page), a curated repository of cited knowledge concerning laboratories and informatics. You can find a list of [LIMS vendors](https://www.limswiki.org/index.php/LIMS_vendor) (https://www.limswiki.org/index.php/LIMS_vendor) and [LIS vendors](https://www.limswiki.org/index.php/LIS_vendor) (https://www.limswiki.org/index.php/LIS_vendor) on the site, with each vendor having their own cited, non-marketing page providing information about the company and its offerings. Some vendors even make their pricing public, which is also indicated on the vendor page when available.

Additionally, those vendor pages have categories assigned to them based off the industries the vendor claims to serve. This categorical organization of [LIMS vendors by industry](https://www.limswiki.org/index.php/Category:LIMS_vendors_by_industry) (https://www.limswiki.org/index.php/Category:LIMS_vendors_by_industry) and [LIS vendors by industry](https://www.limswiki.org/index.php/Category:LIS_vendors_by_industry) (https://www.limswiki.org/index.php/Category:LIS_vendors_by_industry) gives laboratories another useful way to sort through vendor offerings.

Word of mouth is also an important yet underutilized, tool. Have you reached out to other laboratories in your industry and asked them about their experiences with finding and implementing a LIMS? Can they give you additional recommendations or advice about their past or current approach? Are there any upcoming conferences and trade shows where you can learn more? What about talking to members of a trade or professional organization you're part of?

Finally, your laboratory may want to consider the usefulness of a request for information (RFI) in finding vendors who may be able to fulfill your lab's requirements. An RFI is an ideal means for learning more about a potential solution and how it can solve your problems, or for discovering your options when you're not even sure how to solve your problem yet. By posting an RFI, you may find that multiple vendors respond. However, to maximize the number of responses, the RFI should not be unduly long and tedious to complete for prospective vendors. It should be concise, direct and honest. This means not only presenting a clear and humble vision of your laboratory and its goals, but also asking just the right amount of questions to allow potential vendors to demonstrate their expertise and provide a clearer picture of who they are.

3.2 Choosing a LIMS, based on industry

In the previous section, we noted that a vendor will often — but not always — include the industries their solutions serve on the vendor's website. When a vendor takes the time to present how their solution provides functionality beneficial to one or more industries, it allows potential buyers to make more informed decisions early on in their research process. Those potential buyers can also contact a vendor directly to ask them how their solutions fulfill the needs of a clinical diagnostic or research laboratory like yours, and buyers can even ask the vendor to provide references of labs they have served in the buyer's industry.

You may find some vendors take a one-size-fits-all approach to their clinical diagnostic or research LIMS. Depending on how thorough and all-encompassing their development team is in providing functionality, you may or may not find more granular features specific to your clinical lab and its area of expertise. The workflow needs of an anatomical pathology lab will differ slightly from those of a blood banking lab, and the LIMS used in those contexts will ideally have slightly different features to accommodate those lab types.

The following subsections examine the more common lab types that make up the realm of clinical diagnostics and research, as well as the unique industry-based functionality required of a LIMS.

3.2.1 Clinical diagnostics

(https://www.limswiki.org/index.php/File:Phlebotomy-drawing_blood_with_a_lancet.jpg)

Often referred to as simply a medical or clinical laboratory, the clinical diagnostics lab performs tests on clinical specimens in order to get information about the health of a patient as it pertains to the diagnosis, treatment, and prevention of disease.[1] There are, however, additional "flavors" of the clinical diagnostics lab — including the anatomical and clinical pathology labs, the physician office lab (POL), and the integrative medicine lab, among others — that provide more specific clinical diagnostic services, requiring unique functionality from its informatics solutions.

The ordinary clinical diagnostics lab will seek a LIMS that can provide, at a minimum, the essential functionality listed in section 2.3. Additionally, the LIMS may need to provide features and functions specific to one or more clinical diagnostic subtypes, described below.

3.2.1.1 Anatomical and clinical pathology

In common medical practice, general pathology is mostly concerned with analyzing known clinical abnormalities that are markers or precursors for both infectious and non-infectious disease and is conducted by experts in one of two major specialties: anatomical pathology and clinical pathology. These two sciences have slightly differing workflows, and both bring with them the need for specific LIMS functionality to better address their unique workflows.

In addition to the essential features of a standard LIMS, the anatomical and clinical pathology lab will also be looking for a system that can (or allows users to)[2][3][4][5]:

- Configure the system using templates for histology and cytology case types.
- Add, view and link pre-generated organ maps and other diagrams.
- Add, view and link custom annotated pathology imaging.
- Track abnormal results and provide trending reports for monitoring disease populations.
- Support blocks and slides as specimens, with predefined descriptions.
- Document grossing examinations.
- Print slides and cassettes.
- Provide case management, reporting and test requisition.
- Provide specialty workflow for autopsy.
- Provide specialty workflow for gynecological cytology, including HPV + Pap co-testing for cervical cancer.
- Provide stain panels and histology worksheets.
- Support shared management of tissue samples among departments.
- Support EHR integration.
- Support polymerase chain reaction (PCR) workflow and reporting.
- Support pathology-specific reflex testing.
- Provide the option to combine same-day anatomical and clinical pathology results and reporting.
- Flag unusual cases for conference or committee reporting.

3.2.1.2 Physician office

On average, the physician office laboratory (POL) may not produce the same level of daily specimen throughput as a larger clinical diagnostic laboratory, but that should not detract from the benefits a POL can gain from a laboratory informatics solution. The POL employing laboratory informatics will still need much of the same standard clinical functionality mentioned prior, and the system will still need to comply with data management and sharing regulations such as those found with HIPAA and CLIA.

If there is any additional consideration to be made for the POL seeking a LIMS or LIS, it will be with how well a given solution is able to interface with the electronic health record (EHR) solutions the POL and its stakeholders are using. The POL should examine the potential integration capabilities of the LIMS solutions they are evaluating, as well as the currently used EHR and other clinical solutions. The lab

should also be sure to consider any future potential of integrating their systems with other external data management systems, including those of other reference laboratories. A LIMS without the robust capability of integrating with other software systems only places additional burdens on the POL, now and into the future.

