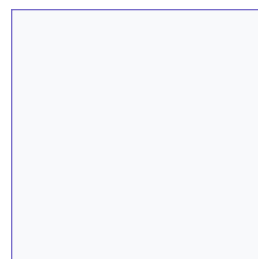


# Choosing a LIMS for Molecular Diagnostics

2026 Buyer's Guide



Selecting a LIMS is one of the most consequential technology decisions a molecular diagnostics lab will make. Molecular diagnostics workflows are complex for three reasons:

- 1. Heterogeneous, multi-assay workflows:** Molecular assays vary widely from one to the next, and many require a long sequence of steps with branching and retest paths that depend on QC outcomes. NGS adds indexing and pooling, where many samples are combined into a single run and each result has to be traced back to its source. Labs running NGS, PCR, and other molecular tests in the same environment compound this, since each method brings its own preparation steps and processing paths.
- 2. A steady stream of new assays to bring online:** As labs expand their test menus, they must accommodate new workflows and data requirements alongside existing assays. A LIMS must enable teams to configure and deploy new assay workflows without lengthy development cycles.
- 3. The need to evolve quickly without sacrificing regulatory control:** When extraction methods, library preparation protocols, or QC criteria change, teams must introduce updates efficiently while completing appropriate validation. They must also preserve a clear record of which workflow version was used to generate each result.

This guide discusses the six questions that lab operations, IT, and quality leaders should evaluate when considering a LIMS for molecular diagnostics. For each one, we outline what a strong platform looks like in practice and the questions worth asking before choosing a solution.



# 1

## How Should a Molecular Diagnostics LIMS Handle Workflow Complexity and Configurability?

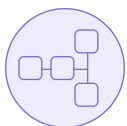
Molecular diagnostics workflows are rarely straightforward, but a LIMS designed around the way molecular labs actually run their assays can help bring clarity. These systems should allow teams to model reflex testing, pooling and demultiplexing, plate layouts, parent/child aliquot tracking, QC holds, and reruns through a visual workflow editor, without coding.

As assay menus grow, systems built around rigid workflows become difficult to manage, and labs often compensate by layering custom code on top of their LIMS. Every custom script then becomes something to validate, maintain, and retest with each upgrade, and the lab ends up dependent on whoever wrote it. Instead, look for a LIMS that lets teams update and iterate on workflows quickly through configuration instead of custom scripting, with each change reviewed and approved before it reaches production.

Every modification to a workflow must be explicitly versioned, maintaining an exhaustive audit log alongside full rollback functionality. Once updates are authorized, the platform should offer a seamless mechanism to transition in-flight samples, guaranteeing that active runs are never stranded on legacy protocols or migrated without complete traceability.

The flexibility to define and iterate on workflows should be balanced with control during execution. Once an assay is in production, the LIMS should enforce its required steps and QC checks with consistency and accuracy.

### What to evaluate:



Can the system model branching and conditional workflows visually, without custom code?



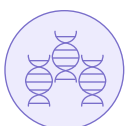
Does the system enforce required QC checks and approvals during execution, or only flag missed steps afterward?



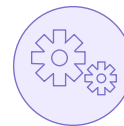
Does workflow execution stay responsive as sample volumes grow, including large batches and full plates?



Can lab teams configure workflows themselves, or does routine configuration require IT or vendor professional services? How long does a typical workflow change take, from request to validated and live in production?



Does the system natively support multiplexing, pooling, and demultiplexing, including tracking each sample's index through a pooled run?



How well does it integrate with business systems? Can workflow steps trigger actions, such as consuming inventory or initiating billing, as samples move through the lab?



Can workflows include nested protocols, where one protocol runs as a step inside another, without duplicating configuration?

# 2

## How Should a Molecular Diagnostics LIMS Handle Sample Traceability and Operational Visibility?

For molecular diagnostics labs, sample traceability is a regulatory and operational requirement.

The LIMS should connect samples, derivatives, results, reagents, instruments, operators, and workflow steps in a searchable and navigable way. Teams should be able to start with a single sample and quickly understand its complete operational context, without needing to manually cobble together information from multiple reports or fragmented systems.

A modern LIMS should also provide lab managers with a real-time picture of what is happening on the bench, so they can identify and address bottlenecks before they affect turnaround time.

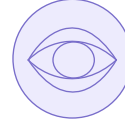
### *What to evaluate:*



Can a user start from a single sample and see its full history, including derivatives, reagents, instruments, operators, and workflow steps, from receipt through final result in one view?



Can lab users trace a reagent lot to associated samples and results, including derivatives and repeat tests, without custom queries?



Does the system provide real-time visibility into sample status, batch progress, queues, and workflow bottlenecks?



Can a user seamlessly move between an individual sample and a pool?

# 3 How Does a Molecular Diagnostics LIMS Support Compliance and Inspection Readiness?

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A molecular diagnostics LIMS should natively support CLIA, CAP, and applicable 21 CFR Part 11 requirements instead of forcing users to fill gaps with manual workarounds. This includes immutable, tamper-evident records and authenticated e-signatures, with sign-off restricted to users with the appropriate role.

Underlying data integrity principles, such as ALCOA+, are also crucial. When a workflow is updated, historical sample records must remain intact and clearly linked to the version used to process each sample.

