Affordable Point-of-Care Testing device for Diabetes, Anaemia, Kidney, Lipid and Liver Profiles

a thesis

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SAHIL JAGNANI

Centre for Nanotechnology

Indian Institute of Technology Guwahati

Guwahati, Assam-781039, India

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CENTRE FOR NANOTECHNOLOGY
INDIAN INSTITUTE OF TECHNOLOGY GUWAHATI
GUWAHATI, ASSAM-781039

DECLARATION

The thesis titled **"Affordable Point-of-Care Testing device for Diabetes, Anaemia, Kidney, Lipid and Liver Profiles"** represents my original research work carried out in the Centre for Nanotechnology, Indian Institute of Technology Guwahati, India, under the supervision of Prof. Dipankar Bandyopadhyay.

Sincere efforts have been made to acknowledge contributions from other investigators that helped in conceptualizing and executing the research work. Those who have provided suggestions and technical help have been duly acknowledged. All the research articles and resources used have been cited in the reference section.

5 December 2025

Sahil Jagnani

Mr. Sahil Jagnani
Roll number: 196153006
Centre for Nanotechnology
Indian Institute of Technology Guwahati

CENTRE FOR NANOTECHNOLOGY
INDIAN INSTITUTE OF TECHNOLOGY GUWAHATI
GUWAHATI, ASSAM-781039

CERTIFICATE

This is to certify that the work described in the thesis titled, **Affordable Point-of-Care Testing device for Diabetes, Anaemia, Kidney, Lipid and Liver Profiles** submitted by **Sahil Jagnani** (Roll No. 196153006) to the Indian Institute of Technology Guwahati, India, for the award of the degree of Doctor of Philosophy is an authentic record of the research work carried out under my supervision in the Centre for Nanotechnology, Indian Institute of Technology Guwahati, India.

This thesis or any part thereof has not been submitted elsewhere for the award of any other degree or diploma.

5 December 2025

Dipankar Bandyopadhyay

Prof. Dipankar Bandyopadhyay
Professor, Department of Chemical Engineering &
Centre for Nanotechnology,
IIT Guwahati, Guwahati-39

To my beloved family

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Synopsis

Introduction

Non-communicable diseases (NCDs) have become the leading cause of death globally, accounting for over 70% of all deaths annually. Approximately 41 million people die from NCDs each year, with more than 85% of these premature deaths occurring in low- and middleincome countries [1]. Among these, liver disorders, pancreatic dysfunctions, anaemia, and diabetes constitute a major subset that significantly impairs quality of life and places a substantial economic burden on healthcare systems [2][3].

For example, liver diseases such as hepatitis, cirrhosis, and non-alcoholic fatty liver disease (NAFLD) often progress silently until advanced stages. Pancreatic dysfunctions, including both exocrine (e.g., pancreatitis) and endocrine disorders (e.g., diabetes mellitus), are interlinked with metabolic syndromes and require biochemical assessments for early detection. Anaemia, most commonly due to iron, folate, or vitamin B12 deficiencies, is a major public health problem affecting over 1.6 billion people worldwide [3]. Diabetes, especially type 2 diabetes mellitus, continues to rise at an alarming rate and is projected to affect over 643 million people globally by 2030 [4]. These diseases not only share overlapping risk factors but also often co-exist, requiring comprehensive diagnostic screening at multiple levels of the healthcare system. The diagnosis of liver, pancreas, anaemia, and diabetesrelated disorders relies on the analysis of key biochemical markers. Commonly used analytical methods include:

(i) Spectrophotometric assays, which measure enzyme activities such as Glucose, Hemoglobin, Creatinine, Total Bilirubin, and Total protein etc, based on light absorbance at specific wavelengths [5].

(i). Enzyme-linked immunosorbent assays (ELISA), used to detect antibodies and proteins such as insulin or pancreatic enzymes.

(ii). Electrochemical and optical biosensors, widely used in glucose meters and increasingly in multi-analyte testing.

(iii). Chromatographic and molecular methods, such as high-performance liquid chromatography (HPLC) and polymerase chain reaction (PCR), are often used in specialized laboratories.

While these methods offer precision and reliability, they are typically restricted to centralized laboratory settings. They require expensive equipment, skilled operators, cold chains for reagents, and involve long turnaround times, not ideal for point-of-care (POC) or rural use [6][7]. The diagnostic device market includes high-end analyzers and POC tools for single-analyte testing. Large-scale automated systems like Abbott's Architect, Roche's Cobas, and Siemens' Dimension series are common in tertiary hospitals. On the other end, glucometers, Hb meters, and lateral flow test strips are used for home monitoring or emergency screening [8]. However, these tools present certain limitations:

(i) Most POC devices are single-analyte, limiting their use in multi-disease contexts. (ii) Lab-based instruments are inaccessible to resource-constrained settings due to size, cost, and dependency on infrastructure.

(iii) Data integration and portability remain minimal in many older POC models.

These constraints highlight the need for a unified platform that is affordable, portable, capable of multi-analyte testing, and operable by non-experts. The major gap exists in the current diagnostic ecosystem: the lack of a compact, multi-parametric, low-cost, and decentralized testing solution suitable for primary healthcare delivery. This gap is especially critical in rural India and other developing regions, where laboratory facilities are scarce, travel time to testing centers is high, and healthcare professionals are few [9]. The unavailability of devices that can simultaneously test for multiple markers of NCDs, like liver enzymes, blood glucose, hemoglobin, and pancreatic biomarkers, at the point of care delays timely interventions. Moreover, there is insufficient incorporation of low-power sensor technology with conventional biochemical tests, leaving a technological vacuum that must be addressed to make diagnostics truly inclusive and scalable [7].

Need Identification

In this context, the development of a Point-of-Care Testing (POCT) biochemistry analyzer becomes imperative. Such a tool should be able to:

(i). Deliver rapid, real-time, and quantitative results at or near the patient site.

(ii). Operate with minimal sample volumes (e.g., finger-prick blood).

(iii). Be portable, battery-operated, and rugged enough for field conditions.

(iv). Require minimal training to use, thereby democratizing diagnostics at the community level.

Devices like these can serve frontline health workers, telemedicine hubs, mobile clinics, and disaster relief operations, extending the reach of modern diagnostics far beyond hospital walls [6]. In order to address this unmet need, the Mobilab device has been conceived as an indigenous, cost-effective, sensor-based POCT biochemistry analyzer. The device integrates colorimetric assays with optical sensing and digital signal processing to provide accurate measurements of key NCD biomarkers. Designed for operation in low-resource settings, Mobilab requires minimal user intervention, consumes low power, and can deliver results in under 30 minutes. Unlike many existing POC tools, Mobilab is being built as a multi-analyte platform, capable of testing parameters including: (i) Glucose (Diabetes), (ii) Creatinine, Urea (kidney function), (iii) Triglycerides (lipid/cardiovascular function), (iii) Total Bilirubin, Total Protein, and AST (liver function), (iv) Hemoglobin (anemia).

By consolidating these assays into a single platform, the MobilabTM aims to improve efficiency, reduce costs, and enable proactive health monitoring in settings ranging from rural clinics to low-resource settings. Sensor-based diagnostics are transforming the landscape of healthcare by enabling real-time, digital, and decentralized monitoring. Optical sensors, in particular, offer several advantages:

(i). Miniaturization: Making the devices lightweight and portable.
(ii). High sensitivity and specificity: Enabling detection of low analyte concentrations.
(iii). Low power consumption: Essential for battery operation in field conditions.
(iv). Data integration: Allowing results to be stored, transmitted, and integrated with telehealth systems [10].

The POCT device proposed here, namely, Mobilab, incorporates optical sensors that detect colorimetric changes in test reagents, processed through a photometric circuit and translated into digital results. This provides a balance of analytical performance, ease of use, and cost-effectiveness ideal for primary care deployment. The decision to use colorimetric assays in Mobilab is based on their simplicity, reliability, and compatibility with low-cost optical sensors. In colorimetry, the concentration of an analyte is correlated to the intensity of color produced in a chemical reaction, an approach that is both well-established and easy to automate [10][7].

Advantages of colorimetry for POCT include:

(i) Ease of interpretation: Visual cues supported by quantitative optical readings.

(ii) Minimal infrastructure: No need for complex optics like those used in fluorescence or chemiluminescence.

(iii) Low reagent cost: Assays are widely available and easy to produce.

(iv) Stability: Reagents can be stored at room temperature, reducing cold chain dependency.

This method enables Mobilab to deliver laboratory-grade accuracy without the infrastructure demands of centralized testing, fulfilling a critical gap in the NCD care continuum. In view of this background, the present thesis focuses on three major technical objectives as follows:

Objective 1: Development and optimization of the portable device Mobilab-Uni for accurate measurement of health parameters for liver, diabetes, and anemia.

Objective 2: Upgradation to the POCT device Mobilab-Duo to optimize and validate the test results of liver and kidney parameters (AST and Urea).

Objective 3: Integration of diagnostic system Mobicase to execute its clinical validation across diverse healthcare/clinical environments.

Overall, the thesis starts with a comprehensive introduction of the aforesaid objectives in Chapter 1 before consisting of three technical chapters 2-4 as mentioned above, before concluding with the future scopes in Chapter 5. The summary of chapters 2-3 is provided as follows:

Chapter 2: The objective of this chapter is to develop portable, optimized, and accurate devices for determining the parameters for liver, diabetes, and anemia. It is well known that the NCDs, such as liver dysfunction, diabetes, anaemia, and dyslipidaemia, contribute significantly to the global disease burden, accounting for over 70% of deaths worldwide and over 60% in India alone [1,3]. These conditions often remain undiagnosed until complications arise due to limited access to affordable and timely diagnostic services, especially in rural and underserved populations. To address these pressing challenges, Mobilab-Uni, a portable, IoTenabled point-of-care testing (POCT) platform, was developed at the Centre for Nanotechnology, IIT Guwahati. The device leverages colorimetric biochemical principles to deliver rapid, accurate, and affordable diagnostics near the patient, minimizing the need for complex infrastructure or skilled personnel. The development of Mobilab-Uni prioritized five key biochemical parameters selected from essential clinical profiles: Liver Function, Kidney Function, Lipid Profile, and Diabetes and Anaemia due to their diagnostic relevance, clinical utility, and prevalence in primary health settings. These parameters are:

(a) Total Bilirubin (Liver Function Test - LFT): Total bilirubin is a critical marker used to evaluate liver function, bile excretion, and the presence of jaundice or hepatic injury. Elevated levels are associated with liver diseases such as hepatitis, cirrhosis, and bile duct obstruction [2]. The test in Mobilab-Uni is based on the Modified Jendrassik-Grof method, which allows sensitive detection of conjugated and unconjugated bilirubin.

(b) Total Protein (Liver Function Test - LFT): Total protein is an important biochemical marker used to assess the overall nutritional status, liver synthetic function, and the presence of chronic illness or protein metabolism disorders. It primarily reflects the combined concentration of albumin and globulin in serum. Abnormal total protein levels may indicate conditions such as liver disease, nephrotic syndrome, malnutrition, dehydration, chronic infections, and immunological disorders [2]. The Total Protein assay on the Mobilab-Uni platform is based on the Biuret method, in which proteins form a violet-colored complex with copper ions under alkaline conditions. The intensity of the color formed is directly proportional to the total protein concentration in the sample, enabling accurate quantitative estimation.

(c) Creatinine (Kidney Function Test - KFT): Creatinine is a metabolic waste product eliminated by the kidneys. Its concentration in blood is a well-established indicator of renal function. Increased creatinine levels suggest impaired kidney filtration and potential chronic kidney disease [7]. Mobilab-Uni employs an enzymatic colorimetric method to quantify creatinine from capillary blood samples.

(d) Triglycerides (Lipid Profile): Triglycerides are a form of fat stored in the body and transported in the blood. Elevated levels are associated with cardiovascular risk, metabolic syndrome, and diabetes [5]. The Mobilab test utilizes the GPO-PAP enzymatic method, enabling rapid screening of triglyceride levels in resource-limited environments.

(e) Glucose (Diabetes Monitoring): Blood glucose monitoring is essential for diagnosing and managing diabetes mellitus. Glucose serves as a primary energy source, and dysregulation is a hallmark of diabetes [4]. Mobilab-Uni uses the GOD-PAP enzymatic method, a standard in glucose diagnostics, optimized for small sample volumes and battery-operated analysis.

(f) Hemoglobin (Anemia Assessment): Hemoglobin concentration is a direct indicator of anaemia, which affects more than one-third of the global population, particularly

among women and children [3]. Mobilab-Uni performs hemoglobin testing via the cyanmethemoglobin method, enabling quantification with high accuracy using fingerprick blood samples.

The traditional diagnostic devices are typically single-analyte, expensive, and dependent on stable infrastructure and trained personnel. Mobilab-Uni addresses these limitations by integrating multiple tests into a single, portable device. Its optical sensor-based platform detects colorimetric changes during biochemical reactions, correlating color intensity to analyte concentration. This approach followed in the thesis allows: Real-time quantitative results, Minimal sample volume, Battery-powered portability, IoT-based data transmission for remote monitoring. The focused parameters were chosen based on clinical demand, feasibility for miniaturization, and suitability for decentralized testing. Their combined assessment supports early diagnosis, monitoring, and management of multiple coexisting NCDs in low-resource settings.

It may be noted here that, despite the growing prevalence of NCDs, timely diagnosis and routine monitoring remain significant challenges in India's public health landscape. This is particularly evident in primary healthcare settings and tier-2 or tier-3 cities where diagnostic laboratories are either poorly equipped or completely absent. Some of the pressing issues include:

(i). Limited availability of multi-analyte diagnostic devices in rural areas.

(ii). Over-reliance on centralized labs that delay diagnosis and treatment decisions.

(iii). High costs of existing automated analyzers, which restrict their use to tertiary care hospitals.

(iv). Lack of integration between diagnostic tools and digital health platforms.

(v). Minimal training and technical expertise available at the grassroots level to operate sophisticated diagnostic equipment.

(vi). Moreover, while several POCT tools such as glucometers and hemoglobinometers exist, these are often single-analyte devices, lacking versatility and precision. Furthermore, they fail to provide a comprehensive health profile necessary for integrated NCD management.

Thus, the primary aim of this chapter was to design, develop, and validate a set of sensorbased, colorimetric POCT analyzers tailored for decentralized diagnosis and monitoring of the aforementioned NCDs. The study seeks to achieve the following objectives:

(i). To develop three modular POCT devices: A portable, single-slot device optimized for entry-level biochemical tests such as glucose, bilirubin, or hemoglobin.

(ii). To integrate optical sensor-based detection using colorimetric assay principles with embedded microcontroller systems to ensure accuracy, portability, and low power consumption.

(iii). To validate the performance of the devices through laboratory benchmarking and fieldlevel pilot testing using standardized biochemical assays and reference samples.

(iv). To ensure usability and affordability, such that the devices can be operated by health workers with minimal training and can function in rural settings without continuous power supply or laboratory infrastructure.

This study focuses on the development and validation of Mobilab-Uni, a portable point-ofcare device designed to detect five key biochemical parameters: Total Bilirubin, Creatinine, Triglycerides, Glucose, and Hemoglobin. These markers were selected to support the diagnosis and monitoring of liver dysfunction, kidney health, lipid imbalance, diabetes, and anaemia, major contributors to the burden of non-communicable diseases. The chapter shows that for all these parameters, Mobilab-Uni could achieve more than 90% accuracy as compared to the traditional auto and semi-auto analyzers.

CHAPTER 3: Liver and kidney diseases continue to pose significant public health challenges, particularly in low- and middle-income countries where early detection and regular monitoring remain inadequate. Aspartate Aminotransferase (AST) is a vital enzymatic marker used to assess liver cell injury and hepatocellular integrity, while Urea serves as a key indicator of renal function and protein metabolism [2,9]. Elevated levels of AST are associated with conditions such as hepatitis, liver cirrhosis, and drug-induced liver damage, whereas abnormal urea concentrations indicate compromised kidney filtration and nitrogen waste accumulation [1,7]. Traditional biochemical analyzers used to measure these parameters are primarily centralized, expensive, and infrastructure-dependent—often limiting their utility in rural or underserved regions. As a result, delays in diagnosis and lack of timely intervention contribute to increased disease burden and poor clinical outcomes [6]. To overcome these diagnostic limitations, Mobilab-Duo, an upgraded portable point-of-care testing (POCT) device, has been developed. This device builds upon the foundation of the earlier Mobilab-Uni system by integrating dual-analyte capability, enabling simultaneous, accurate, and low-cost assessment of AST and Urea in a decentralized setting. Utilizing optical colorimetric detection, Mobilab-Duo operates with minimal sample volume, requires no refrigeration for reagents, and delivers real-time quantitative results suitable for primary

healthcare use. The focus of this chapter is to optimize the assay performance for AST and Urea in the Mobilab-Duo platform and validate the test results through method comparison, precision analysis, and clinical benchmarking. This work aims to demonstrate that the device meets acceptable diagnostic standards, thereby supporting its broader application in early detection and management of liver and kidney diseases at the point of care. Again, the chapter shows that for all these parameters, Mobilab-Duo could achieve more than 90% accuracy as compared to the traditional auto and semi-auto analyzers.

CHAPTER 4: Access to timely and accurate diagnostics is a cornerstone of effective healthcare, especially in the management of non-communicable diseases (NCDs). However, in many rural and underserved regions, the lack of laboratory infrastructure, trained personnel, and reliable power supply limits access to routine biochemical testing. While portable pointof-care devices like Mobilab-Uni and Mobilab-Duo have addressed single and dual-analyte testing needs, there remains a critical demand for a fully integrated, field-ready diagnostic system capable of delivering comprehensive biochemical analysis in decentralized settings. To address this gap, the Mobicase system has been developed as an all-in-one, compact, and modular diagnostic kit that integrates the Mobilab device, cartridges, reagents, accessories, and power solutions into a single portable unit.

Mobicase is designed to simplify workflow, improve efficiency, and support diagnostic decision-making at the community level, in mobile health units, and during outreach programs. The system enables multi-parameter biochemical testing (e.g., liver, kidney, diabetes, anaemia) using colorimetric enzymatic methods, with real-time results accessible digitally via IoT-enabled features. This chapter focuses on the development and clinical validation of Mobicase across different healthcare environments. The objective is to evaluate its performance, usability, and reliability under real-world conditions through pilot trials in tertiary hospitals, primary health centers, and mobile screening camps. Through this approach, the study aims to demonstrate Mobicase's potential as a scalable, cost-effective diagnostic platform for universal health coverage and decentralized diagnostics. Using Mobicase, multiple trials were conducted, and a summary of such clinical trials is provided below: **A. Guwahati Medical College and Hospital (GMCH):**

(i). The GMCH trials were conducted to assess the validation of the point-of-care testing (POCT) device against the Vitros 5600 Integrated System, a dry biochemistry analyzer considered the gold standard.

(ii). These trials utilized residual patient samples.

(iii). The parameters assessed included Triglycerides (TBIL), Creatinine (CRE), Total Bilirubin (TBIL), Glucose (GLU) and Hemoglobin (HB) **B. Guwahati Neurological Research Centre (GNRC):**

(i). The trials conducted in GNRC aimed to validate the point-of-care testing (POCT) device against the established gold standard, the Siemens Dimension Analyzer 200, a wet biochemistry analyzer.

(ii). These trials utilized leftover patient samples.

(iii). The parameters assessed included Total Bilirubin (TBIL), Albumin (ALB), and Total Protein (TP).

Chapter 5: The chapter summarized that the thesis successfully demonstrates the development, optimization, and validation of Mobilab-Uni, Mobilab-Duo, and Mobicase affordable, portable, and sensor-based point-of-care testing (POCT) devices for the decentralized diagnosis of non-communicable diseases. These devices integrate colorimetric assays with optical sensing to provide rapid, accurate, and multi-analyte biochemical analysis using minimal sample volumes. Their strong correlation with standard laboratory analyzers and high diagnostic accuracy confirms their potential to bridge gaps in primary healthcare, particularly in low-resource and rural settings. The innovations presented in this work contribute significantly towards strengthening community health diagnostics and supporting universal health coverage through accessible and cost-effective technologies.

CHAPTER 1

INTRODUCTION

1.1. Introduction

The epidemiological transition of the 21st century is unequivocally marked by the rise of Non-Communicable Diseases (NCDs) as the paramount challenge to global public health. Current data from the World Health Organization (WHO) underscores a critical reality: NCDs are responsible for an estimated 41 million deaths per year, constituting nearly three-quarters of all mortality worldwide. A deeply concerning aspect of this burden is its disproportionate impact, with over 85% of these premature deaths occurring within the resource-constrained health systems of low- and middle-income countries (LMICs) [11]. This disparity is not merely a health statistic but a reflection of the profound inequity in access to timely diagnosis and continuous management, which are the cornerstones of effective NCD care [12].

Among the vast spectrum of NCDs, a cluster of conditions, including diabetes mellitus, anemia, and renal and hepatic disorders, presents a particularly complex clinical puzzle. These diseases are frequently interlinked through shared pathophysiological pathways, such as chronic inflammation, metabolic dysregulation, and overlapping risk factors. For instance, Type 2 Diabetes Mellitus is a well-established driver for both chronic kidney disease and nonalcoholic fatty liver disease (NAFLD) [13,14]. Concurrently, anemia is a common comorbidity in both renal and hepatic insufficiency, often manifesting as anemia of chronic disease [15]. This syndemic nature necessitates a holistic and integrated diagnostic approach, which is often fragmented in current healthcare delivery models.

A pivotal challenge in managing these conditions is their frequently asymptomatic progression in early stages. Diseases like NAFLD, early diabetic nephropathy, and irondeficiency anemia can evolve silently over years, only becoming clinically apparent after significant, and often irreversible, organ damage has occurred [16,17]. Consequently, the capacity for early detection and regular monitoring shifts from a clinical advantage to an absolute necessity for mitigating long-term complications and reducing mortality.

The definitive diagnosis and management of these disorders rely heavily on the quantification of specific biochemical markers in blood. Centralized clinical laboratories employ a suite of sophisticated techniques for this purpose:

(i). Photometric Assays: These form the backbone of routine biochemistry, measuring analytes like glucose, hemoglobin, total bilirubin, and liver enzymes through colorimetric or kinetic reactions that absorb light at defined wavelengths [18].

(ii). Immunoassays: Technologies such as the Enzyme-Linked Immunosorbent Assay (ELISA) provide high specificity for detecting proteins, hormones, and antibodies [19].

(iii). Electrochemical Sensing: This principle is the foundation of widespread personal glucose monitors, which detect electrical current generated from enzymatic oxidation [20].

(iv). Advanced Separation Techniques: Methods like High-Performance Liquid Chromatography (HPLC) offer high precision for assays like glycated hemoglobin (HbA1c) but are confined to specialized labs [21].

Despite their analytical robustness, these methodologies are intrinsically centralized. They demand substantial capital investment in bulky instrumentation, a continuous supply of expensive reagents, highly skilled technical staff, and complex logistical chains for sample transport and storage [22, 23]. This central laboratory paradigm creates a critical diagnostic void, especially in rural and peri-urban areas of LMICs where infrastructure is sparse and patient travel to distant testing facilities imposes a significant economic and social burden [24].

The contemporary in vitro diagnostics market is characterized by a technological dichotomy. At one extreme, high-throughput automated analyzers (e.g., Roche Cobas, Siemens Dimension EXL, Abbott Architect, etc.) serve large hospital laboratories but remain financially and operationally inaccessible for primary care clinics [25]. At the other extreme, single-analyte point-of-care testing (POCT) devices, such as glucometers and hemoglobinometers, have demonstrated immense value for specific use cases but are inadequate for comprehensive patient profiling [26]. This fragmentation results in several critical shortcomings:

(i). Diagnostic Inefficiency: Managing a patient with multiple risk factors requires several discrete devices, leading to increased costs, larger total blood volume requirements, and operational complexity [27].

(ii). Infrastructural Dependency: Centralized systems are vulnerable to disruptions in power, supply chains, and skilled human resources, which are common in LMICs [23].

(iii). Data Silos: Many existing POCT devices function as isolated data points, lacking the connectivity to integrate results into electronic health records or telemedicine platforms, hindering coordinated care [28].

This analysis reveals a pronounced and unmet need: a unified, low-cost, multi-parametric, and robust diagnostic platform engineered specifically for the challenges of decentralized healthcare in resource-limited environments. The absence of such a solution directly contributes to delayed diagnoses, missed opportunities for early intervention, and ultimately, a higher burden of advanced-stage NCDs [29].

1.2 Research Rationale and Proposed Technological Solution

In order to address this critical gap, the development of a next-generation, multiparametric Point-of-Care Testing (POCT) device is not just an academic exercise but a public health imperative. An ideal device for this context must be architected around the following core design principles:

(i). Comprehensive Profiling: Capable of measuring a panel of key biomarkers from a single, minimal-volume sample (e.g., capillary blood) to enable synergistic diagnosis of multiple conditions.

(ii). Extreme Accessibility: Characterized by a low manufacturing cost, minimal reagent consumption, and operational independence from continuous electrical power and cold chain logistics.

(iii). Robust Portability: Battery-operated, lightweight, and designed to withstand environmental stresses typical of field use in mobile clinics and remote health centres.

(iv). Usability and Connectivity: Engineered for operation by community health workers with minimal training, and equipped with digital data export capabilities to bridge the gap with digital health infrastructures [30].

(v). AI-Driven Analytical Intelligence: Equipped with onboard or cloud-enabled AI algorithms for automated quality checks, error detection, result interpretation, longitudinal trend analysis, and personalized risk stratification, thereby enhancing diagnostic accuracy and supporting clinical decision-making, especially in lower source settings.

A diagnostic platform embodying these attributes holds significant promise for democratizing access to essential healthcare services by enabling early disease detection at the point of care. Such a system can fundamentally transform population-wide screening programs, enhance the reach of telemedicine services, and strengthen the first line of clinical decision-making in both urban and resource-limited settings. In direct response to this critical unmet need, the present research delineates the phased development and comprehensive validation of the Mobilab platform—an indigenous, sensor-based, multi-analyte point-of-care biochemistry analyzer. The overall research framework is strategically structured to advance from a core proof-of-concept stage to a fully integrated, clinically deployable solution, and is systematically executed through three sequential, outcome-driven objectives that address analytical performance, clinical validation, and real-world implementation.

1.3 Clinical and Biochemical Mapping of Selected NCD-Related Parameters

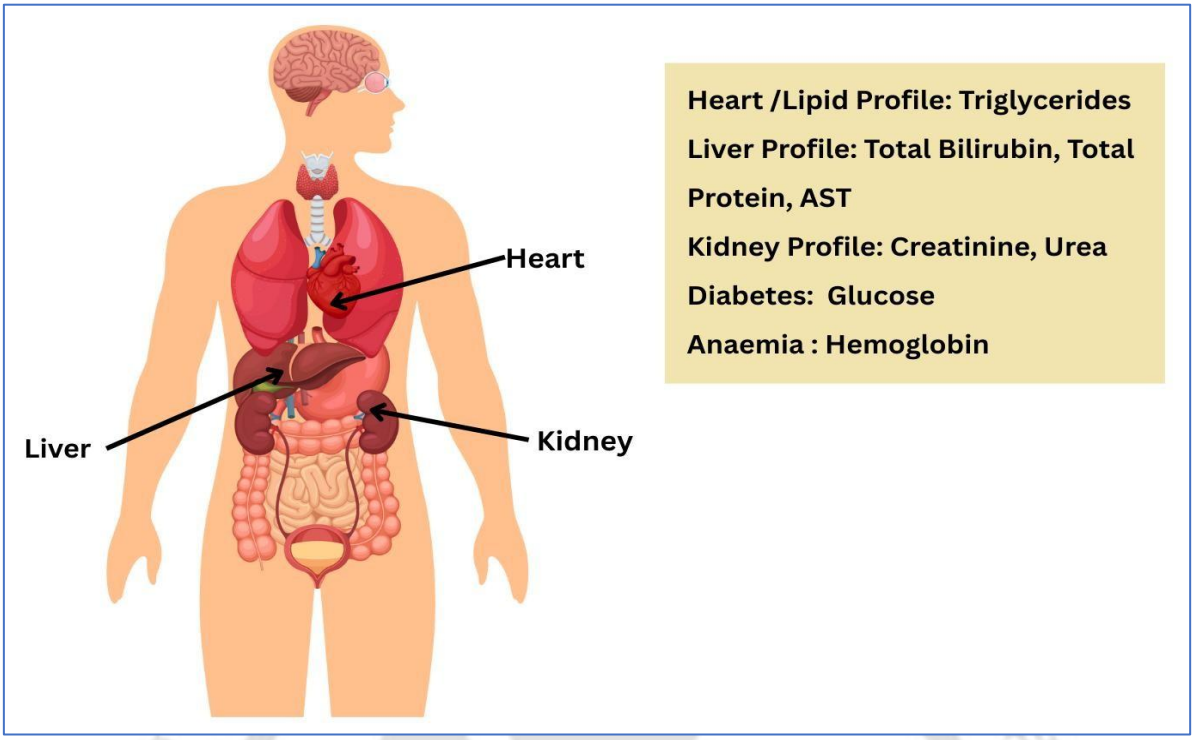

Figure 1: Schematic representation of major organ systems and their associated biochemical test profiles used for routine clinical assessment. The heart, liver, and kidneys are highlighted with corresponding diagnostic markers for cardiovascular, hepatic, renal, metabolic, and haematological evaluation.

Figure 1 highlights the major organs evaluated through the biochemical test panel. Key markers include triglycerides for cardiac/lipid profiling; total bilirubin, total protein, and AST for liver function; creatinine and urea for kidney assessment; glucose for diabetes screening; and hemoglobin for anaemia detection. Together, these parameters enable comprehensive, multi-organ health evaluation at the point of care.

NCDs such as diabetes, anaemia linked to chronic conditions, chronic kidney disease (CKD), dyslipidaemia, and liver disorders are rising rapidly and often remain undiagnosed until complications occur [12–17, 20]. The study aims to develop and validate a focused biochemical panel that captures these high-burden NCDs and their organ-level consequences using standard clinical chemistry principles. This panel includes markers of glycaemic status, oxygen-carrying capacity, renal filtration, hepatocellular injury, biliary clearance, and protein synthesis or nutritional state. Together, these parameters enable early risk stratification, diagnosis, and longitudinal monitoring in both community and clinical settings. Table 1 outlines the core biochemical markers mapped to major NCD categories, each providing direct pathophysiological insight into organ-specific dysfunction. These essential assays enable

rapid screening, clinical stratification, and ongoing monitoring of metabolic, renal, cardiovascular, hepatic, and haematological disorders.