3.2.1.3 Integrative medicine

Integrative medicine is a type of personalized healthcare that takes a more holistic approach to the causes of illnesses. If an integrative medicine laboratory is using a laboratory informatics solution, their requirements will be nearly identical to a standard clinical diagnostic laboratory, meaning the standard clinical functionality mentioned in the second chapter will likely be suitable. If there is a major difference or required piece of additional functionality, it will have to do with a more extensive list of available tests and billing codes for them. This usually consists of expansions into nutritional, metabolic, and toxicity assays, as well as support for diagnostic imaging.[6]

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Image credit: USAID, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:Phlebotomy-drawing_blood_with_a_lancet.jpg)

3.2.2 Molecular diagnostics and cytogenetics

The molecular diagnostics lab will use one or more techniques (e.g., PCR, DNA sequencing, microarrays, gene expression profiling and cytogenetics) in their workflow, and the LIMS used in molecular diagnostics ideally will address those workflow needs. This is especially true for cytogenetics labs, which use specialty techniques like chromosome analysis or karyotyping, fluorescence *in situ* hybridization (FISH) and microarray-based assays such as comparative genomic hybridization.[1][2][3]
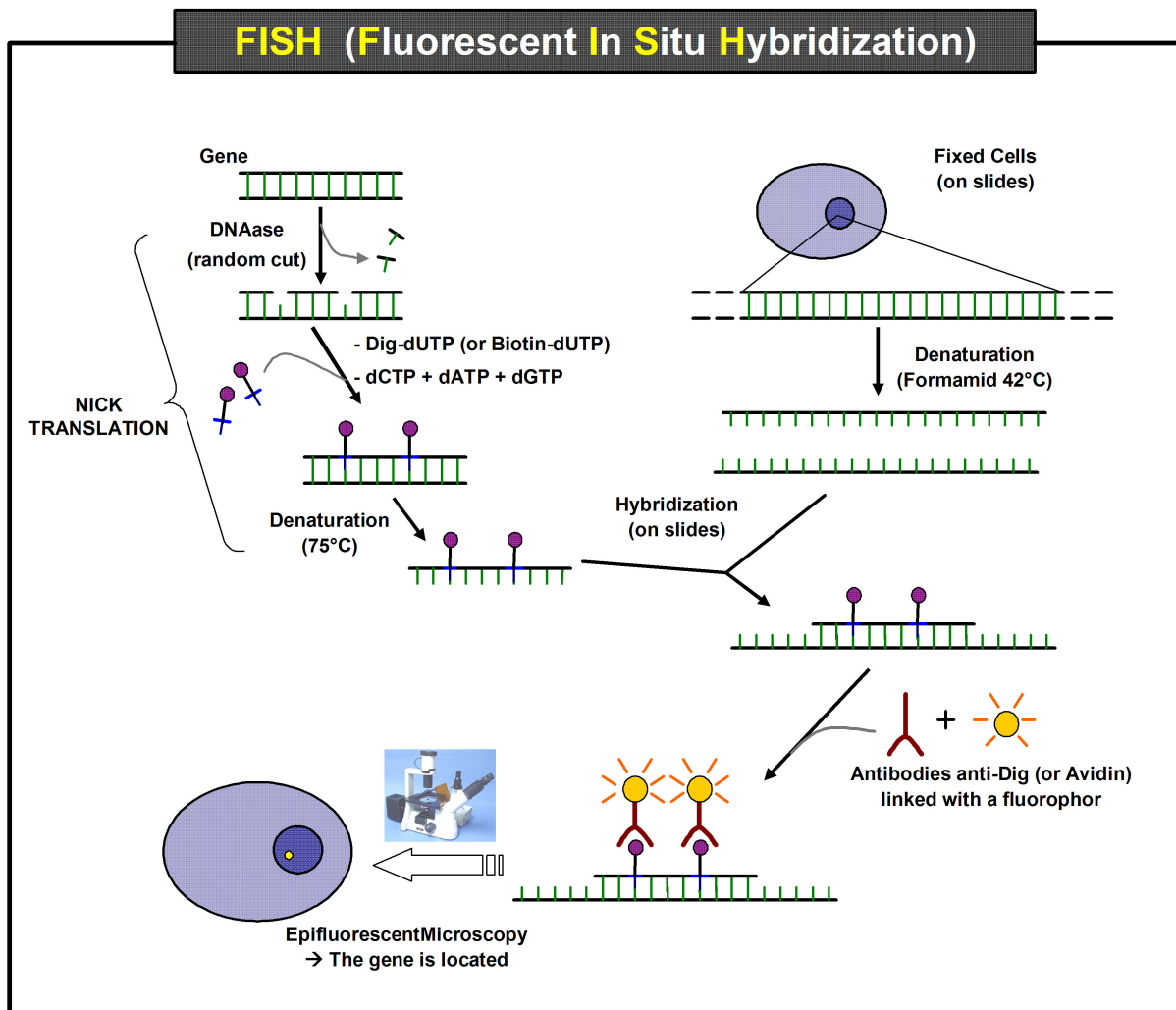
(https://www.limswiki.org/index.php/File:FISH_(Fluorescent_In_Situ_Hybridization).jpg)

In addition to the essential features of a standard LIMS, the molecular diagnostics and cytogenetics lab will also be looking for a system that can (or allows users to)[4][5][6][7]:

- Manage sample collection kits.
- Manage informed consent documentation.
- Provide customized workflows for molecular and next-generation sequencing (NGS) testing.
- Track specimen and aliquot lineage for cell lines, tissues, slides, etc.
- Track nucleic acid quantity and quality of specimens.
- Support a wide array of molecular testing and associated data fields, including biochemical and molecular genetics, carrier screening, immunology, molecular profiling, prenatal and newborn testing, and pharmacogenetics.
- Provide custom workflows for FISH, PCR, gel electrophoresis, cytogenetics, DNA sequencing and more.
- Support specialty testing reimbursement and other revenue management unique to this lab type.
- Support single sign-on with imaging platforms.
- Provide color coding for turn-around time and other testing statuses.
- Provide cleanly formatted rich-text reports customized for molecular diagnostics.

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Image credit: MrMatze, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:FISH_(Fluorescent_In_Situ_Hybridization).jpg)

3.2.3 COVID-19

(https://www.limswiki.org/index.php/File:COVID-19_vaccine_vial_AstraZenaca_2021_(UK).jpg)

While testing for SARS-CoV-2 (https://www.limswiki.org/index.php/SARS-CoV-2), the virus that causes COVID-19 (https://www.limswiki.org/index.php/COVID-19), is technically a part of clinical diagnostics, it integrates aspects of other lab types, such as clinical pathology and molecular diagnostics. As such, it shouldn't be surprising that an effective clinical diagnostics LIMS built for COVID-19 testing should include a few unique features outside of a generic clinical LIMS solution. This becomes even more obvious when you consider the mandatory reporting requirements, specialist workflows, and demanding turn-around time (TAT) and accuracy requirements of testing patients for COVID-19.

