



Overcoming Operational Bottlenecks in High-Throughput Clinical Labs

Key Strategies for Addressing Turnaround Time, Sample
Traceability, Data Fragmentation, and Compliance Challenges
in Today's Diagnostic Lab



Introduction

Clinical laboratories process thousands of samples daily, generating vast amounts of data. With pressures to report accurate results rapidly and maintain rigorous quality standards, labs must have complete visibility and control over day-to-day operations. However, reliance on manual processes and legacy systems hinders visibility and often leads to inefficiencies, lost samples, and compliance risks. Labs can enhance efficiency, accuracy, and performance by identifying and addressing four operational hurdles.

This whitepaper examines four key bottlenecks in today's clinical lab, identifies key paths to resolve them, and presents strategies to overcome them using an end-to-end configurable Laboratory Information Management System (LIMS) as part of a unified informatics platform.

The Four Key Bottlenecks

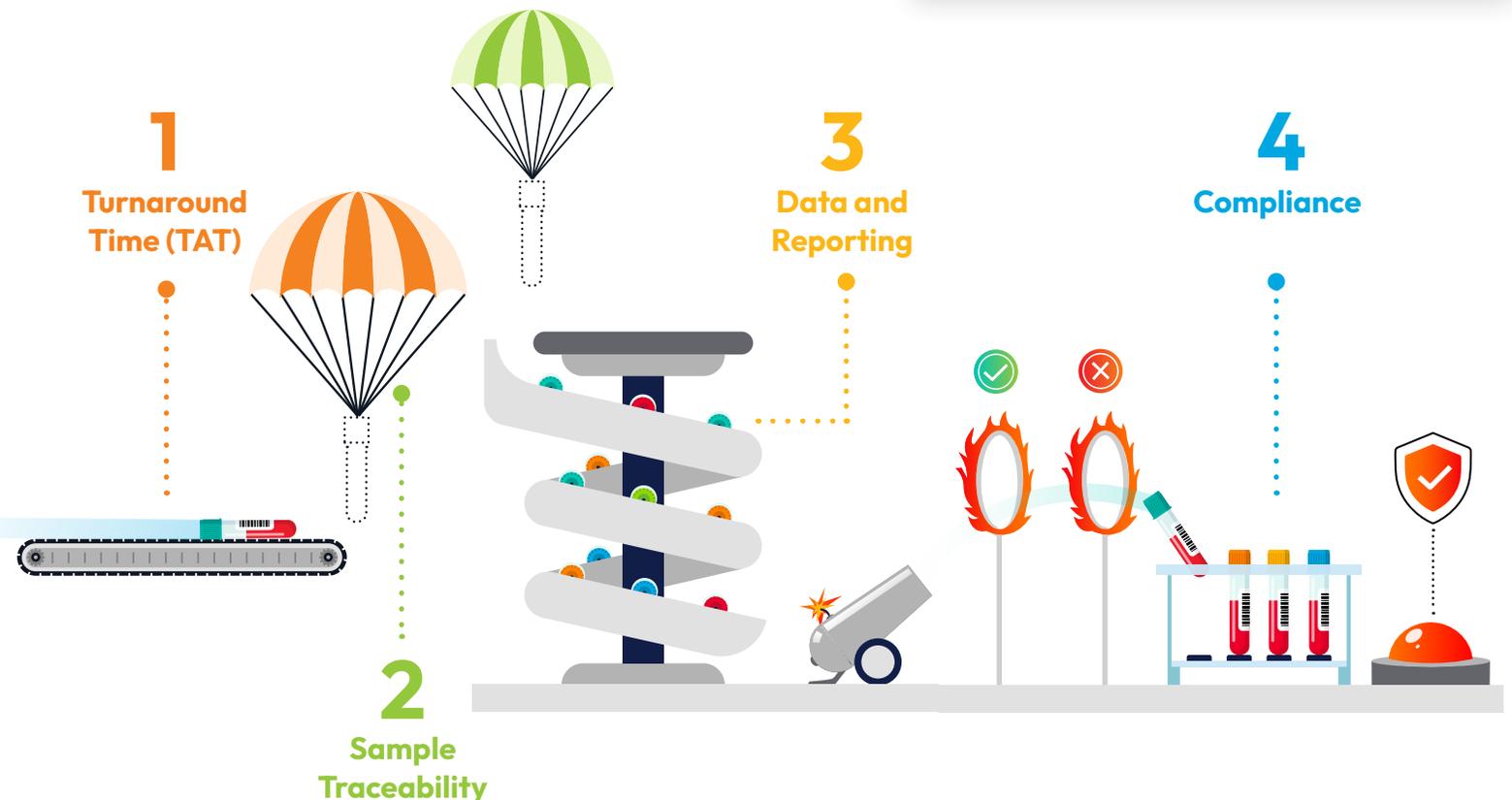


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Bottlenecks Impacting Clinical Labs: Turnaround Time (TAT)

In clinical labs, the speed at which test results are processed and delivered is critical, as faster results and the informed decisions they enable can be lifesaving. According to the Centers for Disease Control and Prevention (CDC), 70% of today's medical decisions rely on laboratory test results.¹ However, despite this crucial role, nearly 80% of clinical labs report receiving complaints about turnaround times.² This underscores the pressing need for labs to address the operational hurdles that slow the testing process.