Data integrity is the foundation. The LIMS should follow ALCOA+ principles, meaning records are attributable, legible, contemporaneous, original, and accurate, as well as complete, consistent, enduring, and available. In practice, when a record is corrected, the original is never overwritten. The system captures who made the change, when, and why.

The same goes for workflow versioning. As assays and procedures change, the LIMS must maintain an easily accessible, human-readable history of workflow changes, including what changed, when, and who made each change.

Together, these controls are what make a lab inspection-ready. When an inspector asks for a sample's full history or the approval record for a workflow change, the lab should be able to pull it up in minutes, not assemble it from exports and spreadsheets.

## ***What to evaluate:***



Does the platform support ALCOA+ data integrity principles? Are records immutable and tamper-evident once created?



Are audit trails easy to access and read, capturing sample activity, workflow execution, configuration changes, and user actions without requiring queries across related tables to reconstruct the full history?



Are e-signatures tied to role-based permissions, and does the system enforce authentication at the moment of signing?

# 4

## How Should a Molecular Diagnostics LIMS Handle New Assays and Workflow Changes?

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For molecular labs on legacy LIMS, a new assay, SOP, instrument, or process improvement can kick off a development cycle that takes weeks or months. The assay may be validated at the bench, but it can't go live until the LIMS catches up, which delays test menu growth and the revenue that comes with it.

Lab teams should be able to make workflow changes themselves, without opening a ticket with IT or engaging the vendor. Look for a LIMS with a defined configuration layer where changes are versioned, traceable, and testable before going into production.

The system should be straightforward for bench scientists and other lab users to configure, so the people who understand the science can also adapt the workflows that support it.

### *What to evaluate:*



Can scientists or lab teams modify workflows without requiring developers or vendor services?



When a workflow changes, does the system show and log exactly what changed and its downstream impact, so revalidation can be scoped accordingly?

# 5 What Integration Capabilities Does a Molecular Diagnostics LIMS Need?

Few molecular diagnostics labs operate through a LIMS alone. The broader environment typically includes bioinformatics pipelines, LIS or EMR systems, ERP and inventory systems, patient or provider portals, instrument-specific software, and other laboratory applications.

The LIMS should connect to these systems through well-documented, consistent APIs that lab and IT teams can use directly to build and maintain integrations. Where file-based exchange is the only option, as it often is with instruments, those transfers should be automated rather than handled by hand.

For molecular labs, the most important connection is often the round trip to bioinformatics. The LIMS should generate sample sheets for sequencing runs, hand data off to analysis pipelines, and bring results and QC metrics back linked to the right samples, without manual file transfers or re-keying. The same applies to instruments: data should be captured automatically when a run completes, not typed in afterward.

Integrations also need to be dependable. When a connection fails or a file doesn't arrive, the lab should find out right away and be able to see exactly what went wrong, rather than discovering the gap when a result is missing.

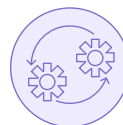
## ***What to evaluate:***



How does the platform integrate with LIS, EMR, ERP, inventory, and other enterprise systems? Are integrations API-first or file-based, and can both be supported?



Can the system capture instrument data automatically at the point of measurement, in addition to supporting file-based transfer?



Are integrations designed to remain stable as connected systems evolve, or are they heavily dependent on customization? Can teams troubleshoot issues with well-documented APIs instead of vendor involvement?

# 6

## How Should a Molecular Diagnostics LIMS Support Implementation and Growth?

Legacy LIMS implementations can stretch for a year or more, and by the time the system goes live, the lab's requirements have often already changed. A strong implementation gets the lab running in months, not years, and leaves the team fully able to run the system on their own.

Vendors with effective implementation models map business processes across the lab's different functions before any configuration begins. Using a shared standard like Business Process Model and Notation (BPMN) makes these maps easier for the whole team to understand. When the platform can ingest these maps directly, configuration reflects how the lab actually works from the start.

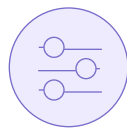
Go-live should also be a handoff of knowledge, not just software. If the lab still depends on the vendor for routine changes months later, the implementation delivered a system without transferring the knowledge to run it.

Finally, the platform should grow with the lab. Sample volumes rise and spike, test menus expand, and labs add sites or acquire other labs. The LIMS should absorb that growth on the same platform, without performance problems or a re-implementation.

### ***What to evaluate:***



What is the typical time to go-live for a lab with your assay complexity, and what does that timeline depend on?



After go-live, can the internal team configure and maintain the system independently?



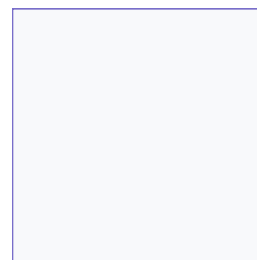
How does platform performance change as sample volume and concurrent usage increase? Can additional assays, sites, or acquired laboratories be brought onto the existing platform?

Use the questions in this guide as a scorecard. Bring them into each vendor evaluation and compare responses side by side, so the decision rests on how each platform handles your specific workflows and regulatory requirements.

See how Labbit supports complex molecular diagnostics workflows in practice:



# labbbit



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