In addition to the essential features of a standard LIMS, the COVID-19 lab will also be looking for a system that can (or allows users to)[1]:

- Conduct the specialty functions found in a clinical pathology LIMS.
- Conduct the specialty functions found in a molecular diagnostics and cytogenetics LIMS.
- Provide a flexible provider portal that includes disease-specific checks for test necessity.
- Support a wide variety of user, provider and patient data.
- Provide a clear preregistration module that can capture critical patient and facility information, as well as national reporting questions.
- Support queue-based specimen tracking.
- Provide default assays and workflows for SARS-CoV-2 testing.
- Set up custom workflows for unique SARS-CoV-2 testing.
- Set up automatic reflex testing.
- Interface with most popular complex and point-of-care instruments used in COVID-19 testing.
- Integrate with mandatory results reporting systems and EHRs.
- Ensure efficient, native report delivery via email, fax or provider portal.
- Provide a customizable dashboard that can display disease-specific data and information.

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Image credit: Whispyhistory, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:COVID-19_vaccine_vial_AstraZenaca_2021_(UK).jpg)

3.2.4 Toxicology

Test types in a toxicology lab will vary based on the lab's focus, making the need for a LIMS that is flexible to the demands of toxicology labs essential. For example, toxicity testing on research animals may involve testing for acute toxicity, subacute toxicity, short-term subchronic toxicity, long-term chronic toxicity, reproductive toxicity, developmental toxicity, mutagenicity assays, irritation, allergic reaction, inhalation and immunotoxicity.[1] However, diagnostic testing will involve testing for drugs of abuse, poisons and heavy metals, or other toxicants. Pharmacogenetic testing may also be performed to develop dosing regiments for a specific drug.[2][3] Given the broad array of specialty analyses and
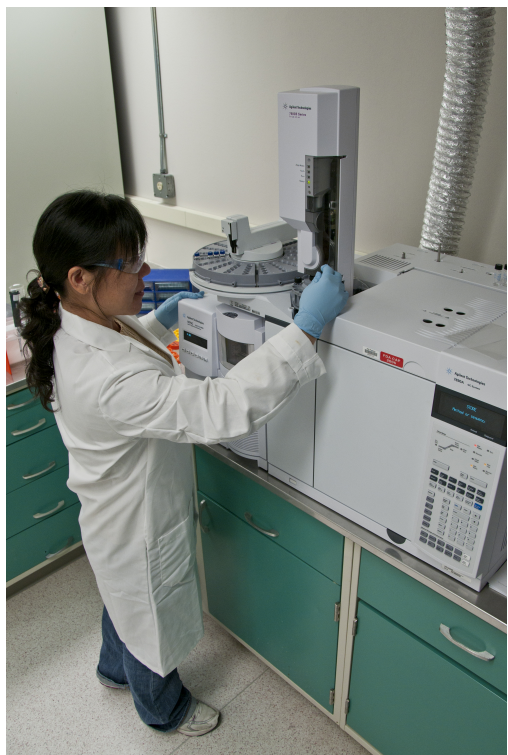
(https://www.limswiki.org/index.php/File:Toxicology_Research_at_FDA_(NCTR_1404)_(6008498003).jpg)

workflows described, it makes sense that the toxicology LIMS will have to address these specific needs.

In addition to the essential features of a standard LIMS, the toxicology lab will also be looking for a system that can (or allows users to)[4][5][6][7][8]:

- Support customizable drug panels and tests.
- Support reference lab activities.
- Track prescribed medicines and associated history.
- Provide management for compounds and compound grouping.
- Provide medication-based compliance monitoring and interpretive reporting on it.
- Provide decision-support rules for pain management and toxicology.
- Provide toxicology-specific reporting formats.
- Manage drug court cases associated with testing.

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Image credit: U.S. FDA, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:Toxicology_Research_at_FDA_(NCTR_1404)_(6008498003).jpg)

3.2.5 Blood bank and transfusion

(https://www.limswiki.org/index.php/File:Blood_Research-_Saving_Lives_(8352)_(9759352093).jpg)

While clinical diagnostic and other related labs will interact with blood, blood banking and transfusion labs have different workflows and end goals, requiring a specialized informatics solution. Activities driving the need for a purpose-built LIMS include screening specimens against high-risk donors such as commercial sex workers and drug users, testing potential donors for infection diseases, documenting

and reviewing (lookback of) donors and recipients, ensuring sufficient time is given for blood testing and cross-matching, and ensuring staff are appropriately trained concerning the risks to them and patients.[1] These specialized workflows and responsibilities require a LIMS that is flexible enough to these specialized testing, documentation and training needs.

In addition to the essential features of a standard LIMS, the blood bank and transfusion lab will also be looking for a system that can (or allows users to)[2][3][4][5]:

- Manage inventory across multiple facilities.
- Manage donor and harvested tissues.
- Support positive patient identification (PPID).
- Support the ISBT 128 standard for medical products of human origin.
- Support for both autologous and directed medical product management.
- Allow for emergency release of inventory.
- Allow for electronic crossmatch of human-based medical products.
- Manage medical product recall and documentation.
- Manage donor demographics, notification, scheduling and history.
- Manage donation drives and other campaigns.
- Track bag and supply lot numbers.
- Track quality control testing.
- Monitor access to and environmental conditions of supply fridges.
- Provide workflow management for non-standard patients.
- Support antibody screening processes.

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Image credit: U.S. FDA, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:200319-N-LH674-1021_(49855955681).jpg)

3.2.6 Hospital

(https://www.limswiki.org/index.php/File:MarkhamStouffvilleHospital23.jpg)

The hospital lab is a unique creature in that it encompasses many departments within a hospital, often spread out over multiple areas. Most of the prior mentioned specialties, as well as many more, will make up the bulk of laboratory testing in a hospital.[1] By extension, the informatics solution used in the hospital must be equally robust. This means the LIMS should be sufficiently feature-rich to allow for pathology, hematology, microbiology, virology, molecular diagnostic and blood banking workflows (to name a few) to be readily implemented. Just about any type of specimen you could imagine may be taken[1], so the LIMS should have vast flexibility in its specimen types. Additionally, given the multiple departments and high daily specimen load of a hospital[1], the LIMS should be automation-friendly and support a wide array of instruments and equipment.

All this culminates into multiple points:

- The hospital LIMS should have not only the essential clinical diagnostic functionality mentioned in the second chapter, but also most of the specialized functionality mentioned with the other laboratory types above.
- The hospital LIMS should have the potential to take the place of the multiple informatics systems that typically run within a hospital lab, reducing data silos and minimizing the impact of system updates.
- The hospital LIMS should have robust integration capabilities with EHRs and any other informatics systems that can't be replaced by the LIMS.
- The hospital LIMS should be highly flexible and configurable to take advantage of new test types, new departments, and more rapid testing (e.g., point-of-care testing).