Key components that contribute to delayed TAT include:



High Sample Volume and Data Complexity

The average clinical lab processes thousands of samples each day, while large labs can process 10k to 100k samples daily. Coupled with massive volumes of data, stringent quality control requirements, and other complexities, clinical labs require extraordinary efficiency and productivity. This is especially true for labs specializing in next-generation sequencing (NGS) or omics technologies (e.g., genomics, proteomics), which present unique demands for intricate sample management, continuous monitoring, instrument integration, and more.



Errors in Pre-Analytical Testing Phase

According to multiple studies, pre-analytical factors can account for 60% to 70% of TAT delays in clinical laboratories.³⁻⁷ The pre-analytical phase includes test requests, patient and specimen identification, specimen collection, transport, accessioning, and processing. The use of paper requisitions or disparate online ordering platforms can further complicate and impede the process. These outdated methods can lead to inefficiencies, delays, and errors in the ordering and accessioning phases.



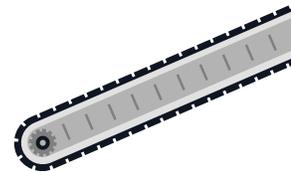
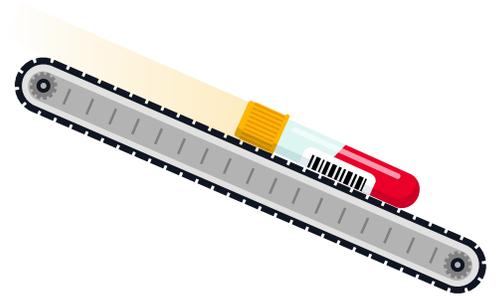
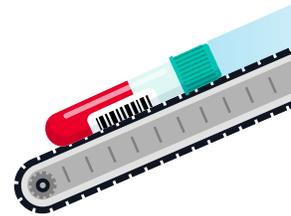
Staffing and Workforce Issues

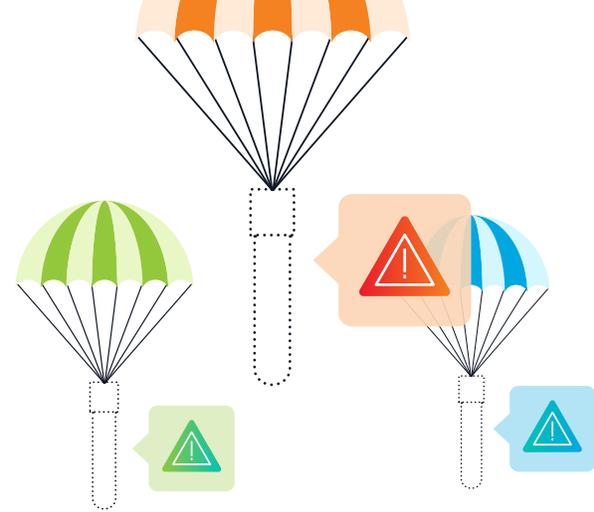
A shortage of skilled laboratory technicians and pathologists can delay the processing and analysis of samples. High workloads and burnout among staff can also affect efficiency and accuracy, further slowing turnaround times.