Table 1. Clinical Mapping of Major NCD Disease Areas to their Key Biochemical Tests and Diagnostic Interpretation

Disease Area	**Key Tests (Representative)**	**What the Tests Indicate Clinically**	**Disease Area**
Diabetes / Metabolic Risk	Glucose	Measures blood sugar status; elevated levels confirm diabetes or poor glycaemic control and help detect risk of complications [14].	Diabetes / Metabolic Risk
Anaemia / Nutritional & Chronic Disease Burden	Hemoglobin (Hb)	Low Hb directly indicates anaemia (iron deficiency, chronic inflammation, renal anaemia, etc.), guiding supplementation or referral [15].	Anaemia / Nutritional & Chronic Disease Burden
Kidney Profile / CKD & Diabetic Nephropathy	Creatinine, Urea	Creatinine reflects glomerular filtration; urea rises with impaired renal clearance. Both are core markers for CKD screening and monitoring [17].	Kidney Profile / CKD & Diabetic Nephropathy
Lipid Profile / Cardiovascular Risk	(Lipid panel typically includes TC, TG, HDL, LDL)	Lipid abnormalities are highly prevalent and predict cardiovascular events; screening supports early statin/lifestyle intervention [13].	Lipid Profile / Cardiovascular Risk
Liver Profile / Hepatocellular & Cholestatic Injury	AST, Total Bilirubin, Total Protein	AST rises in hepatocellular injury; bilirubin elevations indicate jaundice/cholestasis; total protein reflects liver synthetic function and nutrition status [16]	Liver Profile / Hepatocellular & Cholestatic Injury

Non-communicable diseases (NCDs) such as diabetes mellitus, anaemia associated with chronic inflammatory or nutritional deficiencies, chronic kidney disease (CKD), dyslipidaemia, particularly hypertriglyceridemia, and chronic liver disorders continue to rise sharply worldwide and frequently remain undiagnosed until irreversible complications develop [12–17, 20, 36–40]. A major contributor to this diagnostic gap is the absence of decentralized biochemical testing systems capable of providing early, actionable insights into multi-organ dysfunction. To address this limitation, the present study focuses on developing

and validating a comprehensive biochemical panel to capture the metabolic and organ-level signatures of these high-burden NCDs, using standard, clinically established assays. The selected parameters represent key physiological domains including glycaemic regulation, oxygen-carrying capacity, renal filtration and nitrogen balance, hepatocellular integrity, biliary clearance, hepatic synthetic function, nutritional status, and lipid metabolism, with triglycerides playing a central role in assessing cardiometabolic and hepatic risk [13, 18, 33, 46–50]. Together, this integrated biochemical suite supports early risk stratification, differential diagnosis, and longitudinal monitoring in both community and clinical settings.

Glucose, a primary biomarker of glycaemic status, remains the foundational analyte in diabetes screening, diagnosis, and management [14, 20, 36, 47]. According to widely used clinical criteria, fasting plasma glucose values <100 mg/dL are considered normal, 100–125 mg/dL indicate prediabetes, and ≥126 mg/dL on repeat testing confirms diabetes [31, 36]. These thresholds reflect progressive alterations in insulin secretion, β-cell reserve, and tissue insulin sensitivity [47]. Chronic hyperglycaemia exerts toxic effects on multiple tissues through mechanisms including oxidative stress, endothelial dysfunction, mitochondrial impairment, formation of advanced glycation end products (AGEs), activation of the polyol pathway, and chronic low-grade inflammation [34, 45]. These pathways collectively drive the development of diabetic nephropathy, retinopathy, neuropathy, macrovascular atherosclerotic disease, non-alcoholic fatty liver disease (NAFLD), and impaired immune function [13, 36–39]. Conversely, hypoglycaemia (<70 mg/dL) remains a significant clinical risk, particularly in insulin-treated individuals, and may precipitate neuroglycopenia, altered consciousness, seizures, and in severe cases, coma or death [31, 45].

Hemoglobin (Hb) serves as a direct indicator of anaemia, a condition that remains highly prevalent in both developing and developed economies, often linked to nutritional deficiencies, chronic inflammation, parasitic infections, renal insufficiency, or advanced liver disease [15, 43]. The WHO defines anaemia as <13 g/dL in men and <12 g/dL in non-pregnant women [31]. Reduced Hb compromises oxygen delivery to tissues, resulting in fatigue, cognitive impairment, reduced physical productivity, and adverse pregnancy and neonatal outcomes [15, 43]. Anaemia in CKD arises from reduced erythropoietin synthesis, chronic inflammation that alters iron metabolism through the hepcidin pathway, and shortened red cell survival [15, 17, 43]. In chronic liver disease, hypersplenism and impaired hepatic protein synthesis further exacerbate anaemia [16, 39]. Elevated Hb, though less common, may reflect dehydration, chronic pulmonary disease, high-altitude adaptation, or primary bone marrow disorders such as polycythaemia vera [31].

Creatinine and urea constitute the cornerstone biochemical markers for assessing renal function [17, 42]. Creatinine, a product of muscle metabolism, is filtered by the glomerulus and serves as a key input for estimated glomerular filtration rate (eGFR) calculations [17]. KDIGO guidelines recommend creatinine-based screening for early CKD detection [35, 42], especially in individuals with diabetes, hypertension, or a family history of kidney disease. Elevated creatinine reflects impaired glomerular filtration and may indicate acute kidney injury (AKI), progressive CKD, obstructive uropathy, inadequate renal perfusion, or exposure to nephrotoxic substances [17, 35, 42]. Urea, derived from hepatic ammonia detoxification, reflects both protein turnover and renal excretory function [32, 44]. Elevated BUN can result from renal impairment, dehydration, gastrointestinal bleeding, catabolic states, corticosteroid use, or high-protein diets [31–32, 44]. Extremely low BUN may signify severe liver dysfunction, protein malnutrition, or overhydration [32, 44]. When interpreted together, creatinine and BUN help differentiate prerenal (high BUN/creatinine ratio), intrinsic renal, and post-renal causes of kidney injury [17, 35, 42].

Assessment of liver function requires a multi-dimensional biochemical approach. Aspartate aminotransferase (AST) is released during hepatocellular injury and rises in conditions such as NAFLD, non-alcoholic steatohepatitis (NASH), viral hepatitis (HBV/HCV), alcohol-associated liver injury, drug-induced hepatotoxicity, and ischemic hepatitis [13, 16, 38–41]. Although not exclusively liver-specific, AST remains a sensitive marker of hepatocyte membrane integrity [16, 41]. Total bilirubin reflects the liver's ability to conjugate and excrete heme breakdown products [31, 44]. Elevated bilirubin indicates impaired hepatocellular clearance, cholestasis, biliary obstruction, or haemolysis [16, 31, 39]. Persistent hyperbilirubinemia is a hallmark of clinically significant hepatic dysfunction and helps differentiate between hepatocellular and obstructive patterns [16, 39]. Total protein, which includes albumin and globulins, reflects both hepatic synthetic function and nutritional status [32, 44–45]. Low total protein may indicate cirrhosis, malnutrition, malabsorption, nephrotic-range protein loss, or chronic inflammatory disease [16, 32, 44]; elevated levels may reflect chronic inflammation, dehydration, or monoclonal gammopathies [32, 44].

A critical addition to this biochemical panel is triglycerides, a central biomarker of metabolic health and cardiovascular risk [13, 18, 33, 46–50]. Triglycerides are a hallmark indicator of insulin resistance and play a crucial role in diagnosing dyslipidaemia, metabolic syndrome, and atherogenic risk [37, 46, 49–50]. Elevated triglycerides are strongly associated with NAFLD/NASH, poorly controlled diabetes, abdominal obesity, CKD-related lipid abnormalities, and hypothyroidism [13, 18, 38–41, 46–50]. Hypertriglyceridemia (>500

mg/dL) significantly increases the risk of acute pancreatitis [33, 49] and contributes to the formation of small dense LDL particles, a highly atherogenic lipid species [48–50]. Low triglycerides may reflect malnutrition, malabsorption, hyperthyroidism, or chronic wasting illnesses [33, 45].

Collectively, the selected panel of glucose, hemoglobin, creatinine, AST, total bilirubin, total protein, and triglycerides provides a comprehensive and integrative representation of key pathophysiological processes in NCDs [12–20, 31–50]. Their combined interpretation enables early detection, monitoring, and management of coexisting metabolic, renal, hepatic, and haematological disorders, supporting a more holistic, patient-centred diagnostic approach, particularly in underserved settings. Table 2 presents the standard adult reference ranges for key biochemical parameters used in evaluating diabetes, anaemia, and kidney and liver dysfunction, along with clinical implications of abnormal levels. These diagnostic thresholds support early identification of metabolic imbalance, organ injury, and systemic disease severity, guiding timely intervention and monitoring.

Table 2 (a). Biochemical Parameters selected in the Assessment of Diabetes, Anaemia, Kidney, and Liver Disorders: Adult Reference Ranges with Clinical Consequences of Abnormally High and Low Results

Test (Profile)	**Typical Adult Reference Range**	**If High (Possible meaning & consequences)**	**If Low (Possible meaning & consequences)**
Glucose – Fasting (Diabetes)	70–99 mg/dL normal; 100–125 prediabetes; ≥126 diabetes (repeat) [36]	Hyperglycaemia/Diabetes → risk of retinopathy, neuropathy, CKD, cardiovascular disease, infections, poor wound healing [14, 20].	Hypoglycaemia (<70) → sweating, tremor, confusion; severe cases seizure/coma, esp. on insulin/sulfonylureas [31].
Hemoglobin (Hb) (Anaemia)	Men: 14–18 g/dL; Women: 12–16 g/dL [43]	Polycythaemia/dehydration/ COPD/high altitude → ↑ blood viscosity → headache, hypertension, thrombosis/stroke risk [31].	Anaemia (iron/B12/folate deficiency, CKD, chronic disease, bleeding) → fatigue, dyspnea, poor work capacity, pregnancy/child-growth risks; severe → cardiac strain/failure [15, 43].

Triglycerides (Lipid / Metabolic Health)	<150 mg/dL normal; 150–199 borderline; 200–499 high; ≥500 very high [37, 49]	Hypertriglyceridemia → NAFLD/NASH, metabolic syndrome, pancreatitis risk (>500 mg/dL), atherogenic dyslipidaemia [37, 49–50].	Low TG → malnutrition, malabsorption, hyperthyroidism, chronic illness [33].
Creatinine (Serum) (Kidney)	Men: ~0.74–1.35 mg/dL; Women: ~0.59–1.04 mg/dL [17]	Reduced GFR/AKI/CKD, dehydration, obstruction, nephrotoxic drugs → uremia, electrolyte imbalance, fluid overload, HTN; progression to renal failure if persistent [17, 35, 42].	Often due to low muscle mass, malnutrition, pregnancy, overhydration; usually less critical alone [31].
Urea / BUN (Kidney)	BUN: 7–20 mg/dL; blood urea ≈ 15–40 mg/dL [32]	Renal dysfunction, dehydration, high protein intake, GI bleed, HF → azotemia/uremia, nausea, weakness, confusion; very high may need urgent care [32, 44].	Severe liver disease, low-protein intake, overhydration, pregnancy → reduced urea synthesis or intake [32].
AST (SGOT) (Liver)	~8–33/45 U/L [40]	Hepatocellular injury (fatty liver, hepatitis, alcohol), muscle/cardiac injury → persistent elevation suggests ongoing tissue damage; very high indicates acute hepatitis/ischemic injury [13, 16, 38–41].	Usually not clinically significant [31].
Total Bilirubin (Liver)	0.2–1.2/1.3 mg/dL [31]	Jaundice due to hepatitis/cirrhosis, biliary obstruction, haemolysis → yellow skin/eyes, dark urine, pruritus; persistent high suggests liver/bile pathology [16, 39].	Typically, not clinically concerning [31].

1.4 Thesis Objectives and Structural Outline

The development of an accessible, multi-parameter biochemical diagnostic platform requires a systematic approach integrating assay chemistry, device engineering, and clinical validation. The present thesis focuses on the design and validation of the Mobilab platform as a portable point-of-care biochemical analyzer intended for decentralized healthcare settings. The detailed clinical motivation, epidemiological background of non-communicable diseases (NCDs), and limitations of existing diagnostic systems have already been discussed in the Synopsis and earlier sections of Chapter 1.

Chapter 1:

Chapter 1 provides the epidemiological background, clinical rationale, and technological motivation underpinning the project. It discusses the burden of NCDs, limitations of current diagnostic systems, biochemical relevance of selected analytes, and the need for novel pointof-care solutions tailored for LMIC health systems. This chapter concludes by presenting the core objectives that shape the research trajectory.

Chapter 2:

Chapter 2 explains the technical objective 1: Development and optimization of portable device Mobilab-Uni for accurate measurement of health parameters for liver, diabetes, and anemia. This chapter details the foundational development phase of the platform. It includes:

(i). Selection, adaptation, and optimization of colorimetric assays for Total Protein, Total Bilirubin, Glucose, and Hemoglobin.

(ii). Design and fabrication of the optoelectronic architecture, including LED–photodiode detection modules and wavelength-specific alignment.

(iii). Development of the embedded firmware and signal-processing algorithms, enabling calibration, real-time measurement, and user interface functions.

(iv). Laboratory validation studies evaluating accuracy, precision, linearity, stability, and system robustness.

(v). The outcome of this phase is a functional, laboratory-validated proof-of-concept device, establishing the analytical foundation for multi-parameter point-of-care biochemistry.

Chapter 3:

Chapter 3 explains the technical objective 2: Upgradation to POCT device Mobilab-Duo to optimize and validate the test results of liver and kidney parameters (AST and Urea). Building on the Mobilab-Uni framework, Chapter 3 describes the expansion of test capability

to include more complex assays: Development and optimization of kinetic methods for Aspartate Aminotransferase (AST) and Urea.

- Introduction of enhanced hardware modules for precise temperature regulation, essential for reliable rate-based enzymatic reactions.
- Firmware and analytical algorithm upgrades to facilitate time-resolved optical readings, slope calculations, and reaction-rate monitoring.
- Analytical validation of the Mobilab-Duo device, including comparison against reference laboratory instruments.
- This phase culminates in a second-generation dual-slot system with demonstrably improved analytical performance and expanded biochemical coverage.

Chapter 4:

Chapter 4 explains the technical objective 3: Integration of diagnostic system Mobicase to execute its clinical validation across diverse healthcare/clinical environments. Chapter 4 focuses on the translational and deployment-oriented stage, which includes:

- Industrial design refinement for usability, portability, and ruggedness, resulting in the integrated Mobicase system.
- Workflow optimization to ensure compatibility with primary health centres, mobile medical units, rural clinics, and field health programs.
- Clinical validation studies assessing accuracy, usability, environmental robustness, and operational feasibility under real-world conditions.
- Feedback-driven refinement of both hardware and software to ensure safe and effective performance in decentralized healthcare ecosystems.
- By the end of this phase, the Mobilab platform transitions from a laboratory prototype to a clinically validated, field-ready diagnostic solution.

Chapter 5:

Summary, Conclusions, and Future Directions: The final chapter consolidates the findings from all phases of development. It presents:

- An overarching summary of the technological advancements achieved across Mobilab-Uni, Mobilab-Duo, and Mobicase.
- Conclusions drawn from analytical and clinical validation studies.
- Limitations encountered during development.

- Recommendations for future improvements, scaling strategies, regulatory pathways, and opportunities for integrating additional biochemical or immunoassay-based analytes.

Table 2 (b): Comparison of Mobilab with Existing Point-of-Care Diagnostic Devices

Feature / Parameter	Mobilab Platform	Conventional Clinical Chemistry Analyzer	Single-Analyte POCT Devices (e.g., Glucometer, Hb Meter)	Cartridge-Based Multiparameter Systems
Number of detectable analytes	Multiple biochemical parameters (Glucose, Bilirubin, Creatinine, Cholesterol, Hb etc.) in one platform	Large menu (50–100+) but laboratory-based	Usually single analyte	Limited panel depending on cartridge
Sample volume required	Low micro-volume sample (≈20–40 µL)	Higher sample volume (100–500 µL)	Very small sample (1–10 µL)	Moderate sample volume
Portability	Fully portable device suitable for field use	Large bench-top instrument	Handheld portable	Portable but requires dedicated cartridges
Power requirement	Low power; can operate on battery	Requires continuous electricity and laboratory infrastructure	Battery operated	Requires stable power supply
Turnaround time	Rapid results (few minutes per test)	Longer due to batch processing and sample handling	Rapid single test	Moderate depending on cartridge
Suitability for decentralized healthcare	Designed for rural clinics, mobile health units, and primary health centers	Not suitable for field deployment	Suitable but limited diagnostic scope	Suitable but relatively expensive
Cost per test	Expected to be low due to simplified reagents and minimal infrastructure	High due to equipment, reagents, and maintenance	Low for single parameter	High due to proprietary cartridges

Operational requirements	Minimal training required	Requires trained laboratory technicians	Minimal training	Moderate training required
Infrastructure requirement	Minimal infrastructure	Requires laboratory setup and controlled environment	Minimal	Requires cartridge supply chain
Integration capability	Integrated multi-test platform	High throughput laboratory system	Single test per device	Fixed test panels

CHAPTER 2

MOBILAB-UNI: DEVELOPMENT OF PORTABLE POINT-OF-CARE TESTING DEVICE

Abstract

Non-communicable diseases (NCDs) such as diabetes, liver disorders, renal dysfunction, dyslipidaemia, and anaemia constitute a major global health burden, particularly in resourcelimited settings where access to centralized laboratory diagnostics is restricted. This study reports the design, development, analytical validation, and clinical performance evaluation of Mobilab-Uni, a portable, multi-analyte point-of-care (POC) biochemical analyzer developed for decentralized diagnostics. Mobilab-Uni integrates colorimetric spectrophotometry, embedded electronics, and IoT-enabled data transmission to quantify glucose, triglycerides, total bilirubin, total protein, creatinine, and hemoglobin using established enzymatic and chemical assay principles.

Analytical validation included linearity, limit of blank (LOB), limit of detection (LOD), intra-day precision, and method-comparison against reference laboratory analyzers. Linearity was confirmed across clinically relevant concentration ranges with strong correlation coefficients ($R^2 \geq 0.99$ for most parameters). LODs were sufficiently low for all analytes, and precision studies yielded coefficients of variation below 5%. Clinical validation was performed using 50–52 patient samples per parameter collected from GNRC Hospital, Guwahati. Method comparison using Passing–Bablok regression, Bland–Altman analysis, and paired t-test demonstrated excellent agreement between Mobilab-Uni and reference analyzers ($p > 0.05$ for all parameters). Diagnostic accuracy exceeded 90% for glucose, triglycerides, bilirubin, and hemoglobin.

The results confirm that Mobilab-Uni delivers laboratory-comparable analytical performance with minimal sample volume (20–50 µL), rapid turnaround time (10–15 min), and reliable digital reporting. The device offers a scalable, affordable, and portable solution for multi-analyte biochemical screening in primary healthcare, mobile clinics, and underserved rural settings, enabling early disease detection, real-time decision-making, and improved community healthcare outcomes.

Manuscript submitted in IEEE Sensors Journal (Under review)

2.1 Introduction

Non-communicable diseases (NCDs) such as diabetes, liver dysfunction, kidney disorders, dyslipidaemia, and anaemia are responsible for more than 70% of global mortality and approximately 60% of deaths in India [51]. Early detection and continuous monitoring of biochemical parameters related to these conditions are crucial for effective disease management. However, the majority of diagnostic tools currently available are either centralized laboratory-based instruments or single-analyte point-of-care (POC) devices [52, 53].

Conventional analyzers such as Abbott Architect, Roche Cobas, and Siemens Dimension series offer highly accurate and automated diagnostic testing but require trained personnel, stable infrastructure, and costly reagents. In contrast, single-analyte POC devices such as glucometers or hemoglobinometers, while affordable and portable, provide limited diagnostic scope and fail to capture a comprehensive health profile needed in primary healthcare [54, 55].

This diagnostic gap is most pronounced in rural and resource-limited settings, where laboratory facilities are scarce and patients must travel long distances for tests, delaying treatment initiation[56, 57]. To address this unmet need, the Mobilab-Uni device was conceptualized and developed at the Centre for Nanotechnology, IIT Guwahati. Mobilab-Uni represents an IoTenabled, portable, and sensor-based biochemical analyzer capable of performing multiple assays relevant to NCD management.

2.2 Rationale for the Development of Mobilab-Uni

The guiding principles behind the development of Mobilab-Uni included:

(a) **Multi-analyte capability:** To simultaneously evaluate multiple biochemical parameters rather than relying on single-analyte devices.

(b) **Portability and robustness:** To ensure usability in rural clinics, mobile health units, and outreach programs without dependency on large infrastructure.

(c) **Affordability:** To lower costs compared to centralized analyzers, thereby making diagnostics accessible to underserved populations.

2.3 Biochemical Parameters

The biochemical assay used in this work are well-established methods commonly employed in clinical laboratories. The key innovation of the present study lies in the engineering integration of multiple established biochemical assays into a compact, portable, and low-power diagnostic platform. This required optimization of the optical detection system, reaction

chamber design, micro-volume reagent handling, and embedded signal processing, enabling reliable biochemical testing in decentralized healthcare settings.

The Mobilab-Uni device was designed with only one slot for the testing to address five critical biochemical parameters: total bilirubin, creatinine, triglycerides, glucose, and hemoglobin, which were carefully chosen based on their clinical significance and prevalence in non-communicable disease management.

In conventional automated clinical chemistry analyzers, the typical sample requirement ranges from approximately 100–500 µL of serum or plasma per assay, mainly due to larger reaction cuvette volumes and automated pipetting systems designed for high-throughput laboratory testing. In contrast, the Mobilab platform was developed for micro-volume biochemical analysis, enabling reliable testing with significantly smaller sample volumes. This reduction was achieved through the miniaturization of the optical reaction chamber, optimization of reagent-to-sample ratios, and calibration of the LED–photodiode optical detection system for low-volume reactions.

[1]. Total bilirubin (Liver Function Test - LFT): Total bilirubin is a crucial biochemical parameter used to evaluate liver function, bile excretion capacity, and the presence of hepatocellular or post-hepatic injury [58]. Bilirubin is an end product of heme catabolism, primarily derived from the breakdown of hemoglobin in senescent red blood cells by the reticuloendothelial system. The heme moiety is first converted to biliverdin by heme oxygenase, which is then reduced to bilirubin by biliverdin reductase [59]. This unconjugated bilirubin, being lipid-soluble and water-insoluble, is transported in the bloodstream bound to albumin to the liver for further processing [60].

Within the hepatocytes, bilirubin undergoes conjugation with glucuronic acid catalyzed by the enzyme UDP-glucuronyl transferase, forming bilirubin monoglucuronide and diglucuronide. This conversion renders bilirubin water-soluble (conjugated form), enabling its excretion through bile into the intestine [61]. Any impairment in bilirubin metabolism, such as excessive haemolysis, hepatic dysfunction, or bile duct obstruction, can result in elevated serum bilirubin levels, clinically manifested as jaundice [62].

To quantify bilirubin accurately, Mobilab-Uni integrates the Modified Jendrassik–Grof method, a well-established and standardized colorimetric assay known for its precision and robustness [63]. Figure 2 illustrates the biochemical principles underlying the Modified Jendrassik-Grof method for total bilirubin estimation. In this reaction, sulfanilic acid is diazotized to form diazosulfanilic acid, which then reacts with bilirubin to produce the

chromogenic azobilirubin complex. An accelerator mixture containing caffeine and sodium benzoate disrupts bilirubin–albumin binding, solubilizes unconjugated bilirubin, and enhances its reactivity with the diazo reagent. Caffeine facilitates hydrogen-bond displacement and internal bond disruption, allowing efficient color development. The azobilirubin formed exhibits strong absorbance in the 560–600 nm range, enabling quantitative spectrophotometric detection. This method minimizes interference, improves assay linearity, and is widely used in clinical chemistry and point-of-care bilirubin measurement systems [64]. The reaction occurs under specific pH conditions optimized to differentiate direct (conjugated) from indirect (unconjugated) bilirubin fractions [65].

The azobilirubin formed exhibits a characteristic absorbance peak typically measured at 546 nm, which is detected spectrophotometrically by the Mobilab-Uni's optical system. The analyzer's integrated micro-spectrophotometer captures absorbance data, converts it into concentration units via a pre-calibrated algorithm, and provides a digital output of total and direct bilirubin values.

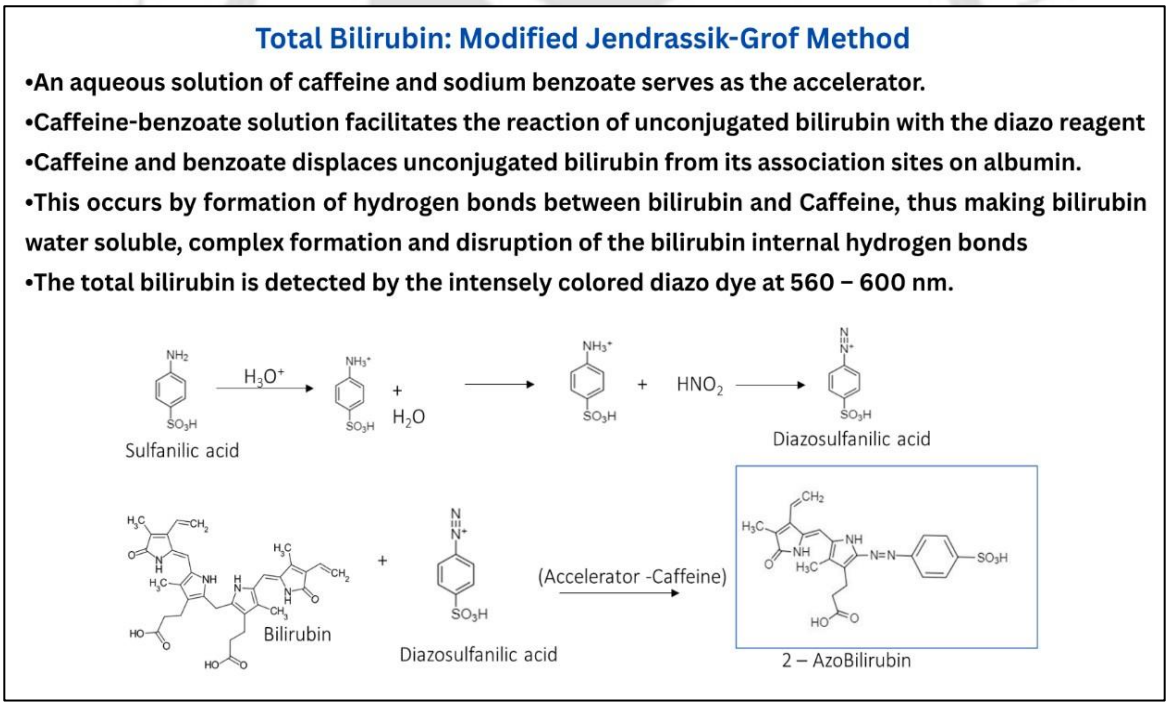

Figure 2: Principle of total bilirubin estimation by the modified Jendrassik–Grof method. The figure illustrates the diazo reaction of bilirubin in the presence of a caffeine–sodium benzoate accelerator, leading to formation of the colored azobilirubin complex measured at 560–600 nm.

The principle of Modified Jendrassik–Grof method mentioned in the Figure 2. In the modified Jendrassik–Grof method, caffeine and sodium benzoate displace unconjugated

bilirubin from albumin and render it water-soluble by hydrogen-bond interaction. The freed bilirubin then reacts with diazotized sulfanilic acid to form azobilirubin, an intensely colored chromogen. The reaction scheme shown summarizes these steps—from sulfanilic acid diazotization to azobilirubin formation—which underpins total bilirubin measurement in serum. It offers several advantages over older methods, such as the Malloy-Evelyn technique: it demonstrates improved linearity, reduced interference from hemoglobin, lipemia, or ascorbic acid, and enhanced stability of the azobilirubin complex, ensuring analytical reliability even in portable systems [66]. This makes it particularly suitable for point-of-care testing (POCT) applications such as Mobilab-Uni, where minimal sample volume, rapid processing time, and diagnostic accuracy are critical [67].

In clinical practice, bilirubin assessment using the Mobilab-Uni provides a rapid, accurate, and cost-effective solution for screening liver disorders and monitoring treatment outcomes, especially in resource-limited healthcare settings. Integration of this assay within a portable biochemical analyzer allows real-time assessment of liver function, facilitating early diagnosis and intervention in patients with hepatic dysfunction or obstructive jaundice [68].

[2] Total Protein (Liver Function Test - LFT): Total protein is a key biochemical parameter used to assess nutritional status, liver synthetic function, and the presence of systemic inflammatory or metabolic disorders [69]. Serum proteins primarily consist of albumin and globulins, which play critical roles in maintaining oncotic pressure, transporting biomolecules, supporting immune responses, and sustaining metabolic balance [70]. Alterations in total protein reflect diverse clinical conditions, including liver disease, nephrotic syndrome, malnutrition, malabsorption, dehydration, and chronic inflammation.

The Biuret method, employed in Mobilab-Uni for total protein estimation, is based on the formation of a characteristic violet-colored coordination complex between cupric ions (Cu^{2+}) and peptide bonds present in proteins [71]. When proteins are exposed to Cu^{2+} ions in an alkaline medium, coordinate bonds form between the copper ion and the carbonyl oxygen and amide nitrogen atoms of adjacent peptide linkages, generating a stable chelate structure [72]. The intensity of the violet-colored complex is directly proportional to the number of peptide bonds reacting and thus correlates with the concentration of protein in the sample [73]. Amino acids and dipeptides do not react, whereas tripeptides, oligopeptides, and polypeptides yield a measurable color change.

In the Biuret method, peptide bonds in proteins chelate cupric ions (Cu^{2+}) in an alkaline medium to form a stable violet coordination complex. Each Cu^{2+} ion coordinates with the

carbonyl oxygen and amide nitrogen of neighbouring peptide linkages, and the intensity of the resulting purple colour is directly proportional to the number of peptide bonds—and thus to the total protein concentration in the sample. Free amino acids and dipeptides show negligible reaction, whereas tripeptides, oligopeptides and polypeptides produce a strong colour response.

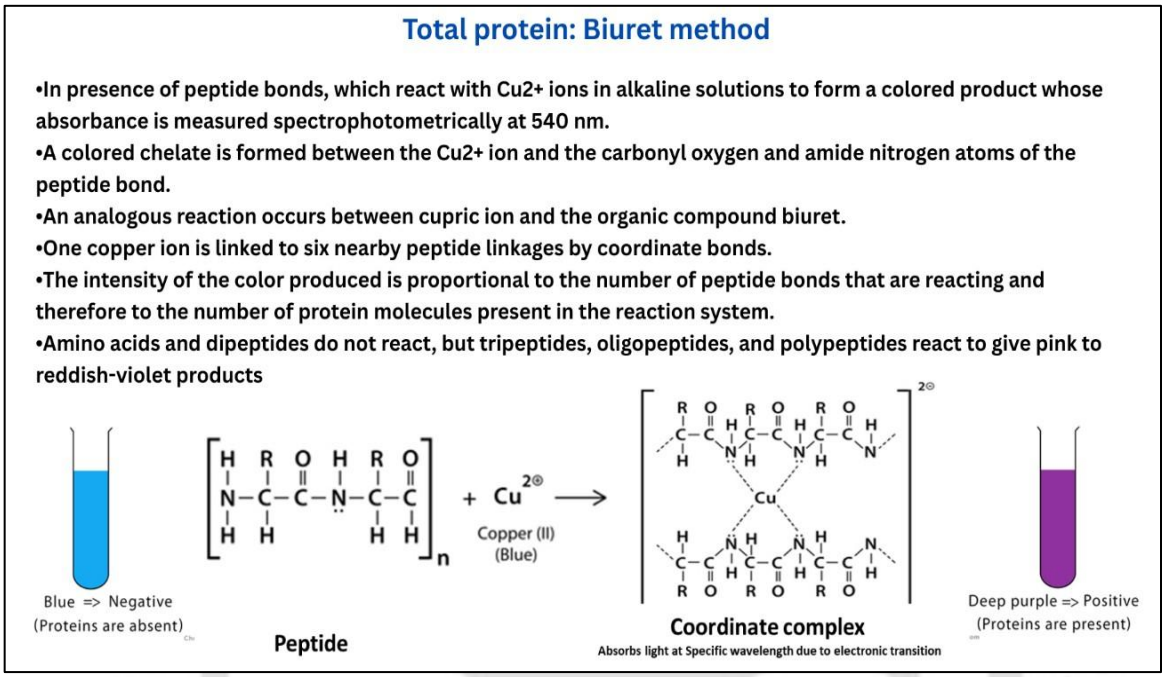

Figure 3. Principle of total protein estimation by the Biuret method. The figure shows how peptide bonds in proteins react with cupric (Cu^{2+}) ions in alkaline medium to form a violet colored coordination complex, which is measured spectrophotometrically at 540 nm.