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Image credit: Raysonho, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:MarkhamStouffvilleHospital23.jpg)

3.2.7 Public health

A public health laboratory is unlike the average clinical diagnostics laboratory as it must typically meet more stringent requirements. For example, they must adhere to not only CLIA (for labs in the United States), but also additional regulations laid out by the departments, agencies and other regulatory bodies

(https://www.limswiki.org/index.php/File:Colorado_Department_of_Public_Health_and_Environment.JPG)

of local, state and/or national governments. Additionally, the public health lab serves entire populations, not just individuals.[1][2] As such, these differences require the public health LIMS to provide additional functionality to help public health labs meet their population-based mandates.

In addition to the essential features of a standard LIMS, the public health lab will also be looking for a system that can (or allows users to)[3][4][5][6]:

- Provide specialty workflow for newborn screening.
- Provide surge capacity for high-priority analyses.
- Provide workflow and tools for managing microorganisms and toxins of elevated risk.
- Support most medical test protocols and specimen types.
- Support ELISA, DNA extraction, sequencing and other molecular workflows.
- Support for a robust set of decision support rules for reflex testing.
- Support the Centers for Disease Control and Prevention's PHIN Messaging System.
- Support other electronic data exchange standards for critical community partners.

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Image credit: Jeffrey Beall, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:Colorado_Department_of_Public_Health_and_Environment.JPG)

3.2.8 Clinical trials

(https://www.limswiki.org/index.php/File:Clinical_Trial_Participant_Receives_Injection_(34033294061).jpg)

Medical research laboratories (e.g., central and contract labs) form the backbone of today's effective medical treatments, through the pathway of clinical trials. These clinical trials involve analytical testing and other activities across many domains, including pathology, immunology, microbiology, flow cytometry, biomarker testing, pharmacokinetic testing, genomic testing, and specimen and biorepository management.[1][2] These activities require extra features beyond those found in a basic clinical diagnostics LIMS in order to effectively collect and use the clinical trial data in a secure and meaningful way.

In addition to the essential features of a standard LIMS, the central and contract research lab conducting clinical trials will also be looking for a system that can (or allows users to)[3][4][5][6]:

- Manage and track clinical trial kits.
- Manage multi-site logistics of specimens.
- Provide a reservation function for specimens.
- Manage clinical trials and their various functions, including recruitment, study protocols, treatment groups, metadata, multi-site master scheduling, consent checks and other required reporting.
- Provide special access privileges to sponsors, monitors and investigators.
- Support a wide variety of data transfer formats, including CDISC, ASCII, SAS and XML.

- Provide patient management, including demographics, consent forms, clinical notation and test results.
- Provide highly configurable "blinding" features for reports and the user interface.
- Track contracts, budgets and other financials.
- Develop exclusion rules and monitor exclusions.
- Support testing for a wide variety of disciplines.
- Provide study-specific monitoring and alerts.
- Provide granular cumulative reporting.
- Provide study-specific project portals that allow review of documents, data visualizations, training material and other study information.

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4. Vendor and Implementation Considerations
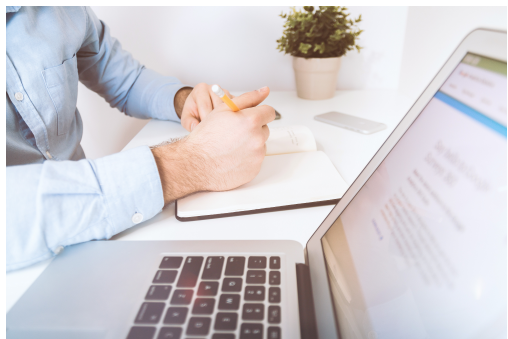
(https://www.limswiki.org/index.php/File:Businessman_working_and_writing_notes_in_office_(Unsplash).jpg)

When considering a LIMS, its implementation must be thoroughly considered. It is easy to get carried away with the look and feel of the LIMS' user interface (UI), its fancy features and its promises of pain-free workflows. However, there's more to a LIMS than its functionality and appearance. You also want to consider how your future LIMS will be implemented.

You don't have to look far to find lab professionals with horror stories of software implementations that were unnecessarily complicated, ultimately being abandoned due to cost overrides or the realization that the system would never meet the lab's needs. The good news is that doesn't have to be the case. A LIMS can be flexible and adaptable without requiring extensive configuration or customization, ready to go live if properly pre-optimized for your specific lab type. Coupled with clear vendor expertise and a full complement of vendor services and support, the implementation process can be short, within budget and meet all expectations successfully. This chapter explores how to achieve that.

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(https://commons.wikimedia.org/wiki/File:Businessman_working_and_writing_notes_in_office_(Unsplash).jpg)

4.1 Vendor expertise

If the ideal LIMS is in part defined by the implementation process, it's important to examine the level of expertise a vendor has with implementing a LIMS in your industry. If a vendor doesn't quite fit the bill, you may have to resort to using third-party service providers to fill the gaps. When that responsibility is spread across multiple entities, it can lead to a disjointed implementation and disaster. This requires clear vendor expertise and experience, as well as exceptional project management, requirements gathering, and documentation efforts. If these three implementation aspects are conducted well, your LIMS will be poised to remedy laboratory workflows and provide quality return on investment (ROI).

4.1.1 Project management

v.limswiki.org/index.php/File:Project,_program_managers_get_lesson_in_risk_communication_(11437247733).jpg)

A dedicated project manager (PM) is crucial to a successful implementation. The PM should be able to competently demonstrate critical aspects of project management, including paying attention to detail, managing multiple tasks simultaneously, and managing team members and their activities. By

extension, this means the PM must take the time to become thoroughly familiar with your laboratory and its processes. They must also be experts on the LIMS itself in order to ensure your lab's needs and the LIMS' capabilities match.

In order to accomplish this, effective communication between the lab's and vendor's project team is vital, with the PMs for both teams needing to be great communicators. Real-time information flow and discussion means team members of both the lab and the vendor are working together optimally. Beyond effective requirements gathering and scope definition, this is probably the single most important factor that determines successful implementation. The project managers from both teams should agree upon appropriate communication methods (e.g., online or onsite meetings, phone calls, emails, project management application documentation, etc.) and frequencies that will best facilitate effective communication.