Sample and Workflow Management

Effective workflow management is crucial in minimizing turnaround times in clinical laboratories. Poor workflow management, such as the failure to prioritize urgent samples and inefficient sample handling procedures, can lead to significant delays. Implementing automated systems and standardized protocols can help streamline processes, ensuring that samples are processed in a timely and accurate manner, thus reducing overall TAT.





Problems can arise early in the test ordering phase if the lab does not provide clear instructions in their test compendiums at the front end of the ordering process. An integrated LIMS platform can solve this problem by seamlessly updating clinician-facing instructions like test description, sample requirements, collection instructions, and more with the touch of a button.

- Mike Cudemo, Director of Business Development, Sapio Sciences

Bottlenecks Impacting Clinical Labs: Sample Traceability

In 2016, the University of Minnesota Medical Center (UMMC) laboratories detected a trend of lost specimens. Upon investigation, they found that, on average, the laboratory could not account for 6 to 7 specimens per week or 25 to 30 specimens per month.⁴ Mislabeled specimens occur frequently, and specimen loss or mislabeling events can lead to catastrophic outcomes such as consequential delays in cancer diagnoses or unnecessary major surgical procedures.⁵

The ability to track and trace samples throughout their journey within the lab is a significant concern for clinical laboratories. Ensuring samples are correctly handled, tracked, and not lost is crucial for maintaining the lab's service quality and reputation. Accessioning, sample lineage, and chain of custody are critical components of this process.

Key factors that contribute to lost samples include:



Manual Accessioning Errors

Manual accessioning can lead to human errors, such as incorrect data entry, sample identification, registration, or mislabeling. These errors can result in samples being misrouted to the wrong testing process or improperly tested, which can compromise the integrity of test results or even lead to lost samples.



Chain of Custody Issues

Without a reliable chain of custody from collection to analysis, verifying that samples have been handled correctly throughout their lifecycle is challenging. This can lead to difficulties in identifying and resolving issues such as locating a missing sample or investigating discrepancies in test results.



Lack of Real-Time Data Tracking

Manual processes can make it difficult to track samples in real-time, leading to delays in identifying where samples are in the workflow. This lack of visibility can hinder the ability to prioritize urgent cases, identify bottlenecks, or provide feedback to physician clinics on result status and test completion dates.



Inconsistent Tracking Systems

Maintaining a comprehensive record of sample handling and movement within the lab is challenging. Tracking who handled the sample, what tests were performed, and where the sample was at any given time is often fragmented. This lack of continuity can lead to gaps in the sample's history, making it difficult to ensure complete traceability and accountability for results reporting and audits.

Bottlenecks Impacting Clinical Labs: Data & Reporting

Fragmented test data and reporting is a significant challenge in clinical laboratories. Fragmentation arises when different departments use legacy systems, poorly integrated data, inconsistent data standards, old manual entry techniques, and siloed information, leading to delays and errors in results reporting. This impedes the lab's ability to deliver accurate and timely results, affecting patient care and operational efficiency.

Key factors that contribute to fragmented data include:



Siloed Data Management

Different departments may use various data management systems that do not integrate effectively. This lack of integration can result in fragmented data, inconsistent formats, and redundant data entries. These inconsistencies make it challenging to maintain a unified and accurate data repository.



