

LIMS FOR TESTING LABORATORIES – AN OVERVIEW OF FEATURES AND COMPLIANCE FOR TESTING LABORATORIES



A laboratory that performs any type of test can be categorized as a testing laboratory. There are different types of testing laboratories such as food and beverage, environmental, cannabis, clinical, petrochemical, etc. Each testing laboratory needs to follow certain standard guidelines and compliance in order to receive recognition from regulatory bodies. The recognized International Standard for testing laboratories is ISO/IEC 17025:2005. It underlines the general competence requirements to carry out test and calibration across the globe. Additionally, it includes testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods. The standards are to be maintained by all laboratories performing test and/or calibration regardless of the sector to which it belongs i.e. private, government, semi-government, etc. Test results obtained by ISO/IEC 17025 compliant laboratories are relied upon by regulatory bodies and their customers. A Laboratory Information Management System (LIMS) can help testing laboratories to seamlessly meet the compliance requirements and present the testing data to third-party regulatory authorities during auditing. This white paper presents a general overview of the features and compliance requirements of testing laboratories and explains how a LIMS can help these laboratories meet them.

TYPE OF TESTS

At the highest level, there are two types of tests that testing laboratories usually perform:

qualitative and quantitative.

Qualitative Test: A qualitative test is used to determine the presence of an analyte in a sample based on its physical, chemical and biological properties. The response of a qualitative method is either the presence or absence of the analyte being tested in a sample. It does not determine the absolute/relative quantity of the analyte present in the sample.

Quantitative Test: A quantitative test provides an accurate estimation of the quantity of one or more analytes present in a sample.

To determine the accuracy of a quantitative test result, the test is replicated. The tests can be repeated as many times as required to ascertain the accuracy of the test result. There are two different methods to replicate a test.

- 1) The test can be performed either by the same technician twice.
- 2) Alternatively, two different technicians can perform the same test and the observed values of both tests can be compared to determine the accuracy of the test result.

Sometimes, the average of all observed values is calculated to determine the quantity of an analyte present in a sample.

REQUIREMENTS OF ISO/IEC 17025

Any testing laboratory interested to meet international testing standards and receive

ISO/IEC 17025 certification has to meet certain requirements. Some of them are outlined below:

1) Technical Requirements of Personnel Performing any Test

Technical competence of technicians performing laboratory tests is an important factor which governs the accuracy of test results. The testing laboratory should have an appropriate procedure for recruitment of efficient technicians. The technicians should have relevant practical experience and should be proficient enough to conduct specific tests without supervision. Post recruitment, the laboratory should take care of the training of the recruited technicians. This is to ensure that they have the required technical acumen for performing the tests assigned to them. The training program should include details of all methods or parts of methods and techniques that a technician is required to perform for successfully accomplishing the test. All relevant internal or external training details should be completely documented in training records. Each technician/analyst should also demonstrate their competency to conduct the test. Additionally, the laboratory supervisor/PI should continuously monitor the competency of all technicians performing tests using appropriate means (for example, visual observation).

2) Laboratory Work Space Organization and Environmental Conditions

In order to minimize any possible chances of

cross-contamination, it is imperative to organize all laboratory activities associated with any test. A laboratory workspace should be organized so that various activities such as sample preparation, extraction and analysis are spatially segregated. Alternatively, if a laboratory has a space constraint, the different activities should be performed at different time points.

Proper ventilation of a testing laboratory is crucial to avoid any cross-contamination. The temperature and humidity should be monitored closely round the clock.

3) Equipment

A testing laboratory should be fully equipped with the instruments required for the accurate performance of all tests. All testing equipment required for sampling, processing, and analysis of experimental test data should be available in standard condition in the laboratory. Additionally, the instruments requiring calibration should be calibrated as required to ensure accuracy of test results. A LIMS can help a laboratory manager setup calibration date reminders and maintenance schedules on time for such instruments so that the accuracy of test results is not compromised.

4) Choice of Test Methods

There is no restriction as far as the selection of a test method is concerned. The test method(s) can be determined based on the requirements of the client. All information pertaining to the new test

method should be disseminated to the client to ensure the range and accuracy of values obtained are in accordance with the client's needs. A laboratory can use a test method that is not taken from validated sources. However, any new test method needs to be properly validated before implementation. Besides, there should be detailed documentation of the new method for reference and auditing purposes. Whenever feasible, the testing methods should comply with the essential elements of regulatory standards.