Figure 3 illustrates this principle: the reagent appears blue in the absence of protein and turns purple when the Cu^{2+}–peptide complex forms. The structural representation of the coordination complex and the corresponding colour change are shown, with absorbance measured spectrophotometrically at 540 nm for quantitative estimation of serum total protein. In the assay, the Biuret reagent containing copper sulphate, sodium hydroxide, and potassium sodium tartrate, provides the alkaline environment and stabilizing agents required for the copper–protein interaction [74]. Potassium iodide is commonly included to prevent auto-reduction of Cu^{2+} ions. Upon reaction, the resulting Cu^{2+}–protein complex exhibits a prominent absorbance peak around 540–560 nm, which is detected spectrophotometrically by the Mobilab-Uni optical system [75].

The analyzer measures the absorbance of the chromogenic complex and converts it to total protein concentration using a pre-calibrated linear regression model integrated in the device firmware [76]. The Biuret method is widely preferred because of its robustness, minimal

interference, broad linearity range, and compatibility with both manual and automated systems, including point-of-care devices like Mobilab-Uni [77].

Clinically, total protein assessment using Mobilab-Uni provides rapid, reliable screening for conditions such as chronic liver disease (low albumin), nephrotic syndrome (protein loss), protein-energy malnutrition, and inflammatory disorders associated with elevated globulin fractions [78]. The ability to perform this test in a portable format allows real-time decisionmaking in primary care, rural clinics, and low-resource environments, improving early diagnosis and follow-up of patients with metabolic or hepatological disorders [79].

[2]. Creatinine (Kidney Function Test - KFT): Creatinine is an essential biochemical marker widely used for evaluating renal function and estimating glomerular filtration efficiency [80]. Figure 4 illustrates the multi-step enzymatic pathway used for creatinine measurement in the enzymatic (Trinder-based) assay. In the first step, creatinine present in the sample is converted to creatine by creatinine amidohydrolase. Creatine is then hydrolyzed by creatine amidinohydrolase to produce sarcosine and urea. Sarcosine oxidase subsequently catalyzes the oxidative demethylation of sarcosine, generating glycine, formaldehyde, and hydrogen peroxide. In the final chromogenic reaction, hydrogen peroxide reacts with N-ethylN-sulfopropyl-m-toluidine (ESPMT) and 4-aminoantipyrine in the presence of horseradish peroxidase to form a quinoneimine dye with maximum absorbance at 546 nm. The intensity of the colored product is directly proportional to the creatinine concentration in the sample. This multi-enzyme cascade forms the basis of the enzymatic creatinine assay used in clinical chemistry and in point-of-care platforms such as Mobilab-Uni. It is produced at a nearly constant physiological rate through the non-enzymatic degradation of creatine and phosphocreatine in skeletal muscle, thereby reflecting both muscle mass and basal metabolic activity [81]. After its formation, creatinine enters the bloodstream and is eliminated predominantly by glomerular filtration, with minimal tubular secretion under normal physiological conditions [82]. Because its production remains relatively stable and is only minimally affected by dietary or hepatic factors, serum creatinine serves as a dependable indicator of kidney function [83].

Elevated serum creatinine levels indicate impaired renal filtration capacity and are directly associated with a reduction in glomerular filtration rate (GFR). Persistent increases are characteristic of chronic kidney disease (CKD) or renal insufficiency, conditions that are growing global health concerns [84]. In India, epidemiological studies estimate the prevalence of CKD to be approximately 15-17%, with diabetes mellitus and hypertension serving as the

major etiological contributors [85]. Therefore, early, precise, and serial measurement of creatinine is vital for diagnosis, staging, and therapeutic monitoring of individuals at risk for kidney failure [86].

To facilitate efficient creatinine quantification in point-of-care testing (POCT) environments, Mobilab-Uni utilizes an enzymatic colorimetric assay, which offers improved specificity and analytical robustness compared to the traditional Jaffe alkaline picrate method [87]. The enzymatic method minimizes common analytical interferences from substances such as glucose, ketones, bilirubin, and proteins, thereby enhancing accuracy when working with low-volume capillary blood samples, an important advantage for decentralized screening and bedside diagnostics [88]. When compared with conventional laboratory chemistry analyzers, Mobilab-Uni demonstrates high concordance, reduced turnaround times, minimal operator dependence, and significantly lower sample volume requirements. Beyond renal assessment via creatinine measurement, the platform also integrates additional biochemical parameters related to liver function, metabolic health, and cardiovascular risk, thereby providing a comprehensive multi-analyte diagnostic capability within a compact, portable system [89]. This integrated approach represents a substantial advancement in rapid biochemical screening, enabling early disease detection and continuous monitoring in both clinical and community settings. The enzymatic creatinine assay employed in Mobilab-Uni is based on a multi-step reaction cascade, where creatinine undergoes sequential enzymatic conversions leading to the formation of a coloured quinonimine pigment measurable spectrophotometrically. The biochemical reaction sequence is as follows:

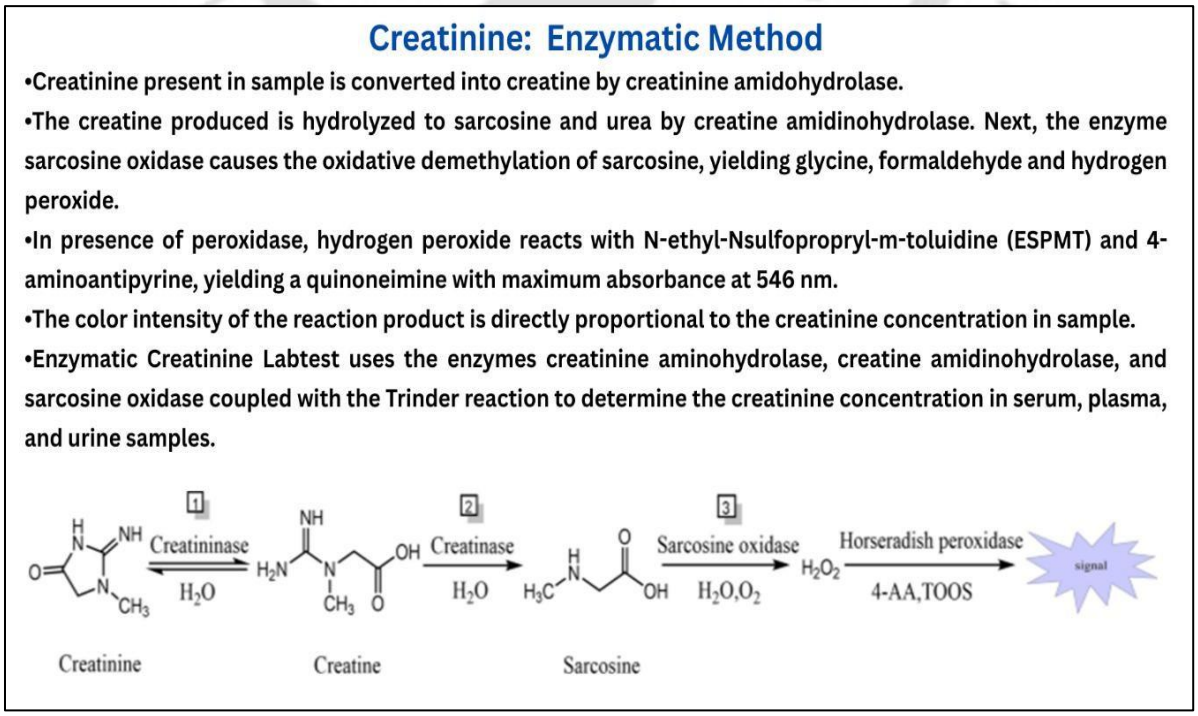

Figure 4. Principle of creatinine estimation by the enzymatic method. The scheme shows sequential enzymatic conversion of creatinine to a quinoneimine chromogen via creatininase, creatine amidinohydrolase, sarcosine oxidase, and peroxidase, with the final coloured product measured at 546 nm.

Figure 4 illustrates the principle of the enzymatic creatinine assay. In this method, creatinine in the sample is first converted to creatine by creatininase, then hydrolysed to sarcosine and urea by creatine amidinohydrolase. Sarcosine oxidase catalyses the oxidative demethylation of sarcosine to glycine, formaldehyde and hydrogen peroxide. In the presence of peroxidase, the generated hydrogen peroxide reacts with ESPMT and 4-aminoantipyrine to form a quinoneimine dye, whose absorbance at 546 nm is directly proportional to the creatinine concentration in serum, plasma or urine.

Beyond its value as a standalone renal marker, creatinine is the key input for estimating the glomerular filtration rate (eGFR), widely regarded as the most reliable index of kidney function. eGFR calculations combine serum creatinine with age, sex and body size to detect even early or subclinical renal impairment—often before creatinine alone becomes markedly abnormal. By integrating enzymatic creatinine measurement within the Mobilab-Uni platform, clinicians and field workers can obtain accurate, point-of-care creatinine values suitable for eGFR computation, strengthening CKD screening, enabling timely intervention and supporting evidence-based decisions in resource-limited settings.

[3]. Triglycerides (Lipid Profile): Triglycerides (TGs) constitute a major component of the lipid profile and serve as a crucial biomarker for assessing metabolic status, cardiovascular health, and disorders of lipid metabolism [89]. They are esters composed of glycerol and three fatty acids, functioning as the primary energy reservoir stored in adipose tissue and as a central fuel source for cellular metabolism [90]. Figure 5 illustrates the enzymatic sequence underlying the GPO–PAP (Glycerol-3-Phosphate Oxidase–Phenol Aminophenazone) methodology for triglyceride determination. Serum triglycerides are first hydrolyzed by lipoprotein lipase (LPL) to form glycerol and free fatty acids. Glycerol is then phosphorylated by glycerol kinase (GK) in the presence of ATP and magnesium ions to generate glycerol-3phosphate, which is subsequently oxidized by glycerol-3-phosphate oxidase (GPO) to yield dihydroxyacetone phosphate and hydrogen peroxide (H_2O_2). In the final chromogenic reaction, H_2O_2 reacts with 4-aminoantipyrine and TOOS in the presence of peroxidase (POD) to form a stable violet-colored quinoneimine complex. The intensity of the color produced is directly proportional to the triglyceride concentration, enabling quantitative

spectrophotometric measurement. Under normal physiology, triglycerides are synthesized in the liver and intestines and circulate in the bloodstream incorporated within lipoprotein particles, chiefly chylomicrons and very low-density lipoproteins (VLDL) [91].

Elevated plasma triglyceride levels (hypertriglyceridemia) are highly associated with metabolic and cardiovascular pathologies, including obesity, type 2 diabetes mellitus, metabolic syndrome, and atherosclerotic cardiovascular disease [92]. Persistently high triglyceride concentrations contribute to endothelial dysfunction, oxidative stress, and lipid accumulation within arterial walls, accelerating atherogenesis and increasing the risk of coronary artery disease and pancreatitis in severe cases [93]. Conversely, abnormally low triglyceride levels may reflect malnutrition or impaired lipid absorption. Thus, routine triglyceride assessment remains an essential component of cardiometabolic risk evaluation.

For accurate and rapid triglyceride measurement in a point-of-care testing (POCT) format, the Mobilab-Uni analyzer utilizes the GPO-PAP (Glycerol-3-Phosphate Oxidase–Phenol 4Aminophenazone) enzymatic colorimetric method [94]. This assay is widely regarded as the gold standard for triglyceride estimation due to its high specificity, wide linear range, and compatibility with both laboratory and portable diagnostic platforms [95]. The method proceeds through a sequence of enzymatic reactions in which triglycerides are hydrolyzed to glycerol, converted to glycerol-3-phosphate, and subsequently oxidized to produce hydrogen peroxide (H_2O_2).

In the final reaction step, the H_2O_2 generated acts as an oxidizing agent and reacts with 4aminophenazone and phenol in the presence of peroxidase (POD), yielding a stable quinoneimine chromophore. The intensity of the pink-colored dye, measured at approximately 540-560 nm, is directly proportional to the triglyceride concentration in the sample [96]. The overall biochemical reactions involved in the GPO–PAP method are as follows:

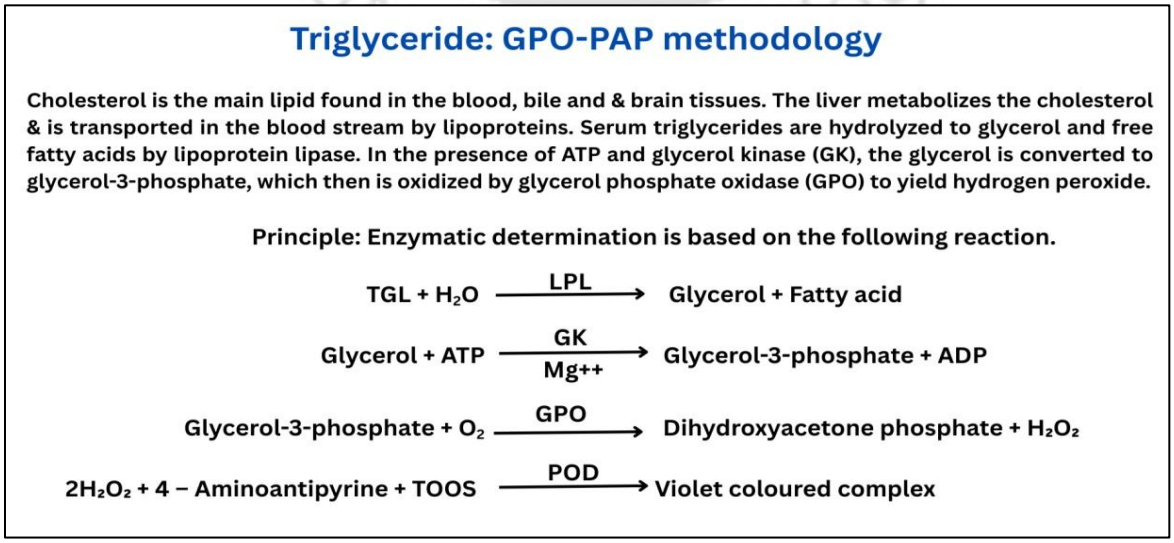

Figure 5. Principle of triglyceride estimation by the GPO–PAP method. The figure depicts the enzymatic hydrolysis of triglycerides to glycerol and their subsequent conversion through glycerol kinase and glycerol-3-phosphate oxidase to generate hydrogen peroxide, which finally forms a violet chromogen with 4-aminoantipyrine and TOOS in the presence of peroxidase.

Figure 5 illustrates the GPO–PAP enzymatic pathway used for serum triglyceride measurement. Triglycerides are first hydrolysed by lipoprotein lipase to glycerol and free fatty acids. Glycerol is phosphorylated by glycerol kinase to glycerol-3-phosphate, which is then oxidised by glycerol-3-phosphate oxidase to dihydroxyacetone phosphate and hydrogen peroxide. In the final Trinder step, hydrogen peroxide reacts with 4-aminoantipyrine and TOOS under the action of peroxidase to yield a violet-coloured complex. The absorbance of this dye is directly proportional to the triglyceride concentration in the sample. Mobilab-Uni integrates this enzymatic chemistry into its micro-spectrophotometric optical system, which quantifies absorbance accurately using minimal specimen and reagent volumes. A precalibrated standard curve constructed from known triglyceride concentrations enables automated conversion of absorbance values into quantitative triglyceride measurements, achieving analytical performance comparable to standard laboratory analyzers [97]. The GPO–PAP method offers several notable advantages for POCT applications:

- High specificity with minimal interference from bilirubin, hemoglobin, ascorbic acid, and other endogenous substances.
- Rapid enzymatic kinetics, enabling test completion within minutes.
- Excellent stability of the quinoneimine dye, enhancing reproducibility and precision.
- Suitability for very small sample volumes (10–20 µL capillary blood), making the method ideal for decentralized testing [98].

Through the integration of triglyceride measurement into a portable multi-analyte device, Mobilab-Uni provides healthcare workers with a powerful diagnostic tool for assessing dyslipidaemia, metabolic syndrome, and cardiometabolic risk at the point of care. When interpreted alongside other lipid parameters—total cholesterol, LDL-C, HDL-C—it enables comprehensive lipid profiling and supports early intervention in both clinical and resourcelimited environments

[4]. Glucose (To monitor Diabetes): Glucose is a central biomarker for the diagnosis, monitoring, and therapeutic management of diabetes mellitus, a chronic metabolic disorder characterized by persistent hyperglycemia due to impaired insulin secretion, insulin

resistance, or a combination of both [99]. Dysregulation of glucose homeostasis not only defines diabetes but also drives its long-term complications, namely, cardiovascular disease, diabetic nephropathy, neuropathy, and retinopathy, thereby contributing significantly to global morbidity and mortality. According to recent projections by the International Diabetes Federation, more than 643 million individuals are expected to be affected by diabetes by 2030, highlighting the need for accurate, accessible, and rapid glucose assessment tools [100]. Continuous monitoring of blood glucose enables clinicians to evaluate glycemic control, titrate pharmacological interventions, and prevent acute metabolic crises such as diabetic ketoacidosis and hyperosmolar hyperglycemic state. Regular glucose screening also supports early identification of prediabetes and impaired glucose tolerance, facilitating timely lifestyle or therapeutic interventions and thereby reducing the risk of progression to overt diabetes [101].

Mobilab-Uni utilizes the Glucose Oxidase–Phenol 4-Aminophenazone (GOD–PAP) enzymatic colorimetric method, a widely validated and reliable assay adapted for smallvolume capillary blood samples obtained through finger-prick collection. This methodology provides rapid and accurate glucose quantification, making it highly suitable for point-of-care testing (POCT), community-based health programs, and decentralized clinical settings [102]. In this assay, glucose is oxidized by glucose oxidase to produce gluconic acid and hydrogen peroxide (H_2O_2). The H_2O_2 generated subsequently reacts with phenol and 4-aminophenazone in the presence of peroxidase (POD), forming a stable quinoneimine chromophore. The resulting pink color exhibits maximal absorbance between 500-550 nm, with its intensity directly proportional to the glucose concentration [103]. The GOD–PAP method demonstrates high analytical specificity with minimal interference from substances such as ascorbic acid, uric acid, or hemoglobin, ensuring reliable measurement even in small-volume samples. The

GOD-PAP method relies on a series of enzymatic and colorimetric reactions.

Figure 6 illustrates the enzymatic glucose determination based on the Glucose Oxidase–Phenol 4-Aminophenazone (GOD-PAP) reaction principle. Glucose, the primary carbohydrate and major energy source in the body, is oxidized by the enzyme glucose oxidase to form gluconic acid and hydrogen peroxide (H_2O_2). In the subsequent peroxidase-mediated step, H_2O_2 reacts with phenol and 4-aminoantipyrine to generate a stable quinoneimine chromophore, producing a measurable color change. The intensity of the quinoneimine dye, typically read at 500–550 nm, is directly proportional to the glucose concentration in the

sample. This GOD-PAP method is widely used in clinical biochemistry due to its high specificity, minimal interference, and suitability for point-of-care diagnostic platforms.

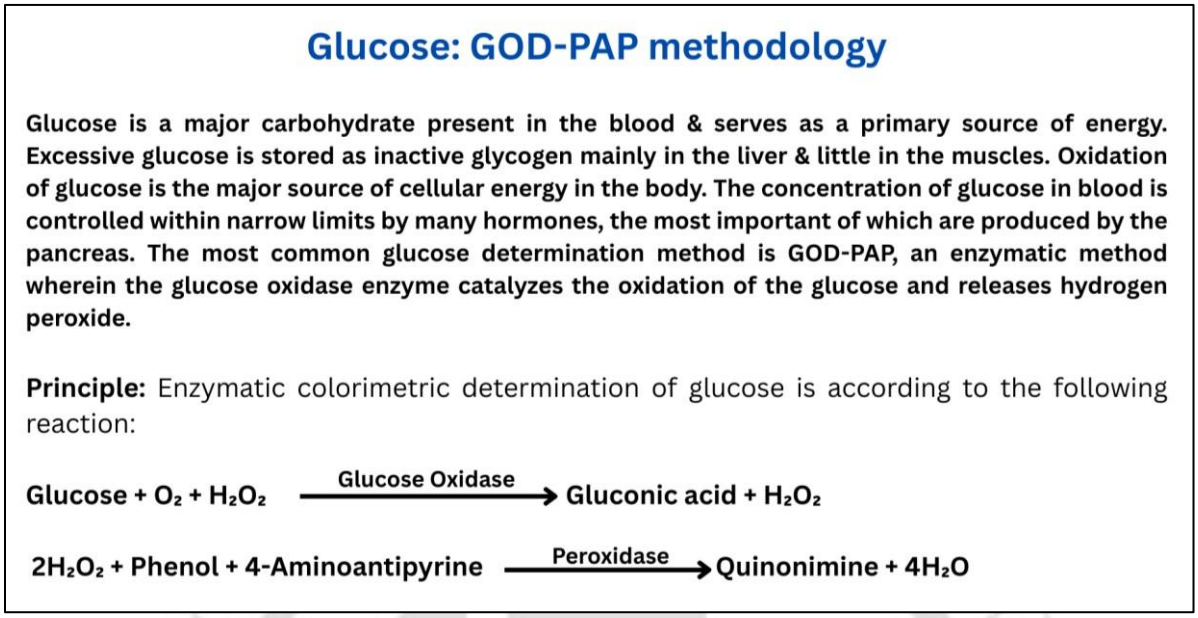

Figure 6. Principle of glucose estimation by the GOD–PAP method. The figure shows enzymatic oxidation of glucose by glucose oxidase to form gluconic acid and hydrogen peroxide, followed by a peroxidase-mediated Trinder reaction that generates a colored quinoneimine dye used for photometric glucose measurement.

Figure 6 summarizes the GOD–PAP colorimetric method for blood glucose determination. Glucose is oxidized by glucose oxidase to gluconic acid with concurrent formation of hydrogen peroxide. In the presence of peroxidase, this hydrogen peroxide reacts with phenol and 4-aminoantipyrine to form a quinoneimine chromogen. The intensity of this colored product, read spectrophotometrically, is directly proportional to the glucose concentration in the sample.

Integration of this assay into the Mobilab-Uni platform confers multiple advantages:

- Rapid turnaround time: Glucose results are available within minutes, enabling prompt clinical decisions.
- Minimal specimen requirement: Only 10–20 µL of finger-prick blood is sufficient, enhancing patient comfort and usability.
- Portability and ease of use: The device's micro-spectrophotometric system and automated reagent handling support deployment in field camps, clinics, and home settings.

- High analytical accuracy: Calibration against standard laboratory glucose assays ensures strong correlation with conventional diagnostic methods [104].

By combining accuracy, speed, and portability, Mobilab-Uni offers a robust platform for real-time glucose monitoring in diabetic patients and for screening high-risk populations. When integrated alongside liver, renal, lipid, and haematological parameters within a single handheld device, glucose measurement supports comprehensive metabolic profiling at the point of care—an especially critical feature in decentralized and resource-limited healthcare environments [105].

[5]. Hemoglobin (Anemia Assessment): Hemoglobin (Hb) is a fundamental biomarker for assessing anemia, a haematological disorder defined by reduced oxygen-carrying capacity due to decreased hemoglobin levels, abnormal hemoglobin structure, or inadequate red blood cell mass. Anemia affects more than 1.6 billion people globally, with the highest burden among women of reproductive age, young children, and low- and middle-income populations [106]. Chronic anemia is associated with fatigue, impaired cognitive development, compromised immunity, reduced productivity, and elevated maternal and neonatal morbidity, making it a critical global health challenge [107]. Quantifying hemoglobin concentration is essential for diagnosing anemia, monitoring therapeutic response, and identifying underlying causes such as nutritional deficiencies, chronic diseases, or hemoglobinopathies. Rapid and reliable Hb measurement is particularly crucial in rural, field-based, and resource-restricted settings where laboratory infrastructure is limited [108].

Mobilab-Uni utilizes the cyanmethemoglobin method, an internationally accepted reference technique for hemoglobin estimation known for its analytical accuracy, reproducibility, and compatibility with small capillary blood volumes used in point-of-care diagnostics [109]. This method involves converting hemoglobin into a stable cyanmethemoglobin complex through sequential chemical reactions that yield a quantifiable colored derivative.

The resulting cyanmethemoglobin displays a characteristic reddish-brown color whose absorbance at 540 nm correlates linearly with hemoglobin concentration, allowing precise measurement using the micro-spectrophotometer embedded in the Mobilab-Uni device [110]. The biochemical reactions are as follows:

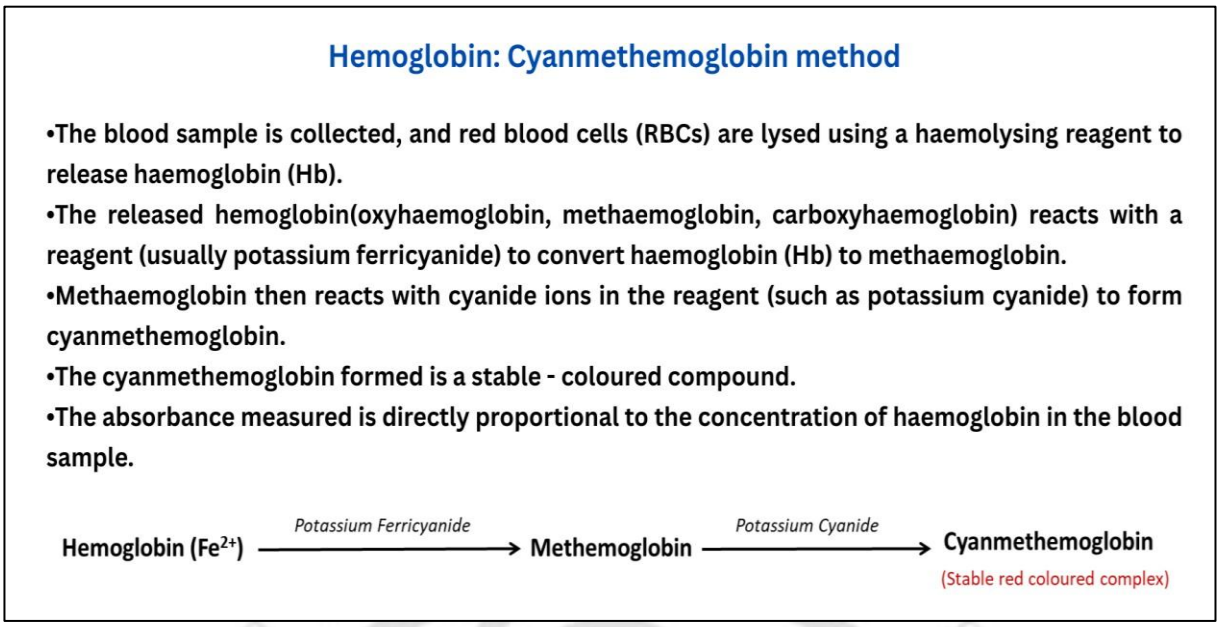

Figure 7. Principle of hemoglobin estimation by the cyanmethemoglobin method. The figure shows the conversion of hemoglobin to methemoglobin by potassium ferricyanide, followed by formation of the stable cyanmethemoglobin complex in the presence of potassium cyanide, which is then measured calorimetrically.

Figure 7 illustrates the chemical principle underlying the cyanmethemoglobin method for hemoglobin determination. In this assay, whole blood is treated with a homolysing reagent to release hemoglobin (Hb) from red blood cells. The liberated hemoglobin derivatives (oxyhaemoglobin, methaemoglobin, and carboxyhaemoglobin) react with potassium ferricyanide to form methaemoglobin, which subsequently reacts with potassium cyanide to produce cyanmethemoglobin, a stable, red-colored complex. The absorbance of this complex is measured at 540 nm, and the intensity of the color is directly proportional to the hemoglobin concentration in the sample. The schematic representation shows the sequential oxidation of hemoglobin to methaemoglobin and its conversion to the cyanmethemoglobin chromogen.

The cyanmethemoglobin method offers several advantages:

- High chromogen stability, allowing consistent measurements even with delayed reading.
- Excellent analytical specificity with minimal interference from bilirubin, lipemia, or hemoglobin variants.
- Suitability for small-volume finger-prick samples, ideal for pediatric and community screening.

- Seamless compatibility with automation and digital quantification in portable diagnostic devices such as Mobilab-Uni [111].

By incorporating this method, Mobilab-Uni delivers rapid, accurate, and field-deployable hemoglobin quantification, improving real-time anemia assessment across diverse healthcare settings. When combined with additional metabolic, hepatic, renal, and cardiovascular biomarkers, the device provides a comprehensive multi-analyte diagnostic profile—an essential advantage in resource-limited regions where comprehensive laboratory services are often inaccessible [112].

2.4 Device Design and Working Principle

The design of Mobilab-Uni was guided by the principles of simplicity, portability, and reliability, while ensuring that the analytical performance remained comparable to standard laboratory analyzers. The device integrates well-established colorimetric assay principles with optical sensing and embedded electronics, enabling the quantification of multiple biochemical parameters from a single portable platform.