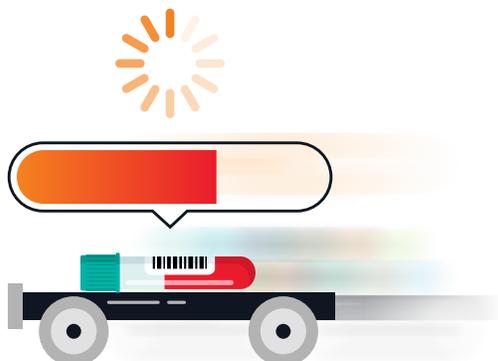
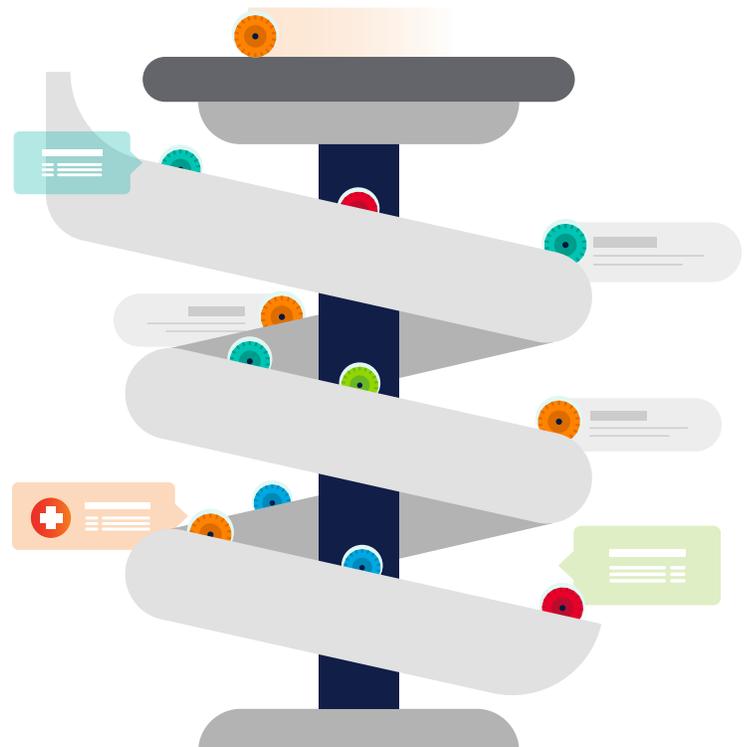
Challenges in Compiling Test Reports

Compiling results from multiple departments becomes time-consuming when data is fragmented. This can lead to difficulties consolidating test information for comprehensive analysis and delays in generating reports, which delay the delivery of crucial information to physicians and patients. Such delays can potentially impact treatment decisions and outcomes, compromising patient care.



Lack of Reporting Flexibility

Different departments may use various data management systems that do not integrate effectively. This lack of integration can result in fragmented data, inconsistent formats, and redundant data entries. These inconsistencies make it challenging to maintain a unified and accurate data repository.



Bottlenecks Impacting Clinical Labs: Compliance

Adhering to regulatory standards is a fundamental requirement for clinical labs. Non-compliance can result in penalties (including loss of regulatory certification), legal issues, and damage to the lab's reputation. Continuous monitoring, accurate record-keeping, and integrated data systems are essential to meet these standards and ensure comprehensive audit trails.

Key factors that can compromise regulatory compliance include:



Fragmented, Error-Prone Record Keeping

Fragmented and error-prone record keeping in a clinical diagnostics lab can lead to incomplete or inaccurate documentation, making it difficult to trace the history of sample handling and test results. Manual data entry, a lack of integrated systems, and incompatible data standards undermine compliance with regulatory standards, potentially resulting in failed audits, legal liabilities, and compromised patient care and safety.



