

Laboratory Information Management Services (LIMS)



# **Table of Contents**

Sr. No.	Particulars	Page No.
1	About Us	3
2	Laboratory Information Management System (LIMS)	6
3	PCS LIMS Solutions Matrix	8
4	PCS LIMS Sample Pathways	10
5	PCS LIMS Quality Control Features	12
6	Clients	16



## **About Us**

Established in 1983, PCS is a celebrated Indian IT solutions provider, delivering cutting-edge and innovative solutions that are tailored for your business objectives. With a global presence in over 20 Offices, 30 Service Centers along with 200+ direct point of presence across India, we help you enhance business performance by leveraging proven processes and technology solutions.



## **Creating Business Value**

PCS has decades of experience in delivering unparalleled customer delight through a distinctive business model. Our model functions on :

#### • Unique Pro-Customer Approach

Our client engagement transcends beyond business associations. We consider our clients as our partners, and offer flexible engagement models to create maximum value. Our teams work with you to understand your business goals and requirements, to help you cost-effectively streamline your operational efficiency and productivity, and achieve competitive edge.

At PCS, customer satisfaction is of utmost importance. Leveraging our culture of thought leadership and constructive ideation, we explore unique and novel solutions to ensure we exceed your expectations. A testimony to this is our wide clientele of prestigious Blue-chip and Fortune 500 companies.



### Global Partnerships for NextGen Solutions

We believe that two is better than one. This is why we establish long-lasting partnerships with the leaders in the field of technology to keep abreast of the evolving market dynamics and global trends.

Through symbiotic relationships, we ensure that our products and services are cutting-edge, aligned for the next generation market. We understand your challenges and work with you to deliver cost-effective and pragmatic solutions that meet not only your current requirements, but also your future objectives.

### Quality Excellence

We believe in achieving highest quality in all our operations and functions. To ensure superior quality in every parameter of our deliverables, we ensure that our business models surpass and create new global industry benchmarks.

Our processes comply with international best practices such as ITIL (Information Technology Infrastructure Library). In addition, our operations have been ISO certified for excellence in quality, services and security:

o **ISO 20000-1**: IT Service Management

o **ISO 27001**: Information Security

o **ISO 9001:2008** : Quality Management Systems





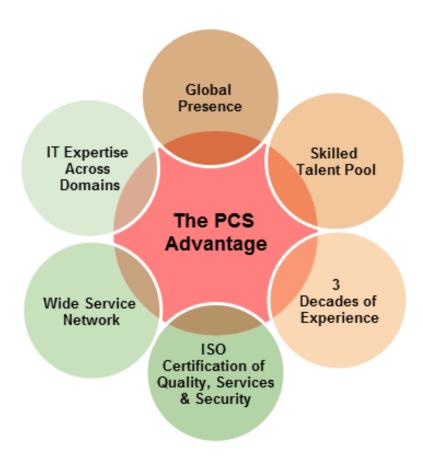


## Our Key Strengths

- Global presence
- Over 3 decades of experience in delivering business-critical, customized, cost-effective solutions
- o IT expertise across domains BFSI, Manufacturing, Media, Retail, Healthcare, Energy, Transportation, etc.
- Wide spectrum of service areas
- Expert talent pool of professional and experienced engineers
- Unmatched Services ISO 20000-1 Certified
- Robust Information Security ISO 27001 Certified



o Excellence in Quality - ISO 9001:2008 Certified





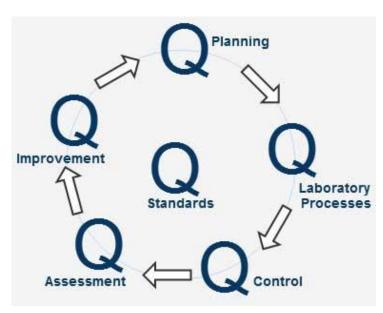
# **Laboratory Information Management System (LIMS)**

The precision and accuracy of data is vital in diagnostics laboratories due to its critical role in further patient therapy and clinical outcome. With multiple stages in the data cycle and a multitude of samples, manual information management becomes prone to errors.