2.4.1 Device Design

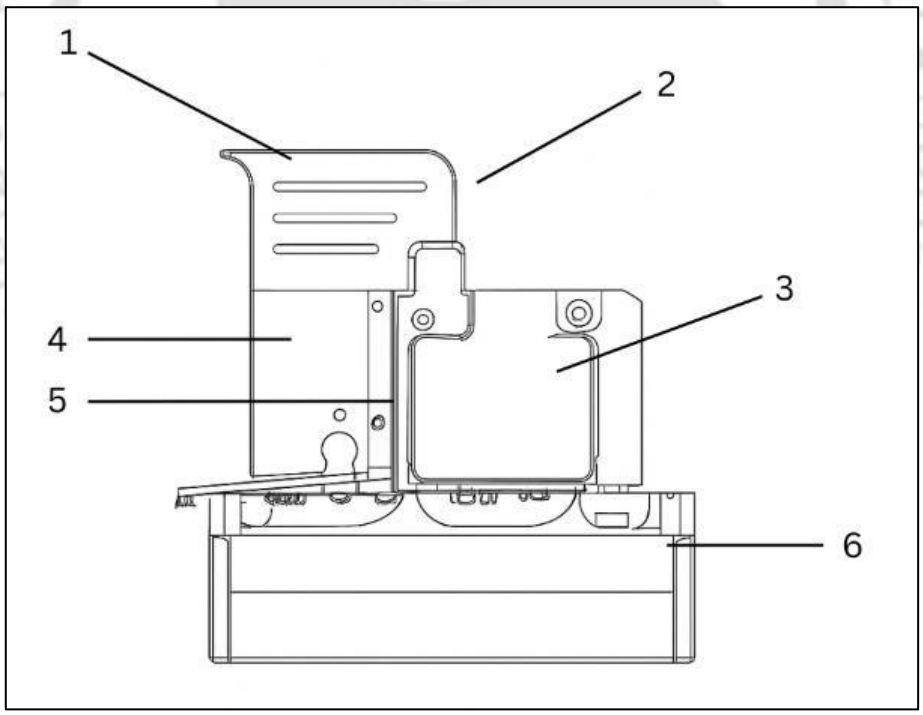

Figure 8. FDM fabricated a portable optical system for spectrophotometric analysis of biochemical parameters. It shows a schematic diagram of the portable optical system for spectrophotometric analysis (1). A cartridge filled with a specific chemical, and the sample is inserted by opening the Lid (2), the source present at the front part (3) is illuminated momentarily based on a specific algorithm. and the transmitted light through the cartridge is registered in the CMOS sensor present at the back (4). Both the front (3) and back parts of

the optical system are fastened at (5) by fastening means and are coupled with a control circuit at the bottom. Bottom unit (6) consists of the Lithium-Ion batteries for backup; the control circuit further communicates with a computing device through a USB B port to any computing device that can be a PC or a Smartphone via UART protocol. After receiving the intensity data, the absorbance is calculated for a fixed wavelength using Beer-Lambert's Law and correlated with the concentration of the biomarker under observation. But this system had to be optimized in terms of repeatability, sensitivity and accuracy with a significant number of challenges that need to be overcome as discussed in the next section.

Figure 8 shows a cuvette or cartridge containing reagent and sample is inserted by opening the lid (2). The light source (3) is pulsed according to a predefined algorithm, and the transmitted light is captured by the CMOS sensor (4). The front and rear modules are rigidly fixed together at point (5) and connected to the control circuit located in the bottom unit (6), which also houses lithium-ion batteries for portable operation. The control circuit communicates with an external PC or smartphone via USB–UART, from which intensity data are processed to calculate absorbance at a fixed wavelength using Beer–Lambert's law and convert it to biomarker concentration. Subsequent work focused on improving repeatability, sensitivity, and accuracy, as discussed in the next section.

Light Emitting Diodes (LEDs): The optical sensing unit of Mobilab-Uni is equipped with LEDs that provide light at specific wavelengths corresponding to the absorption maxima of the respective biochemical reactions. The transmitted or reflected light from the reaction mixture is detected by highly sensitive photodiodes, which convert the light intensity into an electrical signal. This signal is then processed by an embedded microcontroller unit (MCU), which executes pre-programmed calibration algorithms to convert raw absorbance values into analyte concentrations. The system is calibrated against known standards to ensure accuracy and reproducibility across different batches of reagents and cartridges.

IoT-enabled interface: One of the distinguishing features of Mobilab-Uni is its IoTenabled interface, which allows diagnostic results to be displayed on the device's screen as well as transmitted digitally to connected platforms. This feature enables real-time reporting, remote monitoring by physicians, and integration into electronic health record systems, thereby enhancing the scope of community-based healthcare delivery. The device is powered rechargeable portable battery pack, making it fully portable and suitable for deployment in rural and resource-limited environments where an uninterrupted power supply is not guaranteed.

Compactness and Usability: The physical design of Mobilab-Uni (Figure 9) emphasizes compactness and usability. The device housing, fabricated from lightweight but durable materials, is ergonomically structured to facilitate ease of handling in field conditions. The workflow is simplified to ensure that minimally trained healthcare workers can operate the system after short training sessions. Only a finger-prick blood sample of approximately 2050 µL is required for testing, which is then introduced into disposable cartridges containing dried reagents. These cartridges are inserted into the optical chamber of the device, where the reaction takes place and measurements are recorded. Results are generated within 15-30 minutes, making the device suitable for rapid decision-making in community health camps, mobile clinics, and primary healthcare centres.

Figure 9. Mobilab-Uni point-of-care biochemical testing platform. The figure shows the Mobilab-Uni analyzer connected to a smartphone, forming a compact, mobile-based diagnostic system for near-patient biochemical testing.

Figure 9 illustrates the Mobilab-Uni as an advanced smartphone-enabled point-of-care diagnostic platform engineered for rapid, accurate, and on-site biochemical testing. The analyzer connects seamlessly with a mobile application that facilitates test selection, automated assay execution, real-time optical signal acquisition, data processing, and instant digital report generation. The smartphone interface serves as both the user control panel and data management hub, allowing secure storage, wireless transmission of results, and integration with digital health records. By combining biosensor technology, optical detection, and digital connectivity, Mobilab-Uni exemplifies a scalable solution for decentralized, realtime biochemical diagnostics and telemedicine-enabled healthcare delivery.

2.4.2 Working Principle

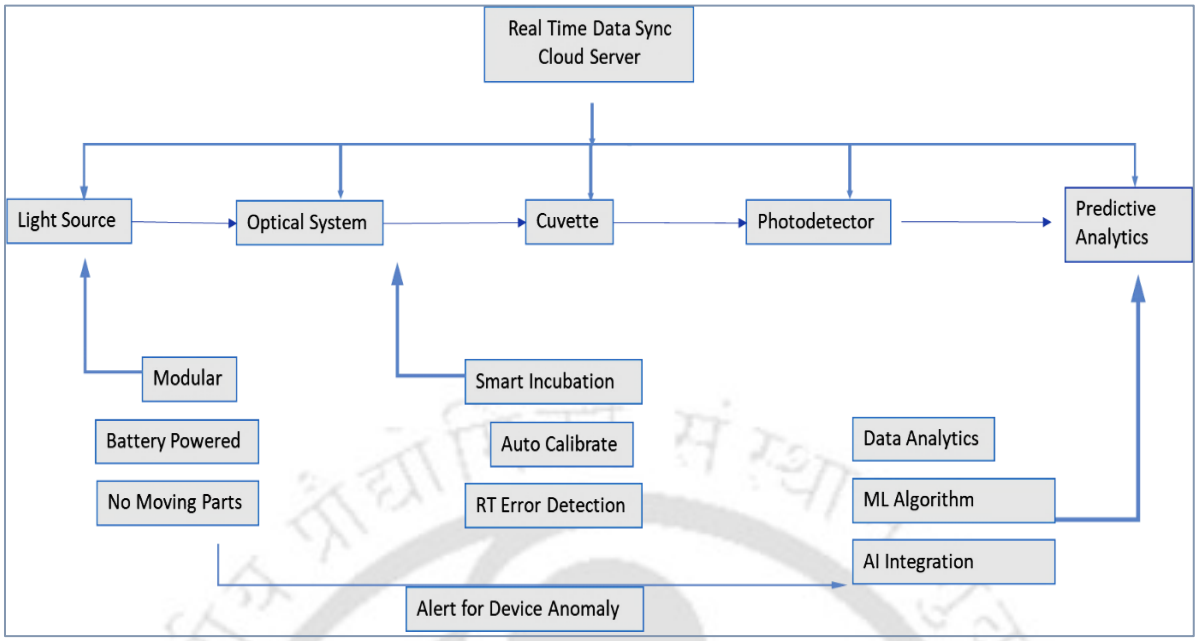

Figure 10. Functional architecture of the smart Mobilab-Uni analytical system. The schematic shows the signal path from light source, optical system, cuvette, and photodetector to predictive analytics, with real-time data synchronized to a cloud server. Key design features include a modular, battery-powered, no-moving-parts optical head; smart incubation with auto-calibration and real-time error detection; and a cloud layer enabling data analytics, ML/AI integration, and automated alerts for device anomalies.

As shown in the Figure 10, the schematic illustrates the integrated operational workflow of the Mobilab POCT system, highlighting the interaction between optical hardware, cuvettebased biochemical testing, data processing, and cloud-enabled analytics. A stable light source passes through a modular, battery-powered optical system with no moving parts, ensuring durability and low maintenance. The transmitted light interacts with the sample contained in the cuvette, which incorporates features such as smart incubation, auto-calibration, and realtime (RT) error detection. The resulting optical signal is captured by the photodetector, which converts it into digital data for immediate interpretation. The processed data is simultaneously sent to the cloud server for real-time data synchronization, enabling large-scale monitoring and remote diagnostics. Advanced predictive analytics, supported by machine learning algorithms, AI integration, and comprehensive data analytics, enhance diagnostic accuracy and enable early detection of device anomalies. Automated alerts provide proactive maintenance support, ensuring reliable device performance in both clinical and field environments.

At the core of the system lies the colorimetric principle [122], which forms the basis for most biochemical assays used in clinical laboratories. In this approach, the concentration of an analyte in a biological sample is correlated with the intensity of color produced during a chemical reaction with specific reagents. For example, glucose produces a colored compound when reacted with glucose oxidase and peroxidase reagents in the GOD-PAP method, while hemoglobin forms a stable colored complex when converted into cyanmethemoglobin. These color changes, though sometimes perceptible to the naked eye, are quantitatively measured by the Mobilab-Uni using its integrated optical detection system.

Overall, the working principle of Mobilab-Uni combines biochemical assay miniaturization, optical detection, embedded electronics, and IoT-enabled reporting into a cohesive system that provides reliable multi-analyte testing at the point of care. By leveraging well-established clinical chemistry methods in a portable and affordable format, Mobilab-Uni bridges the gap between centralized laboratory diagnostics and decentralized primary healthcare delivery.

2.5 Methodology of Development

Many low-powered light sources were examined with varying radiation angles in order to address the optimum condition for the optical system. Pure collimation necessitates the use of a laser with precise wavelengths or a lens array. For low volume applications, we created a low-cost, 3D-printed, portable optical ray guiding system with less sophistication and no mechanical parts. The illumination source, light tunnel, lens, and CMOS sensor are all part of the system. Several experiments were carried out to optimize the following parameters: light tunnel diameter and length, three-dimensional alignment of the source, lens, cartridge, and detector, and internal reflections.

It was observed that the intensity of the illumination source was either fluctuating or incrementing or decrementing in nature, thus interfering with reaction absorbance data. To understand the issue, two experiments were designed for 5 sources, one with a constant voltage source and another constant current source and data from the sensor were observed. Additionally, programmable current source circuits were designed for desired intensity requirements.

The optical system was reiterated for enabling incubation. wherein a CNC machined aluminium part (heating core) was developed that encapsulated the heater. For the right fitting of the cartridge, the tolerance was varied and it was maintained in such a way that it could heat up the cartridge fast without scratching the surface.

Filtering the outliers from the acquired sensor data is essential for low-concentration measurements. Initially Exponential moving average was applied to smooth the curve, then a normal polynomial regression fit and a new regression model fitting were compared. Further, 8 sets of data of the reaction, each for lower and higher concentration, were compared.

The temperature control of the heating core has been achieved using a PID algorithm for the PWM signals to the heater control circuit. Extensive experiments were conducted in order to determine the coefficients of the PID equation. Temperature studies were conducted by varying the temperature of the heating core from 37 to 60 º C, in order to make the reagent reach 37 º C in a faster manner. Initial reagent temperature was also varied from ~8 ºC to ~30 ºC in order to finalize the heating core temperature profile.

2.5.1 Assay Adaptation and Optimization

The first stage of development focused on the adaptation of standard biochemical assays into a format compatible with a portable device. Conventional laboratory assays often require millilitre-scale volumes, refrigerated reagents, and complex instrumentation. To overcome these challenges, the selected assays for total bilirubin, creatinine, triglycerides, glucose, and hemoglobin were miniaturized to work with blood samples (20-50 µL). Reagents were optimized for stability at ambient temperature to avoid the need for cold-chain storage, a common limitation in rural deployments. Each assay was reformulated to ensure that the colorimetric reaction produced a detectable change in absorbance within the optical range of the device's LED photodiode system. This miniaturization not only reduced reagent consumption but also shortened the turnaround time, making the assays more practical for field use.

For portable diagnostic systems such as Mobilab, reagent stability is essential to ensure reliable assay performance under field conditions. To achieve this, buffer compositions were optimized to maintain enzyme activity across a wider temperature range, and stabilizing additives commonly used in clinical chemistry reagents were incorporated to preserve enzyme functionality during storage. Reagents were also stored in sealed containers to minimize exposure to humidity and oxidation. In addition, assay reaction times were optimized to enable rapid color development, reducing the impact of potential reagent degradation during testing. These measures allowed standard biochemical assays to be adapted for reliable use in the portable Mobilab platform.

2.5.2 Optical Sensing Module Development

Once assays were optimized, the next step involved the design of the optical detection unit. For each analyte, a suitable wavelength-specific LED was selected to match the absorbance peak of the corresponding colorimetric reaction product. For instance, glucose oxidase assays produce a chromogen with a strong absorbance in the 505-540 nm range, while cyanmethemoglobin shows maximum absorbance around 540-550 nm. Complementary photodiodes with high sensitivity in these ranges were integrated into the detection circuit. The optical path length was carefully designed to maximize signal-to-noise ratio while minimizing light scattering and stray reflections. The modular design of the optical chamber also ensured that future assays could be added with minimal hardware modifications.

2.5.3 Embedded Electronics and Software Integration

The electrical signals generated by the photodiodes were fed into an analogue-to-digital converter (ADC) embedded within a low-power microcontroller unit (MCU). Custom firmware was developed to process these signals, apply calibration curves, and compute final analyte concentrations. Calibration was achieved using standard control solutions and reference patient samples, ensuring that the device output closely matched clinical laboratory analyzers. The software incorporated error-checking protocols, such as out-of-range detection and blank correction, to minimize analytical variability. In addition to onboard processing, the device was equipped with wireless connectivity to transmit results to smartphones, tablets, or cloud-based health records, thereby enabling remote monitoring and integration with telemedicine platforms.

2.5.4 Result of Device Prototyping and Fabrication

The Mobilab-Uni prototype was fabricated using lightweight materials that ensured both durability and portability. The casing was ergonomically designed for easy handling and included a simple cartridge insertion slot to streamline the workflow. The device was made battery-operated, supporting recharging via USB, and tested for performance under variable field conditions, including high temperature and humidity. A compact LCD interface was incorporated for immediate display of results, thereby reducing dependency on external devices for primary users, though IoT transmission remained available for digital recordkeeping.

Figure 11 shows the CAD iterations and fabrications of the optical system that were done in order to resolve the reinsertion of the cuvette for base reading and sample reading. First, experimentation on constraints: tolerances, layer height, material fittings, interface detailing, CAD, etc., was carried out to get consistency in reading and to improve the CV < 0.1 %.

Secondly, modifications in the Optical system for spectrophotometric analysis in terms of source & sensor alignment, light direction, positioning, and light path optimization were finalized in CAD and experimentally by developing prototypes. Thirdly, integration and design of a ceramic metal heating core for maintaining the inner temperature at a constant 37ºC.

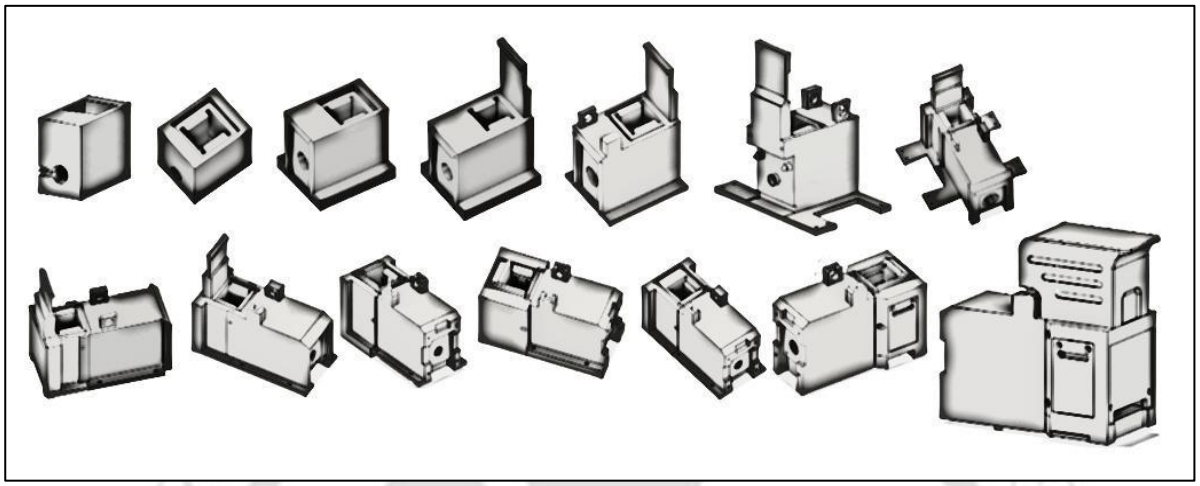

Figure 11. Iterative CAD-based design evolution of the optical system housing. Sequential CAD models illustrate successive refinements of the Mobilab-Uni optical module, highlighting progressive improvements in geometry, component alignment, and mounting architecture, culminating in the final integrated enclosure used in the portable spectrophotometric system.

Figure 11 illustrates the iterative CAD design process of the Mobilab-Uni optical system housing. Starting from simple early enclosures and progressing toward more refined geometries, each model reflects improvements in component alignment, cuvette placement, cable routing, and mechanical stability. The final design on the right represents an integrated, manufacturable enclosure suitable for a compact, portable spectrophotometric device. Some FDM fabrication prototypes have been developed, and experiments were carried out in order to determine the CV at various levels. Below are Tables 3 & 4, which shows the CV for 20 devices for 6 Levels.

Table 3. Experimental test levels, test conditions, number of repetitions, and corresponding time durations used for performance and stability evaluation of the analytical system.

Levels	Meaning	No. of repeats	Time (min)
L1	Continuous Blank Test without incubation	5	15

L2	Continuous Water Test without incubation	5	15
L3	Reinsertion test with water	3	Not specified
L4	Reinsertion test with 4 different dye concentrations	3	Not specified
L5	Continuous Blank test with incubation	3	15
L6	Continuous Water test with incubation	3	15

Table 3 presents the different experimental test levels (L1–L6) employed for system validation under various operating conditions. L1 and L2 represent continuous blank and continuous water tests performed without incubation to assess baseline signal stability. L3 and L4 involve reinsertion tests using water and four different dye concentrations, respectively, to evaluate repeatability and reinsertion variability. L5 and L6 represent continuous blank and continuous water tests performed with incubation to assess the effect of temperature-controlled conditions on system performance. The number of repeats and duration for each level are specified to ensure robustness and reproducibility of the measurements.

Table 4. Coefficient of Variation (CV) values obtained for different experimental test levels (L1–L6) across multiple devices used for system performance and reinsertion reproducibility evaluation.

Device	L1	L2	L3	L4	L5	L6
VB4GRD2	0.0208	0.0193	0.3441	0.4364	0.0266	0.0412
VB4GRD3	0.0421	0.0744	0.6337	0.6164	0.0273	0.034
VB4GRD4	0.0304	0.0349	0.3585	0.5178	0.0442	0.0698
VB4GRD5	0.0463	0.049	0.3349	1.342	0.0522	0.1537
VB4GRD7	0.0207	0.0371	0.4944	0.5991	0.026	0.0723
VB4GRD8	0.0321	0.4097	0.3866	0.3266	0.0556	0.0266
VB4GRD9	0.0233	0.0539	0.9352	0.5985	0.054	0.1565
VB4GRD11	0.0279	0.0524	0.4478	0.6278	0.031	0.0523
VB4GRD12	0.0273	0.03	0.5981	1.3737	0.0542	0.05
VB4GRD13	0.0257	0.0495	0.3759	0.236	0.0251	0.035
VB4GRD14	0.0315	0.1902	1.2574	0.8882	0.0329	0.0339

VB5GRD1	0.0285	0.0494	1.1667	1.1191	0.0391	0.0384
VB5GRD6	0.0268	0.0793	0.2715	0.7174	0.0304	0.0398
VB5GRD7	0.0274	0.0539	1.193	1.0815	0.0503	0.0398
VB5GRD8	0.0442	0.0629	0.3144	0.2647	0.0811	0.0414
VB5GRD9	0.0329	0.0353	0.8643	1.0722	0.0361	0.0302
VB5GRD10	0.029	0.0481	0.1905	0.433	0.0474	0.0839
VB5GRD11	0.0548	0.0577	1.3421	1.1187	0.0783	0.0783
VB5GRD12	0.0471	0.0757	1.7186	1.1136	0.0462	0.0517

This Table 4 presents the coefficient of variation (CV) values for 20 devices tested across six experimental levels (L1–L6). L1 and L2 represent continuous blank and water tests without incubation, reflecting baseline instrument stability. L3 and L4 correspond to reinsertion tests using water and dye cartridges, respectively, assessing reinsertion reproducibility. L5 and L6 represent continuous blank and water tests performed with incubation, evaluating thermal system integration. Overall, the results demonstrate a significant improvement in performance, with CV for water reinsertion improving from ~10% to <1% and dye reinsertion improving from ~13% to <1.5%. These findings confirm robust optical fitting, stable reinsertion performance, and successful integration of the heating core for incubation.

2.5.5 Validation and Benchmarking

The final stage of evaluation involved comprehensive validation of Mobilab-Uni against high-throughput reference laboratory analyzers, including systems such as the Roche Cobas and Abbott Architect. Validation was performed in two sequential phases. First, analytical validation was carried out using standardized control materials that spanned clinically relevant low, normal, and high concentration ranges for each parameter. This phase assessed linearity, accuracy, precision (CV), analytical sensitivity, limit of detection, and bias relative to the reference instruments.

In the second phase, clinical validation was conducted using routine patient samples obtained from participating hospital laboratories following ethical clearance and standard operating procedures. For each analyte, Mobilab-Uni results were compared with paired measurements from the reference analyzers, and performance was quantified using percentage agreement with target values, correlation coefficients (R^2), coefficients of variation, and mean percentage bias. Repeatability and reproducibility were determined

through intra-assay and inter-assay studies across multiple days and operators. Robustness experiments further evaluated device performance under field-like conditions with variable power supply, transport stress, and ambient temperature fluctuations. Collectively, these studies demonstrated that Mobilab-Uni achieved >90% accuracy across all five evaluated parameters, with strong correlation and minimal bias relative to standard auto- and semi-automated analyzers, confirming its suitability for decentralized biochemical testing and point-of-care deployment.

2.5.6 Analytical validation

In order to establish its practical feasibility, the device was first evaluated under controlled laboratory conditions. Analytical validation was carried out by running each biochemical parameter in parallel on the prototype and on a calibrated benchtop UV–visible spectrophotometer. The results were then compared to assess agreement, accuracy, and reliability of the Mobilab-Uni measurements relative to the laboratory gold-standard method. Each assay was tested across multiple concentration levels using calibrators and quality control materials. Performance parameters such as linearity, limit of detection, precision, and carryover were systematically evaluated in accordance with standard clinical laboratory guidelines. These experiments ensured that the analytical performance of Mobilab-Uni met acceptable diagnostic thresholds prior to clinical evaluation.

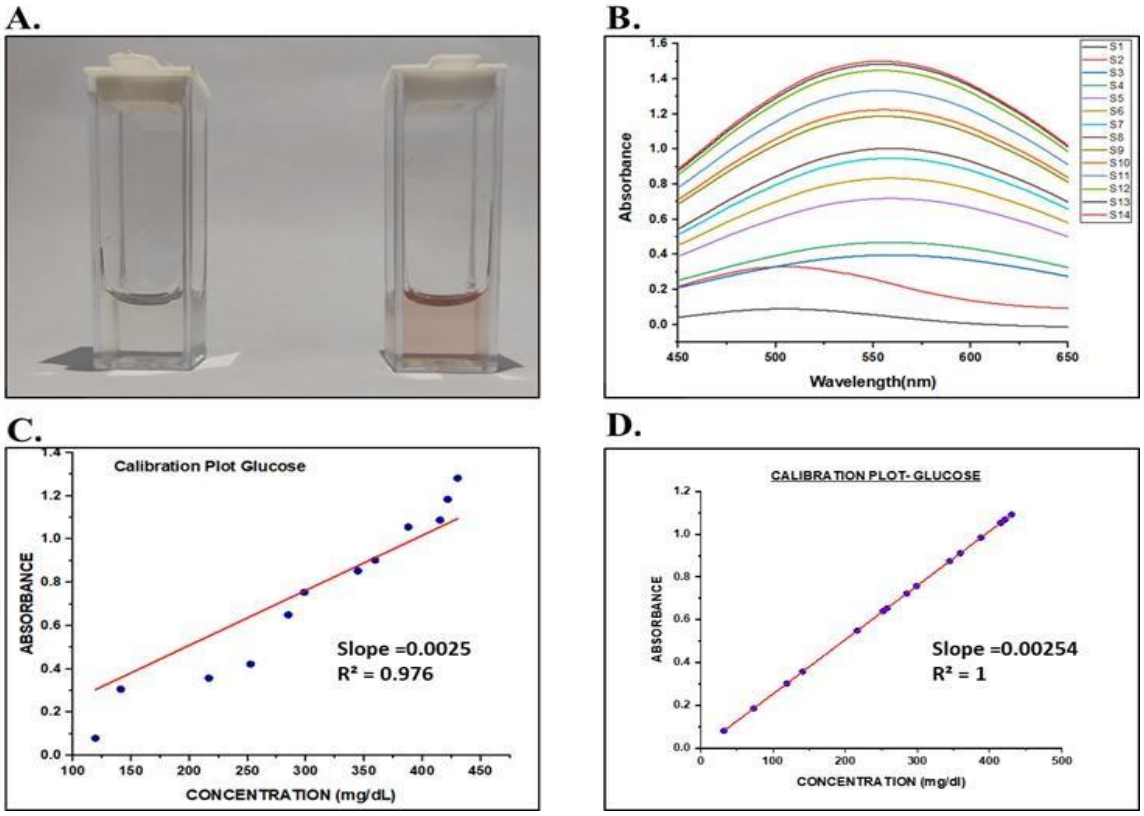

Figure 12. Validation of the glucose assay by the GOD–PAP method. (A) Cuvettes containing glucose reagent and sample before (left) and after (right) color development, showing formation of the characteristic pink quinoneimine dye. (B) UV–Vis absorption spectra of glucose standards concentration (mg/dL) estimation with increasing absorbance and a defined peak in the 500–550 nm range corresponding to the chromophore. (C) Calibration curve generated on a UV–Vis spectrophotometer, demonstrating excellent linearity between absorbance and glucose concentration. (D) Calibration curve obtained on the Mobilab-Uni device, showing close agreement with spectrophotometric values and confirming its suitability for point-of-care glucose estimation.

Figure 12 summarizes the validation of the glucose assay using the GOD–PAP colorimetric method and its translation from a conventional UV–Vis spectrophotometer to the Mobilab-Uni platform. Panel A visually demonstrates the endpoint color change from a nearly colorless solution to a pink quinoneimine dye proportional to glucose concentration. Panel B presents the absorption spectra of a series of glucose standards, highlighting a clear dose dependent increase in signal and a dominant peak in the 500–550 nm region, which is exploited for quantitative analysis. The calibration curve in Panel C confirms excellent linearity of the GOD–PAP reaction under standard laboratory conditions. Panel D shows that the calibration obtained using Mobilab-Uni closely mirrors the UV–Vis reference, indicating strong correlation, preserved linearity, and reliable analytical performance suitable for decentralized, point-of-care glucose testing.

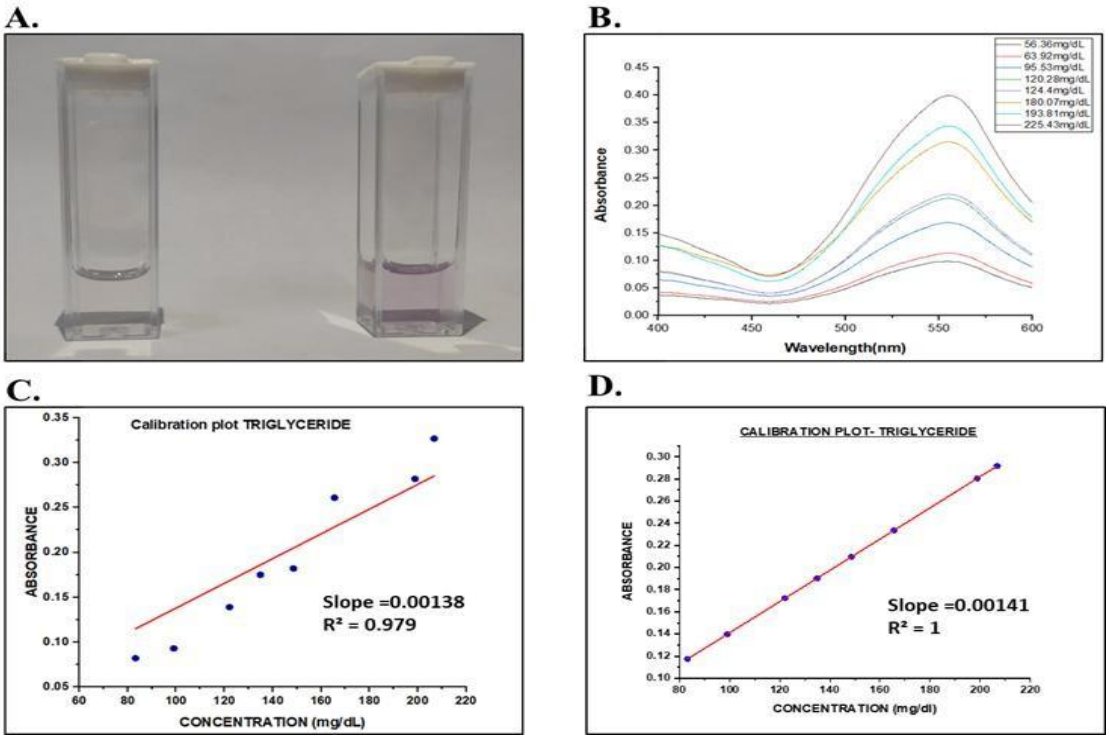

Figure 13. Validation of the triglyceride assay using the GPO–PAP method in UV–Vis and Mobilab systems. (A) Cuvettes containing the triglyceride reaction mixture before and after completion of the GPO–PAP enzymatic reaction, showing development of a pink-violet chromophore. (B) UV–Vis absorption spectra of triglyceride standards (mg/dL) across a physiological range, with a progressive increase in absorbance and a peak near 540–550 nm. (C) Calibration curve obtained on a benchtop UV–Vis spectrophotometer, demonstrating a strong linear relationship between absorbance and triglyceride concentration ($R^2 \approx 0.99$). (D) Calibration curve generated on the Mobilab-Uni device, confirming comparable linearity and analytical performance to the reference instrument.

Figure 13 illustrates the analytical validation of the GPO–PAP triglyceride assay and its transfer from a conventional UV–Vis platform to the Mobilab-Uni system. Panel A visually depicts the endpoint color change from a nearly colorless solution to a pink-violet chromophore proportional to triglyceride concentration. Panel B shows the absorption spectra of standard triglyceride solutions, revealing a clear, concentration-dependent rise in signal with a characteristic maximum near 540–550 nm that is used for quantification. The UV–Vis calibration curve in Panel C confirms excellent assay linearity over the tested range ($R^2 \approx 0.99$). Panel D demonstrates that the calibration obtained using Mobilab-Uni closely matches the benchtop spectrophotometer, indicating preserved linearity and confirming that the device can reliably quantify triglycerides at the point of care.

