Point-of-Care Testing (POCT): A Comprehensive Review of Integration and Validation Across Diverse Clinical Disciplines

Selvakumar Kandaswamy[1], Suganthi Muralidharan[2], Saravanan Radhakrishnan[3]
[1]*Founder and General Secretary, Indian Association of Basic and Paramedical Sciences, Chennai, Tamil Nadu, India*
Consultant Medical Biochemist, Kauvery Reference Laboratory, Chennai, Tamil Nadu, India
[2]*Asst. Professor, Department of Biochemistry, ESIC Medical College, Hospital, K K Nagar, Chennai, Tamil Nadu, India*
[3]*Asst. Professor, Department of Biochemistry, Indira Medical College, Hospitals, Pandur, Chennai, Tamil Nadu 631203 India*

Abstract - Point-of-care testing (POCT) has emerged as a transformative approach in clinical diagnostics, providing rapid results at or near the site of patient care. Its increasing use in emergency departments, intensive care units, and outpatient clinics has redefined diagnostic pathways by shortening turnaround time and facilitating timely therapeutic decisions. However, the benefits of POCT can only be realized if implementation is structured, validation is rigorous, and quality assurance measures are sustained. This review critically examines the evolution of POCT, strategies for clinical integration, and frameworks for analytical validation, while contrasting POCT with central laboratory systems. The roles of external quality assessment (EQA), daily internal quality control (QC), and institutional governance—including oversight by laboratory directors, quality managers, and point-of-care coordinators—are emphasized. The review also outlines challenges such as cost, operator variability, and data integration, and explores emerging trends including multiplex assays, digital connectivity, and artificial intelligence-driven diagnostics. Together, these insights provide a comprehensive overview for laboratory professionals, clinicians, and policy makers to guide safe and effective adoption of POCT in line with international standards.

Keywords- Point-of-care testing (POCT); Implementation; Validation; Quality assurance; Multiplex diagnostics; Regulatory frameworks; Digital health; Clinical governance

I.INTRODUCTION

The demand for rapid diagnostic information has led to an unprecedented expansion of point-of-care testing (POCT) across healthcare systems worldwide. Unlike conventional laboratory testing, which involves centralized sample processing and longer reporting intervals, POCT enables clinicians to obtain actionable results within minutes, often at the patient's bedside. This immediacy is particularly valuable in acute care settings where decisions must be made swiftly, such as in the management of myocardial infarction, sepsis, or hypoglycemia (1,2).

The global growth of POCT has been propelled by technological innovation, including portable immunoassay devices, microfluidics, and integrated biosensors. Equally important has been the recognition by regulatory bodies and professional organizations that decentralized testing requires structured oversight to ensure accuracy and reliability. Standards such as ISO 15189:2022 and ISO 22870:2016 now explicitly incorporate POCT within the scope of laboratory quality and competence, requiring institutions to demonstrate compliance in areas such as staff training, method verification, and quality assurance (3–5).

Despite its advantages, POCT is not without limitations. Variability in operator competency, lack of connectivity with laboratory information systems, and higher per-test costs compared with central laboratory testing remain significant barriers (6). To address these issues, implementation strategies increasingly emphasize multidisciplinary governance, with oversight by laboratory directors, dedicated point-of-care coordinators, and quality managers who ensure

adherence to validation protocols, internal quality control (QC), and external quality assessment (EQA) schemes.

This review aims to provide a comprehensive examination of POCT from both clinical and laboratory perspectives. Specifically, it discusses the historical evolution and implementation of POCT across departments, explores approaches to validation and quality monitoring, contrasts POCT with central laboratory methodologies, and highlights challenges and future directions. In doing so, the review underscores that POCT is not a substitute for central laboratory services but a complementary diagnostic strategy that must be integrated within institutional quality frameworks to maximize patient benefit.

II.HISTORICAL CONTEXT AND EVOLUTION OF POCT

The origins of point-of-care testing (POCT) can be traced back to the early 20th century with the development of simple bedside assays such as urine dipsticks and glucometers. These early devices, though limited in scope, demonstrated the potential of providing clinicians with rapid diagnostic information without reliance on centralized laboratory workflows. By the 1980s and 1990s, the introduction of portable blood gas analyzers, handheld coagulation meters, and rapid pregnancy tests marked a turning point in the clinical acceptance of POCT as more than a niche technology (7,8).