5) Validation of the Test Method

Validation of a test method is crucial for any testing laboratory because it helps to ascertain the appropriateness of the test method for the intended purpose. For example, a method developed for determining the presence of a contaminant/microorganism in a food sample should be first validated to ensure that it can accurately identify the contaminant/microorganism. The method used for testing should meet the set standards for validation such as accuracy, specificity, calibration, range/limit of detection, ability to obtain the same, or almost the same test results on identical test material, under the same conditions within a short interval of time (i.e., repeatability) and the ability to obtain the same or nearly the same test results under different conditions (i.e., reproducibility). A method validation document is expected to include a detailed description of the test method used, preparation of calibration standard, potential interferences, a brief outline of the tests

performed to determine the validation parameters, signature of authorized personnel, etc. Once a method is validated, it can be used by the laboratory. The test results generated using this method should be duly signed along with a date and time stamp by an approving authority. A LIMS can help a laboratory manager/or authorized person to electronically record the results along with the date and time stamp and digitally sign it. These electronic records are referred to by the regulatory bodies during the audit process.

Periodical inspection of the implemented validated method is also required in order to confirm accuracy of the ongoing method. A LIMS can help in documenting the required frequency of inspection of validated methods and can timely alert the laboratory manager.

6) Proficiency Testing

This type of test helps monitor continuous performance of a laboratory for specific tests. In order to ensure that the testing laboratory continues to be ISO/IEC 17025 compliant, they are regularly monitored through proficiency testing. Participation of competent laboratories in proficiency testing and inter-laboratory test result comparison may be required periodically to demonstrate their technical competence. If a laboratory shows poor performance during proficiency testing, it needs to determine the factors responsible for poor performance and take the appropriate corrective measures.

GOOD LABORATORY PRACTICE (GLP)

GLP compliance is a set of principles designed to regulate the non-clinical safety testing of analytes present in pesticides, cosmetics, veterinary drugs, food items, industrial chemicals, etc. The primary objective of GLP principles is to promote generation of high quality test data that is validated. When data is submitted by a GLP compliant laboratory, it assures regulatory authorities that it corresponds to the actual results obtained during a study/test, deeming it as reliable. GLP principles are not intended to define scientific standards, rather it defines the quality standards for conducting a test or study, data collection, and reporting of results.

GLP Principles Include:

1) SOP (Standard Operating Procedure)

This outlines step-by step instructions to help laboratory personnel carry out routine testing operations. GLP does not exactly specify all the necessary details to be included while documenting SOPs. However, it ascertains that all laboratory personnel follow the same procedures as documented in the SOP. A LIMS can help in electronically documenting SOPs, and provide quick access to all authorized users.