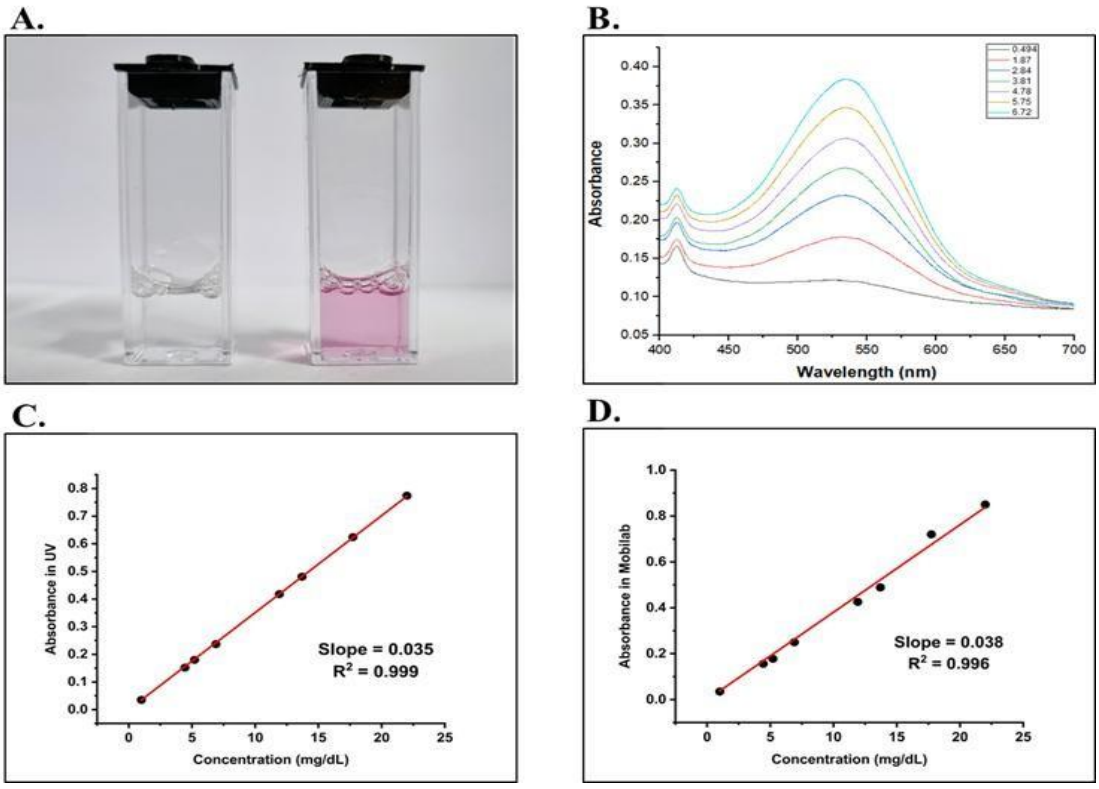

Figure 14. Total bilirubin assay characterization using the modified Jendrassik–Grof method on UV–Vis and Mobilab-Uni platforms. (A) Cuvette used in Mobilab-Uni showing the total bilirubin reaction before (blank, left) and after color development (right), with formation of the characteristic pink azo-bilirubin complex. (B) UV–Vis absorption spectra of bilirubin standards (mg/dL), demonstrating a diazo chromophore peak in the 550–560 nm region that increases with bilirubin concentration. (C) Calibration curve obtained on a benchtop UV–Vis spectrophotometer, showing a linear relationship between absorbance and total bilirubin (slope = 0.035; R^2 = 0.999). (D) Calibration curve generated using the Mobilab-Uni optical system, confirming excellent linearity and close agreement with reference measurements (slope = 0.038; R^2 = 0.996).

Figure 14 presents the development and validation of the total bilirubin assay based on the modified Jendrassik–Grof method and its implementation on the Mobilab platform. Panel A illustrates the visible change from a blank reaction to the pink azo-bilirubin complex within the used cuvette, corresponding to the diazo coupling of bilirubin. Panel B shows the UV–Vis spectra of bilirubin standards, with a well-defined absorption maximum around 550–560 nm that increases proportionally with concentration. The benchtop UV–Vis calibration in Panel C demonstrates excellent linearity (R^2 = 0.999), confirming the robustness of the underlying chemistry. Panel D shows that the Mobilab-Uni derived calibration closely matches the reference slope and correlation, indicating that the portable optical system can accurately quantify total bilirubin and is suitable for point-of-care liver function assessment.

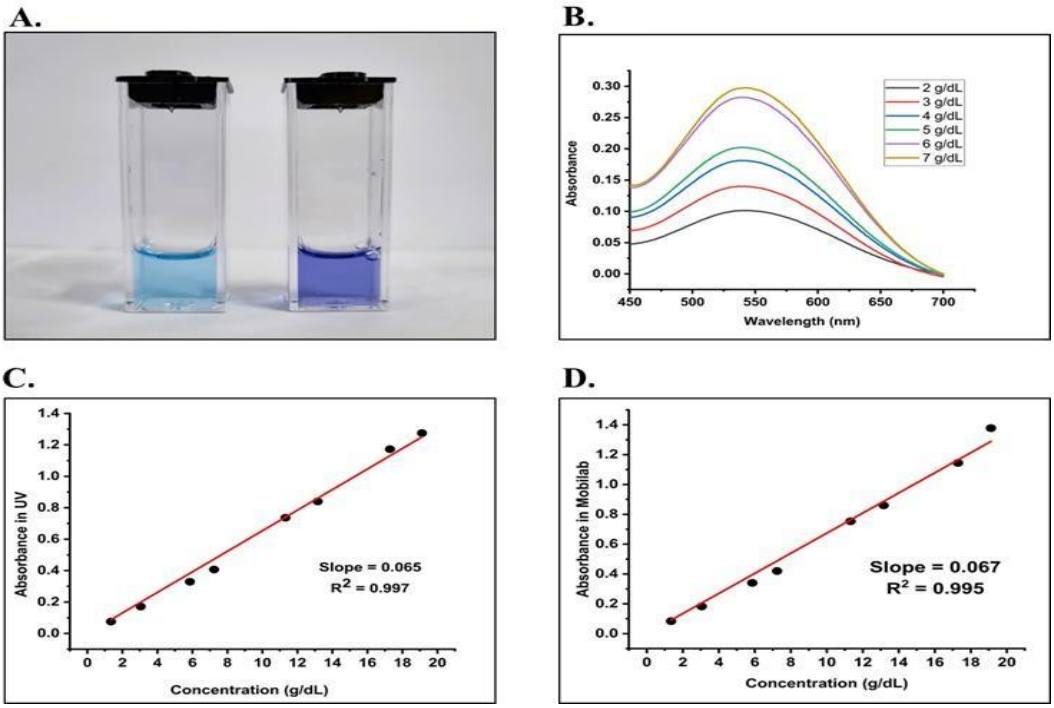

Figure 15. Total protein assay characterization using the Biuret method on UV–Vis and Mobilab-Uni platforms. (A) Cuvette used in Mobilab-Uni showing the Biuret reagent before reaction (left, blue) and after color development in the presence of protein (right), forming a bluish-violet complex. (B) UV–Vis absorption spectra of protein standards (g/dL), demonstrating formation of the Cu^{2+}–peptide coordination complex with a broad peak around 540–560 nm that increases with protein concentration. (C) Calibration curve obtained using a benchtop UV–Vis spectrophotometer, showing strong linear correlation between absorbance and total protein (slope = 0.065; R^2 = 0.997). (D) Calibration curve acquired using the Mobilab-Uni optical detection system, confirming excellent agreement with UV–Vis measurements (slope = 0.067; R^2 = 0.995).

Figure 15 describes the development and validation of the total protein assay based on the Biuret reaction and its implementation on the Mobilab-Uni platform. In Panel A, the transition from blue Biuret reagent to a bluish-violet product within the cartridge reflects formation of the copper–peptide chelate in the presence of protein. Panel B shows the UV–Vis spectra of protein standards, with a broad absorbance band centered near 540–560 nm that increases proportionally with protein concentration, confirming the expected spectral signature of the Biuret complex. The benchtop UV–Vis calibration in Panel C demonstrates highly linear response across the tested range, indicating robust assay performance under standard laboratory conditions. Panel D shows a closely matching calibration obtained with Mobilab-Uni, with comparable slope and R^2 values, thereby validating the platform's analytical capability for accurate total protein quantification at the point of care.

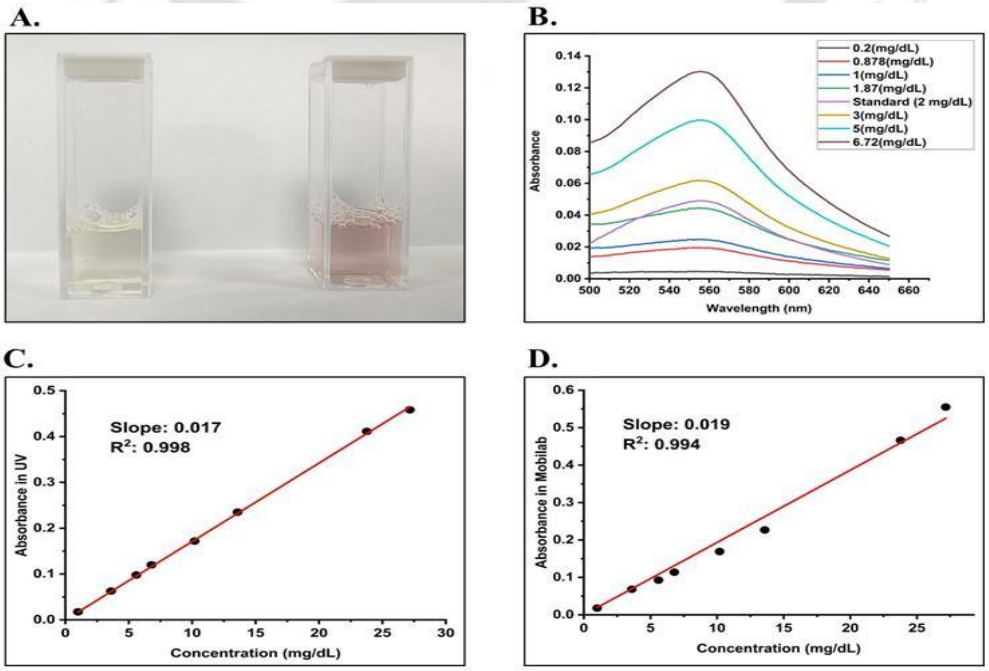

Figure 16. Creatinine assay characterization using the enzymatic method on UV–Vis and Mobilab-Uni platforms. (A) Cuvettes used in Mobilab-Uni, showing the creatinine reagent before reaction (left) and after completion of the enzymatic cascade (right), with formation of the pink quinoneimine dye. (B) UV–Vis absorbance spectra of creatinine standards after the enzymatic reaction, demonstrating a characteristic peak around 540–560 nm that increases with creatinine concentration. (C) Calibration curve obtained on a benchtop UV–Vis spectrophotometer, showing excellent linearity between absorbance and known creatinine concentrations (slope = 0.017; R^2 = 0.998). (D) Calibration curve generated using the Mobilab-Uni optical detection system, confirming strong correlation with UV–Vis measurements (slope = 0.019; R^2 = 0.994).

Figure 16 summarizes the development and validation of the enzymatic creatinine assay and its translation from a conventional UV–Vis platform to the Mobilab-Uni system. In Panel A, the visual transition from colorless reagent to a pink quinoneimine dye within the cartridge reflects completion of the multi-enzyme Trinder-based reaction, proportional to creatinine concentration. Panel B presents the UV–Vis spectra of creatinine standards, showing a welldefined absorption band near 540–560 nm that increases in intensity with rising analyte levels. The calibration curve obtained on a benchtop spectrophotometer (Panel C) demonstrates excellent linearity across the tested range, confirming robust assay performance under laboratory conditions. Panel D shows that Mobilab-Uni produces a closely matching calibration with comparable slope and correlation, validating its analytical performance for accurate creatinine quantification at the point of care.

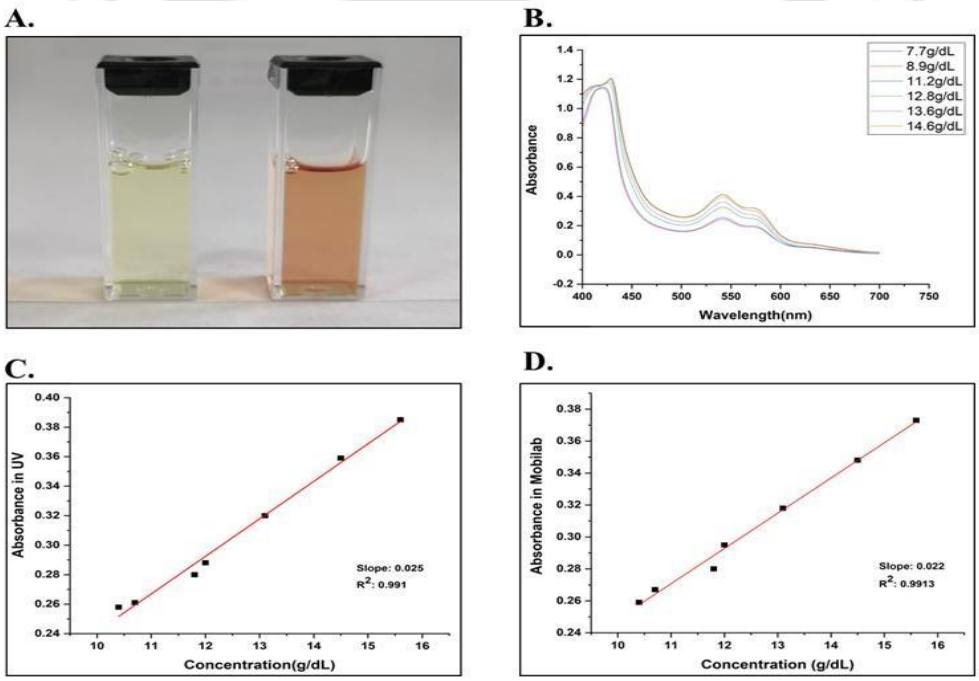

Figure 17. Hemoglobin assay validation using the cyanmethemoglobin method on UV–Vis and Mobilab platforms. (A) Cuvettes containing blood-derived samples before and after reaction, showing conversion of hemoglobin derivatives into a stable reddish-brown cyanmethemoglobin complex. (B) UV–Vis absorption spectra of hemoglobin standards (7.7–14.6 g/dL), with a characteristic peak in the 500–550 nm region corresponding to cyanmethemoglobin. (C) Calibration plot generated using a benchtop UV–Vis spectrophotometer, demonstrating a linear relationship between absorbance and hemoglobin concentration (slope = 0.025; R^2 = 0.991). (D) Calibration plot obtained using the MobilabUni device, showing similarly strong linearity (slope = 0.022; R^2 = 0.9913), confirming accurate hemoglobin estimation.

Figure 17 presents the characterization of the hemoglobin assay based on the cyanmethemoglobin method and its implementation on the Mobilab-Uni platform. Panel A visually depicts the transition from pre-reaction sample to the reddish-brown cyanmethemoglobin complex, which is stable and suitable for photometric measurement. Panel B shows the UV–Vis spectra of hemoglobin standards, with a distinct absorbance band in the 500–550 nm region that increases proportionally with hemoglobin concentration. The benchtop UV–Vis calibration in Panel C confirms good linearity across the tested range, while Panel D demonstrates that Mobilab-Uni produces a closely matching calibration curve, with comparable slope and R^2 values, indicating that the portable system can reliably quantify hemoglobin in a manner consistent with standard laboratory analyzers.

Following successful validation across multiple clinical settings, Mobilab-Uni was operated by healthcare workers with minimal technical training. Structured feedback on ease of use, workflow clarity, and result interpretation indicated that the device could be used confidently after a brief orientation, supporting its suitability for deployment in primary health centres, community clinics, and rural health camps. Through this systematic pathway—encompassing assay adaptation, sensor and optics optimization, software development, hardware fabrication, and rigorous analytical and clinical validation, the Mobilab-Uni device was established as a reliable, portable, and affordable multi-analyte diagnostic platform for point-of-care use.

2.6 Materials & Methods with Clinical samples

2.6.1. Materials

All the reagent kits for all parameters were purchased from Agappe (India). A GLU reagent kit (GOD-PAP method) [123] with REF no: 51406001. A TBIL reagent kit (Modified

DMSO/Diazo method) [124] with REF no: 51003003. A TP reagent kit (Direct Biuret method) [125] with REF no: 51013002. HB reagent kit (Cyanmethemoglobin method) [126] with REF no: 51011001. A TGL reagent kit (GPO-PAP method) [127] with Ref no.: 51410002. A CRE reagent kit (Enzymatic method) [128] with Ref no.: 51420003. 4 mL polystyrene cuvettes were purchased from Axibio (France), a device Mobilab-Uni, Mobimix a mixer device an Android smartphone (Redmi 9A, Xiaomi), and a micro-USB OTG cable. 0.9% NaCl, Liquid Assayed Multiqual control serum Level 1 (LOT NO. 45931) and Level 3 (LOT NO. 45933) were purchased from Bio-Rad (California, United States) to assess the analytical sensitivity, linearity, and precision for all the test parameters on the Mobilab-Uni device. The UV-Vis Spectrophotometer LABMAN LCD LMSP-UV1900 (India) was selected as the reference for determining linearity in Mobilab-Uni.

2.6.2 Methods

Mobilab-Uni has dimensions of 93.26 mm in length, 56.99 mm in width, 98.07 mm in height, and weighs 312 g, as shown in Figure 18(i). The portable mixer has a dimension of 94.42 mm in length and 108.71mm in height [Figure 18(ii)].

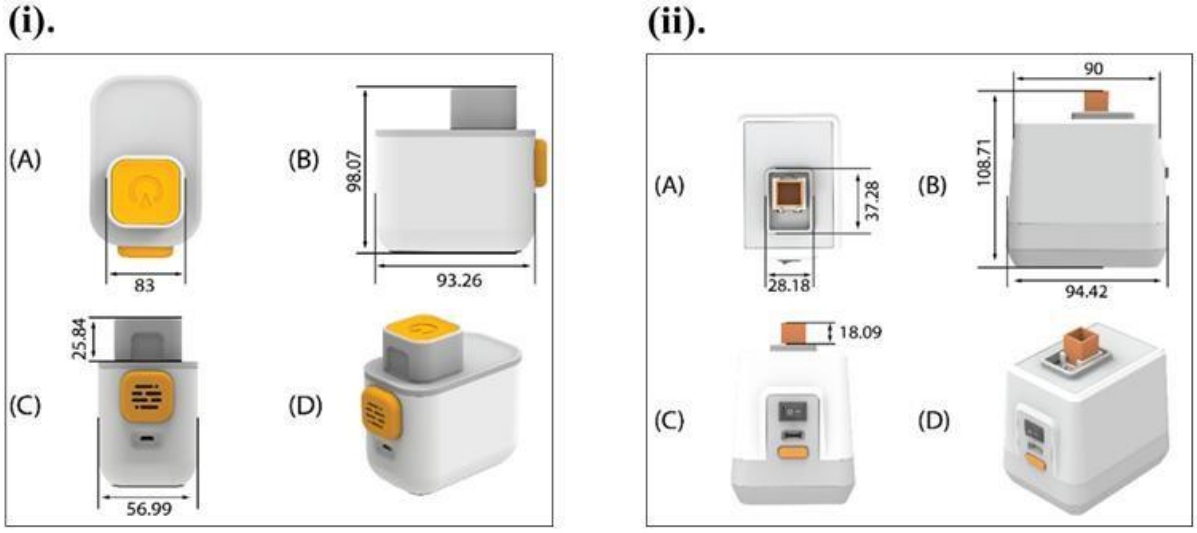

Figure 18. Mobilab-Uni analyzer and Mobimix mixer: orthographic views and key dimensions. (i) Mobilab-Uni device: (A) Top view showing the device cap with a breadth of 83 mm. (B) Side view indicating a length of 93.26 mm and a height of 98.07 mm. (C) Front view displaying the ambient sensor and data port. (D) Isometric view highlighting the cap, sensor, and data port arrangement. (ii) Mobimix mixer: (A) Top view of the cuvette holder, measuring 37.28 mm in length and 28.18 mm in breadth. (B) Side view showing a length of 94.42 mm and a height of 108.71 mm. (C) Front view featuring the On/Off switch, mode selector, and charging port. (D) Isometric view illustrating the On/Off switch, cuvette holder with inserted cuvette, mode switch, and charging port.

Figure 18 presents the design and compact footprint of the Mobilab-Uni analyzer and its companion Mobimix mixer. The orthographic and isometric views of Mobilab-Uni (panels iA–iD) emphasize its small form factor, front-facing ambient sensor, and data port placement, enabling easy positioning near the patient and seamless connectivity with external devices. The Mobimix mixer (iiA–iiD) is engineered around a dedicated cuvette holder and simple user interface with discrete power and mode switches, allowing rapid and reproducible reagent–sample mixing. Together, these devices form an integrated, ergonomically optimized system for point-of-care biochemical testing in constrained clinical and field environments.

The quantitative measurement using Mobilab is conducted according to the following steps: a. A precise volume of reagent is pipetted into a test cuvette and inserted into the device, for the initial base reading. b. The sample is added to the cuvette and subjected to uniform mixing in a uniform mixing device, Mobimix, [Figure 18(ii)]. c. The sample containing the cuvette is then reinserted into the Mobilab device. It measures the absorbance of the products formed at the end of every reaction, or during, applying the Beer-Lambert law d. The final result is calculated, and a digital test report is generated in the Android application. This process of quantitative measurement by Mobilab-Uni is illustrated in the schematic diagram, Figure 19.

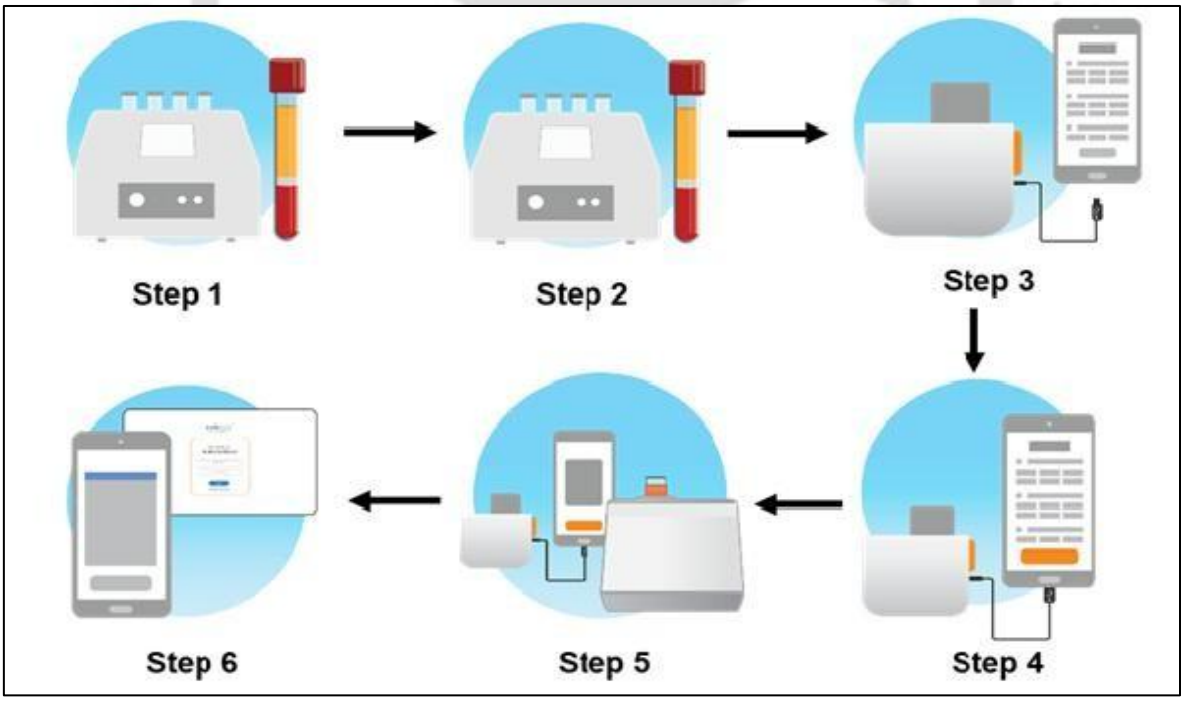

Figure 19. Workflow of the Mobilab-Uni point-of-care testing process.Illustrative flow diagram showing six sequential steps: Step 1 – venous blood collection; Step 2 – serum separation by centrifugation; Step 3 – connecting the Mobilab-Uni device to a smartphone via

OTG cable; Step 4 – initiating the test by selecting "Start Test," entering patient details, and choosing required assays; Step 5 – following in-app instructions to mix serum with the corresponding reagent using the Mobimix mixer; Step 6 – automatic generation of a digital test report immediately after analysis.

The Figure 19 summarizes the end-to-end operational workflow of Mobilab-Uni in a typical clinical setting. After sample collection and serum preparation, the handheld analyzer is paired with a phone, and the test is configured through the Mobilab app. Guided, on-screen instructions standardize reagent handling and mixing, reducing operator variability. Once the cuvette is read by the device, results are processed and displayed as a digital report, which can be stored or shared electronically to support rapid clinical decision-making at the point of care

2.6.3 Sample collection

Samples were obtained from GNRC Hospital, North Guwahati, following the approval of study protocols from the hospital authority. Serum samples retained after patient testing were examined for biochemistry parameters using the SDA 200 clinical chemistry analyzer, and whole blood samples were assessed for hemoglobin content using the BC DxH 900 Hematology Analyzer. Collection and transportation of samples to our laboratory adhered to the clinical guidelines and regulations set forth by the ethical committee of the institute. Patient confidentiality was strictly maintained throughout the study. Samples were stored at 4°C, subjected to no more than two freeze/thaw cycles before assessment. Reference ranges for GLU, TGL, TBIL, TP, CRE, and HB were considered as outlined in Table 5.

Table 5. Methods of detection and reference ranges for different parameters used at GNRC Hospital, Guwahati and Mobilab-Uni.

Parameters	Analytical Method (GNRC)	Analytical Method (Mobilab-Uni)	Reference range (Adult)
Glucose (GLU)	Hexokinase method	GOD-PAP method	0-100 mg/dL
Triglyceride (TG)	GPO-POD method	GPO-POD method	30 - 150 mg/dL
Total Bilirubin (TBIL)	Jendrassik-Grof method	Modified DMSO/Diazo method	0.2 – 1.0 mg/dL
Total Protein (TP)	Biuret method	Direct Biuret method	6.4 - 8.2 g/dL

Creatinine (CRE)	Alkaline picrate method	Enzymatic method	0.55 – 1.30 mg/dL
Hemoglobin (HB)	Spectrophotometric method	Cyanmethemoglobin method	12 - 18 g/dL

[a)]GOD-PAP= Glucose Oxidase (GOD); Phenol 4-aminoantipryrine (PAP); [b)]DMSO= Dimethyl Sulfoxide; [c)]mg/dL=milli gram per deciliter; [d)]g/dL=gram per deciliter

2.6.4 Performance comparison

The study compared Mobilab's method, analytical sensitivity, linearity, repeatability, and performance with SDA 200, an automated chemical analyzer and BCDxH 900, a hematology analyzer, which were used at GNRC Hospital. This evaluation covered GLU, TG, TBIL, TP, CRE and HB parameters, confirming Mobilab's suitability for producing reliable point-ofcare results. The methods employed for this performance comparison are briefly outlined below:

2.6.4.1 Method comparison

This evaluation was done with respect to the analytical method used in the GNRC hospital with the SDA 200 clinical chemistry analyzer and BC DxH 900 hematology analyzer. The study involved statistical analysis such as: Passing & Bablok Regression analysis, BlandAltman plot, and t-Test to determine the degree of agreement between the analytical methods used in the auto analyzers and Mobilab. Below is the list of analytical methods used to compare both the analyzers for each of the 6 tests.

Passing & Bablok Regression: Passing and Bablok regression analysis is a statistical technique enabling the estimation of agreement between analytical methods and potential systematic biases between them. This method is non-parametric and robust against errors' distribution and outliers in the data. Proper application of Passing and Bablok regression requires data with continuous distribution and linear relationships between measurements obtained from two analytical methods. The findings are shown as an equation, regression line, and scatter plot, in which the slope denotes proportionate measurement error, and the intercept denotes a constant. The 95% Confidence Intervals (CI) for both intercept and slope evaluate if their values significantly deviate from 0 and 1, respectively [48].

Bland-Altman Plot: A Bland-Altman plot is an effective method to visually represent the relationship between two paired variables measured on the same scale. Unlike formal hypothesis testing, it examines the phenomenon without conducting statistical tests, thereby not providing the same level of error in decision-making about the variables [49]. The plot is constructed by plotting the differences between paired data from two variables (AutoAnalyzer

of GNRC Hospital and Mobilab Device) against the average of these readings. The mean difference line is accompanied by ± 2SD lines, representing the Confidence Interval (CI). This plot aids in identifying outliers, evaluating agreement, and detecting any systematic bias in the data.

Paired t-test: Another statistical method involves determining the p-value. A significance threshold of 0.05 is established to identify significant disparities between the devices. If the p-value is greater than 0.05, the null hypothesis is accepted, suggesting no substantial distinction between the actual and reference devices. Conversely, if the p-value is less than 0.05, the alternate hypothesis is accepted, indicating a significant difference between the devices [50].

2.6.4.2 Method Validation

Linearity Test: Linearity plays a pivotal role in ensuring the credibility of any analytical process. In this investigation, Mobilab underwent examination across a broad spectrum of concentrations to evaluate its capacity for accurately detecting diverse concentration levels of the specified parameters. The concentration range for each test parameter on Mobilab (y-axis) was subsequently juxtaposed against that on the UV-spectrophotometer (x-axis). This assessment highlights Mobilab's capability and consistency in maintaining linearity across a range of concentrations.

Analytical Sensitivity: This clinical aspect highlights how well an analytical technique can accurately and dependably identify lower levels of test substances. The current research clarifies the concepts of Limit of Blank (LOB) and Limit of Detection (LOD) for these substances, which define the method's sensitivity. LOB refers to the concentration detected by the device even when there is no substance present. It is established by repeatedly measuring samples without the substance to establish a baseline. Conversely, LOD indicates the lowest concentration of the substance that can be consistently and accurately detected through multiple repetitions. Determining the LOB and LOD provides insights into Mobilab's precision and reliability in detecting test substances and the parameters being investigated.

Precision test: The intra-day precision assessment of all five test parameters has been consistently conducted using Liquid Assayed Multiqual control serum from Bio-Rad: Level 1 (L1) and Level 3 (L3) for 20 consecutive runs. Mobilab's intra-day precision is evaluated under identical conditions for all test parameters to examine the consistency of the study by calculating the coefficient of variation (CV%). A lower coefficient of variation (CV%) indicates that Mobilab results exhibit higher precision in the precision study for these test

parameters. Therefore, conducting an intra-day precision study helps to better understand the accuracy of Mobilab's test results when repeatedly analyzing the same substance at identical concentrations.

