LabLynx

Improve Laboratory Accuracy and Reporting Quality with a LIMS

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Analytical mistakes represent a shrinking share of errors in well-run laboratories. In multiple studies of clinical testing laboratories, more than 90% of errors occur before or after tests are performed. [1] Relatively error-free testing should not be surprising. After all, the bench is where laboratories can exert the most control using:

- Standards-based processes,
- Instrument maintenance and calibration,
- Professional certification,
- Proficiency testing,
- Quality management, and
- Laboratory informatics.

Reducing analytical errors is a logical priority for a laboratory beginning its quality journey. At a certain point, however, laboratories must broaden their definition of testing. This total testing process starts with the initial test request or order and extends through the customer's interpretation of the final report. Errors may appear at any point in this total testing process, lengthening turnaround times, reducing efficiency, or leading customers to poor decisions based on incorrect or missing data.

This article will discuss ways errors creep into the total testing process and explain how to reduce or mitigate these errors by digitizing laboratory processes with a laboratory information management system (LIMS).

1. Looking beyond the test to control laboratory errors

When looking beyond purely analytical sources of errors, attention naturally focuses on sample preparation or results validation. Before and after the analysis, however, you can find many other ways things could go wrong. Potential problems include:

- Incomplete or illegible orders,
- Inappropriate test selection,
- Contaminated or poorly collected samples,
- Poor transportation conditions,
- Transcription errors in receiving,
- Lost or misplaced samples,
- Incorrect sub-sampling,
- Expired reagents,
- Transcription errors during data collection,
- Transcription errors during report creation,
- Lost or misdirected reports, and
- Customer misinterpretation of results.

Laboratories can control some of these error sources directly since they happen in the lab. Others occur at the interface between labs and their customers.

1.1 Learning from clinical laboratories

Because of the extensive literature discussing laboratory errors in the clinical setting, this article will extend the healthcare industry's framework to laboratory testing in general. Although specifics in other industries will vary, laboratory practices are similar enough to be useful for our purposes.

In an industry where test results directly affect patients' lives, clinical laboratories have a duty-and a legal responsibility-to reduce errors through rigorous quality management. The 2000 landmark report *To Err Is Human: Building a Safer Health System* put the human cost of medical errors in stark perspective. [2] An estimated 44,000-98,000 Americans died yearly from medical errors, a death rate higher than traffic accidents, breast cancer, or AIDS. This report helped change perspectives within the healthcare industry by highlighting the need to adopt more systematic approaches to medical quality.

Laboratories have since reduced testing errors; one study reports a decline from 0.47% in 1997 to 0.33% in 2007. [3] However, the downstream effects of these errors can be significant. As many as 30% of laboratory errors lead to problems in patient care [4], yet less than 10% of laboratory errors occur during the analytical stage. [1]

Laboratory error rates in other industries may not perfectly match the clinical experience, but they will be similar. To bring error rates under control, labs must look at where the problems are.

1.2 Stages in testing: Pre-analytical, analytical, and post-analytical

Studies of laboratory testing performance define three stages in the total testing process, which this article will follow: pre-analytical, from the initial request through the receipt, registration, and storage of samples; analytical, from sample preparation through the collection of test data; and post-analytical, from results validation through report generation, approval, and distribution, to interpretation by the customer.

Pre-analytical sources account for most laboratory errors-as high as 95% for specific tests-followed by post-analytical sources. [1, 4, 5, 6]

2. Eliminating pre-analytical errors

Any process depends on the quality of its inputs. Pre-analytical errors increase order-to-report turnaround times and make laboratories less productive. Minimizing the risks of pre-analytical errors requires a systematic evaluation of every stage in the process, even those outside the lab.

2.1 Order requests and sample collection

Many pre-analytical errors appear before samples arrive at the lab. Customers may not fill out order forms correctly, may skip fields, and may not even request the correct test. One clinical study found physician uncertainty about orders in 15% of cases [5], while another found at least one data entry error in 4.8% of orders. [4]

Labs can use standard operating procedures (SOPs), training, and quality control to ensure their staff collects samples correctly. However, laboratory customers or other third parties collect the samples in many cases. If they do not have similar sampling procedures, sample quality could suffer. While preparing for its ISO 9002 certification, a Thai clinical laboratory attributed 60% of its pre-analytical errors to sample quality, quantity, and container selection. [7] Similar sampling errors are common in other industries. For example, the physical properties of gold nuggets and the surrounding rock can lead to sampling errors ranging from 20% to 70%. [8]

Rough handling or environmental conditions during transportation can affect sample quality. Samples may become unusable when customers use inappropriate containers or shipping methods. One study found that 3.4% of clinical samples took too long to reach the lab, while 1.2% were exposed to excessive temperatures. [5]

Even though ordering and sampling errors are not directly the laboratory's responsibility, a LIMS solution can help reduce these errors.