Image credit: U.S. Army Corps of Engineers Europe District, via Wikimedia Commons (https://commons.wikimedia.org/wiki/File:Project,_program_managers_get_lesson_in_risk_communication_(11437247733).jpg)

4.1.2 Requirements gathering

Comprehensive and accurate requirements gathering is also critical to a successful implementation. This process ensures everyone understands what the lab's actual needs are and how the proposed LIMS is able to assist with those needs. This responsibility rests on both the lab's and vendor's shoulders, not only in the development of requirements documentation but also in reviewing and refining the requirements. If this process isn't given the attention required, significant time and money may be wasted.

The vendor should be able to demonstrate industry knowledge throughout this process. A vendor who is not well acquainted with the workflows, regulations and standards affecting a particular industry will lead to problems in communication and understanding. Similarly, the vendor who is not well-acquainted with how their own solution meets the requirements of an industry results in poor or even inaccurate implementations. The inexperienced vendor may cause delays in implementation times or, even worse, attempt to gloss over the details, leaving the lab to deal with the fallout later on. The experienced vendor will be attentive to your lab's requirements and may be able to offer solutions to problems you didn't know you had.

4.1.3 Documentation

Finally, the vendor should be able to provide all necessary documentation at each stage of implementation. They should provide not only a top-level requirements specification, but also a full statement of work (SOW) with detailed tasks, which then can serve as work tickets during implementation. These and other documents such as verification and validation materials, training materials and records of meetings and other communications together constitute comprehensive documentation of the project. Not only does strong documentation cover liability issues, but it also ensures more rapid and cost-friendly implementations.

4.2 Vendor services and support

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In addition to seeking vendor expertise in LIMS implementation, the lab should also consider what technical services and support the LIMS vendor provides. Can the vendor address the following aspects?

- **Setup**: All LIMSs require a certain amount of setup. This can range from simply adding users and their access levels, to a more complicated setting up of assays, results ranges and reports or managing the fields on particular screens. Setup is best accomplished by the vendor working side-by-side with your designated LIMS administrator(s) as a form of hands-on training. Configuration and customization are also important elements of system setup. A system that can readily be tailored to the lab's needs from the start tends to have a longer life due to its adaptability.

- **Migration**: If your laboratory is already established, you have raw data, audit records, reports and other types of information that will need to be loaded into the new system. Data migration (https://www.limswiki.org/index.php/Data_migration) can be a tricky process depending on the state and formats of the data to be transferred. Cleaning that data and information (i.e., weeding out

duplicates, errors, etc.) and putting it into a transferable format can be tedious and costly. An experienced LIMS vendor will be able to automate the process as much as possible. However, your lab may still want to ensure metadata is properly represented and consistent to prevent additional vendor effort and save on costs.

- **Verification**: Before a LIMS implementation can be deemed complete, it must be fully tested and accepted as working to an agreed upon specification. System verification should be used to check that each LIMS function and feature is to spec and bug-free. This should occur throughout the implementation as each task is completed, and as part of final user acceptance testing (UAT) of the fully-delivered LIMS. Additionally, a verification process before go-live should check that the system actually meets the needs of the lab and adheres to relevant standards like CLIA, HIPAA, ISO 15189 and ISO 9001.

- **Training**: A clinical LIMS is a highly complex system, managing many aspects of the clinical lab. No matter how user-friendly it is, users must be introduced to the LIMS's capabilities and become familiar with its operation. The vendor should provide appropriate training, as well as materials like manuals and videos that can be used to train other employees going forward.

- **Support**: Post-implementation services can be divided into maintenance and warrantied work, with maintenance representing requested work (e.g., updates and upgrades that support the growth and changes of your lab over time) and warrantied work being the covered resolution of any system faults. However, regardless of an agreed upon post-implementation maintenance and warranty plan, the vendor should also provide some included level of support through the LIMS' launch and for a reasonable period thereafter to ensure a smooth transition.

- **Cloud and security services**: Labs are increasingly finding value in moving informatics infrastructure and security requirements to a third-party. A LIMS vendor with veteran experience working with cloud infrastructures (https://www.limswiki.org/index.php/Cloud_computing) and security as a service provides more than a few benefits to the informatics-driven laboratory. With solutions in the cloud, for example, there is less of a need to address every user workstation every time there is a minor update, fix or upgrade since workstations access the LIMS via a web browser. Cloud can also provide valuable scalability, reduced responsibility and lower operational costs to labs. Labs can also inherit the security strengths (and weaknesses) of cloud vendors and their related services. Of course, the lab is not completely removed from security responsibilities (as seen with the shared responsibility models of many cloud providers) and must take a strong cybersecurity (https://www.limswiki.org/index.php/Cybersecurity) stance even when its informatics solutions are in the cloud. An experienced vendor can successfully guide a clinical lab towards best-practice use of cloud computing and security, and assist the lab in meeting its cybersecurity goals.

Image credit: mikemacmarketing, via Wikimedia Commons (File:VPN & Internet Security on Your Computer for Online Privacy.jpg)

4.3 Keys to successful implementation

Clinical labs must do more than ascertaining one or more vendors' level of expertise on implementing a clinical diagnostics LIMS and what services and support they provide. They also must have a strong understanding of why they want to implement a LIMS, what underlying technologies are used, how to

support those technologies, and how to prepare the workplace for the positive change that a LIMS can bring. The following subsections address these considerations.

4.3.1 Understanding the lab's requirements

:le:Loading_a_centrifuge_with_samples_to_separate_components_of_the_extraction_process._(48788935101).jpg)

Effective implementation and use of a LIMS in the laboratory is partially a function of understanding both the processes of the lab and the capabilities and functions of a LIMS. When neither is fully understood, LIMS implementations tend to falter. This means that accurate feedback of end users of a current or potential clinical informatics solution is incredibly useful.

This process usually begins with end users describing their workflows and how they imagine a LIMS would benefit it. They may not initially understand how the LIMS can assist them with what they need done — for example, sending an automated message to whoever is in charge of results approval post-analysis — but they should be able to at least articulate their needs. Feedback solicited, the lab's PM can then attempt to match up the requirements feedback with a formal requirements document. They may turn to an existing medical diagnostics and research specification like LIMSpec (https://www.limswiki.org/index.php/LII:Laboratory_Informatics_Buyer%27s_Guide_for_Medical_Diagnostics_and_Research/Blank_LIMSpec_template_for_medical_diagnostics_and_research_labs), which includes a comprehensive set of requirements most clinical labs may have. Requirements that the LIMS support standardized clinical terminology, application programming interfaces (APIs) for instruments, alerts for out-of-specification test results and much more can be found in LIMSpec. Once requirements have been compiled into a "wish list" and compared to a formal specification document like LIMSpec, the PM also has the chance to discover other requirements in the specification that end users may have missed.