Performance Metrics: Performance metrics were calculated to gauge the accuracy of the proposed device, encompassing sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and Diagnostic Accuracy (DA). As shown in Table 6, the calculation was done with the following test results: True Positive (TP), True Negative (TN), False Negative (FN), and False Positive (FP). The specificity was calculated to identify how often Mobilab correctly detect the absence of a condition. PPV assessed the frequency with which Mobilab accurately identified true positive results among all positive outcomes. NPV analysis quantified the ratio of true negative results detected by Mobilab among all negative occurrences. DA is computed to ascertain the total count of true positives and true negatives identified among all test outcomes.

Table 6. The tabular illustration of the performance matrices and their respective formulas to calculate diagnostic accuracy for the Mobilab device.

		Siemens Dimension EXL 200		
		Positive	**Negative**	
Mobilab	**Positive**	True Positive (TP)	False Positive (FP)	Positive Predictive Value (PPV) $\frac{TP}{(TP+FP)} \times 100$
	Negative	False Negative (FN)	True Negative (TN)	Negative Predictive Value (NPV) $\frac{TN}{(FN+TN)} \times 100$
		Sensitivity $\frac{TP}{TP+FN} \times 100$	Specificity $\frac{TN}{TN+FP} \times 100$	Diagnostic Accuracy (DA) $\frac{TP+TN}{TP+FN+FP+TN} \times 100$

2.7. Results & Discussion

In this study, we investigated the clinical performance of the portable clinical chemistry analyzer, Mobilab with the goal of assessing its practicality and diagnostic accuracy. The

study involved testing 50-52 samples for each parameter individually, employing meticulously designed experimental setups. All calibration curves presented in this study were generated using replicate measurements across multiple analyte concentration levels. For each calibration point, three independent measurements were performed, and the average absorbance value was used for regression analysis. The variability among replicate measurements was calculated and represented as standard deviation, which is shown as error bars in the calibration plots where applicable. This approach ensured the reproducibility and reliability of the analytical measurements obtained using the Mobilab system.

2.7.1 Method Comparison

Method comparison studies performed using Passing–Bablok regression and Bland–Altman analysis demonstrated strong agreement between the Mobilab measurements and reference laboratory analyzers. Within the analyzed sample set, no consistent systematic over-prediction or under-prediction trends were observed for the evaluated biochemical parameters. Minor variations observed between the two measurement systems were within acceptable analytical limits and are expected when comparing independent analytical platforms. These results indicate that Mobilab provides reliable quantitative estimates suitable for clinical screening and monitoring purposes.

2.7.1.1 Passing & Bablok Regression

As shown in Table 7 and Figure 20, the regression analysis for all six biochemical parameters: GLU, TG, TBIL, TP, CRE, and HB, demonstrates that the calculated slope and intercept values for the device fall entirely within their respective 95% Lower Confidence Limits (LCL) and 95% Upper Confidence Limits (UCL). This indicates a strong linear agreement between the test device and the reference method across the full clinically relevant concentration range. The absence of significant proportional or constant bias provides robust statistical evidence supporting the acceptance of the null hypothesis, confirming equivalence between the two methods.

Figure 20 summarizes the method-comparison analysis between Mobilab-Uni and standard laboratory analyzers using Passing–Bablok regression for glucose (GLU), triglycerides (TGL), total bilirubin (TBIL), total protein (TP), creatinine (CRE), and hemoglobin (HB). Across all parameters, slopes are close to 1.0 and intercepts are near zero, indicating minimal proportional and constant bias. Very high coefficients of determination ($R^2 \approx 0.99$ for GLU, TGL, TBIL; 0.95 for HB; and >0.88 for TP and CRE) demonstrate strong agreement between Mobilab and reference systems over the measured clinical ranges. These

results confirm that Mobilab-Uni provides laboratory-comparable quantitative performance suitable for routine use in decentralized and point-of-care settings.

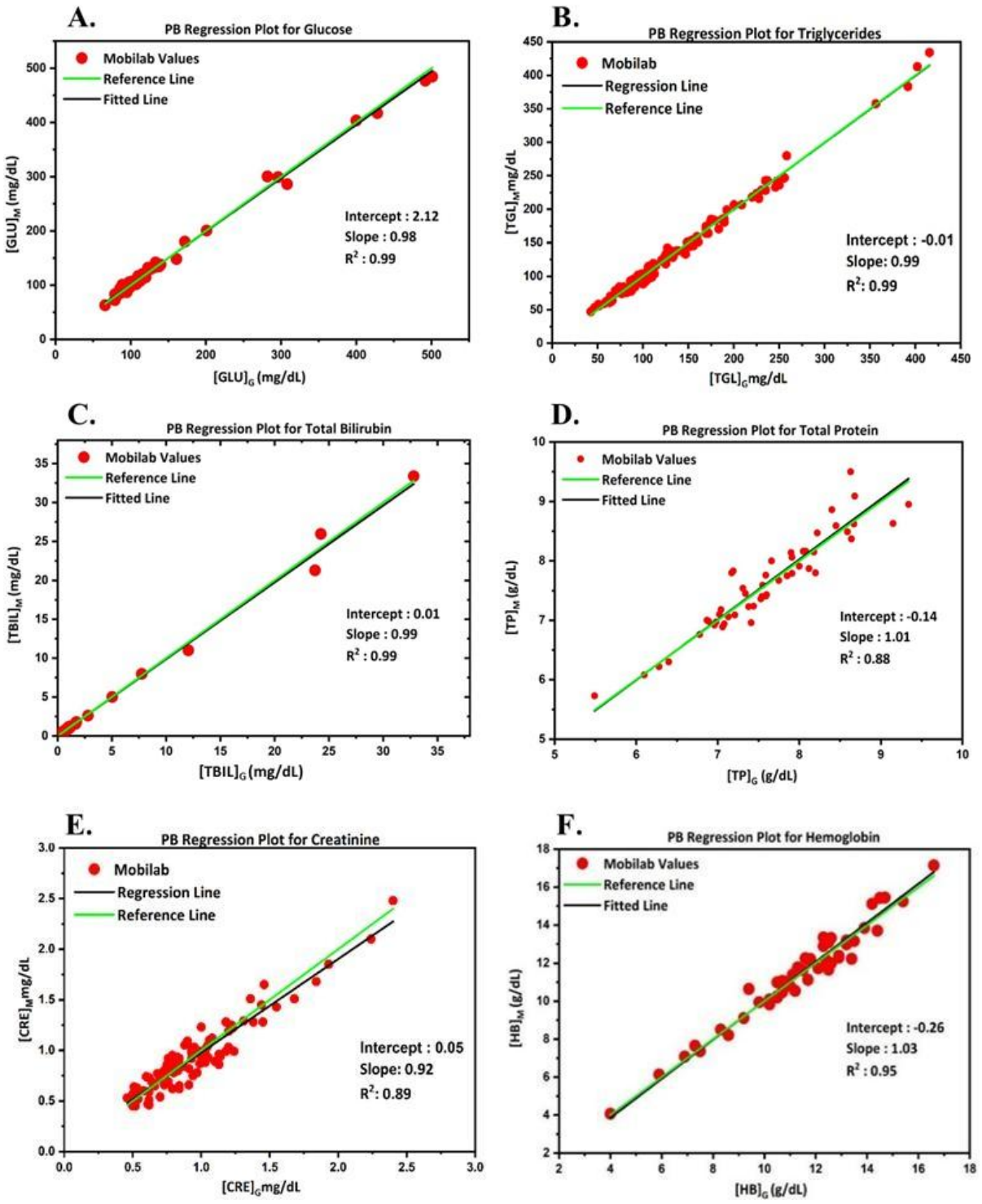

Figure 20. Passing–Bablok regression analysis comparing Mobilab-Uni with reference analyzers for six biochemical parameters. (A) GLU: Patient serum glucose values from the reference analyzer $[GLU]^G$ (mg/dL, x-axis) versus Mobilab $[GLU]^M$ (mg/dL, y-axis); intercept = 2.12, slope = 0.98, R^2 = 0.99. (B) TGL: Triglycerides in blood $[TGL]^G$ (mg/dL)

vs $[TGL]^M$ (mg/dL); intercept = 1.56, slope = 0.98, R^2 = 0.99. (C) TBIL: Total bilirubin in serum $[TBIL]^G$ (mg/dL) vs $[TBIL]^M$ (mg/dL); intercept = 0.01, slope = 0.99, R^2 = 0.99. (D) TP: Total protein in serum $[TP]^G$ (g/dL) vs $[TP]^M$ (g/dL); intercept = –0.14, slope = 1.01, R^2 = 0.88. (E) CRE: Creatinine in blood $[CRE]^G$ (mg/dL) vs $[CRE]^M$ (mg/dL); intercept = 0.01, slope = 0.97, R^2 = 0.89. (F) HB: Hemoglobin in blood $[HB]^G$ (g/dL) vs $[HB]^M$ (g/dL); intercept = –0.26, slope = 1.03, R^2 = 0.95. In all panels, the green line represents the line of identity (y = x), the black line shows the Passing–Bablok regression fit, and red dots denote individual Mobilab measurements.

2.7.1.2 Bland-Altman Plot

Based on the results presented in Table 7 and Figure 21, the minimal bias observed indicates a high level of agreement between measurements obtained using the Mobilab system and the comparative reference method used at GNRC Hospital. The mean bias values were 0.15 mg/dL for GLU, −0.05 g/dL for HB, 0.03 mg/dL for TBIL, 0.02 g/dL for TP, −0.22 mg/dL for TGL, and −0.02 mg/dL for CRE, reflecting negligible systematic deviation between the two methods. The majority of data points lay within the 95% limits of agreement (±2 SD), with only a few outliers observed, 4 for GLU, 2 for HB, 3 each for TBIL, TP, and TGL, and 4 for CRE, which are most likely attributable to random analytical variability rather than systematic error. The Bland–Altman analysis further substantiated the overall agreement between the two methods, confirming the clinical reliability of the Mobilab system for routine biochemical testing. These findings indicate that the observed differences are clinically insignificant and fall well within acceptable analytical error limits recommended for routine biochemical testing.

Figure 21 summarizes the inter-method agreement between Mobilab and standard laboratory analyzers using Bland–Altman plots for glucose (GLU), triglycerides (TGL), total bilirubin (TBIL), total protein (TP), creatinine (CRE), and hemoglobin (HB). For each parameter, the mean difference between methods is close to zero and the 95% limits of agreement are narrow relative to the clinical decision ranges, indicating that systematic bias is minimal. The majority of data points fall within the ±2 SD limits, with only a few isolated outliers attributed to random analytical error rather than consistent method disagreement. Collectively, these results demonstrate that Mobilab measurements are clinically interchangeable with those of the reference analyzers for the evaluated parameters.

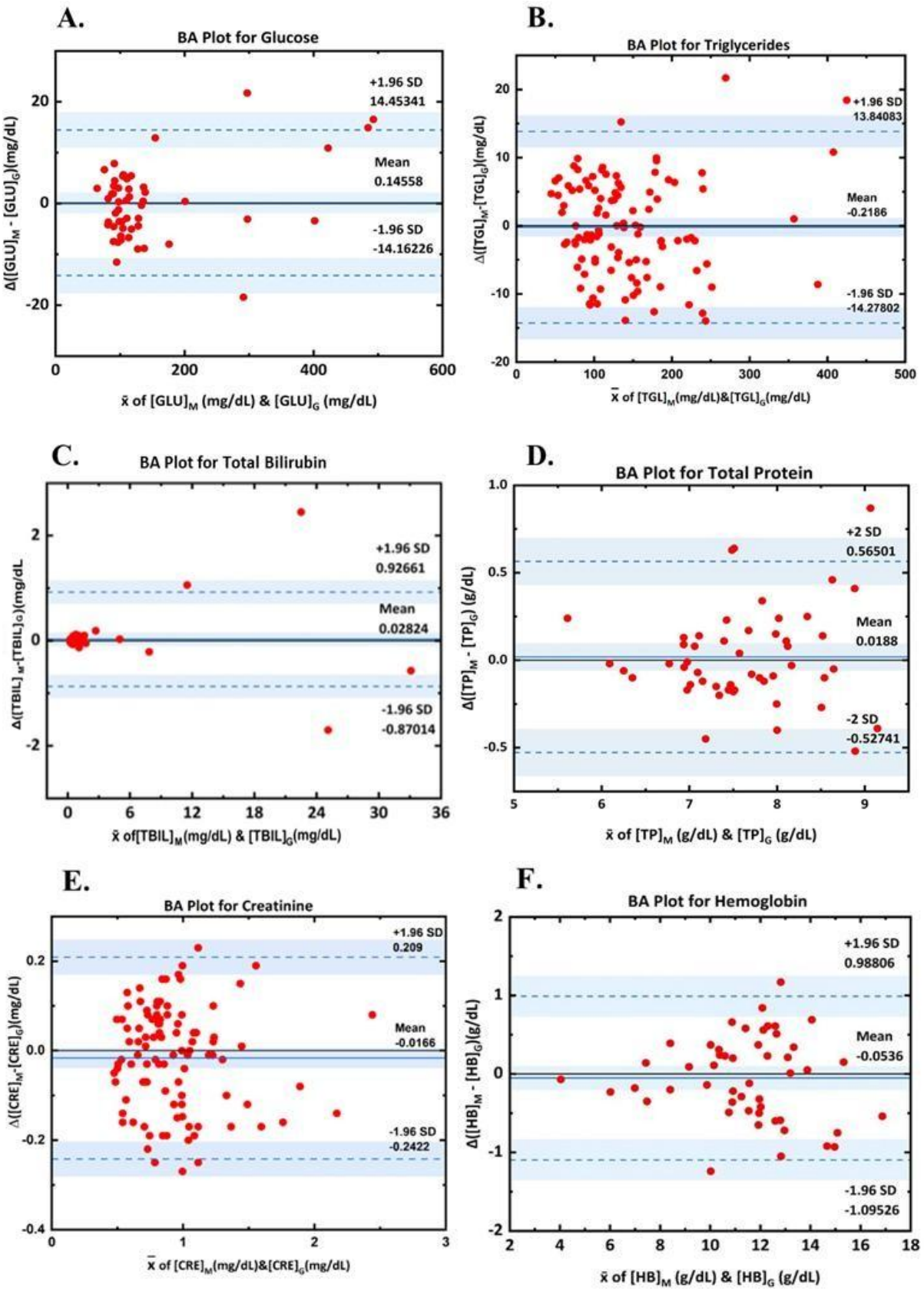

Figure 21. Bland–Altman analysis of agreement between Mobilab and reference analyzers for six parameters. Bland–Altman plots showing the difference between Mobilab measurements and reference analyzer values (y-axis) versus their mean (x-axis) for: (A) GLU, $\Delta([GLU]^M–[GLU]^G)$, mean bias = 0.146 mg/dL, upper LoA = 14.45 mg/dL, lower LoA = –

14.16 mg/dL; (B) TGL, bias = –0.219 mg/dL, upper LoA = 13.84 mg/dL, lower LoA = –14.28 mg/dL; (C) TBIL, bias = 0.028 mg/dL, upper LoA = 0.93 mg/dL, lower LoA = –0.87 mg/dL; (D) TP, bias = 0.019 g/dL, upper LoA = 0.57 g/dL, lower LoA = –0.53 g/dL; (E) CRE, bias = –0.715 mg/dL, upper LoA = 12.45 mg/dL, lower LoA = –13.88 mg/dL; (F) HB, bias = – 0.054 g/dL, upper LoA = 0.99 g/dL, lower LoA = –1.09 g/dL. In all panels, the central solid line represents mean bias and the dotted blue lines denote 95% limits of agreement (±2 SD); a small number of outliers lie outside these limits, attributable to random analytical variation.

2.7.1.3 Paired t-test

The Table 7 presents the results of a comprehensive method comparison study between Mobilab and reference analyzers using Passing–Bablok regression, Bland–Altman analysis, and paired t-tests. For glucose, triglycerides, total bilirubin, total protein, and creatinine, comparison was performed against the SDA 200 analyzer, while hemoglobin was compared against the BC DxH 900 system. The regression parameters (slope, intercept, and R^2) demonstrate strong linear agreement for all analytes. Bland–Altman bias values are minimal, with narrow limits of agreement (LOA), indicating negligible systematic differences between methods. The paired t-test p-values (>0.05 for all parameters) confirm the absence of statistically significant differences between Mobilab and the reference instruments, validating the clinical equivalence and analytical reliability of the Mobilab system.

The findings indicate that the mean values obtained using the GNRC Hospital reference method and Mobilab are statistically comparable, demonstrating strong agreement between the two measurement systems. This is corroborated by the Pearson correlation analysis, where the values for GLU (0.99), TGL (0.99), TBIL (0.99), TP (0.88), CRE (0.89) and HB (0.95) are close to 1. This suggests a strong relationship between the results obtained from Mobilab and those from SDA 200 analyzer used at GNRC hospital. The paired t-test for the Mobilab device yielded a p-value greater than the chosen significance level of 0.05 for all tested parameters (0.89 for GLU, 0.98 for TGL, 0.66 for TBIL, 0.63 for TP, 0.74 for CRE, and 0.48 for HB). This lends substantial weight to the null hypothesis, according to which the test findings obtained from Mobilab and the SDA 200 analyzer used in GNRC hospital are comparable.

Table 7. Summary of method comparison analysis and paired t-test for biochemical parameters assessed between Mobilab and SDA 200 for GLU, TG, TBIL, TP, and CRE, and between Mobilab- Uni and BC DxH 900 for hemoglobin.

Method Comparison	**Passing Bablok Plot**			**Bland-Altman plot**		**t-test**
	Slope	**Intercept**	**R^2**	**Bias**	**LOA**	**p-value**
Glucose	0.98	2.12	0.99	0.146 (mg/dL)	-14.16 to 14.45 (mg/dL)	0.89
Triglyceride	0.98	1.56	0.99	-0.22 mg/dL	-14.28 to 13.84 mg/dL	0.98
Total Bilirubin	0.99	0.01	0.99	0.028 (mg/dL)	-0.87 to 0.93 (mg/dL)	0.66
Total Protein	1.01	-0.14	0.88	0.019 (g/dL)	-0.53 to 0.57 (g/dL)	0.63
Creatinine	0.97	0.01	0.89	-0.02 mg/dL	-0.24 to 0.21 mg/dL	0.74
Hemoglobin	1.03	-0.26	0.95	-0.053 (g/dL)	-1.09 to 0.99 (g/dL)	0.48

[a)] R^2=Coefficient of determination; [b)] LOA=Limit of assay

2.8 Method Validation

2.8.1 Linearity Test

Method-comparison linearity plots for glucose, triglycerides, total bilirubin, total protein, creatinine, and hemoglobin across their respective concentration ranges are shown n Figure 22. In each panel, Mobilab-Uni readings are plotted against reference values from a benchtop UV–Vis spectrophotometer. Slopes close to 1, small intercepts, and very high coefficients of determination ($R^2 \geq 0.99$ for most parameters) confirm excellent linear response and strong agreement between the two systems. These findings demonstrate that Mobilab-Uni accurately tracks changes in analyte concentration over the full analytical range, supporting its use for quantitative point-of-care testing.

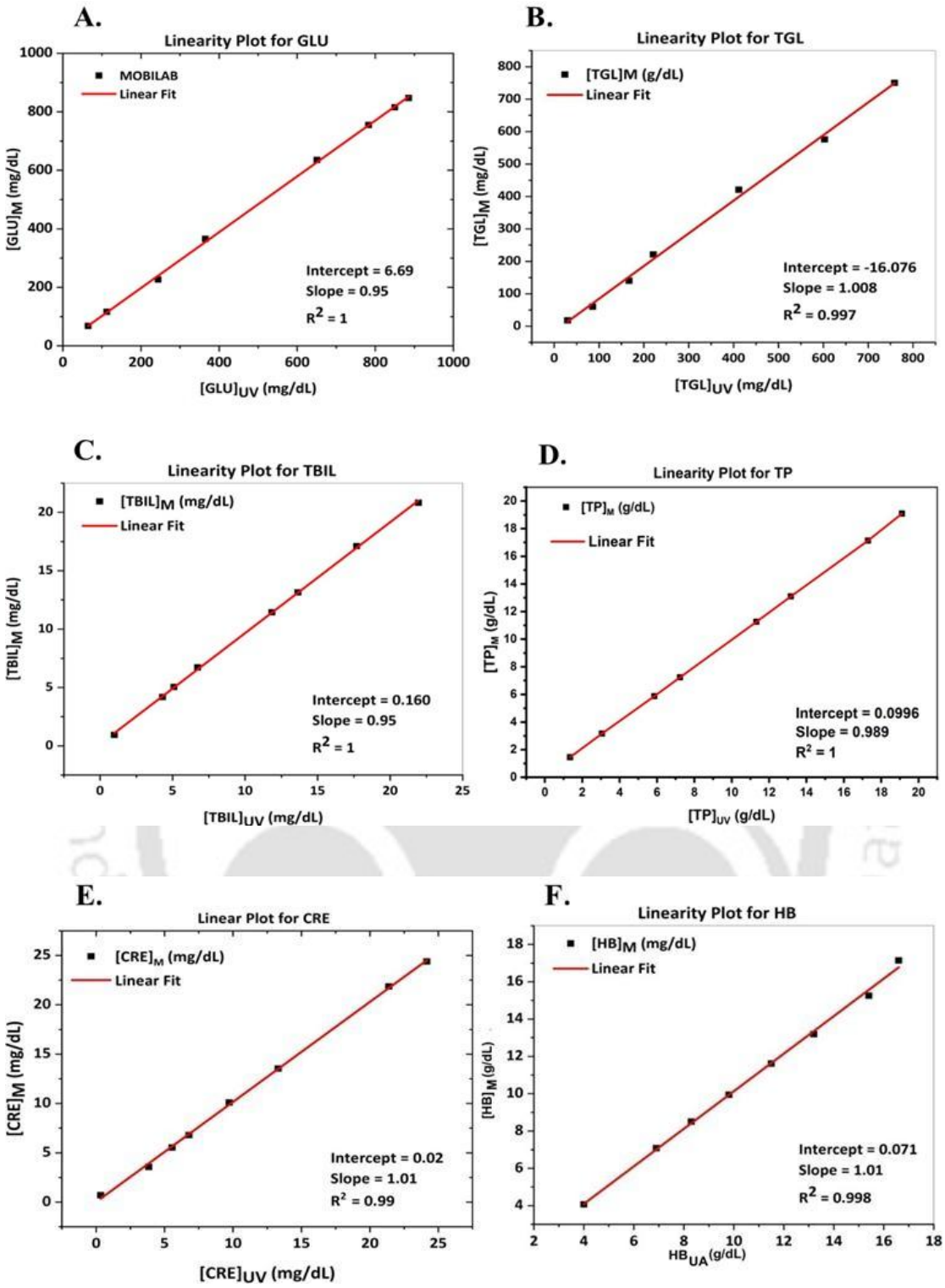

Figure 22. Linearity plots comparing Mobilab-Uni with UV–Vis spectrophotometer measurements for six analytes. (A) GLU: Mobilab glucose values $[GLU]^{M}$ (mg/dL, y-axis) vs UV–Vis $[GLU]^{UV}$ (mg/dL, x-axis); slope = 0.95, intercept = 6.69, R^2 = 1.00. (B) TGL: Mobilab triglyceride values $[TGL]^{M}$ vs UV–Vis $[TGL]^{UV}$; slope = 1.01, intercept = –16.08, R^2 = 0.99. (C) TBIL: Mobilab total bilirubin $[TBIL]^{M}$ vs UV–Vis $[TBIL]^{UV}$; slope = 0.95, intercept = 0.160, R^2 = 1.00. (D) TP: Mobilab total protein $[TP]^{M}$ vs UV–Vis $[TP]^{UV}$; slope = 0.989, intercept = 0.0996, R^2 = 1.00. (E) CRE: Mobilab creatinine $[CRE]^{M}$ vs UV–Vis

$[CRE]^{UV}$; slope = 1.01, intercept = 0.02, R^2 = 0.99. (F) HB: Mobilab hemoglobin $[HB]^{M}$ vs UV–Vis $[HB]^{UV}$; slope = 1.01, intercept = 0.071, R^2 = 0.998.

Figure 22 and Table 8 presents linearity assessment comparing Mobilab-Uni measurements with those obtained using a standard UV–Vis spectrophotometer for six analytes. Panels A–F display glucose (GLU), triglycerides (TGL), total bilirubin (TBIL), total protein (TP), creatinine (CRE), and hemoglobin (HB), respectively, with Mobilab-Uni values plotted on the y-axis against corresponding UV–Vis reference values on the x-axis. Each analyte shows slopes near 1.0, minimal intercept deviations, and consistently high coefficients of determination ($R^2 \geq 0.99$), indicating strong linear correlation. These results confirm that Mobilab-Uni reliably reflects analyte concentration variations across the full measurement range, demonstrating its suitability for accurate quantitative point-of-care diagnostics.

Table 8. Summary of Linearity in the Method Validation study for all parameters compared Between Mobilab and SDA 200 for GLU, TGL, TBIL, TP, CRE, and BCDxH 900 for HB

Method Validation (Linearity Study)	Slope	Intercept	R^2 a)	Linearity
Glucose	0.95	6.69	1	upto 850.13 mg/dL b)
Triglyceride	1.01	-16.08	0.99	upto 759 mg/dL b)
Total Bilirubin	0.95	0.160	1	upto 21.95 mg/dL b)
Total Protein	0.989	0.0996	1	upto 19.12 g/dL c)
Creatinine	1.01	0.02	0.99	upto 24.16 mg/dL b)
Hemoglobin	1.01	0.071	0.998	16.6 g/dL c)

a) R^2=Coefficient of determination; b) mg/dL=milli gram per deciliter; c) g/dL=gram per deciliter

2.8.2 Analytical Sensitivity

The limit of blank (LOB) for GLU is 1.55 mg/dL, TGL is 3.79 mg/dL, TBIL is 0.06 mg/dL, TP is 0.20 g/dL, and CRE is 0.24 mg/dL, indicating that any concentration below this value for respective parameter is indistinguishable from background noise. The limit of detection (LOD) for GLU is 2.45 mg/dL, for TGL is 5.87 mg/dL, for TBIL is 0.1 mg/dL, for TP is 0.35 g/dL, and for CRE is 0.33 mg/dL. This indicates that the device can reliably detect concentrations as low as the LOD value for each respective parameter (Table 9). Analytical sensitivity for HB could not be performed due to the unavailability of control whole blood.

Table 9. Summary of Analytical Sensitivity in the Method Validation study for all parameters compared between Mobilab-Uni and SDA 200 for GLU, TGL, TBIL, TP, CRE, and BCDxH 900 for HB.

Method Validation (Analytical Sensitivity)	LOB[a)]	LOD[b)]
Glucose	1.55 mg/dL	2.45 mg/dL[c)]
Triglyceride	3.79 mg/dL	5.87 mg/dL[c)]
Total Bilirubin	0.06 mg/dL	0.1 mg/dL[c)]
Total Protein	0.20 g/dL	0.35g/ dL[d)]
Cholesterol	0.34 mg/dL	1.4 mg/dL[c)]
Creatinine	0.24 mg/dL	0.33 mg/dL[c)]

[a)] Limit of Blank; [b)] LOD=Limit of Detection; [c)] mg/dL=milli gram per deciliter; [d)] g/dL= gram per deciliter

2.8.3 Precision test

Using Level 1 and Level 3 Bio-Rad control serum over 20 repeats, the coefficient of variation (CV%) is of approximately 2.26% and 2.7%, respectively for GLU test, 2.75% and 3.3% respectively for TGL, 3.9% and 2.56% respectively for TBIL test, 2.73% and 1.31% respectively for TP, 2.66% and 2.92% respectively for CRE. Intraday precision test was done with whole blood samples (Sample 1 and Sample 2), which yielded a CV% of 2.61% and 2.73% respectively, for HB. These findings indicate a high level of precision, suggesting consistent and reliable test outcomes (Table 10).

Table 10. Summary of Intra-Day Precision in the Method Validation study for all parameters compared between Mobilab-Uni and SDA 200 for GLU, TG, TBIL, TP, CRE, and BCDxH 900 for Hemoglobin.

Method Validation (Intra Day Precision)	With Control serum (Level 1) (%)	With Control serum (Level 3) (%)
Glucose	2.26	2.7
Triglyceride	2.75	3.3
Total Bilirubin	3.9	2.56
Total Protein	2.73	1.31
Creatinine	2.66	2.92
Hemoglobin	2.61 (sample 1)	2.73 (sample 2)

2.8.4 Performance Metrices

The Mobilab-Uni analyzer demonstrates 92.31% sensitivity for GLU, 95% for TGL, 94.44% for TBIL, 70.27% for TP, 77.78% for CRE, and 97.37% for HB indicating its ability to correctly identify these parameters in true positive cases. The Specificity of the MobilabUni analyzer is 81.25% for GLU, 98.51% for TGL, 100% for TBIL, 87.30% for TP, 89.04% for CRE, and 91.67% for HB indicating its ability to correctly identify true negative cases for these parameters. PPV of 84.21% for GLU, 97.44% for TGL, 100% for TBIL, and 76.47% for TP, 72.41 for CRE, and 97.37% for HB implies that the device predicted a respective mentioned positive value for each parameter. NPV implies that the device predicts true negative values correctly by 90.70% for GLU, 97.06% for TGL, 98.80% for TBIL, and 83.33% for TP, 91.55% for CRE, and 91.67% for HB of the time. DA of 87% for GLU, 97.20% for TGL, 99% for TBIL, 81% for TP, 86% for CRE, and 96% for HB implies that out of 100 times, the device predicted 87 times for glucose, 97 times for TGL, 99 times for TBIL, 81 times for TP, 86 times for CRE, and 96 times for HB correctly (Table 11).

Table 11. Summary of Performance Matrices in the Method Validation study for all parameters compared between Mobilab-Uni and SDA 200 for GLU, TGL, TBIL, TP, CRE, and BCDxH 900 for HB.

Method Validation (Performance matrices)	Sensitivity (%)	Specificity (%)	Diagnostic accuracy (%)
Glucose	100	76.19	90.38
Triglyceride	95	98.51	97.20
Total Bilirubin	92.86	100	98.04
Total Protein	100	97.30	98
Creatinine	77.78	89.04	86
Hemoglobin	97.06	93.75	96

2.9 Summary

This chapter presents the development process followed by a comparative analysis between the Mobilab-Uni portable chemistry analyzer and a fully automated laboratory analyzer, using leftover clinical samples from GNRC Hospital. Five vital parameters, including GLU, TGL, TBIL, TP, CRE and HB, were analyzed with the chemistry analyzer SDA 200 and hematology analyzer BCDxH 900, demonstrating good agreement with Mobilab-Uni. However, some outliers were observed, which were attributed to hemolyzed

samples and manual errors. To assess the repeatability of Mobilab-Uni, 20 consecutive runs were conducted for two different concentrations of each parameter, resulting in acceptable coefficient of variation (CV%) values (<5%), indicating good precision and consistency. Furthermore, the sensitivity, specificity, PPV, NPV, and diagnostic accuracy (DA) were calculated for Mobilab-Uni, demonstrating its reliability and consistency in assessing the various parameters. The key findings indicate that Mobilab-Uni can accurately diagnose multiple parameters in both human serum and whole blood, while simultaneously providing real-time digital patient data. This capability can significantly strengthen community healthcare delivery, especially in resource-limited settings. The rapid diagnostics, portability, and ease of use of POCT devices like Mobilab-Uni enable timely decision making, especially in settings where laboratory facilities are limited. By facilitating early diagnosis and intervention, Mobilab-Uni can ultimately reduce healthcare costs by minimizing clinic visits and hospitalizations while optimizing resource utilization for better overall healthcare outcomes.