Technological progress has since expanded the menu of POCT devices to include immunoassays for cardiac biomarkers, molecular platforms for infectious diseases, and portable analyzers capable of performing multiplex testing. The COVID-19 pandemic further accelerated innovation by highlighting the role of POCT in public health surveillance and mass screening. Rapid antigen and molecular assays became frontline diagnostic tools, underscoring both the strengths of POCT in accessibility and its limitations in sensitivity and quality variability across manufacturers (9).

III.IMPLEMENTATION OF POCT IN HEALTHCARE SYSTEMS

The successful implementation of POCT depends on more than device availability. It requires an integrated program that balances clinical utility, cost-effectiveness, and quality assurance. Hospitals and healthcare networks typically adopt POCT in areas where rapid turnaround is critical—such as emergency departments, intensive care units, operating theaters, neonatal intensive care units, and transplant wards. In these contexts, immediate results directly influence clinical management, making POCT indispensable (10,11).

From a systems perspective, implementation involves several key steps:

1. Needs assessment – Determining which clinical questions require immediate diagnostic support.
2. Device selection – Evaluating technologies against criteria such as accuracy, connectivity, operator usability, and compliance with standards (CLSI POCT09 provides structured guidelines).
3. Training and competency assessment – Ensuring that non-laboratory staff such as nurses and physicians are trained and regularly assessed in performing POCT correctly.
4. Governance structure – Establishing oversight through a POCT committee that includes the laboratory director, point-of-care coordinator, and quality manager.
5. Integration with information systems – Linking devices to laboratory and hospital information systems to enable real-time result capture, traceability, and audit.

Implementation models vary globally depending on healthcare structure. High-income countries often integrate POCT into electronic health records with strong laboratory oversight, while resource-limited settings rely more on rapid diagnostic tests (RDTs) for conditions like malaria, HIV, and tuberculosis, often supported by WHO programs (12). Regardless of setting, structured governance is universally recognized as the cornerstone of safe POCT deployment.

IV.VALIDATION AND PRACTICAL BENEFITS OF POCT

Validation is the cornerstone of safe and reliable point-of-care testing (POCT). Unlike centralized

laboratories where methods undergo extensive regulatory clearance and validation, POCT devices are often used by non-laboratory staff in decentralized settings. This makes rigorous validation and continuous quality monitoring essential for ensuring patient safety and diagnostic accuracy (13).

Analytical Validation of POCT

Validation of POCT must address several dimensions:

- Accuracy and comparability: Results should be benchmarked against central laboratory instruments, often using method comparison studies (CLSI EP09 guidelines). For example, glucose meters and blood gas analyzers are validated by running patient samples in parallel with core laboratory systems to establish bias and limits of agreement.
- Precision and reproducibility: Repeated testing on control materials or patient samples helps identify variability introduced by operators or environmental factors.
- Detection limits and linearity: Particularly critical for cardiac markers such as troponin, where clinical decision thresholds are narrow.
- Matrix effects: Whole blood, capillary samples, and plasma can yield different results compared to serum in central labs, requiring careful verification of matrix equivalence.

Comparison with Central Laboratory Testing

While central laboratories remain the gold standard for accuracy and breadth of testing, POCT provides unique advantages in clinical decision-making. For instance:

- Turnaround time (TAT): POCT can reduce TAT from hours to minutes, critical for myocardial infarction, sepsis, and neonatal hypoglycemia.
- Workflow impact: Rapid results allow clinicians to initiate therapy at the bedside, reducing unnecessary admissions or delays in treatment.
- Accessibility: In remote or resource-limited settings, POCT can be the only available diagnostic tool.

However, central laboratories provide more robust quality assurance, including automated calibration, continuous internal QC, and extensive external quality assessment (EQA). Thus, POCT should be viewed as complementary, not as a replacement.