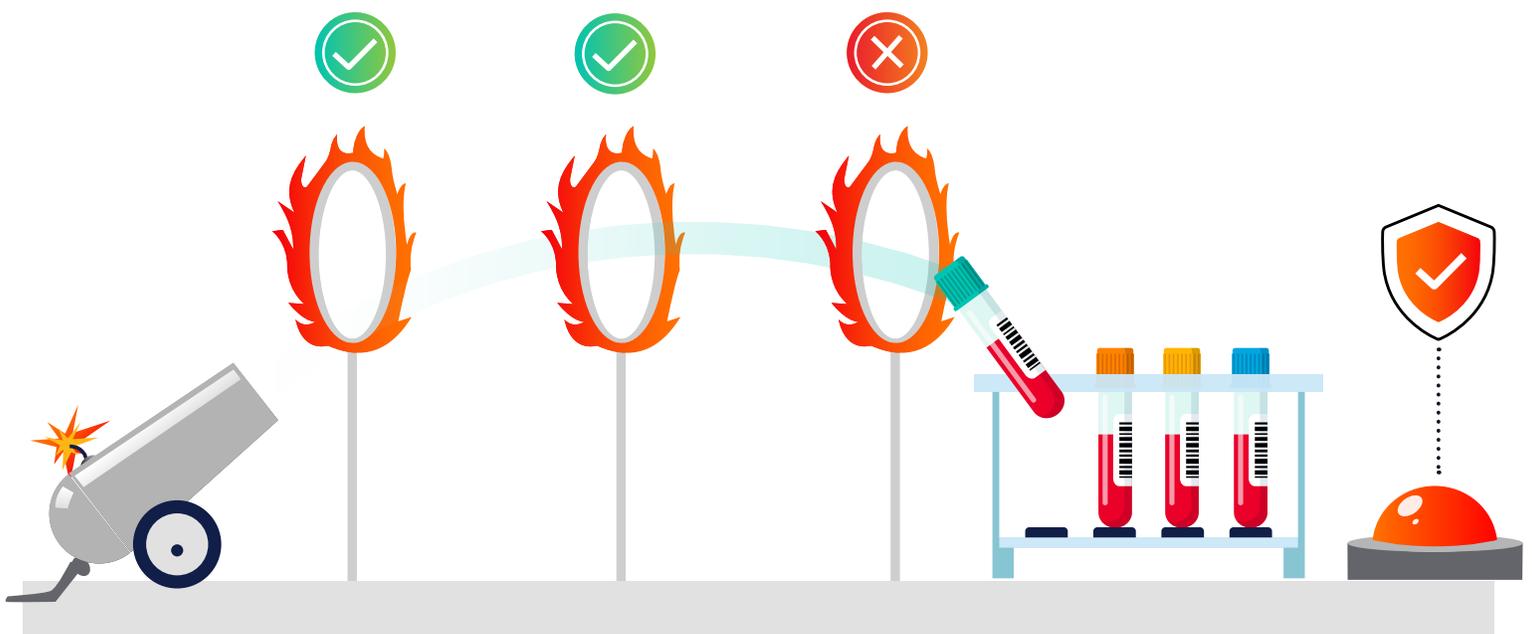
When Compliance is an Afterthought

Regulatory compliance mandates accurate and traceable data from sample collection to test results — which should be considered part of the workflow and lab processes rather than an afterthought. When compliance is an afterthought, audit trails, chain of custody, quality control, and compliance reports become tremendously time-consuming and difficult as your staff struggle to access the information they need to fulfill business obligations.



Flexibility to Manage Regulatory Updates and Audits

Modern Laboratory Information Management Systems (LIMS) are designed to meet laboratories' stringent regulatory requirements, such as Good Laboratory Practices (GLP) and Good Clinical Practices (GCP), ISO standards, and FDA regulations. They offer robust audit trails, data security features, and compliance reporting capabilities. Regulatory standards and guidelines are periodically updated. Labs must stay informed about these changes and promptly adjust their processes and documentation. Regular internal audits and inspections are crucial for ongoing compliance.





The Path to Solving 4 Clinical Diagnostic Lab Bottlenecks

A configurable, no-code Laboratory Information Management System (LIMS) effectively addresses these bottlenecks, enhancing operational efficiency, accuracy, and reliability.

The Path to Solving Clinical Lab Bottlenecks: Accelerating Lifesaving Decisions

A LIMS digitizes the sample lifecycle from accessioning to reporting, significantly enhancing turnaround time. Automated workflows reduce manual interventions and speed up processes. Real-time tracking identifies and resolves delays quickly, ensuring timely results. An end-to-end LIMS, integrated into your existing lab workflows and systems, ensures efficient processes, effective use of resources and staff, and integrated, easily accessible data.



Digital Accessioning and Order Processing

Reducing manual accessioning and order processing with the LIMS ensures samples are accessioned, transcribed, and processed accurately. This ensures a smooth and rapid transition from order placement to specimen sectioning and distribution to the appropriate internal workflows, enhancing TAT.



Point of Care Physician Portal

A physician portal extends the clinical workflow and order intake to the provider clinic, allowing physician customers to create orders, track status, and stay abreast of results. This improves communication, reduces confusion and frustration, and streamlines order placement, status tracking, and report delivery.