2.10 Advantages of Mobilab-Uni

The validation studies confirmed several advantages of Mobilab-Uni:

- **High accuracy:** Correlation coefficients ($R^2 > 0.9$) and >90% diagnostic accuracy demonstrates comparability with reference analyzers.
- **Low sample requirement:** Only 20-50 µL of blood, obtained from a finger-prick, is sufficient, eliminating the need for venepuncture and laboratory-based sample preparation.
- **Rapid turnaround time:** Results are available within 10-15 minutes, a significant improvement over centralized laboratory workflow.
- **Portability and robustness:** The device is lightweight, battery-operated, and suitable for field deployment, making it ideal for rural healthcare delivery.
- **Cost-effectiveness:** Reduced reagent volumes, low-cost optical sensors, and simplified electronics lower the overall per-test cost, enhancing affordability.
- **Digital integration:** IoT-enabled connectivity allows real-time transmission of results to physicians, cloud platforms, and electronic health records, facilitating telemedicine and remote monitoring.
- Collectively, these features ensure that Mobilab-Uni has strong potential to serve as a scalable diagnostic platform in primary healthcare systems.

It should be noted that the 20–50 µL sample volume refers to the amount of blood required for performing a single biochemical assay on the Mobilab-Uni platform. Each parameter is measured individually using a dedicated reagent mixture within the device's testing slot. Therefore, the stated sample volume corresponds to a single test parameter rather than the entire panel of biochemical assays. This micro-volume requirement enables the use of finger-prick blood samples and significantly reduces patient discomfort and sample handling requirements compared to conventional laboratory analyzers.

2.11 Conclusions

This comparative study was conducted to assess the performance of Mobilab-Uni analyzer by comparing its results with those of a fully automated analyzer at GNRC Hospital. Thirteen vital parameters, including GLU, TGL, TBIL, TP, CRE, and HB, were analysed with the chemistry analyzer SDA 200 and Hematology analyzer BCDxH 900, demonstrating good agreement with Mobilab-Uni analyzer.

The performance of biochemical assays in portable diagnostic systems may be influenced by environmental conditions such as temperature variations, reagent storage conditions, and long-term calibration stability. In the present study, assay validation experiments were conducted under controlled laboratory conditions using commercially available reagent formulations with established stability profiles. However, for large-scale field deployment, systematic evaluation of reagent stability under varying temperature and storage conditions will be important. Long-term studies evaluating calibration drift and environmental robustness will therefore form an important component of future work to ensure sustained analytical accuracy of the Mobilab platform during extended field use.

However, some outliers were observed, which were attributed to haemolyzed samples and manual errors. To evaluate the repeatability of Mobilab-Uni analyzer, we performed 20 runs of two concentrations of control serum for each parameter, except hemoglobin where whole blood samples were used. Results revealed an acceptable coefficient of variation (CV%<5%), indicating good precision and consistency. Furthermore, we calculated sensitivity, specificity, PPV, NPV and DA for Mobilab-Uni, revealing its reliability and consistency in diagnosing various parameters. Our findings suggest that Mobilab-Uni has the potential to accurately diagnose multiple parameters in both human serum and whole blood, providing real-time digital patient data that can significantly improve community healthcare, particularly in resource-constrained areas. The rapid diagnostics, portability and ease of use of devices like Mobilab-Uni enable timely decision making, especially in settings where laboratory facilities are limited. By facilitating early diagnosis and intervention, Mobilab-Uni can ultimately

reduce healthcare costs by minimizing clinic visits and hospitalizations while optimizing resource utilization for better overall healthcare outcomes.

CHAPTER 3

OPTIMIZATION AND VALIDATION OF ASPARTATE-AMINOTRANSFERASE (AST) AND UREA USING MOBILAB DUO

Abstract

Mobilab-Duo is a dual-slot point-of-care (POC) clinical chemistry analyzer designed for simultaneous biochemical analysis to enable early detection of liver and kidney disorders in resource-limited settings. Evolving from the single-slot Mobilab-Uni, this dual-slot system enables rapid measurement of AST and urea through miniaturized kinetic UV assays adapted from standard laboratory protocols. The device integrates dedicated LED–photodiode detection pairs, low-volume cuvettes, battery-powered operation, and smartphone-based data reporting to support decentralized use in PHCs, CHCs, and mobile clinics.

AST is measured using the IFCC-recommended NADH oxidation method at 340 nm, while urea is analyzed via a coupled urease–GLDH enzymatic reaction monitored through NADH depletion. Assay conditions—including sample volume, buffer chemistry, and incubation—were optimized for robust, low-volume, field-ready operation without the need for cold-chain storage.

Analytical validation using Bio-Rad QC materials demonstrated strong linearity ($R^2 \approx 0.99$), low intra-day variation (CV < 4%), and appropriate LOB/LOD values. Clinical comparison with ~50 patient serum samples per analyte showed excellent correlation with a reference laboratory analyzer, with Passing–Bablok slopes near 1.0, minimal bias in Bland–Altman analysis, and diagnostic accuracy exceeding 94% for both AST and urea.

Overall, Mobilab-Duo achieves laboratory-comparable performance in a portable, lowcost format, enabling reliable biochemical testing at the point of care and supporting improved diagnosis and monitoring of liver and kidney diseases in underserved regions. Of care, the platform has strong potential to improve early detection, triage, and longitudinal management of liver–kidney disorders within decentralized and resource-constrained healthcare systems.

Manuscript is under preparation

3.1 Introduction

Liver and kidney disorders constitute a major component of the global non-communicable disease (NCD) burden and are responsible for substantial morbidity, premature mortality, and healthcare expenditure worldwide [129,130]. Chronic liver disease (CLD) and chronic kidney disease (CKD) frequently coexist due to shared risk factors such as diabetes, hypertension, obesity, alcohol misuse, and viral infections, and together they account for millions of deaths annually, with a disproportionate impact on low- and middle-income countries where access to diagnostics is limited [131]. Early detection and routine biochemical monitoring are therefore critical to interrupt disease progression, guide therapy, and reduce downstream costs to patients and health systems [132].

Aspartate aminotransferase (AST) and urea are among the most widely used biochemical markers in the clinical evaluation of hepatic and renal function, respectively [133,134]. AST is a pyridoxal phosphate–dependent enzyme localized predominantly in hepatocytes, but also present in cardiac and skeletal muscle, kidney, brain, and erythrocytes. It is released into the circulation following cellular injury, making it a sensitive, though not fully specific, indicator of hepatocellular damage [133]. Elevated AST levels are typically observed in acute viral hepatitis, drug-induced liver injury, alcohol-related liver disease, cirrhosis, and ischemic hepatitis, as well as in extra-hepatic conditions such as myocardial infarction, myopathies, and hemolysis [134,135]. Urea, in contrast, is the principal nitrogenous end-product of protein catabolism formed in the liver via the urea cycle and excreted primarily by the kidneys [136]. Serum urea concentration reflects the balance between hepatic production and renal excretion and is routinely used as a marker of renal function and nitrogen metabolism [136].

The “disease map” of AST encompasses a spectrum of hepatic and extra-hepatic conditions that can be inferred from the magnitude and pattern of elevation, especially when interpreted alongside alanine aminotransferase (ALT), bilirubin, and alkaline phosphatase (ALP) [133]. Marked AST elevation (often with ALT) is characteristic of acute viral or toxic hepatitis, whereas moderate, chronic elevations are more typical of cirrhosis and nonalcoholic steatohepatitis. A disproportionately higher AST relative to ALT (AST/ALT ratio >2) is frequently associated with alcohol-related liver disease [134,135]. Mild to moderate AST elevation in the context of normal bilirubin and ALP may suggest extra-hepatic sources such as myocardial infarction, skeletal muscle injury, or hemolysis, particularly when accompanied by relevant clinical findings or elevated creatine kinase and troponins [135]. Thus, AST serves

as a key node in the disease map linking hepatocellular injury, cardiomyopathy, and muscle pathology.

Although ALT is more liver-specific than AST, AST remains a widely used biomarker for assessing hepatocellular injury and is routinely included in liver function panels. The AST assay is also well suited for colorimetric kinetic analysis and portable optical detection, making it compatible with the Mobilab-Duo platform. Future versions of the system may incorporate ALT to further improve diagnostic specificity.

The disease map of urea reflects alterations across prerenal, intrinsic renal, and postrenal compartments, as well as hepatic synthetic capacity [136]. Elevated urea levels (azotemia) may indicate prerenal states such as dehydration, hypovolemia, shock, or heart failure, where reduced renal perfusion impairs clearance; intrinsic renal causes, including acute tubular necrosis or advanced CKD; or postrenal obstruction due to stones, tumours, or prostate enlargement [136]. In contrast, abnormally low urea can be seen in severe liver failure, where urea synthesis is impaired, or in conditions of low protein intake and malnutrition [136]. When interpreted together with creatinine, electrolytes, and liver enzymes, urea helps differentiate prerenal from intrinsic renal failure, and hepatic from renal causes of azotemia, thereby mapping biochemical patterns to specific clinical syndromes in liver–kidney axis disorders [133–136].

Conventional, laboratory-based analyzers can measure AST and urea with high analytical precision, but their reliance on centralized infrastructure, trained technical staff, electricitydependent systems, and often expensive reagents makes them poorly suited for primary health centers, mobile units, and rural clinics [137]. These constraints contribute to delayed testing, under-diagnosis, and late presentation of liver and kidney diseases in resource-limited settings [131,137,138]. To address this gap, the Mobilab-Duo device was developed as an upgraded, dual-analyte point-of-care platform derived from the single-parameter Mobilab-Uni system, with the specific objective of enabling simultaneous or sequential testing of AST and urea at the bedside or in peripheral facilities in a cost-effective, portable format. The present work aims to demonstrate that this dual-parameter system achieves acceptable diagnostic performance compared to standard laboratory methods and is suitable for early detection, triage, and longitudinal monitoring of liver and kidney diseases at the point of care, particularly in low-resource and decentralized healthcare environments.

3.2 Rationale for Mobilab-Duo Development

Mobilab-Uni, the first-generation platform in the Mobilab ecosystem, demonstrated that a compact, battery-operated device could reliably perform multi-analyte biochemical testing for NCD screening in outpatient, camp-based, and primary-care settings. Its deployment in field pilots confirmed that frontline healthcare workers could successfully use a smartphonelinked device to generate rapid, laboratory-comparable results, thereby reducing turnaround time and dependence on centralized laboratories. However, the initial test menu of MobilabUni was restricted to a small panel of basic metabolic and cardiometabolic markers and did not incorporate critical organ-specific parameters that clinicians routinely rely on for evaluating hepatic and renal function, such as AST and Urea.

In parallel, the burden of chronic liver disease (CLD) and chronic kidney disease (CKD) in India and globally has continued to increase, frequently in association with diabetes, hypertension, obesity, alcohol misuse, and viral hepatitis [139, 140, 141]. Patients living in rural and semi-urban regions often present late to tertiary centers because intermediate-level facilities lack access to timely biochemistry testing. In these settings, the ability to measure liver and kidney function at the point of first contact, PHCs, CHCs, mobile medical units, and outreach clinics, could substantially improve early detection, risk stratification, and followup of high-risk individuals [141,142]. AST and Urea were therefore identified as high-priority additions: AST as a core hepatocellular injury marker when interpreted with other liver function tests, and Urea as a fundamental indicator of renal excretory function and nitrogen balance, especially relevant in differentiating prerenal, intrinsic renal, and hepatic components of azotemia [133,136,141].

Building on these clinical and public-health imperatives, Mobilab-Duo was conceptualized as the next evolutionary step in the Mobilab product line, with a focus on dualanalyte testing and enhanced suitability for real-world primary-care workflows. The device was designed not merely as an incremental hardware upgrade, but as a platform that integrates optimized reagent chemistry, improved electronics, and AI-enabled interpretation with fieldready ergonomics. The overarching intent was to shift AST and Urea testing from highcomplexity laboratories to decentralized sites without sacrificing analytical rigour, thereby closing a critical diagnostic gap in liver–kidney disease management at the community level [141–142].

Mobilab-Duo was thus developed around the following specific objectives:

(i). To enable dual-analyte testing of AST and Urea simultaneously, thereby reducing time and cost per patient.

(ii). The device was engineered to allow measurement of AST and Urea from a minimal sample volume on a single platform, either in the same visit or same workflow, reducing the need for multiple instruments or repeat sampling. This dual-analyte capability is intended to lower per-test cost, shorten turnaround time, and provide a more holistic view of hepatic and renal status in a single point-of-care encounter, which is especially valuable in busy PHCs and mobile clinics where patient follow-up can be uncertain [141,142].

(iii). To optimize assay protocols for miniaturized and portable use without compromising accuracy.

(iv). Conventional AST and Urea assays were reformulated and adapted for low-volume cuvettes and stable, field-robust reagent systems, with a focus on maintaining analytical performance parameters—linearity, precision, limit of detection, and interference resistance, comparable to standard laboratory methods [133,136,140]. This required systematic optimization of reagent concentration, incubation times, temperature control, and optical path length to ensure reproducible results under variable environmental conditions typical of peripheral facilities, including intermittent power and limited climate control [137,140].

(v). To validate device performance against gold-standard analyzers (Vitros 5600 Integrated Biochemistry Analyzer, Siemens Dimension 200).

(vi). A core element of the rationale was to demonstrate that Mobilab-Duo can meet clinically acceptable agreement with established high-throughput analyzers used in reference laboratories. Method-comparison studies were planned using paired patient samples measured on Mobilab-Duo and reference systems (such as Vitros 5600 and Siemens Dimension 200), with statistical evaluation of correlation coefficients, bias, Bland-Altman limits of agreement, and total error against predefined performance goals [143]. This step is critical to ensure that results generated at the point of care can be confidently interpreted alongside, or in continuity with, central laboratory data.

(vii). To enhance field applicability by ensuring portability, low power consumption, and a user-friendly workflow.

(viii). The device architecture, user interface, and consumable handling were refined to support use by nurses, lab technicians, and community health workers with minimal training [142]. Key design requirements included lightweight form factor, compatibility with battery or solar-based power sources, an intuitive touchscreen or smartphone-based interface, minimal manual steps per test, and clear on-screen guidance to reduce operator-dependent error. Integration with digital health platforms and offline data storage was also prioritized to support longitudinal tracking, teleconsultation, and programmatic monitoring of liver and kidney disease at the population level [137,142].

By achieving these objectives, Mobilab-Duo aims to move point-of-care testing beyond basic metabolic screening to include clinically impactful organ-function markers, thereby strengthening early detection, triage, and ongoing management of liver and kidney diseases in low-resource and decentralized healthcare environments.

3.3 Assay Principles and Device Function

3.3.1 Aspartate Aminotransferase (AST) Assay

The Karmen method (Figure 23) is a well-established and widely used spectrophotometric technique for the quantitative determination of Aspartate Aminotransferase (AST), also referred to as Serum Glutamate Oxaloacetate Transaminase (SGOT). AST is a key hepatic enzyme that catalyzes the reversible transamination between L-aspartate and α-ketoglutarate, producing oxaloacetate and L-glutamate. In the coupled kinetic UV assay, the oxaloacetate formed in the primary reaction is rapidly reduced to malate by Malate Dehydrogenase (MDH), accompanied by the oxidation of NADH to NAD^+. The rate of NADH depletion is directly proportional to AST activity and forms the basis of quantitative measurement [143-147]. The overall reaction sequence is summarized below:

Figure 23 depicts the biochemical basis of the Karmen method for AST determination. The primary reaction converts glutamate and oxaloacetate to α-ketoglutarate and aspartate via AspAT, linking amino acid and keto acid metabolism. The oxaloacetate produced is immediately consumed in a secondary indicator reaction, where MDH reduces it to malate while NADH is oxidised to NAD^+. Because NADH absorbs strongly at 340 nm whereas NAD^+ does not, the rate of decrease in NADH absorbance is directly proportional to AST activity in the sample. This coupled assay design enables sensitive, kinetic spectrophotometric measurement of AST in serum.Because NADH has a strong absorbance peak at 340 nm, whereas NAD^+ does not, the progressive oxidation of NADH during the reaction results in a

measurable decrease in absorbance at 340 nm. The rate of this decrease (ΔA/min) is directly proportional to the AST activity in the sample, provided that MDH, NADH, and substrates are present in excess and the reaction is performed under defined conditions of pH, temperature, and buffer composition [144].

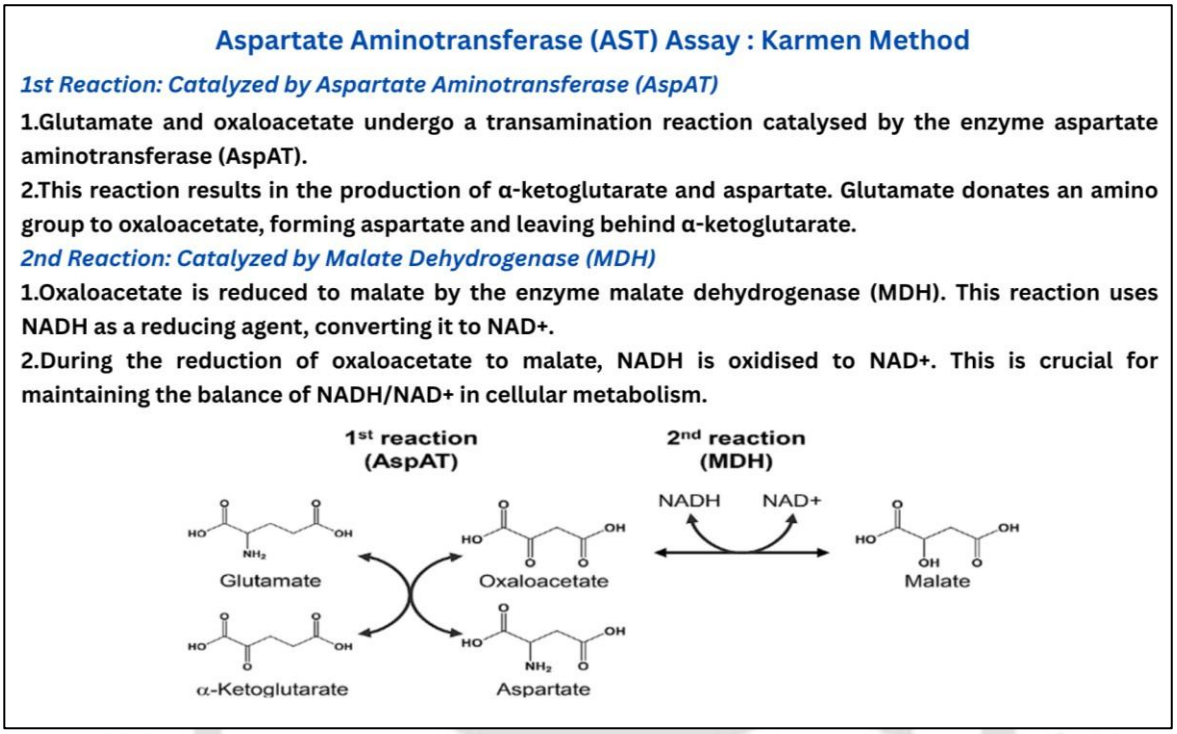

Figure 23. Principle of the Aspartate Aminotransferase (AST) assay using the Karmen method. The figure illustrates the two-step coupled enzymatic reaction used to measure AST activity. In the first reaction, catalysed by aspartate aminotransferase (AspAT), glutamate and oxaloacetate undergo transamination to form α-ketoglutarate and aspartate. In the second reaction, catalysed by malate dehydrogenase (MDH), oxaloacetate is reduced to malate with simultaneous oxidation of NADH to NAD^+.

In the Mobilab-Duo system, this Karmen-based AST assay is miniaturized and adapted for point-of-care use. The reaction is carried out in a low-volume cuvette using pre-formulated reagent mixtures containing L-aspartate, α-ketoglutarate, MDH, and NADH in optimized concentrations suitable for UV kinetic measurement. A dedicated UV LED (centered around 340 nm) and an integrated photodiode detector form the optical subsystem, allowing precise monitoring of NADH absorbance over time. The device maintains controlled reaction conditions (e.g., temperature regulation via an onboard incubator module where applicable) to ensure consistent reaction kinetics across runs.

After sample addition, the Mobilab-Duo performs an initial blanking step to account for the background absorbance of reagents and the cuvette. It then records the change in absorbance at 340 nm at fixed time intervals (kinetic mode) over a predefined measurement window. The instrument's firmware calculates the slope (ΔA/min) from the linear portion of the absorbance–time curve and converts this to AST activity expressed in U/L using an internally stored calibration factor derived from the molar absorptivity (ε) of NADH, optical path length, and reaction volume configuration [144, 148, 149].

To enhance analytical robustness, the system incorporates signal smoothing and quality checks (e.g., verification of linearity of the kinetic trace and rejection of aberrant curves due to bubbles, improper mixing, or hemolysis). The use of LED-photodiode technology minimizes drift and reduces energy consumption, making the method suitable for field deployment. The miniaturized reaction volume reduces reagent usage and waste generation while preserving the essential features of the reference Karmen method, thereby enabling laboratory-grade AST estimation on a portable, point-of-care platform [144, 148, 149].

3.3.2 Urea Assay

The enzymatic urease-GLDH (glutamate dehydrogenase) method (Figure 24**)** is a wellestablished and widely applied spectrophotometric technique for the quantitative determination of urea in biological fluids such as serum, plasma, and urine [150,151]. Urea is the principal nitrogenous end-product of protein catabolism and reflects the balance between hepatic production and renal excretion; its measurement is therefore central to the evaluation of renal function, hydration status, and overall nitrogen metabolism in clinical practice [152].

In this coupled enzymatic system, the first reaction is catalyzed by urease, which hydrolyzes urea under mild physiological conditions to produce ammonia (NH_3) and carbon dioxide (CO_2) [150]. The liberated ammonia then enters a secondary reaction catalyzed by glutamate dehydrogenase (GLDH), where it reacts with α-ketoglutarate in the presence of reduced nicotinamide adenine dinucleotide (NADH). During this GLDH-mediated reaction, ammonia is assimilated to form L-glutamate while NADH is oxidized to NAD^+ [151]. Because NADH exhibits strong absorbance at 340 nm, whereas NAD^+ does not, the progressive oxidation of NADH leads to a measurable decrease in absorbance at 340 nm. Under conditions where urease, GLDH, α-ketoglutarate, and NADH are present in excess, the rate of NADH decrease (ΔA/min) is directly proportional to the urea concentration in the sample [150,151].

In the Mobilab-Duo system, this classical urease-GLDH method is miniaturized and automated to enable point-of-care biochemical analysis. The reaction is carried out in

lowvolume cuvettes pre-loaded with optimized reagent formulations containing urease, GLDH, α-ketoglutarate, and NADH, stabilized for field conditions [153]. A narrow-band UV LED (≈340 nm) and high-sensitivity photodiode detector form the core of the optical module, allowing detection of small changes in NADH absorbance over time. The optical path length, cuvette geometry, and mixing characteristics are engineered to maximize signal-to-noise ratio while minimizing reagent and sample consumption. Temperature effects on enzyme kinetics are mitigated through controlled reaction conditions and device-level calibration, thereby improving precision and inter-run comparability [153,154,155].

As shown in the Figure 24, Urea is the principal nitrogenous waste product formed during protein metabolism in humans and mammals and is derived mainly from the amino groups of amino acids. Its concentration is determined using a coupled enzyme assay based on the Urease/GLDH method. In the first step, urea is hydrolyzed by urease to produce ammonia and carbon dioxide. In the second step, the ammonia reacts with 2-oxoglutarate in the presence of the enzyme glutamate dehydrogenase (GLDH), converting NADH to NAD^+. The resulting decrease in NADH absorbance at 340 nm (or 334/366 nm) is measured photometrically and is directly proportional to the urea concentration in the sample.

The overall reaction sequence may be summarized as:

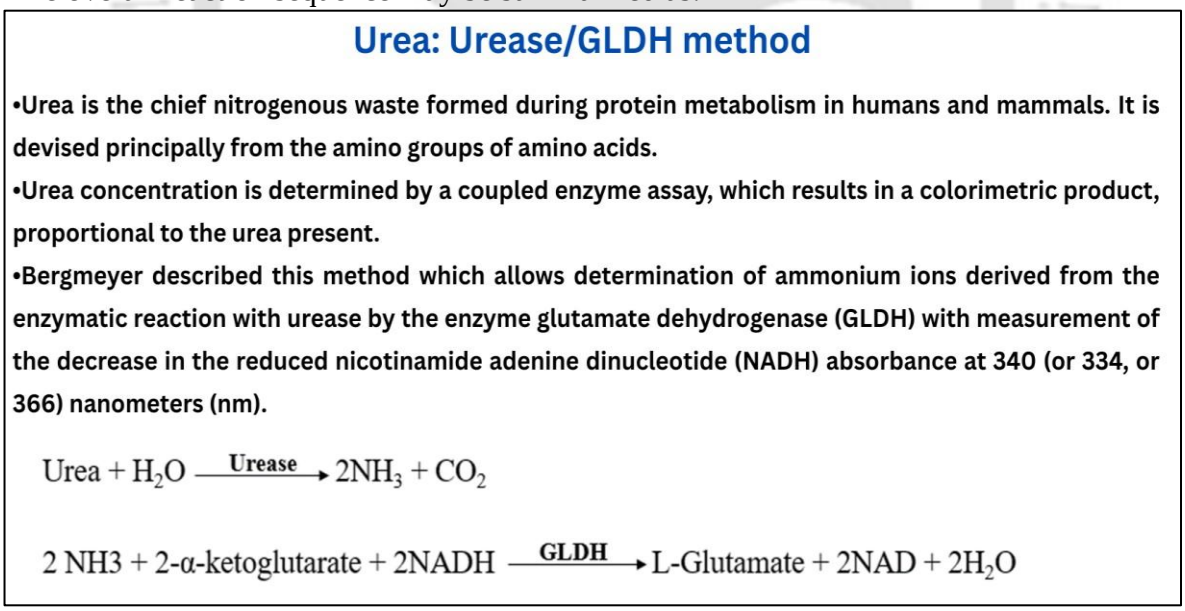

Figure 24. Principle of urea estimation by the Urease/GLDH enzymatic method.Urea is hydrolyzed by urease to ammonium, which is subsequently utilized by glutamate dehydrogenase (GLDH) in a coupled reaction that consumes NADH. The decrease in NADH absorbance at 340 nm is directly proportional to the urea concentration in the sample.

As shown in the Figure 24, Urea is the principal nitrogenous waste product formed during protein metabolism in humans and mammals and is derived mainly from the amino groups of amino acids. Its concentration is determined using a coupled enzyme assay based on the Urease/GLDH method. In the first step, urea is hydrolyzed by urease to produce ammonia and carbon dioxide. In the second step, the ammonia reacts with 2-oxoglutarate in the presence of the enzyme glutamate dehydrogenase (GLDH), converting NADH to NAD^+. The resulting decrease in NADH absorbance at 340 nm (or 334/366 nm) is measured photometrically and is directly proportional to the urea concentration in the sample.

Following sample addition, Mobilab-Duo performs an initial blank measurement to correct for the background absorbance of reagents and the cuvette. The device then records absorbance at 340 nm at fixed intervals in kinetic mode and computes the slope (ΔA/min) from the linear segment of the absorbance-time curve. Using built-in calibration factors derived from the molar absorptivity of NADH, path length, and reaction configuration, the firmware converts the slope into urea concentration expressed in mg/dL or mmol/L [150,153]. Quality-control algorithms evaluate the linearity of the kinetic trace and flag aberrant measurements due to bubbles, incomplete mixing, or extreme hemolysis.

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By implementing the urease–GLDH method in a miniaturized, LED-based kinetic format, Mobilab-Duo delivers rapid, precise, and reagent-efficient urea estimation suitable for routine monitoring of renal function and metabolic disorders at both clinical facilities and decentralized healthcare sites. This approach combines the methodological robustness of reference laboratory assays with the practicality and accessibility required for point-of-care diagnostics in resource-constrained settings [153-154].

3.3.3 Device Architecture and Workflow

Mobilab-Duo features a dual-slot cartridge system, allowing for the parallel testing of AST and Urea. Each slot houses a disposable cartridge pre-loaded with dried reagents, activated upon sample introduction. The optical system includes LED emitters and photodiode detectors tuned to specific assay wavelengths. The embedded microcontroller unit (MCU) processes absorbance signals, applies calibration algorithms, and displays analyte concentrations on the device interface. Additionally, an IoT-enabled module allows wireless data transmission to smartphones or cloud servers for digital health record integration. Figure 25 shows the visual representation of Mobilab-Uni and Duo devices.

Figure 25. Mobilab point-of-care ecosystem: analyzers and accessories. Rendered image of the Mobilab hardware family comprising (from left to right): the Mobicube incubator, the Mobilab Uni single-cuvette analyzer, the Mobilab-Duo dual-cuvette analyzer, and the Mobimix mixer.

Figure 25 showcases the integrated Mobilab ecosystem designed for decentralized biochemical testing. Mobicube provides controlled incubation for multiple cuvettes, enabling temperature-sensitive assays. Mobilab-Uni and Mobilab-Duo serve as compact optical analyzers for single- and dual-parameter workflows, respectively, optimized for use with the Mobilab smartphone application. Mobimix complements these analyzers by delivering standardized cuvette mixing for reagents and samples. Together, these modules form a portable, modular platform suitable for use in clinics, health camps, and other resource-limited settings.

3.4 Methodology

3.4.1 Device Prototyping

A compact dual-slot analyzer chassis was developed to accommodate two reaction cartridges simultaneously, enabling true dual-analyte operation. The optical and electronic modules were integrated into a single rigid housing, with each slot having its own dedicated LED–photodiode pair and optical path, while sharing a common control board and power system. The enclosure was ergonomically contoured for handheld or tabletop use and built from lightweight, impact-resistant polymer to facilitate transport in primary-care and field settings.

The system is powered by a high-capacity rechargeable battery, providing approximately 8–10 hours of continuous operation under typical use, thus allowing a full day of field work without dependence on mains electricity. A color touchscreen interface was incorporated on

the front panel to guide the user through test selection, cartridge insertion, incubation timing, and result display. The graphical user interface was designed with large icons and minimal text prompts to minimize operator error and reduce training requirements.

For data management, the prototype supports wired connectivity via USB-OTG, allowing export of test results to smartphones, tablets, or computers for storage, analysis, and integration with electronic medical records. Internal memory stores recent test logs with timestamps and sample identifiers, enabling basic on-device review and audit trails. Together, these design features ensure that the Mobilab-Duo prototype is portable, field-robust, and compatible with routine clinical workflows.