2.1.1 Customer web portals

At the order-entry stage, reliance on paper forms and their PDF equivalents introduces errors due to incorrect, missing, and illegible information. A web portal integrated with your lab's LabLynx LIMS software reduces customer data entry errors in several ways.

A web portal's content can provide more information than a simple menu of available tests. Adding richer content about your lab’s testing services can help customers select the right test the first time. You can also reduce errors through the web portal’s layout. For example, making some fields required ensures that customers enter all necessary information. Programmable fields can also automatically populate the information that customers often forget. Drop-down boxes, lists, and other form elements minimize the information customers must manually enter. And validation rules ensure customer-entered data is correct.

Once the order is placed, additional content on the portal can guide customers through the sampling process.

2.1.2 Barcoded sample labels

Your LabLynx LIMS software can generate barcoded labels for every sample. Customers can download labels from your portal while placing their orders. For other ordering processes, your staff can email the electronic file or send printed labels to the customer.

2.1.3 Sample Information Collection Kits

LabLynx can also include Sample Information Collection Kits (SIC Kits), comprising a wireless tablet, barcode scanner, and label printer. WiFi connections to your lab's LIMS display sample data entry screens with the same capabilities as a web portal. Once complete, they generate and print a barcoded label for the sample. Distributing SIC Kits to regular customers streamlines their sample collection activities and improves the quality of sample information arriving at your lab.

2.2 Sample registration

Copying information from paper forms or spreadsheets is prone to transcription errors, a rate as high as 39% in some studies. [4] Web portals and customer-applied barcode labels significantly reduce the risks of errors during the registration process. Once these samples arrive at your laboratory, all associated information is already in the LIMS.

When your staff must process sample paperwork, they use a screen in your LIMS with design features like a web portal. Field types, programmability, and validation reduce data entry errors. Your staff can also document the conditions of newly registered samples, flagging issues that may impact further analysis. To help resolve issues quickly, your LabLynx LIMS software can email reports to customers and send notifications to appropriate laboratory personnel.

2.3 Sample storage, routing, and distribution

Usually, samples do not go straight into the testing process. Technicians may extract sub-samples, perform initial preparations, or place the samples into storage cabinets until their assigned test run.

With barcode scanners at each point in the sample's journey, your LabLynx LIMS can track each sample throughout the lab. The LIMS records the identity of technicians handling the sample at each stage, improving accountability, and providing a chain of custody. You can map your lab's sample storage down to the room, cabinet, and shelf location to reduce the number of times samples go missing.

2.4 Sample preparation

Automation of sample preparation has reduced errors in high-throughput testing labs. Robotics and automated workstations take the human factor out of extraction, evaporation, and other techniques. They can also reduce exposure to hazardous materials. Integrating your LabLynx LIMS solution with sample preparation equipment removes any remaining opportunities for human error.

3. Eliminating analytical errors

Although errors in the analytical stage have declined dramatically, they still impact laboratory performance and yield incorrect test results. Professional training, SOPs, standards-based methodologies, and other aspects of the analytical stage help reduce these errors. Still, mistakes will happen whenever people are part of the process. [9]

3.1 Instrument maintenance and calibration

Without regular calibration, laboratory instruments will introduce analytical bias into test results. [10] A 2004 National Institute of Standards and Technology (NIST) study of calibration error in clinical testing found that analytical bias could appear in 15% of calcium tests, with a potential annual economic impact of $199 million. [11]

LabLynx LIMS software solutions, integrated with your laboratory instruments, make it easier to manage instrument performance. You can plot control charts based on data from control samples. Scheduling regular maintenance and calibration events through your LIMS helps minimize disruption to your lab's operations. And your LabLynx LIMS stores all calibration records for future inspection.

3.2 Employee competence

Anyone conducting a test must have the experience and decision-making skills to do it correctly. In many industries, employees must meet minimum competency levels to perform specific test methods. In addition to training sessions and independent certifications, laboratories may regularly assess employees through direct observation. [12]

Your LIMS can maintain records of every employee's training and competency histories. Digitizing assessment forms can improve the consistency and objectivity of competency assessments. Data from your LIMS will populate the form automatically to eliminate transcription errors. Once the assessment is complete, your LIMS can generate an unalterable PDF of the final report. These records can quickly be made available to auditors during accreditation inspections to prove your lab competently performs its testing services.