2) Proper Labeling of Reagents

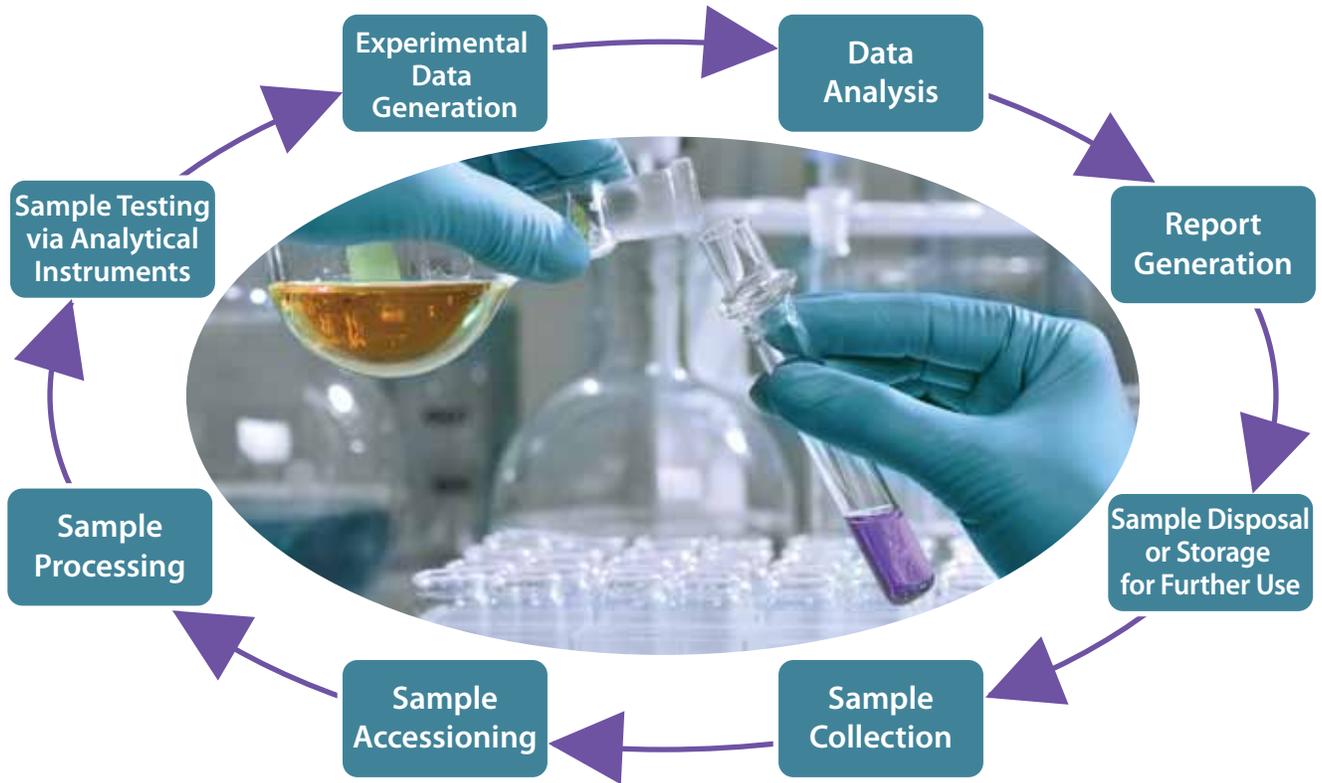
Proper labeling of reagents is essential for any testing laboratory because it enables laboratory

personnel to quickly identify details of a reagent such as its concentration, expiration date, storage requirements, etc. A LIMS can be integrated with label printers to print appropriate labels, which can be easily pasted on the reagent container. This reduces the chances of manual errors. Additionally, a LIMS can alert laboratory manager(s) to replenish stock reagents before they deplete/expire by setting an alarm level and an expiration date. This prevents any delay in performing tests due to the unavailability of required reagents.

3) Reporting of Experimental Data and Results and its Secure Archival

GLP requires experimental data, study plans and final reports to be systematically and securely saved for record keeping, reporting and retrieval whenever required. A LIMS can prove to be a pivotal tool for securely archiving this information. Electronically saving the data in a LIMS also eliminates the legibility issues that is introduced while recording manually.

Laboratories performing clinical tests using biospecimens should follow Good Clinical Laboratory Practice (GCLP). A clinical testing laboratory must have documented procedures for collection of specimens, transportation, and receiving of specimens. This is imperative because the accuracy of test results will depend on the integrity of the sample submitted to the laboratory for testing.



A schematic representation of a testing laboratory workflow

The sample must have the following information: collection site, collector's identity, sample type, collection date and other relevant information. A LIMS empowers laboratories to securely maintain this information. Any missing information should be properly investigated by the laboratory personnel before storing the sample. A complete audit trail, from the time a sample is collected until the time it is disposed off, must be maintained.

HOW A LIMS CAN AUTOMATE TESTING LABORATORY WORKFLOWS?

1) Any testing laboratory usually generates a lot of data. To seamlessly manage such big data, a LIMS plays a key role. It helps in managing samples,

tests, experimental data, control limits, and test results. Besides, any changes made to the test results is recorded in an audit trail. A LIMS helps in automatic accessioning of samples. Each sample is assigned a unique sample ID and subsequently associated with specific test(s) along with the ID of the technician performing the test. A LIMS can also automatically generate unique barcodes for each sample tested, thereby automating the sample tracking process.