PCS provides an agile and scalable solution by integrating isolated systems and functions into one powerful Laboratory Information Management System (LIMS).

PCS LIMS integrates different workflows, work lists and intercommunication between various work areas and collates them for optimized processes. In doing so, PCS LIMS also promotes a paperless work environment.

Through seamless systems implementation, PCS LIMS enhances the quality of information, by eliminating errors, improving data accuracy and ensuring robust data validation.



## **PCS LIMS Framework – Quality Excellence**

A milestone in itself, PCS LIMS is designed on the best practices of Total Quality Management. This ensures systematic and streamlined workflows, enhancing performance of various work areas and functions of the laboratory.

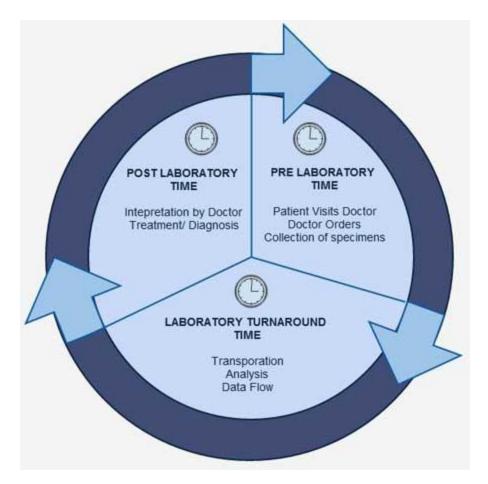
The TOM framework of PCS LIMS aims to achieve quality in every parameter of performance through:

- Quality Goals
- Quality Planning
- Quality Laboratory Processes
- Quality Control
- Quality Assessment
- Quality Improvement

## Quality Laboratory Processes

PCS LIMS helps you optimize laboratory processes, policies, standard operating procedures (SOPs), personnel standards and physical resources. With a focus on achieving accurate results, PCS LIMS streamlines all laboratory functions, making them more efficient and less error-prone. This reduces turnaround time (TAT) and improves efficacy.





## Quality Control (QC)

In order to ensure high quality of results, PCS LIMS helps you closely monitor the work processes, identify issues of nonconformance promptly, and initiate and track swift remediation. With PCS LIMS, you can efficiently manage and evaluate statistical process controls and quality controls, thereby maximizing the analytical performance of laboratory processes.

#### Quality Assessment (QA)

PCS LIMS enables you to keep a check on all the features and characteristics required for meeting customer requirements, including turnaround time, patient preparation, specimen acquisition, etc. Through PCS LIMS, you can monitor QA characteristics and ensure improved patient care and experience.

With a focus on optimizing TAT, PCS LIMS ensures seamless communication between different functions of the laboratory. This in turn enables a valid relationship between the patient and the result, thereby increasing productivity and brand equity.



## **PCS LIMS Solutions Matrix**

	Modules	PCSLABPLUS Enterprise	PCSLABPLUS	PCSLAB	PCSLAB-LITE	PCS LINK
1	PCS LABPLUS - CORE	~	~	-	-	-
2	Sample Registration OR 3rd Party Integration	~	~	Only Sample Registration	Only Sample Registration	-
3	Bar-coding & Sample Collection	~	~	~	-	-
4	Sample Acceptance	~	~	-	-	-
5	Work Area Management & Worksheets	~	~	Limited	-	-
6	Automation (Interfacing) Core Module	~	~	~	~	~
7	Unidirectional Interfacing (Per Analyzer)	~	~	~	~	~
8	Bidirectional Interfacing(Per Analyzer)	~	~	~	~	~
9	Authentications and History tracking	~	~	-	-	-
10	Result Entry & Reporting	<b>~</b>	~	~	~	-
11	MIS Information	Advanced	Advanced	Basic	Basic	-
12	Dispatch	~	~	-	-	-
13	Billing and Referral Analysis	~	~	~	-	-
14	Audits	~	~	-	-	-