3.3 Standard methods and workflows

Industry standards and validated internal methods improve test accuracy and precision by specifying science-based procedures for conducting repeatable and reproducible analyses. While these methods can be documented in SOPs and uploaded into a database, a LabLynx LIMS solution takes the next step by digitizing every step in the standard's methods and workflows. Your LIMS prevents sequential steps from being conducted out of order and schedules parallel steps to complete at the correct times. Digitizing test methods ensures that technicians follow proper test procedures every time.

LabLynx configures your LIMS implementation with standard methods common to your industry. These configurations are not locked in code. When a method must be adapted for a new testing scenario, simple tools let your staff quickly re-configure your methods and workflows. Where standard methods do not exist, your lab must develop and validate internal methods. Data fields, test criteria, and other elements in your LabLynx LIMS are easily changed. Should auditors or customers ask about a custom method's validation, your LIMS retains a permanent record of the tests you perform along with final reports.

3.4 Test setup and data collection

Preparing instruments and conducting the test has always been a manual process, creating opportunities for analytical errors. A study attributed 2.6% of a clinical lab's errors to transcription mistakes while transferring data between instruments and other systems. [5] To avoid these mistakes, analysts may take hours to ensure that the dozens of parameters for each sample are entered correctly. [13]

Once the test is complete, manually parsing the instrument's raw data is just as time-consuming. Instrument vendors may structure and format their data files differently. [14, 15] Field descriptions, for example, will not be the same. Using spreadsheets to parse instrument output files manually adds to the risk of analytical errors.

Integrating laboratory instruments with a LabLynx LIMS software solution eliminates these basic analytical errors. Setting up tests and batches in the LIMS rather than the instrument limits data entry errors. Test parameters that are specified by the standard cannot be altered. The LIMS can validate any parameters analysts must modify.

Once the batch has been created, the LIMS generates an instrument run list that analysts transfer to the instrument. Analysts take the instrument's results file and upload it into the LIMS. In both directions, the LIMS takes care of parsing the way each instrument structures and formats data.

4. Post-analytical errors

Errors introduced after analyses are complete can account for 18-47% of laboratory errors. [4] Incorrect calculations are common, but so are issues created by a laboratory's internal processes. [16, 17] Staff may skip validation and review. Final reports may be inaccurate or incomplete and may take too long to reach the customer, and once a report leaves the lab, the customer still has the opportunity to misinterpret the results.

4.1 Report creation and review

Analysts must process test data, calculate derived values, and compare the results to reference intervals and other criteria. [5, 12] Spreadsheet templates can simplify this process but carry the risk of transcription errors and autocorrect errors. [18]

Managing laboratory information in a LIMS streamlines results validation and report creation. The LIMS automatically evaluates results and flags issues such as out-of-range values. If the results pass critical thresholds, the LIMS can generate alerts for immediate action. This also applies to QC samples and standards.

The report itself is automatically generated in PDF or other electronic formats. Your LIMS populates all values in the report to eliminate the chance of data entry errors. The LIMS can also insert comments, charts, images, and other supporting information stored in its database.

4.2 Timely report distribution

A perfectly performed and analyzed test may be irrelevant if the customer does not receive the report on time. Excessive turnaround times are a form of laboratory error. [16] In the post-analytical stage, report delivery delays can result from drawn-out review processes or distribution mistakes.

A LabLynx LIMS software solution will expedite your lab's review process. When an analyst approves results in a batch and overall testing is complete, the LIMS queues up the order for review by an authorized supervisor. That approval tells the LIMS to generate the final PDF report.

Your LIMS can automatically distribute reports. Posting the reports to your customers' web portal accounts lets them download them at their convenience. LIMS integrations can transmit data to enterprise resource planning (ERP), electronic health record (EHR), or other systems. Alternatively, the report can be queued for physical distribution. Since the LIMS associates all customer information with every order, the chances of a misdirected report are minimal.

4.3 Report clarity

Reports must be easy for customers to read and interpret. Depending on the industry and use case, customers may receive hundreds of reports a week. A fraction of those reports—8% to 30% in some studies—will be misinterpreted. [5, 19] Reports must display measurement results, critical values, and other relevant information such as the analysts' comments.

LabLynx LIMS software solutions include report design tools that let you create templates for your lab reports. Use industry standards and conventions, as well as graphic design principles, to layout reports in ways that effectively communicate test results. Linking the template's data fields to your LIMS database ensures every report always has the correct information.

5. Digitizing lab processes with a LIMS improves lab quality

Reducing errors at every stage of the total testing process is essential to delivering consistent, quality services to your customers. Yet, using a LIMS to constrain sources of pre-analytical, analytical, and post-analytical errors offers benefits beyond improving test accuracy.