Faster Reporting Through Integrated Test Data

Since many clinical labs have an existing IT landscape of systems and instruments, your laboratory informatics platform must be open, meaning it can automate data integration across these otherwise siloed data sources. An open lab platform helps consolidate data and automatically generate unified reports based on results from various diagnostic departments such as FLOW, FISH, hematology, biochemistry, etc. Once signed, reports are automatically delivered back to the Physician Portal, ensuring timely and accurate communication of results, further accelerating the reporting process.



End-to-End Operational Backbone

A laser focus on efficiency and throughput is where a configurable, end-to-end lab operational backbone will accelerate your business velocity and excellence. This is achieved by bringing together all the elements of your process into one seamless flow and eliminating the friction and potential disconnections in handoffs between each step — from the clinic to logistics and distribution, accessioning, order processing, lab workflow, patient reporting, and compliance.



The Path to Solving Clinical Lab Bottlenecks:

Tackling Sample Traceability Bottlenecks

Effective sample tracking ensures that your business has full visibility of the sample status, location, history, and progress in real-time. This is essential to the integrity and reliability of test results. Barcoding and labeling systems provide precise identification and tracking.



Digital Accessioning and Order Processing

An open LIMS platform will digitize and automate sample registration, accessioning, and order processing to minimize manual errors. Digital accessioning will electronically register and log patient samples into a LIMS upon receipt, ensuring that each sample is uniquely identified and linked to the correct patient and test order. Order processing involves the digital handling and management of test orders—from entry into the system to assigning the appropriate laboratory tests and routing results to the relevant departments for analysis.



Automatic Sample Lineage & Chain of Custody

The LIMS platform should maintain sample lineage, including its source and any transformations or handling it has undergone during its lifecycle in a lab. This can include the documentation of where the sample came from, how it was processed and modified, and where it has been within the lab's workflow. As a sample continues its journey and is sectioned and distributed, the LIMS maintains a detailed chain of custody to track the control, transfer, and analysis of a sample from collection to final disposition.



Cross-Departmental and Geographic Location Tracking

Since a sample's journey is often complex—it can be sectioned, divided, and distributed to different departments and/or redirected to different locations or instruments for processing using specialized workflows—maintaining a birds-eye view of its progress is essential. Zooming in and out of different departmental tracking information must be possible to ensure samples are being processed efficiently.



Real-Time Test Reporting

Automated LIMS systems provide real-time updates on the location and status of each sample. This includes monitoring a sample's journey through various processing, analysis, and storage stages. Real-time test reporting helps prevent misplacement, delays, or loss of samples and/or reports for physician customers.



Reflex Testing

Setting up triggers for additional testing based on initial results ensures comprehensive diagnostics without manual intervention—maintaining traceability and accelerating the testing process.



Kit Management

Pre-registering kits and shipping them to patients for remote collection streamlines the process and ensures accurate tracking from start to finish. This proactive management reduces errors and improves traceability.



The Path to Solving Clinical Lab Bottlenecks: Unifying Data

Fragmented data hinders lab efficiency and accuracy. A centralized, open LIMS integrates data from various sources into a unified platform, eliminating silos. Standardized data formats reduce inconsistencies, making analysis and reporting easier. The platform automates data consolidation, generating comprehensive patient reports.



Centralized Data Access

Unifying lab data into a single system ensures that all relevant data is accessible from one location, reducing the risks of data fragmentation. This streamlined access improves the efficiency of real-time reporting by allowing quick retrieval of comprehensive data sets.



Improved Data Consistency

By consolidating lab data, discrepancies and variations across different data sources can be minimized, leading to more consistent and accurate data. Consistent data supports more reliable real-time reporting, enabling more accurate and timely decision-making.