Quality Assurance: Daily QC and EQA

Maintaining quality in POCT programs requires structured internal and external checks:

- Daily QC: Devices must be run with control materials at defined intervals, with results reviewed by the POCT coordinator or central laboratory staff. Failures trigger troubleshooting and retraining.
- External Quality Assessment (EQA): Participation in proficiency testing schemes ensures benchmarking against peer laboratories. EQA also highlights systemic issues such as lot-to-lot variability in test strips or operator performance differences.
- Documentation and traceability: Results, QC, and operator identity must be electronically logged for audit, as mandated by ISO 15189:2022.

Clinical Benefits

Validated and well-managed POCT programs provide several benefits:

- Faster clinical decisions in emergencies.
- Reduced burden on central laboratories for high-volume, near-patient tests.
- Improved patient satisfaction due to shorter waiting times.
- Better disease surveillance in community and resource-limited settings.

Ultimately, the value of POCT lies in its integration with laboratory governance. When combined with strong validation protocols, daily QC, and EQA, POCT can significantly improve patient care without compromising analytical quality.

V.CHALLENGES, GOVERNANCE, AND FUTURE DIRECTIONS

Matrix-Level Challenges in POCT: A fundamental consideration in point-of-care testing (POCT) is the effect of biological matrices on test performance. Unlike central laboratories that generally analyze serum or plasma following standardized pre-analytical processing, POCT devices frequently utilize whole blood obtained from capillary, venous, or arterial sources. Differences in hematocrit, protein content, lipemia, or cellular components can introduce significant bias in analyte measurement. For example, high hematocrit levels may affect glucose oxidase-

based strip methods, leading to underestimation of blood glucose, while hemolysis may interfere with electrolyte readings on portable analyzers (14).

Additionally, POCT often occurs in environments outside strict laboratory control—such as emergency rooms, wards, or even community clinics—where temperature, humidity, and sample handling may vary widely. Such conditions can compromise assay stability and reproducibility. Addressing matrix-related challenges requires careful method verification at the institutional level, ensuring that device performance in whole blood or capillary specimens aligns with central laboratory results in plasma or serum. Manufacturers' claims must be independently verified by the implementing laboratory as mandated by ISO 15189:2022.

VI.GOVERNANCE AND OVERSIGHT STRUCTURES

The complexity of POCT implementation necessitates a multilayered governance framework to safeguard patient safety. Accreditation standards such as ISO 15189:2022 and its companion ISO 22870:2016 clearly articulate the roles and responsibilities required to maintain compliance.

- Laboratory Director: Holds ultimate responsibility for ensuring that POCT services meet the same quality standards as central laboratory testing. The director must approve device selection, validation protocols, and quality management systems. In many institutions, the laboratory director also chairs the POCT committee, ensuring alignment with institutional priorities.
- Quality Manager (QM): Provides oversight of the quality management system, ensuring adherence to internal quality control (QC), external quality assessment (EQA), documentation, and audit processes. The QM ensures that deviations are tracked, corrective actions implemented, and continuous improvement maintained.
- POCT Coordinator: Acts as the operational link between the laboratory and clinical departments. Responsibilities include training non-laboratory staff, supervising competency assessments, monitoring daily QC, troubleshooting device errors, and maintaining communication with suppliers. The coordinator also ensures that POCT results are captured in the laboratory information system (LIS) or electronic medical record (EMR).

Together, this governance triad establishes accountability, minimizes risk, and ensures that POCT programs operate under the same quality umbrella as laboratory medicine.

VII.TRAINING, COMPETENCY, AND HUMAN FACTORS

Since POCT is often performed by non-laboratory staff such as nurses or physicians, human factors play a critical role in result accuracy. Errors are frequently pre-analytical—arising from improper specimen collection, inadequate mixing of anticoagulants, or failure to adhere to device instructions. Post-analytical errors may also occur, such as incorrect result transcription or delayed communication to clinicians (15).

Effective training programs are therefore non-negotiable. Staff must demonstrate competency through structured assessments, and retraining must be scheduled regularly or whenever errors are identified. Simulation-based training has been shown to improve operator confidence and reduce error rates in high-stress environments like intensive care units. Furthermore, competency assessment should extend beyond technical skills to include awareness of limitations, such as recognizing when confirmatory testing in the central laboratory is required.