Productivity will improve dramatically. Your technicians, analysts, and scientists are highly trained professionals who spend too much time on routine manual tasks. Digitizing and automating these manual processes lets them do work that matches their skills. Freeing hours of their time, in turn, increases your lab's testing capacity.

A LabLynx LIMS solution is the foundation of your lab's quality and productivity. Your LIMS consolidates all laboratory data, from sample tracking to instrument maintenance to test results, in a single system. You can show accrediting agencies how you monitor laboratory performance, detect problems early, and continuously improve processes.

Contact LabLynx to learn how our LIMS software solutions can wring errors out of your lab's total testing process.

[1] Bilello JA. "CLIA Compliance for Pre-Analytic, Analytic, and Post-Analytic Testing Phases." *Lab Manager*. Oct 23, 2018.

[2] Institute of Medicine. *To Err Is Human: Building a Safer Health System*. The National Academies Press. 2000. doi: 10.17226/9728.

[3] Lippi G, Plebani M, Simundic AM. "Quality in laboratory diagnostics: from theory to practice." *Biochem Med* (Zagreb). 2010;20:126-130.

[4] Plebani M. "Errors in clinical laboratories or errors in laboratory medicine?" *Clin Chem Lab Med* 2006;44(6):750–759. doi: 10.1515/CCLM.2006.123.

[5] Mrazek C, Lippi G, Keppel MH et al. "Errors within the total laboratory testing process, from test selection to medical decision-making – A review of causes, consequences, surveillance and solutions." Biochem Med (Zagreb). 2020 Jun 15; 30(2): 020502. doi: 10.11613/BM.2020.020502.

[6] Reithel J. "Minimizing laboratory errors with automation." *Medical Laboratory Observer*. July 21, 2021.

[7] Wiwanitkit V. "Types and frequency of preanalytical mistakes in the first Thai ISO 9002:1994 certified clinical laboratory, a 6-month monitoring." *BMC Clin Pathol* 1, no. 5 (2001). doi: 10.1186/1472-6890-1-5.

[8] Dominy SC, Purevgerel S, Esbensen KH. "Quality and sampling error quantification for gold mineral resource estimation." *Spectroscopy Europe* 32, no. 6 (2020).

[9] "TGEP 32: Managing Risk on Geotechnical Projects Through Quality Laboratory Testing Programs." Engineering Management Institute. September 2021.

[10] "Good Laboratory Practice for the Quality Assurance of Laboratory Measurement Results." National Institute of Standards and Technology. May 2019.

[11] Gallaher MP, Mobley LR, Klee GG, Schryver P. "The Impact of Calibration Error in Medical Decision Making." National Institute of Standards and Technology. May 2004.

[12] Krleza JL, Honovic L, Tanaskovic JV et al. "Post-analytical laboratory work: national recommendations from the Working Group for Post-analytics on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine." *Biochem Med* (Zagreb). 2019 Jun 15; 29(2): 020502. doi: 10.11613/BM.2019.020502.

[13] Turner E, Paszko C, Kolva D. "Implementing a Laboratory Information Management System (LIMS) in an Army Corps of Engineers' Water Quality Testing Laboratory." *JALA: Journal of the Association for Laboratory Automation*. 2001;6(5):60-63. doi: 10.1016/S1535-5535-04-00158-3.

[14] Boogaard P, Segalstad S, Liscouski J, Sodano C, Trigg J, Muñoz-Willery I, Castelnovo R. "Building a Smart Laboratory 2018." *Scientific Computing*. Europa Science, 2018.

[15] Greene G , Ragland J , Trautt Z et al. "A Roadmap for LIMS at NIST Material Measurement Laboratory." Technical Note (NIST TN) 2216. National Institute of Standards and Technology. April 2022. doi: 10.6028/NIST.TN.2216.

[16] Plebani M. "The Detection and Prevention of Errors in Laboratory Medicine." *Annals of Clinical Biochemistry* 47, no. 2 (March 2010): 101–10. doi: 10.1258/acb.2009.009222.

[17] Teshome M, Worede A, Asmelash D. "Total Clinical Chemistry Laboratory Errors and Evaluation of the Analytical Quality Control Using Sigma Metric for Routine Clinical Chemistry Tests." *J Multidiscip Healthc*. 2021;14:125-136.

[18] Lewis D. "Autocorrect errors in Excel still creating genomics headache." *Nature*. (Aug 13 2021). doi: 10.1038/d41586-021-02211-4.

[19] Valenstein, P. "Formatting Pathology Reports: Applying Four Design Principles to Improve Communication and Patient Safety." *Arch Pathol Lab Med* (2008) 132, no. 1 (2008). doi: 10.5858/2008-132-84-FPRAFD.