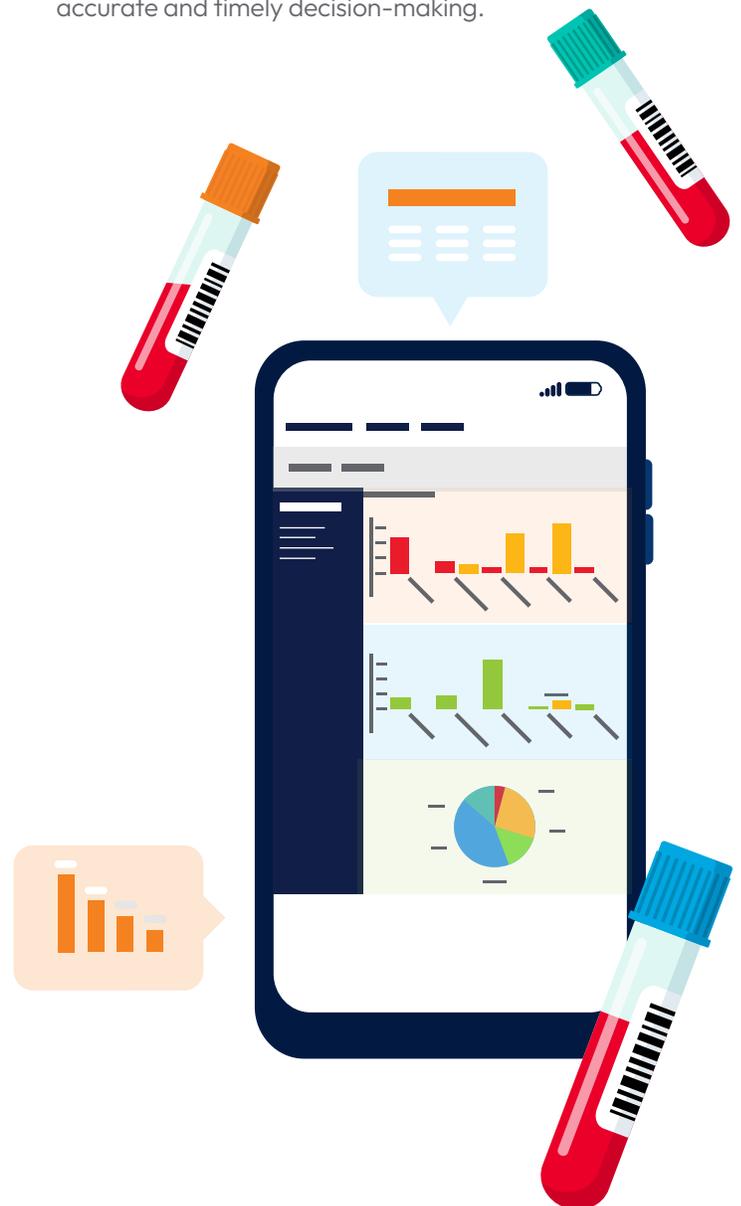
Enhanced Data Integration

Unifying lab data allows for seamless integration of various data types and formats, often fragmented across different platforms. This integration facilitates comprehensive real-time reporting by providing a complete view of all relevant data in one place.



Streamlined Workflow Automation

A unified lab data system supports the automation of data processing and reporting tasks, reducing manual interventions that can cause delays and errors. Automation improves the speed and accuracy of real-time reporting, enabling faster and more informed responses.



The Path to Solving Clinical Lab Bottlenecks: Built-In Compliance

Adhering to regulatory standards is crucial for lab credibility. A LIMS automates documentation, ensuring accurate records of procedures, results, and quality control measures. It provides real-time monitoring and auditing tools, helping labs stay compliant with current regulations and properly prepare for inspections. The platform maintains staff training and competency assessment records and is updated to reflect regulatory changes.



Automated Audit Reporting

A configurable no-code LIMS can automatically generate audit reports that comply with regulatory standards, reducing the burden on lab personnel. This automation ensures that audit trails are comprehensive, accurate, and readily available, making compliance easier and more reliable.



Error Reduction in Records

A no-code LIMS minimizes human errors in record-keeping by providing built-in validation rules and automated data entry processes. This leads to more accurate data, which is crucial for maintaining compliance and ensuring that records stand up to scrutiny during audits.