Connectivity and Data Integration

One of the persistent challenges in POCT programs is integrating results into institutional information systems. Historically, POCT results were recorded manually, increasing the risk of transcription errors and incomplete records. Modern POCT devices now feature connectivity solutions that enable automatic upload to LIS and EMR platforms. Such integration not only ensures accuracy but also facilitates audit trails, QC monitoring, and clinical decision support.

The ISO 15189:2022 standard requires full traceability of results, including operator identity, device ID, QC status, and calibration records. Therefore, connectivity is no longer optional but essential for accreditation and for maximizing the clinical utility of POCT. Institutions that fail to implement robust connectivity solutions risk fragmentation of patient data and reduced trust in POCT results.

Economic Considerations

Although POCT offers clear clinical benefits, cost remains a significant concern. Per-test costs of POCT devices are typically higher than equivalent central laboratory tests due to proprietary consumables, calibration cartridges, and maintenance contracts. However, the total cost of care may be reduced by faster clinical decision-making, decreased hospital stays, and improved patient throughput. Cost–benefit analyses must therefore consider both direct and indirect savings. For example, early detection of sepsis through POCT lactate measurement may justify higher consumable costs by reducing intensive care admissions and associated mortality.

External Quality Assurance (EQA) and Accreditation

Participation in external quality assurance (EQA) programs is essential to demonstrate the comparability of POCT results with peer laboratories. EQA schemes provide independent verification of accuracy and highlight systemic errors, such as lot-to-lot variability in test strips or device calibration drift. Institutions must establish clear procedures for responding to unsatisfactory EQA performance, including root cause analysis and retraining.

Accreditation bodies such as the College of American Pathologists (CAP), Joint Commission International (JCI), and national boards (e.g., NABH in India) mandate active participation in EQA. Failure to do so jeopardizes accreditation status and undermines clinical trust in POCT results.

VIII.FUTURE DIRECTIONS IN POCT

The future of POCT is being shaped by innovations in multiplexing, digital health, and artificial intelligence (AI). Multiplex devices allow simultaneous testing of multiple analytes, supporting syndromic panels for respiratory infections or cardiovascular risk assessment. Digital health integration enables POCT data to feed directly into clinical dashboards and decision-support algorithms, enhancing precision medicine. AI is increasingly being applied to interpret complex POCT outputs, flag abnormal patterns, and predict clinical deterioration (16).

Wearable biosensors represent another frontier, providing continuous monitoring of glucose, electrolytes, or cardiac parameters. These devices blur the boundaries between diagnostic testing and patient monitoring, raising new challenges for validation, data privacy, and regulatory oversight.

Finally, sustainability considerations are gaining prominence. Many POCT devices rely on single-use plastics and electronic components, contributing to biomedical waste. Future development must balance clinical performance with environmentally sustainable design.

The challenges of POCT extend beyond analytical performance to encompass matrix effects, human factors, economic sustainability, and governance structures. Successful programs hinge on the collaboration of laboratory directors, quality managers, and POCT coordinators who ensure compliance with international standards. While challenges persist, advances in connectivity, multiplexing, and AI are poised to expand the role of POCT in modern healthcare. With rigorous validation, robust governance, and continuous quality improvement, POCT can evolve from a supplementary diagnostic tool into an integral component of patient-centered care.

IX.CONCLUSION

Point-of-care testing (POCT) has transitioned from a niche diagnostic tool to a cornerstone of modern healthcare delivery. Its capacity to deliver rapid, actionable results at the patient's side has transformed clinical workflows, particularly in emergency, critical care, and resource-limited settings. However, the benefits of POCT are realized only when its implementation is supported by robust validation, structured governance, and sustained quality assurance.

This review highlights that POCT is not a replacement for central laboratory testing, but a complementary approach that extends diagnostic capacity to the bedside. Matrix-specific validation, daily internal quality control, and participation in external quality assurance schemes are essential to maintaining reliability. Equally vital is the governance framework, where laboratory directors, quality managers, and POCT coordinators collectively ensure accountability and compliance with international standards such as ISO 15189:2022, CLSI, NABH, and JCI requirements.

Looking ahead, the integration of POCT with digital platforms, multiplexed assays, and artificial intelligence promises to expand its clinical relevance,

enabling more precise, patient-centered care. Yet, challenges such as cost, operator training, connectivity, and environmental sustainability must be carefully addressed.