2) A chain of custody (COC) is required in many laboratories that handle environmental, clinical, and forensic testing, as well as other laboratories that want to assure reliability of reported results. It is required in laboratories that handle samples

bound by legal or regulatory directives, including those enforced by United States government agencies such as the Department of Transportation (US DOT), the Environmental Protection Agency (US EPA), and the Food and Drug Administration (US FDA). To meet those legal and regulatory requirements, many laboratories are required to maintain a detailed chain of custody for all samples that move through their facilities. A LIMS facilitates maintaining Chain of Custody (COC) for all tests performed by a laboratory.

3) In testing laboratories, manual entry of analytical instrument data to a LIMS drastically hinders laboratory efficiency since it is error-prone and time consuming. A LIMS can be directly integrated with analytical instruments through an Application Programming Interface (API) to facilitate seamless uni-directional or bidirectional data transfer. This minimizes the chances of manual errors and reduces sample turnaround time, thereby escalating laboratory efficiency.

4) Flagging of test results which fall outside the normal reference range is crucial to bring it to the immediate attention of the technician performing the test or data reviewers. Abnormal test results can be attributed to a number of factors such as error in sample processing, error in performing the test, sample contamination, etc. It is also possible that the analyte being tested actually falls outside the normal reference range. A LIMS automatically flags test results if it falls outside the reference

range. This helps the technician/ laboratory manager to determine if a test needs to be repeated in order to confirm accuracy of the test result. If it is a quality assurance test, this would result in the batch being rejected for failing to meet the quality criteria.

5) Preserving data integrity is of paramount importance. In order to get approval from regulatory authorities, it is important to assure them that the data submitted is the actual data obtained during a test, and hence data integrity has not been compromised. A LIMS helps in preserving integrity of the test data and prevents unauthorized data obscuring or modification. Any changes made are authenticated by an authorized user through digital signature and are audit recorded. Thus, a LIMS enables testing laboratories to get approval from regulatory authorities seamlessly.

6) Manual generation of test report or certificate of analysis, and its delivery to the client or the concerned person is a major cause of inefficiency. By automating test report generation and delivery of the reports, a testing laboratory can enhance its efficiency and can enable laboratory researchers to focus on their actual work. A LIMS facilitates automated test report generation in an attractive format for presentation to the client or regulatory authorities. Besides, it also facilitates automated emailing of test results to the client, thereby reducing sample turnaround time.

CLOUD-BASED LIMS FOR TESTING LABORATORIES

A cloud-based LIMS is a cost effective LIMS solution with innumerable service advantages. In case of cloud-based LIMS, the actual LIMS software resides on a highly secure remote server and all authorized users can access it using their unique login credentials. Since the data is on the cloud, users can access it anytime, anywhere, using an internet-ready device. Cloud technology enables researchers and laboratories to share their data and results in real time with external researchers and their clients, thereby minimizing the testing turnaround time. Additionally, it minimizes the chances of data loss due to natural calamities since the data is saved on mirror servers located in disparate geographical locations. A cloud-based LIMS is highly scalable which enables laboratories to seamlessly cope with the ever changing laboratory data management needs. Software as a Service (SaaS) is the preferred delivery model of a cloud-based LIMS. SaaS leverages the power of Pay As You Go (PAYG) payment model to reduce expenses. Laboratory users can simply subscribe to use the software and scale as the laboratory requirements increase. Hence, a cloud-based LIMS requires

virtually a zero budgetary outlay, unlike on-premise LIMS, and is the preferred choice of testing laboratories for managing their data, reporting test results and for automating laboratory workflows.

CONCLUSION

Testing laboratories are under constant pressure to reduce cost, enhance efficiency and constantly improve the quality of search results. These laboratories need to effectively manage the entire life-cycle of each test sample, which includes sample accessioning, recording tests performed on the samples, managing experimental data and test results, besides permanent disposal of samples (if required). These laboratories are also subjected to compliance such as ISO/IEC 17025, GLP, and are required to follow them in order to receive international recognition from regulatory authorities. Managing laboratory data and meeting the regulatory requirements can be challenging, time consuming, and tedious. A cost-effective cloud-based LIMS seamlessly aids testing laboratories in managing big data, automating laboratory workflows and in meeting regulatory compliance, thereby saving time, cost and resources.