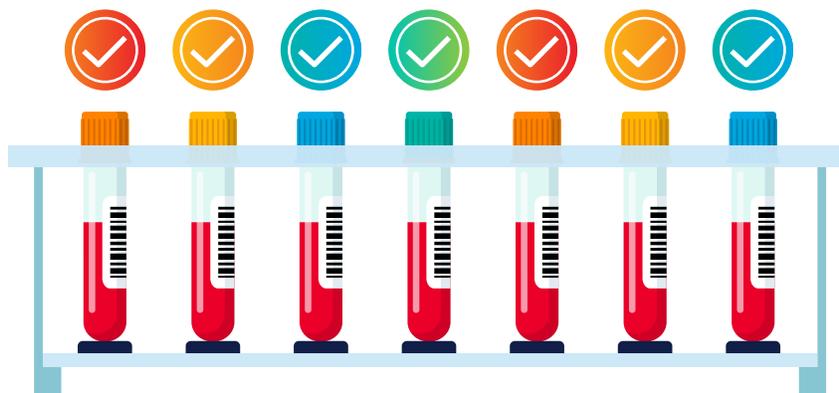
Flexibility to Changing Reporting Needs

A no-code LIMS allows easy customization of reporting templates and workflows without extensive programming. This flexibility ensures that labs can quickly adapt to new compliance requirements or changes in regulatory standards, maintaining ongoing compliance with minimal disruption.



Real-Time Compliance Monitoring

The LIMS, as part of a unified informatics platform, can continuously monitor data against compliance criteria, alerting users to any potential issues as they arise. This proactive approach allows for immediate corrective actions, helping maintain compliance and preventing issues before they escalate.





Summary

Clinical laboratories face significant challenges in turnaround times (TAT), sample traceability, data fragmentation, and compliance, which can hinder accuracy and efficiency. High sample volumes, pre-analytical errors, and workflow management issues delay TAT, while manual accessioning errors and inconsistent tracking systems compromise sample traceability.

Fragmented data from incompatible systems leads to delays in reporting and non-compliance with clinical regulations.

Implementing a configurable, no-code Laboratory Information Management System (LIMS), like [Sapio LIMS](#), can address these issues by automating workflows, ensuring real-time tracking, consolidating data, and supporting regulatory compliance. Sapio LIMS improves accuracy and enhances operational efficiency, providing a comprehensive solution for modern clinical diagnostics for better patient outcomes.

Introducing Sapio LIMS for Clinical Diagnostics

[Sapio LIMS](#) for Clinical Diagnostics is specifically designed to address the complex needs of clinical and molecular diagnostic laboratories. It provides a comprehensive, open, and configurable platform that tracks samples in real-time, unifies test data, automates workflows, and enhances diagnostic accuracy. It supports compliance needs and drives better outcomes, turnaround times, and operational efficiency.

Real-Time Sample Traceability

Sapio LIMS offers real-time sample traceability by providing a comprehensive, up-to-the-minute view of each sample's location, status, and history throughout its lifecycle in the laboratory. This capability ensures precise tracking and minimizes errors.

Configurable No-Code Workflow

Automate complex laboratory workflows to reduce manual errors, speed up processing times, and increase productivity, allowing lab professionals to focus on critical tasks.

End-to-End Platform

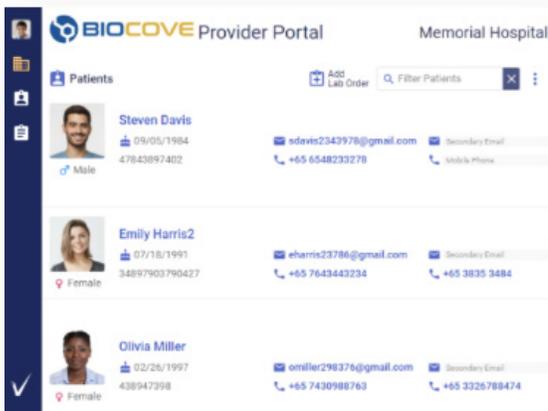
Sapio LIMS offers an end-to-end platform that seamlessly connects every stage of the diagnostic process, from physician portal to result reporting, providing a unified, streamlined, single-user experience.

Unified Data and Reporting

Efficiently manage large volumes of clinical and molecular diagnostic data with Sapio LIMS, ensuring secure storage, easy retrieval, and seamless integration across various laboratory systems.

Built-In Regulatory Compliance

Sapio LIMS supports compliance with industry standards and regulations, provides robust auditing capabilities, and ensures all processes adhere to applicable standards and guidelines.



Looking to learn about Sapio's scalable LIMS for clinical diagnostics?

Learn More



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