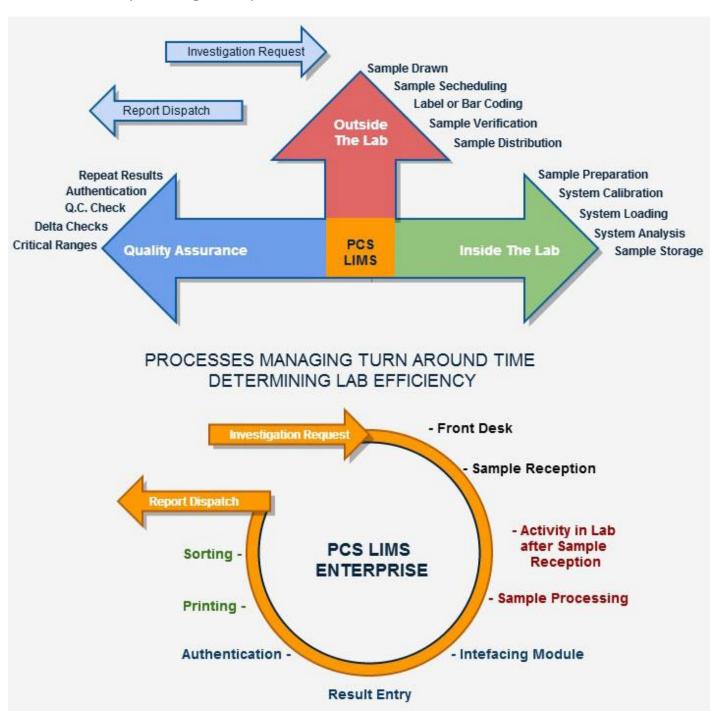


15	Web Appointment	~	~	-	-	-
16	Microbiology	~	~	-	-	-
17	Histopathology	~	~	-	-	-
18	Web Reporting (Add on Module)	~	~	~	~	-
19	Reagent Monitoring System	~	~	-	-	-
20	Radiology Information System	~	~	-	-	-
21	Storage Module	~	~	-	-	-
22	Customer Relation Module	~	-	-	-	-



## **PCS LIMS Sample Pathways**

PCS LIMS Enterprise optimizes workflows and turnaround time as per your customers' requirements, using an array of plug and play modules (optional systems). It employs structured sample pathways to ensure swift and efficient processing of samples.



PCS LIMS Sample Pathways



## The PCS LIMS Advantage

- Powerful, Integrated, Agile Laboratory Information System (LIS)
- Comprehensive Laboratory Management
- Improved Patient Care Quality
- Exhaustive Validation for Enhanced Data Accuracy & Precision
- Robust TQM (Total Quality Management) for Quality & Performance Excellence
- Reduced TAT, Improved Cost Savings, Enhanced Productivity
- Paperless Work Environment

To learn more about how PCS LIMS ensures superior quality, <u>download PCS LIMS Quality Control Features</u>.



# **PCS LIMS Quality Control Features**

#### **REQUEST LINE AUDIT**

"PCS LIMS", allows to audit these links - both top-down and bottom-up - for example when making a follow-up of a complaint as described in the scenario above. "PCS LIMS" permit's a detailed audit of this kind in both directions.

## Sample-line Audit

The result should be produced by an investigation performed on a given sample that has been collected from a certain individual. Implicit in this statement is "PCS LIMS" provides systems for sample labelling and identification that acts together with the sample cycle so as to prevent sample exchange by mistake.

#### Medical validation

A technologist responsible for patient results validation is using a "PCS LIMS" workstation. In the investigation of an unexpected result value of the measurement of parameter, alerted by a delta-check alarm, the technologist performs the following:

## Sample view

Sample view of results the technologist wants to see the results of the other measurements performed in the same sample, as this might give a clue, Logically the technologist then follows the relations from the result, through the investigation up to the sample and from the sample down through all investigations requested for that sample to their results.