The lab should, however, be careful about overwhelming vendors with their specification-driven wish list early on. Before approaching vendors, it's advisable to narrow down the full specification to the most critical requirements for you lab. You can then initiate dialog with one or more vendors based on those must-have requirements. Once the vendor pool is narrowed down to one or two vendors, you can then go through several demos of the software with the vendor. This gives your lab a clearer idea of what their

LIMS can do, and you can match their functionality to your full specification document. From there, you can then send the full specification document to the vendor and ask them how they address all your lab's needs.

In the end, this careful internal research on requirements paired with feedback from LIMS vendors experienced in implementing clinical diagnostics solutions for clients provides greater clarity of what is required of a LIMS and how it will actually benefit the lab.

Image credit: Yellowstone National Park, via [Wikimedia Commons (https://commons.wikimedia.org/wiki/File:Loading_a_centrifuge_with_samples_to_separate_components_of_the_extraction_process._(48788935101).jpg)](https://commons.wikimedia.org/wiki/File:Loading_a_centrifuge_with_samples_to_separate_components_of_the_extraction_process._(48788935101).jpg)

4.3.2 Understanding the technology and how to support it

It's ideal to discuss how using a software solution can improve laboratory workflows and further regulatory compliance, but the solution should not be viewed simply in terms of "install and use." Your lab will need to learn more about the underlying technologies and what resources will be required to further support their effective and secure use. What security standards and protocols does the system use and what will the lab need to do, if anything, to support them? How will cloud technologies change internal thinking about and responsibility for cybersecurity? Will staff need to be trained on any aspects of information technology? Who will support the lab in matters of technology and cybersecurity if those knowledge resources aren't available internally? These and other similar questions will need to be addressed in advance before even deciding on a LIMS to implement.

4.3.3 Preparing the workplace

For a LIMS implementation to be most successful in a clinical lab, it must properly plan for it and have critical buy-in from core stakeholders. This is most effectively accomplished through change management strategies that help the lab understand, plan for, implement and communicate the change a LIMS will bring. Understanding is brought about by defining the goals and envisioned successes associated with the LIMS, and what steps that will need to be taken to achieve those successes. Planning involves garnering management and other stakeholder buy-in to those goals and successes and defining LIMS implementation scope and responsibility. Implementing change requires establishing success indicators, identifying training requirements, appointing key support personnel for the LIMS, and tracking and acting upon laboratorians' concerns and criticisms. Finally, communicating change — one of the most critical aspects of change management — involves finding the right tone, relevance, and clarity to the change you're prescribing to the lab. That communication should highlight the other three components of change management, while imparting a tone of awareness of and desire to change, as well as practical knowledge about how to implement and sustain the change in the long term.

4.4 Translating your workflows to the new system
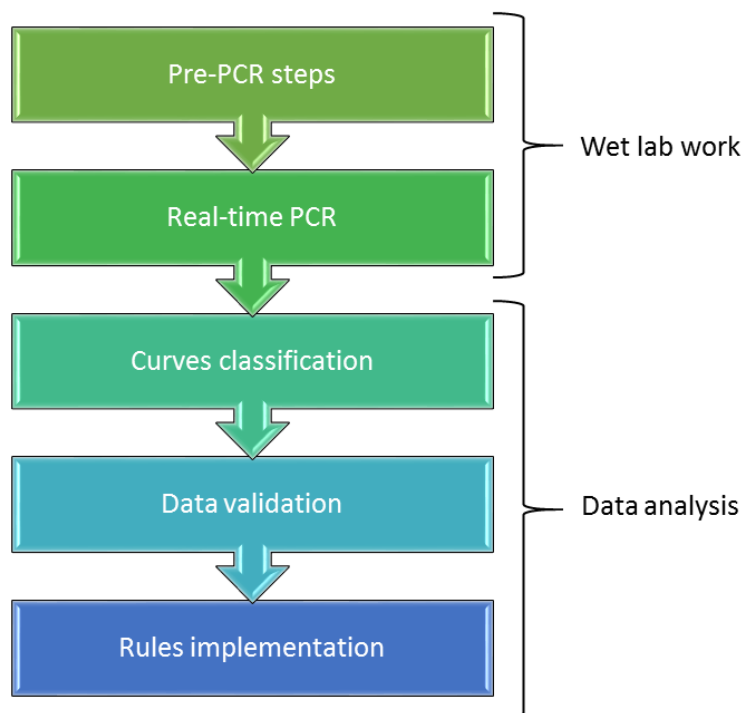
(https://www.limswiki.org/index.php/File:Workflow_of_a_process_involving_real-time_PCR.png)

Ideally, the clinical laboratory will want any implemented LIMS to be structured to fit the laboratory's workflow, but not in a way that boxes the lab in. The base LIMS should contain key pieces that suit most any clinical laboratory but be flexible enough to allow the lab to match and adjust the system workflows to the lab's unique daily requirements. No two labs are exactly the same, after all.

In order for the LIMS to be configured to your workflow requirements, your lab will need to be able to fully understand and describe those workflow steps to the vendor. This means working through your entire process, including accessioning, preparing, and testing specimens; retrieving results from instruments (eliminating the need of manual data entry); reviewing and approving results; ordering re-runs if necessary; and reporting final results as required. Secondarily, this means advising the vendor about all these details up-front, and later describing what does and doesn't work for you when implementing the LIMS. Clearly communicating these aspects to the vendor before and during implementation is more effective than simply hoping the system will alleviate any workflow issues as they arise post-implementation. When all is said and done, your lab should have an ideal LIMS at its fingertips, one that is flexible enough to not only address today's workflows but also the workflows of tomorrow.

Image credit: Tzachi Bar, via [Wikimedia Commons](https://commons.wikimedia.org/wiki/File:Workflow_of_a_process_involving_real-time_PCR.png) (https://commons.wikimedia.org/wiki/File:Workflow_of_a_process_involving_real-time_PCR.png)

5. Elements of Cost and Pricing
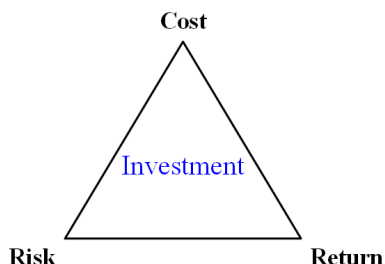
(https://www.limswiki.org/index.php/File:Cost_Risk_Return.png)

Inevitably, the topic of cost comes up early in discussions about the ideal clinical diagnostics LIMS. This is actually not all that surprising given that performance measurements such as ROI are common in the world of business. A LIMS is indeed an investment, couched in the idea that it will provide tangible and intangible benefits to the clinical lab and its operations. By extension, labs will look to get the most benefit out of their system for the investment they make, with a preference for lower costs. When investigating this aspect of LIMS acquisition, the lab will find that vendors have multiple software licensing methods, and they may also discover a variety of additional, sometimes unexpected costs and fees. The next two sections examine these aspects.