In conclusion, the safe and effective use of POCT depends on a balance between technological innovation and rigorous quality management. Institutions that establish strong governance and validation frameworks will be best positioned to leverage POCT as a driver of improved clinical outcomes and healthcare efficiency in the years to come.

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Table I

Department	Common POCT Tests	Typical Device/Method	Result Type	Notes / Standards Reference
Hematology	Hemoglobin, Hematocrit, WBC differential (limited), Coagulation (PT/INR, aPTT)	Hemocue, CoaguChek, cartridge analyzers	Quantitative	CLSI EP09; ISO 15189:2022

Clinical Biochemistry	Blood glucose, HbA1c, Lipids, Renal panel (creatinine, urea), Electrolytes (Na, K, Cl, iCa), Cardiac markers (Troponin I/T, CK-MB, BNP)	Glucometer, handheld blood gas/electrolyte analyzers, immunoassay cartridges	Quantitative	CLSI POCT09; NABH 6th Ed.
Clinical Pathology	Urinalysis (dipstick: protein, glucose, ketones, blood), Pregnancy tests (β-hCG)	Dipsticks, lateral flow assays	Semi-quant / Qual	WHO RDT guidelines
Microbiology	Rapid antigen tests for Streptococcus, Influenza, RSV, COVID-19	Lateral flow immunoassays (LFIA)	Qualitative	WHO, CLSI POCT07
Serology	HIV, HBsAg, HCV, Syphilis RPR/VDRL	Rapid immunochromatographic tests	Qualitative	WHO STI manual, ISO 22870
Infectious Serology	Dengue NS1, Dengue IgM/IgG, Malaria, Typhoid (Typhi-dot), TB Ag (LAM, others)	Rapid LFIA / card tests	Qualitative	WHO malaria/dengue POCT
Histopathology	Frozen section adequacy (intraoperative)	Cryostat, staining at OR	Qualitative (adequacy)	Not classic IVD; near-patient
Cytology	ROSE (Rapid On-Site Evaluation of FNA samples)	Stain & microscopy near bedside	Qualitative	Good practice, not IVD POCT
Bone Marrow / FNAC	Smear adequacy at bedside/OR	Microscopy	Qualitative	Near-patient adequacy check

TABLE II

Department	Common POCT Menu
Emergency Department	Glucose, Troponin, CK-MB, BNP, ABG, Electrolytes, Lactate, PT/INR, D-dimer, Urinalysis, Pregnancy test
ICU	ABG, Electrolytes, Glucose, Lactate, Co-oximetry, Cardiac markers, CRP, Renal function tests
CCU (Cardiac)	Troponin, BNP, CK-MB, Electrolytes, Coagulation (PT/INR, ACT), ABG
Cath Lab	Activated Clotting Time (ACT), Electrolytes, ABG, Troponin
Transplant Ward	Tacrolimus (emerging POCT), Renal panel, Glucose, Infectious serology (HBsAg, HIV, HCV, CMV)
NICU	Glucose, Bilirubin (TcB/POC bilirubin meters), ABG, Lactate, Electrolytes, CRP
Neonatal Ward	Glucose, Bilirubin, Infectious disease screening (syphilis, HIV, hepatitis)
Gynecology/Obstetrics	Pregnancy test (urine/serum β-hCG), Hb/Hct, Blood glucose, Rapid HIV, HBsAg, RPR/VDRL

TABLE II

Result Type	Examples	Notes / Standards Reference
Qualitative	HIV rapid test, HBsAg, HCV Ab, Malaria RDT, Syphilis card test, Influenza/COVID-19 antigen test, Pregnancy test	WHO STI POCT manual; ISO 22870
Semi-quantitative	Urine dipstick (protein, glucose, ketones, blood), CRP rapid card, HbA1c (POC immunoassay strips)	CLSI POCT07
Quantitative	Glucose, HbA1c (IFCC traceable POC devices), Electrolytes (Na, K, Cl, iCa), ABG, Lactate, Troponin, BNP, PT/INR, ACT	CLSI EP09; ISO 15189:2022