#### **Historical view**

As no explanation for the unexpected value was found, technologist then displays all previous results of the same kind. In this case the route is from the results through the investigation and sample up to the patient, and from the patient down through all samples and investigations of the same type to their results. He now may inspect the historical view of that investigation. (The two last results of this view could be the basis for the delta-check alarm.)

### **Cumulative view**

Finally, it was necessary to display a complete cumulative view of results for this patient. The traces now combine those of the sample and historical views (see above): When moving down from the patient, a set of sample views is generated

#### **Audit View**

To make the audit view possible, it is important that there is workflow information available of all major events along the sample audit trail. All deletions and changes anywhere along this audit trail is traceable in "PCS LIMS".



#### ANALYTICAL TRACE ABILITY:

As defined by accredited bodies, is very important for quality management: The result of an investigation should be traceable back to appropriate analytical standards "through an unbroken chain of comparisons". "PCS LIMS" support's analytical trace ability.

"PCS LIMS" always permit tracing of a measurement result back to a certain analytical run on a given instrument (or in some cases, runs on several types of analytical equipment used in the measurement procedure).

"PCS LIMS" also provides possibilities to record information on the analytical quality of this/these analytical run(s), where this is possible and desirable. Examples of this kind of information include:

- Calibration data
- Results of internal quality controls
- Warning and error messages/codes issued by the analytic equipment employed

"PCS LIMS" present's this information in a user-friendly way on screen and on paper.

## Quality status of an analytical result.

"PCS LIMS" makes it possible to review easily every aspect of quality that may determine the validity and reliability of measurement results. Not forcing the technologist to look up for information in various sources, possibly located at different sites in the laboratory, to review the quality context of the unexpected result

A technologist responsible for patient results validation is using a "PCS LIMS" workstation as a consequence of the situation described in the scenario above, "PCS LIMS" support analytical audit by providing the following pieces of information:

- The instrument and method used for the actual measurement,
- Assessment of the previous calibration
- Status of short-term and long-term internal quality controls,
- Traces of patient result validation (automatic or performed by laboratory staff).

#### Calibration assessment

• "PCS LIMS" acquires calibration data on-line, and to store, process and display it graphically. Data of previous calibration data is also maintained. Automatic monitoring of the raw data produced during calibration is used to alert the operator when the calibration data falls outside specified parameters. When raw data for calibration falls outside the specified parameters, the computer system trigger a fault diagnosis process and suggest corrective action.

#### **Quality control**

 "PCS LIMS" acquire on-line, store and process data obtained during real time quality control, necessary for the technical validation of patient results, and long time quality control, used to assess the performance of each method of measurement over a period of time.



#### PATIENT RESULTS VALIDATION

The overall task of validation can be divided into

### **Technical validation phase:**

"PCS LIMS" have tools for computer-assisted validation of results and alerting functions, which may free the staff from the burden of evaluating a mass of non- suspicious data. Relevant traces of the validation activity is stored in the database both for auditing and documentation

As results are transmitted from the analyser a number of checks are applied to them to ensure that they are technically correct. Results that fail technical validation are put onto a technical validation fail list for investigation before a report is issued. Technologist monitors the technical validation fail list and results may be held while the samples are sent to a list for reanalysis as neat samples, diluted samples, or using increased volumes. Results on the technical validation fail list may be edited with the result from a manual or non-interfaced analysis replacing the original. The report may be passed for clinical validation with some results suppressed if the sample quality is suspect or interference is suspected. Comments may be added to the results explaining problems detected during technical validation.