Image credit: Larry Huang TW, via [Wikimedia Commons](https://commons.wikimedia.org/wiki/File:Cost_Risk_Return.png) (https://commons.wikimedia.org/wiki/File:Cost_Risk_Return.png)

5.1 Licensing

As a means to accommodate the different workloads, sizes and workflow requirements of laboratories, LIMS vendors have adopted multiple ways to pass on the cost of a LIMS to a lab. They may charge for use of the LIMS based on the number of named users of the system, the maximum number of users who will be logged in at any given time (i.e., concurrent users) or the number of specimens processed. Furthermore, a LIMS' cost may be passed on in the form of a one-time license purchase or a regular monthly or annual subscription. Each has its own benefits, depending on the buyer.

Named users licensing: This licensing is based on the number of users (or, in some cases "nodes," which are simply any entities that access the software, including other systems, instruments, etc.). How these are counted can vary. They may be counted as named users, which bases pricing on the actual individual users of the system, even if they may only log in once in a while. In most cases, users may not use each other's login information, though this is prohibited regardless of pricing structure for good practice and other standard- and regulatory-based reasons.

Concurrent users licensing: This licensing bases pricing on the maximum number of users who will be logged in at any given time. You can define an unlimited number of named users in the system, each with their own login credentials. However, only the number of concurrent users specified in the license or subscription agreement may be logged in at any one time.

It may be useful to look at an example comparison of named user and concurrent licenses. Imagine you have 10 users in your clinical diagnostic lab, but due to work processes, shifts or some other reason only up to six might ever be logged in simultaneously. Whereas this would require a named user license for 10, it would only require a concurrent user license for six. In the case of a large lab with upwards of 50 users, neither option may make sense. In some cases, a vendor may offer an unlimited user license, which makes sense for large labs looking for a flat fee for any number of users.

Pay-as-you-go licensing: While not common, some vendors may offer a per-specimen rate for use of their LIMS software. This sort of pricing scheme is useful, however, for contract laboratories looking to eliminate up-front costs and have a predictable cost basis for the work they are contracted for. This is particularly useful in the case of a cloud LIMS, as the contract lab typically doesn't need to invest in additional support or system upgrades; they simply have an account set up, use the LIMS how much they need and get billed for it.

Purchasing vs. subscription: Does your lab want to own the software it wants to use or is it comfortable with "renting" the solution? The lab would look to either a one-time license fee or a subscription plan, respectively. If you have your own dedicated IT department and staff, you may prefer the former. Otherwise, a "software as a service" or SaaS-based (i.e., cloud-hosted) subscription model may be the better and more cost-effective way to go. Aside from local computing and internet access, IT costs remain negligible with SaaS. Either way, this license or subscription represents your up-front cost and, in the case of a subscription, it will also figure in your first year and ongoing costs. Though subscriptions may require several months or up to a year's up-front payment, subscriptions tend to be less expensive than a one-time license fee and self-hosting.

5.2 Additional costs or fees

Most additional costs are associated with additional work beyond the base configuration. For the cost-conscious clinical diagnostics lab, it will be useful to find a solution that meets as many of your needs as possible out of the box. Adding customizations, unique functionality and advance integrations increases costs, as they are a function of the time it takes a developer to add them. As such, consider a highly user-configurable system as much as possible.

Another area of additional cost comes with maintenance, support and warranty (MSW). The MSW plan you pay for will be just as important as the LIMS itself. Your LIMS will be viewed as mission-critical, and having a reliable and responsive team and resources available 24/7 is hugely important in retaining operational and competitive status. Downtime can negatively affect not only immediate customer satisfaction but also your reputation. This is where the MSW comes in. Analyze the vendor's MSW carefully.

Purchase of a LIMS will usually include an MSW as a percentage of the license fee, typically 15 to 20 percent annually. If you've opted for a subscription-based cloud service, the MSW should be included in the monthly or annual subscription costs. The MSW should include a set number of support hours so

(https://www.limswiki.org/index.php/File:Business_man_and_woman_handshake_in_work_office.jpg)

your users can contact the vendor and get help when they encounter problems. It should include updates and upgrades (i.e., maintenance), and unlimited free fixes of any bugs (i.e., warranty).

You may also have a need for additional professional services (e.g., consulting, customization and additional training), including implementation help. These services are generally billed hourly. However, implementation services may be milestone-based. Many vendors operate using something of a combination of the two approaches, providing best estimates for each deliverable, with the caveat that actual costs may vary somewhat. It's always best to construct a budget with around 20 percent additional funds available in case of unforeseen obstacles, or to support additional features or functions down the road.

A few other areas where additional costs or fees may spring up include:

- Maintenance on your self-hosted solution.
- More storage space.
- Data migration.
- Disaster recovery.
- Additional cybersecurity services.
- Additional instrument or software integrations.
- Additional LIMS modules.
- Additional validation services for data or the LIMS.
- Support beyond the MSW.

Image credit: Perzon SEO, via [Wikimedia](https://commons.wikimedia.org/wiki/File:Business_man_and_woman_handshake_in_work_office.jpg) [Commons](https://commons.wikimedia.org/wiki/File:Business_man_and_woman_handshake_in_work_office.jpg) (https://commons.wikimedia.org/wiki/File:Business_man_and_woman_handshake_in_work_office.jpg)

6. What Makes LabLynx Your Ideal Solution

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LabLynx goes beyond standard LIMS offerings to provide you with a comprehensive cloud-based solution for your clinical laboratory. With a robust LIMS, patient portal, physician portal, mobile specimen collection kit, electronic laboratory notebook (ELN) and more, LabLynx for Healthcare is designed to fully support your laboratory's operational goals. All LabLynx solutions are browser-agnostic and secure, meaning you can safely access the system from any location while ensuring your data is safe.