### a) Instrument specific checks

- Technical Limit check. The results are checked to ensure that they are within the measurable limits for the analyser. Results outside the technical limits may be reanalysed, as dilutions or larger sample volumes. In some cases they may be reported as less than or greater than the limit exceeded. Clinically critical results that exceed the technical limits of the analyser, and have no other errors, may be added to an action queue to be given as interim report. E.g. if a glucose result exceeds the technicallimits of an analyser, an interim report is given to the medical team indicating that the glucose is greater than the technical limit and the actual value will follow.
- Analyser Error checks. Modern analysers perform a number of self-monitoring functions and may append a flag to patient results indicating the analyser status. Patient results that have a flag indicating an analyser error that may affect the quality of results (e.g. sampling mechanism operating erratically) must be held for review and/or re-analysis.

#### b) Real-Time Quality Control Status (RTQC Status)

The Fundamental process in assessing the validity of patients' results is establishing the RTQC status. This process may be a simple target value and allowable range for each control material used, or the use of multi-rule and multi-stage processes. The RTQC status must be acceptable for patient results to pass this stage of production. Acceptable RTQC status ensures that the patients' result fall within the defined Allowable Analytical Error (AAE) for each analysis.



#### **Clinical Validation Phase:**

The purpose of this process is to run a "clinical believability" or plausibility check on the results and to identify results requiring discussion with and /or urgent communication to the medical team, i.e. to ensure that results in the final patient report are consistent with each other, previous results, clinical diagnosis and treatment, and do not fit a result pattern that indicates sample contamination or mix-up. Clinically implausible results might indicate a laboratory error; hence it is useful to check further before results are released. The ultimate purpose is to ensure that the report can be used in the diagnosis and treatment of the patient. The results in the final patient report may have been generated by a number of different analysers and/or manual methods. Clinical validation is normally performed once patient results have passed Technical validation. Failure during the Clinical Validation phase will result in further investigation of the report and may include re-analysis of the sample, checking the labelling and identification of the sample, confirming the all pre- analytical variables are known, and that the performance of the analysers is acceptable.

Clinical validation may be used to identify results that are clinically critical and should be communicated to the medical team treating the patient. Results that fail clinical validation are put onto a clinical validation queue for investigation before a report is issued. Senior laboratory staff process this queue by investigating each failed report and confirming the validity of the results. The report is thus validated and can be released to the medical team. The staff processing the validation queue may add comments and explanations to the report, and transfer the report to the ward or for discussion with the medical team. If the results are outside defined limits (e.g. Sodium < 120 mmol/l) the validated report may also be added to a review queue for the laboratory physician.

To assist Clinical Validation, ""PCS LIMS " provides appropriate checking algorithms. Here follow short descriptions of commonly used checks:

- Limits-based checks. Results that fall outside predefined warning and panic limits, and pass deltachecks and clinical detail checks, are held for further investigation or communication to the medical team. As for results that fail the technical limits, clinically critical results that exceed the warning or panic limits can be released as interim report if the laboratory physician has not authenticated the results.
- **Delta-checks.** This process involves the comparison of present results with past results and checking that there is not an unreasonable change between the two results. This is the most common form of clinical validation and is useful in detecting sample mix-ups, pre-analytical errors or laboratory error not detected by technical validation.
- Result Pattern checks. (Co-relational Checks) This is also referred to as Internal Consistency checks. It involves checking abnormal results with other results on the same sample to confirm that they conform to a pattern consistent with a known condition, e.g. a report with a raised creatinine should also have a raised urea. Results that do not fit an acceptable pattern must be held for further investigation. Results can also be checked for patterns that indicate incorrect anticoagulant use (e.g. ETDA) or incorrect storage of samples (e.g. sample left un separated overnight).
- Clinical Details checks. This process evaluates the results with the available details of the medical context. The results are evaluated against the known clinical details of diagnosis, treatment and progression of disease states. The clinical details may be available from the request form or be available from an integrated Hospital Information System and LIS. Results that are not consistent with the clinical details must be held for further investigation.

Laboratories produce large amounts of data and "PCS LIMS" can help in ensuring the quality of this data. Filtering suspicious data can help focus resources and prevent data pollution.



## **Clients**

## Clientele - International























#### Elite Clientele - National





