6.1 LabLynx for Healthcare features

LabLynx ELab LIMS for Healthcare: When designing LabLynx ELab LIMS for Healthcare, the core component of our healthcare solution, it was our goal to create a system that can expand, scale and adapt as your business needs adjust. ELab starts as a highly configurable commercial off-the-shelf (COTS) system that you can tailor to meet your needs. It comes with premium features you can enable or disable as needed, and everything in the system can be adjusted to meet your unique requirements, including system labels and fields, workflows, integrations, reports, functionality and more. ELab was designed to ensure you have a LIMS that fits into your laboratory workflow without having to navigate the challenges that come with building a custom solution. However, custom features and integrations can still be added to the system if desired.

ELab comes with all of the standard features listed in section 2.3 while also enhancing the base ELab functionality with the following industry-specific features:

- Billing management.
- Reference lab requisition.
- Single and batch specimen management.
- Plate well visualization and tracking.
- EHR/EMR integration.
- Regulatory compliance support.

Additionally, ELab is highly extensible with its LIMS add-on applications, providing further flexibility to the ever-expanding clinical lab.

Physician portal: Expand beyond the LIMS and increase communication with your clients through our physician portal. The portal communicates directly with the LIMS for real-time updates and data sharing. Physicians can easily submit test requisition through a user-friendly online platform that updates specimen and sample information in real-time. Upon requisition, you can require the information pertinent to your business directly in the portal, including patient billing information, required specimen information and more. In addition to submitting tests, physicians can use the portal to review past order history, track current test progress and receive result reports as soon as they are available.

Patient portal: In addition to a portal for the physicians your lab works with, LabLynx for Healthcare also offers a patient portal to support direct access to test results. Patients can create an online portal account, sign up for testing events your laboratory hosts and receive test results as soon as they are ready. The portal and LIMS swap data instantaneously, eliminating time lag and increasing workflow efficiency.

Sample Information Collection Kit (SICKIT): Streamline mobile specimen collection with LabLynx's Sample Information Collection Kit (SICKIT). Complete with a tablet, label printer and scanner, SICKIT allows for easier specimen and sample management from the field. You can then remotely upload the information directly to the LIMS through a secure, simplified entry form on the tablet. Once the specimen is registered, you can print out its corresponding label on-site, leaving you ready to run tests when you return to the lab.

ELN: ELab Notes is our ELN, which fully integrates with our ELab LIMS. ELab Notes allows you to seamlessly share data with your LIMS, saving you time and reducing transcription errors. It also allows you to fully document projects in an environment that is easy-to-use, scalable and secure. Easily upload templates of existing forms or data sheets to be used for projects, approve work captured in the ELN, and record notes directly related to a project or as needed. You will no longer need to maintain a paper notebook that can easily be lost or destroyed. All of your notes and data will be stored electronically and can be accessed at any time.

6.2 LabLynx as a vendor

With more than 25 years of experience, LabLynx has applied its knowledge and expertise to create a unique user experience for its clients. LabLynx makes it a priority to support its clients from project initiation to well after implementation and go-live. Here is an overview of what you can expect from LabLynx as a vendor.

Migration: There are various types of data and information migration that can occur when a new system is to be implemented. Migration of existing patient, physician, insurance and other client data can be completed easily enough by importing existing lists to create entries in the system, thus eliminating the need to manually recreate them. Current inventory and equipment lists can also be imported. Even further, previous case and testing data can be migrated from retiring systems, allowing the ability to reference this data quickly and easily.

Project management: You are immediately assigned an experienced project manager who supports you from initial requirement gathering through to system roll-out, go live and beyond. LabLynx's project managers — known as application engineers (AE) — all have a laboratory background and thusly understand the unique challenges you face. They work with your internal team to ensure your ideal laboratory solution is implemented in a timely and effective manner.

Development: One of the unique things about LabLynx as a vendor is all our development work is completed in-house. System updates, new features, software configuration and more are executed swiftly and to the highest of standards. Our AEs work directly with both you and our in-house development team to ensure your project's success.

Training: When your system is complete and ready to go live, LabLynx's AEs provide training customized to the needs of your laboratory. From informatics documentation and training videos to in-person training sessions, your LabLynx AE is there with you from start to finish to help smooth your change management processes and make the system onboarding as painless as possible.

Verification: LabLynx works directly with the client during the course of their implementation to verify their system's operation. At the end of implementation, it is the client's responsibility to test and verify that all agreed upon functionality is working as intended, and if not, report any issues to the AE assisting with the implementation. The client is also responsible for ensuring that all of their LIMS specific processes adhere to any SOPs, work instructions, and /or regulations. The LabLynx AE will assist throughout this entire process, but the client is required to approve all features, functions, processes and deliverables.

Support: During implementation and after your system goes live, LabLynx offers 24/7 support. LabLynx offers online, email and phone support at every step of the way, ensuring your laboratory and system operations see as few interruptions as possible.

Cloud hosting and security services: The security of your data and systems is one of our top priorities at LabLynx. Our cloud infrastructure is hosted on secure servers in state-of-the-art data centers certified to the highest SSAE SOC 2 standards. Databases are backed up hourly, and entire backups are conducted daily. You can rest assured knowing your information is safe on reliable servers that are continuously monitored and maintained by LabLynx's expert, in-house IT personnel.

6.3 LabLynx pricing and next steps

LabLynx offers an annual subscription with a few up-front, one-time costs during implementation. The annual subscription costs include license fees and hosting costs. We conveniently provide a tiered pricing structure, so that more users reduce the cost per user. These licenses are based on concurrent logins to the LIMS, rather than total named users.

For cloud hosting, we offer three hosting options users can choose from:

- Shared – The server is shared but each client has their own database.
- Dedicated – The server and database is dedicated.
- Self-hosting – This option is for clients who prefer an on-premises solution. This cost is necessary for support and access to the system for updates, etc.

Additional server storage is available if necessary and can be added on at any time in the life of the system.

Concurrent user subscriptions	Annual	Monthly/Quarterly/Biannually +20%
Standard subscription: Minimum 2 users	$3,600	$4,300
Standard subscription: 3-9 users	$2,700	$3,200
Standard subscription: 10-14 users	$2,300	$2,800
Standard subscription: 15 or more users	$2,200	$2,600

Hosting – Shared vs. dedicated cloud options	Annual	Monthly/Quarterly/Biannually +20%
Shared server hosting	$3,900	$4,700
Dedicated server hosting	$9,400	$11,300
Self-hosted maintenance	$3,000	$3,600
Extra storage (100 GB)	$900	$1,100
Extra storage (1 TB)	$4,000	$4,800

Sign up for your free tour of LabLynx's Healthcare Solution by contacting our team at sales@lablynx.com (mailto:sales@lablynx.com) or by calling 866-522-5969. Get started with your ideal clinical diagnostics LIMS.