3.4.2 Assay Optimization

Assay conditions for both AST and Urea were systematically optimized to suit lowvolume, point-of-care testing using finger-prick samples. Capillary blood obtained from a finger-prick was either used directly (for whole-blood compatible protocols) or processed to obtain serum as per the specific assay requirements.

(a) Sample volume

The tests were tailored to operate with minimal sample volumes to enhance patient comfort and facilitate use in resource-limited environments. The AST assay was optimized to use 100 µL of sample, ensuring adequate signal for kinetic measurement while maintaining low reagent consumption. The Urea assay, due to its high analytical sensitivity, required only 10 µL of sample, making it suitable for repeated monitoring or use in paediatric and anemic patients where blood volume is a concern.

(b) Reaction conditions

Buffer systems, pH, and reagent concentrations were iteratively refined to achieve rapid and reproducible reaction kinetics compatible with the device's measurement cycle. For both assays, reagent formulations were adjusted to ensure that the reaction reached a stable kinetic phase within approximately 8-12 minutes, allowing timely reporting in a point-of-care context. Incubation temperature, mixing time, and reading intervals were harmonized with the instrument's optical and thermal capabilities to maximize linearity and minimize interference from hemolysis or turbidity.

(c) Reagent stability

To support field deployment without reliance on cold-chain logistics, reagent formulations were engineered for stability at ambient temperatures. Stabilizers, preservatives, and appropriate buffer systems were incorporated to maintain enzymatic activity and minimize

degradation during storage. Candidate formulations were subjected to real-time and accelerated stability evaluations at elevated temperatures to confirm acceptable performance over the intended shelf-life. This optimization ensured that AST and Urea reagents could be transported and stored in typical primary-care and rural health settings without refrigeration, while still delivering reliable analytical performance on the Mobilab-Duo platform.

3.4.3 Validation Studies

Validation of the Mobilab-Duo device was carried out in two clearly defined phases to rigorously establish both its analytical reliability and its clinical applicability. In the first phase (analytical validation), extensive bench-level studies were performed using quality-control materials and calibrators with predetermined concentrations of AST and Urea, covering low, normal, and high clinically relevant ranges. These controls were run repeatedly within a single day (within-run precision) and across multiple days (between-run precision) to assess the stability of measurements over time. Linearity was evaluated by measuring serial dilutions spanning the reportable range and comparing observed values with expected concentrations, allowing calculation of regression parameters and total deviation from linearity. Accuracy was examined by comparing Mobilab-Duo results to target values assigned by the manufacturer of the control materials or by reference methods. Together, these experiments assessed key analytical performance characteristics, accuracy, precision (CV%), linearity, limit of detection, and reproducibility under standardized laboratory conditions. This phase was crucial to demonstrating that Mobilab-Duo could consistently generate results traceable to reference procedures, thereby providing a robust analytical foundation for subsequent clinical validation.

In the second phase (clinical validation), patient samples were tested in parallel on Mobilab-Duo and on established gold-standard laboratory analyzers, including the Siemens Dimension 200 system. For each sample, paired results were obtained for AST and Urea, Figures 26 & 27, respectively, enabling direct method-comparison under real-world clinical conditions. Statistical analyses included calculation of correlation coefficients (R^2), regression slopes and intercepts, mean bias (percentage difference), and Bland-Altman limits of agreement, as well as precision indices where repeat measurements were available. Diagnostic performance was further characterized by calculating accuracy (percentage agreement within predefined allowable error limits), and, where applicable, sensitivity, specificity, and predictive values across clinical decision thresholds.

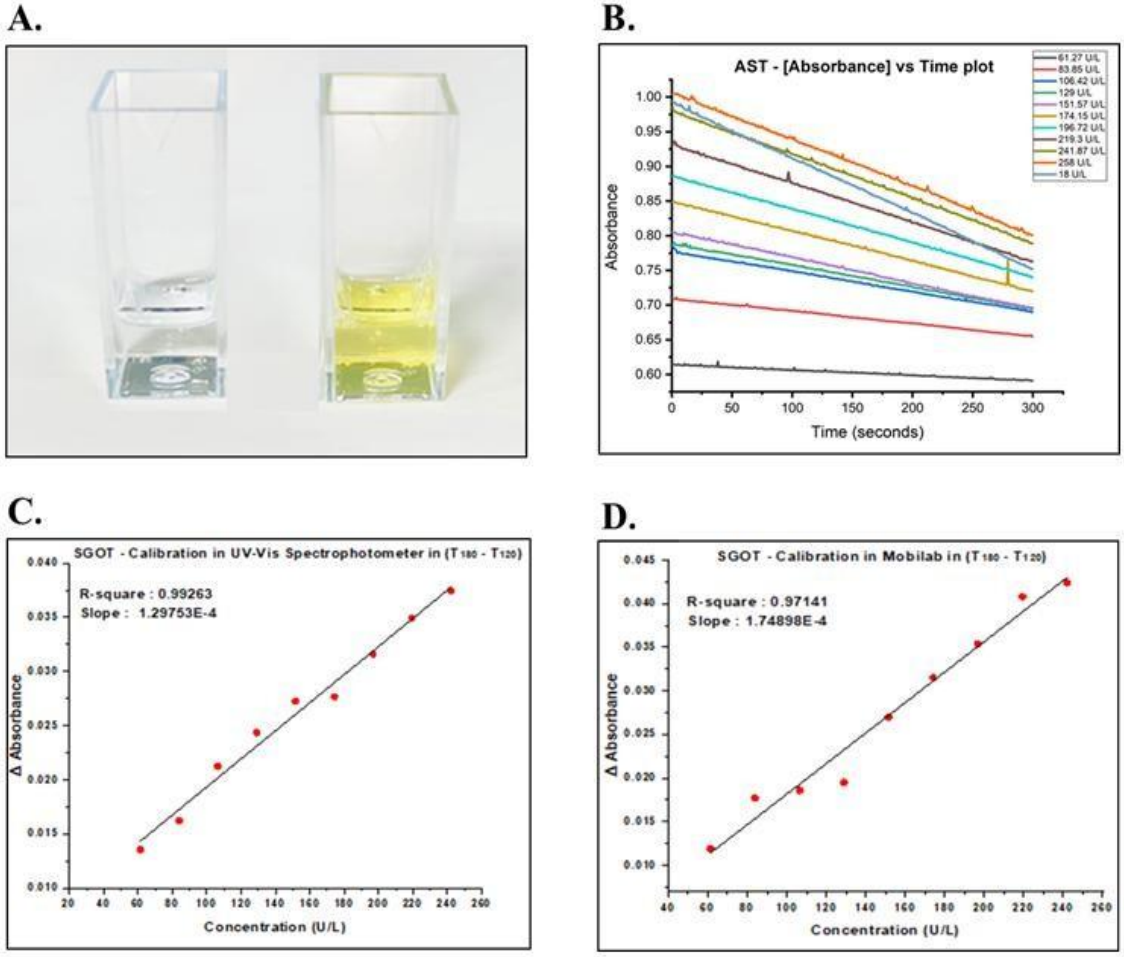

Figure 26. AST (SGOT) assay characterization and calibration in UV–Vis spectrophotometer and Mobilab-Duo. (A) Cuvettes showing the AST reaction mixture before and after incubation, with visible color change following NADH oxidation. (B) Kinetic AST absorbance–time plots for multiple activity levels, demonstrating progressively steeper declines in absorbance at 340 nm with increasing enzyme activity. (C) Calibration curve obtained using a UV–Vis spectrophotometer (ΔA at T_{180}–T_{120}), showing a strong linear relationship between Δ absorbance and AST activity ($R^2 \approx 0.993$; slope ≈ 1.30×10^{-4}). (D) Calibration curve generated using the Mobilab-Duo device under the same timing protocol, also exhibiting good linearity ($R^2 \approx 0.97$; slope ≈ 1.75×10^{-4}) across the tested activity range.

By integrating findings from both phases, the validation framework provided a comprehensive assessment of Mobilab-Duo's diagnostic capability, demonstrating that the device delivers analytically sound, reproducible measurements and maintains strong agreement with high-throughput reference analyzers when used on routine patient samples. The results confirmed strong agreement, accuracy, and reproducibility of Mobilab-Duo under real-world conditions.

Figure 26 illustrates the development and validation of the kinetic AST (SGOT) assay using the Karmen method on both a conventional UV–Vis spectrophotometer and the Mobilab platform. Panel A shows cuvettes before and after reaction, indicating NADH consumption. Panel B presents absorbance–time profiles across low to high AST activities. Panels C and D show the UV–Vis and Mobilab-Duo calibration curves, respectively, demonstrating excellent linearity and close agreement between the two methods, confirming reliable kinetic measurement on the portable device.

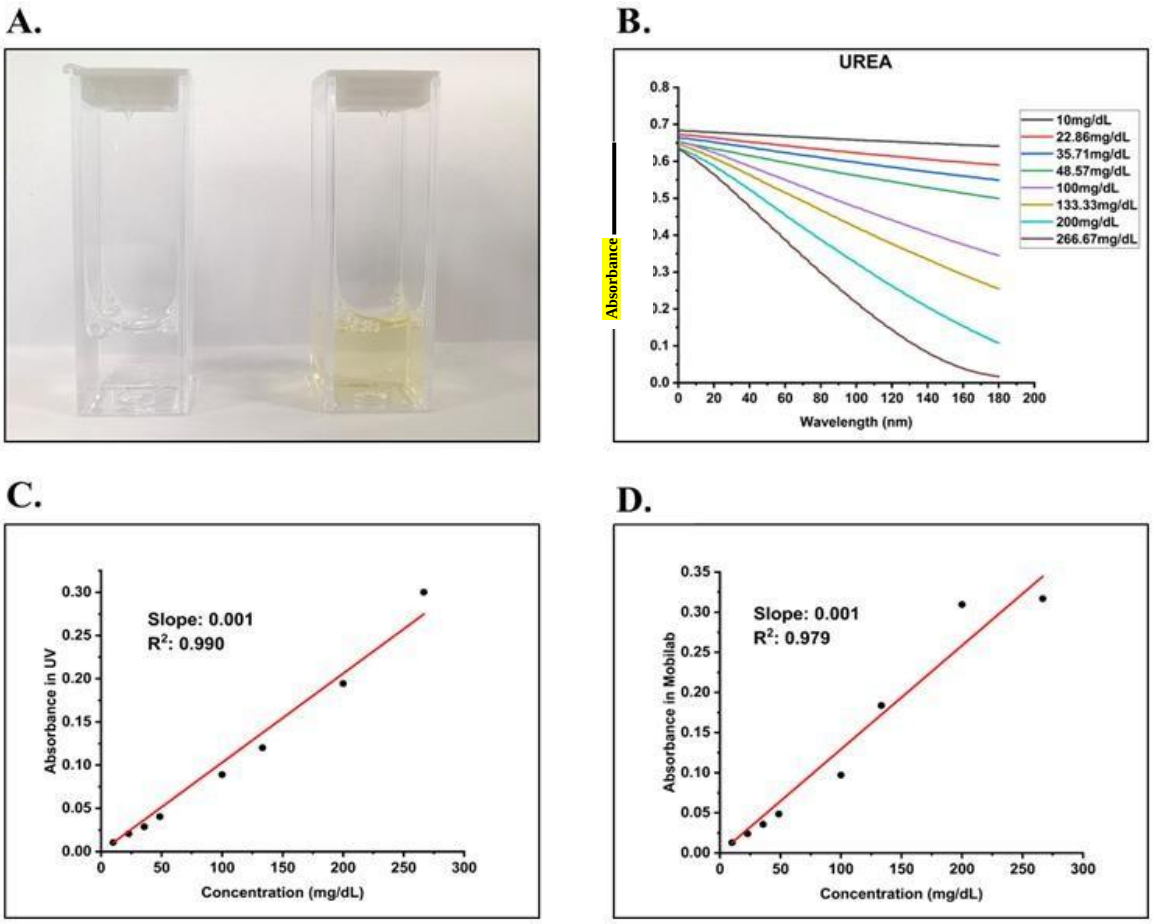

Figure 27. Urea assay characterization in UV–Vis spectrophotometer and Mobilab-Duo.(A) Cuvettes showing the urea working reagent before reaction (left) and after color development with urea standards (right), producing a pale-yellow chromophore. (B) Overlaid spectra of urea standards spanning 10–266.7 mg/dL, demonstrating a progressive change in signal with increasing concentration. (C) Calibration curve obtained on a benchtop UV–Vis spectrophotometer, showing a linear relationship between absorbance and urea concentration (slope = 0.001; R^2 = 0.990). (D) Calibration curve generated using the Mobilab-Duo device, likewise demonstrating strong linearity (slope = 0.001; R^2 = 0.979).

Figure 27 summarizes the analytical validation of the urea assay and its translation from a conventional UV–Vis platform to the Mobilab system. Panel A depicts the visible change in cuvette appearance following reaction of urea with the color reagent. Panel B presents spectra for a series of urea standards across the clinically relevant range, showing a concentration-dependent change in signal suitable for quantification. The UV–Vis calibration in Panel C confirms excellent linearity between absorbance and urea concentration, while Panel D demonstrates that Mobilab-Duo produces a closely matching calibration with comparable slope and R^2. Together, these data confirm that the portable analyzer can accurately measure urea levels for point-of-care kidney function assessment.

3.5. Materials and Methods

3.5.1 Materials

The reagent kits for all parameters were procured from commercial manufacturers but were based on established enzymatic methodologies. Urea estimation was performed using the enzymatic Urease/GLDH method, as originally described and refined in standard clinical chemistry literature [156–158]. AST was measured using the IFCC-recommended UV kinetic method for aspartate aminotransferase, which employs optimized buffer conditions and standardized temperature and wavelength settings for reproducible activity measurement [159,160]. Measurements were carried out on the Mobilab-duo device, with mixing performed using the Mobimix mixer, and data visualization and transfer handled via an Android smartphone (Redmi 9A, Xiaomi) connected through a micro-USB OTG cable.

For evaluation of analytical sensitivity, linearity, and precision on the Mobilab platform, 0.9% NaCl and Liquid Assayed Multiqual control serum Level 1 (Lot No. 45931) and Level 3 (Lot No. 45933) were used as recommended in standard quality-control practice [160,161]. A UV–Vis spectrophotometer (LABMAN LCD LMSP-UV1900, India) served as the reference instrument for linearity studies and method comparison, following conventional spectrophotometric procedures for kinetic enzyme assays [160,161].

3.5.2 Methods

In this study, over 100 samples were tested for each parameter using the Mobilab-Duo analyzer to ensure its comprehensive assessment. The quantitative measurement using Mobilab-Duo is conducted according to the following steps: (i) A precise volume of reagent is pipetted into a test cuvette and inserted into the Analyzer, for the initial base reading. (i) The sample is added to the cuvette and subjected to uniform mixing in a mixing device, Mobimix, (iii) The sample-containing cuvette is then reinserted into the Analyzer. It measures

the absorbance of the products formed at the end of every reaction or during the reaction by applying the Beer-Lambert law [162] (iv). The final result is calculated, and a digital test report is generated by the Android application.

3.5.3 Sample collection

Samples were obtained from GNRC Hospital, North Guwahati, following institutional approval. Serum samples remaining after routine testing were analyzed for biochemistry parameters using the SDA 200. Sample handling, transport, and storage followed ethical guidelines, with storage at 4°C and no more than two freeze–thaw cycles. Patient confidentiality was strictly maintained, and reference ranges for UREA and AST were applied as listed in Table 12.

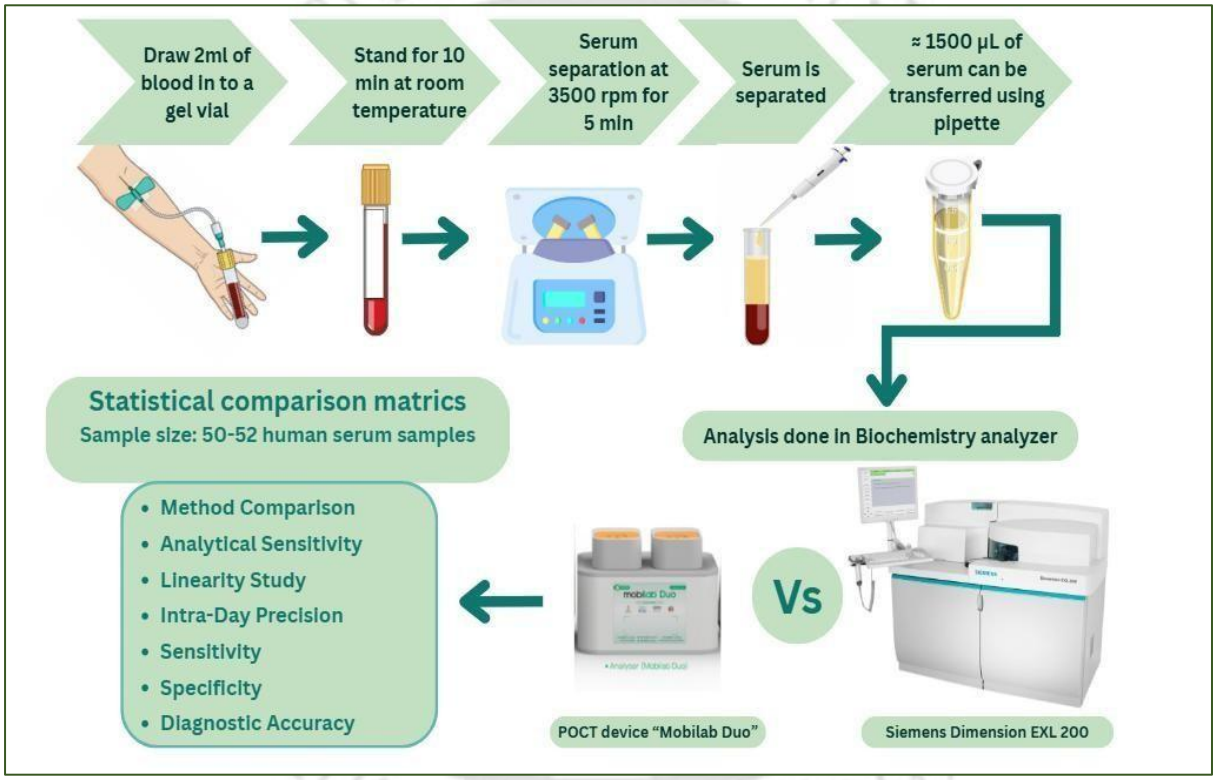

Figure 28. Workflow for comparative evaluation of the Mobilab-Duo POCT device and a laboratory biochemistry analyzer. Schematic showing venous blood collection into a gel vial, clotting at room temperature, serum separation by centrifugation at 3500 rpm for 5 min, and transfer of ~1500 µL serum by pipette for analysis. Processed samples are then tested on the Mobilab-Duo point-of-care device and the Siemens Dimension EXL 200 analyzer for method comparison.

Figure 28 summarizes the experimental workflow used for head-to-head comparison of Mobilab-Duo with a conventional laboratory analyzer. For each subject, 2 mL of blood was collected, allowed to stand for 10 minutes, and centrifuged to obtain serum. Aliquots of the

separated serum were analysed on both platforms. Using 50–52 human serum samples, a series of statistical metrics—including method comparison, analytical sensitivity, linearity, intra-day precision, sensitivity, specificity, and diagnostic accuracy—were computed to evaluate the performance of the POCT device relative to the Siemens Dimension EXL 200.

Table 12. Methods of detection and reference ranges for different parameters used at GNRC Hospital, Guwahati and Mobilab-Duo

Test Name	Analytical Method – GNRC	Analytical Method – Mobilab-Duo	Reference range (Adult)
Urea	Urease, UV Method (BUN)	Urease / GLDH Method[e)]	7-18 mg/dL
Aspartate aminotransferase	UV with P5P (Pyridoxal 5'-phosphate) Method	Karmen/IFCC recommended Method[f)]	15-37 U/L

GLDH = Glutamate dehydrogenase; IFCC = International Federation of Clinical Chemistry and Laboratory

The study compared Mobilab's method, analytical sensitivity, linearity, repeatability and performance with SDA 200, an automated clinical chemistry analyzer used at GNRC Hospital. Table 12 provided the methods used in the biochemistry analyzer of GNRC hospital and in Mobilab-Duo. This evaluation covered AST and UREA parameters, confirming Mobilab-Duo's suitability for producing reliable point-of-care results. The methods employed for this performance comparison are briefly outlined below:

3.5.4 Method comparison

This evaluation was done with respect to the analytical method used in the GNRC hospital with the SDA 200 clinical chemistry analyzer. The study involved statistical analysis such as Passing & Bablok Regression analysis, Bland-Altman plot and t-Test to determine the degree of agreement between the analytical methods used in the established auto analyzers and Mobilab-Duo. The analytical methods used to compare both the analyzers for each of the 2 tests are described under the following headings.

(a) Passing & Bablok Regression: Passing and Bablok regression analysis is a statistical technique enabling the estimation of agreement between analytical methods and potential systematic biases between them. This method is non-parametric and robust to variations in error distribution and the presence of outliers in the data. Proper application of Passing and Bablok regression requires data with continuous distribution and linear relationships between measurements obtained from two

analytical methods [163]. The findings are shown as an equation, regression line, and scatter plot, in which the slope denotes proportionate measurement error, and the intercept denotes a constant. The 95% Confidence Intervals (CI) for both intercept and slope evaluate if their values significantly deviate from 0 and 1, respectively.

(b) Bland-Altman Plot: A Bland-Altman plot is an effective method to visually represent the relationship between two paired variables measured on the same scale. Unlike formal hypothesis testing, it examines the phenomenon without conducting statistical tests, thereby not providing the same level of error in decision-making about the variables [164]. The plot is constructed by plotting the differences between paired data from two variables (Auto-analyzer of GNRC hospital and the MobilabDuo device) against the average of these readings. The mean difference line is accompanied by ±2SD lines, representing the Confidence Interval (CI). This plot aids in identifying outliers, evaluating agreement, and detecting any systematic bias in the data.

(c) Paired t-test: Another statistical method involves determining the p-value. A significance threshold of 0.05 is established to identify significant disparities between the devices. If the p-value is greater than 0.05, the null hypothesis is accepted, suggesting no substantial distinction between the actual and reference devices. Conversely, if the p-value is less than 0.05, the alternate hypothesis is accepted, indicating a significant difference between the devices [165].

3.6 Method validation

3.6.1 Linearity Test

Linearity plays a pivotal role in ensuring the credibility of any analytical process. In this study, Mobilab-Duo was tested across a wide range of concentrations to assess its ability to detect varied concentration levels of the specified parameters. The concentration range for each test parameter on Mobilab-Duo (y-axis) was subsequently juxtaposed against that on the UV-spectrophotometer (x-axis) [166]. The assessment highlights Mobilab-Duo's ability and consistency in maintaining linearity across a range of concentrations.3.6.2 Analytical Sensitivity

This clinical aspect highlights how well an analytical technique can accurately and dependably identify lower levels of test substances. The current research clarifies the concepts of Limit of Blank (LOB) and Limit of Detection (LOD) for these substances, which define the

method's sensitivity [167]. LOB refers to the concentration detected by the device even when there is no substance present. It is established by repeatedly measuring samples without the substance to establish a baseline. Conversely, LOD indicates the lowest concentration of the substance that can be consistently and accurately detected through multiple repetitions. Determining the LOB and LOD provides insights into Mobilab's precision and reliability in detecting test substances and the parameters being investigated.

3.6.3 Precision test

The intra-day precision assessment of all thirteen test parameters has been consistently conducted using Liquid Assayed Multiqual control serum from Bio-Rad: Level 1 (L1) and Level 3 (L3) for 20 consecutive runs. Mobilab's intra-day precision is evaluated under identical conditions for all test parameters to examine the consistency of the study by calculating the coefficient of variation (CV%) [168]. A lower coefficient of variation (CV%) indicates that Mobilab-Duo results exhibit higher precision in the precision study for these test parameters. Therefore, conducting an intra-day precision study helps to better understand the accuracy of Mobilab-Duo's test results when repeatedly analyzing the same substance at identical concentrations.

3.6.4 Performance Metrics

Performance metrics were calculated to gauge the accuracy of the proposed device, encompassing sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV) and Diagnostic Accuracy (DA) [169]. As shown in Table 2, the calculation was done with the following test results: True Positive (TP), True Negative (TN), False Negative (FN) and False Positive (FP).

The specificity was calculated to identify how often Mobilab-Duo correctly detect the absence of a condition. PPV (Positive Predictive Value) assessed the proportion of true positive results accurately identified by Mobilab-Duo out of all the positive test results. NPV (Negative Predictive Value) measured the proportion of true negative results correctly identified by Mobilab-Duo among all negative outcomes. DA is computed to ascertain the total count of true positives and true negatives identified among all test outcomes.

3.7 Results & Discussion

In this study, we investigated the clinical performance of the portable clinical chemistry analyzer, Mobilab-Duo, with the goal of assessing its practicality and diagnostic accuracy. The study involved testing 100-plus samples for each parameter individually, employing

meticulously designed experimental setups. For every parameter, the diagnostic method was compared, followed by determination of analytical sensitivity, linearity, and intra-day precision studies were conducted and evaluated performance metrics. The findings deliberated upon for each parameter (UREA and AST) highlight the device's effectiveness in early detection of NCDs, aiming to enhance individuals' health conditions.

The process begins with drawing 2 mL of venous blood into a gel separation vial, followed by a 10-minute standing period at room temperature to allow clot formation. Serum is then separated by centrifugation at 3500 rpm for 5 minutes. Approximately 1500 µL of clear serum is collected using a pipette and transferred for analysis. The extracted serum samples (n = 50–52) were analyzed using both the Mobilab-Duo point-of-care device with dual slot for analysis and the Siemens Dimension EXL 200 clinical chemistry analyzer. Statistical comparison metrics included method comparison, analytical sensitivity, linearity, intra-day precision, sensitivity, specificity, and diagnostic accuracy to assess the agreement and performance of the POCT device relative to the laboratory-grade analyzer.

3.7.1 Method Comparison

3.7.1.1 Passing & Bablok Regression

Method comparison between the test device and the reference analyzer was performed using the Passing–Bablok regression approach, which is widely accepted for evaluating agreement between two analytical methods without assuming normal data distribution. As presented in Table 13 and Figure 29, the regression analysis for the evaluated parameters—UREA and AST—demonstrated that both the slope and intercept values of the device systematically fall within the corresponding 95% Lower Confidence Limits (LCL) and 95% Upper Confidence Limits (UCL).

This statistical outcome indicates the absence of significant proportional or constant bias between the two methods across the measured concentration ranges. Consequently, the results provide strong quantitative evidence supporting the acceptance of the null hypothesis, confirming that there is no statistically significant difference between the device measurements and those obtained using the reference method. These findings further affirm the analytical equivalence and reliability of the device for routine clinical application.

Table 13. Summary of Method Comparison study for all parameters assessed between Mobilab-Duo and SDA 200 (GNRC Hospital) for UREA, and AST.

Method Comparison	Passing Bablok Plot			Bland-Altman plot		t-test
	Slope	Intercept	$R^{2a)}$	Bias	LOA[b)]	p-value
Urea	0.99	0.09	0.99	7.48 mg/dL	-6.09 to 6.09 mg/dL	0.99
Aspartate Aminotransferase	0.99	0.15	0.99	-0.09 U/L	-7.80 to 7.62 U/L	0.98

[a)] R^2=Coefficient of determination; [b)] LOA=Limit of assay

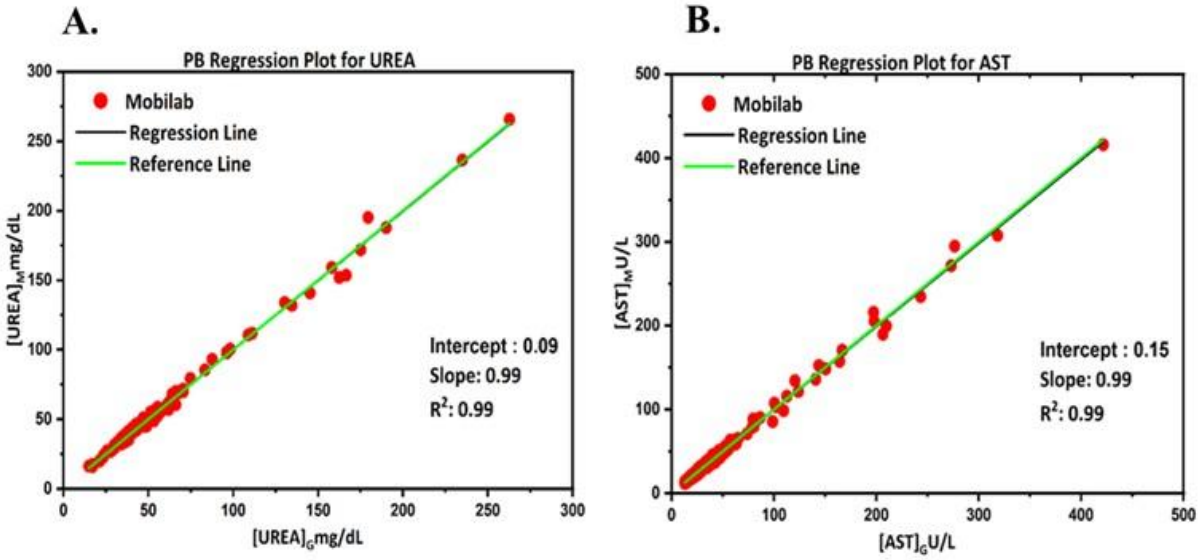

Figure 29. Passing–Bablok regression analysis for urea and AST comparing Mobilab-duo with the reference analyzer. (A) UREA: Patient serum urea concentrations from the reference analyzer $[UREA]^G$ (mg/dL, x-axis) plotted against Mobilab-Duo measurements $[UREA]^M$ (mg/dL, y-axis); Passing–Bablok regression gives intercept = 0.09, slope = 0.99, R^2 = 0.99. (B) AST: Serum AST activity from the reference analyzer $[AST]^G$ (U/L, x-axis) versus Mobilab $[AST]^M$ (U/L, y-axis); regression yields intercept = 0.15, slope = 0.99, R^2 = 0.99. In both panels, the green line represents the line of identity (y = x), the black line shows the Passing–Bablok fit, and red dots denote individual Mobilab-Duo values.

Figure 29 presents method-comparison analyses for urea and AST between Mobilab-Duo and a standard biochemistry analyzer using Passing–Bablok regression. For both analytes,

slopes are essentially unity and intercepts are close to zero, indicating minimal proportional and constant bias over the tested concentration ranges. High coefficients of determination (R^2 = 0.99 for both urea and AST) demonstrate excellent agreement and confirm that MobilabDuo measurements track reference values with high fidelity. These findings support the use of Mobilab-Duo for reliable assessment of renal (urea) and hepatic (AST) function at the point of care.

3.7.1.2 Bland-Altman Plot

Based on the findings shown in Table 13 and Figure 30, the insignificant bias indicates the agreement between measurements obtained from Mobilab-Duo and those from the comparative measuring technique. The mean bias between the device used in GNRC hospital and Mobilab-Duo was 7.48 mg/dL for UREA, and -0.09 U/L for AST. Nearly all sample points were within the 95% confidence interval (±2 SD), 3 points for UREA, and 11 points for AST, which were likely due to random analytical error. Bland-Altman analysis further confirmed the overall agreement between the two methods.

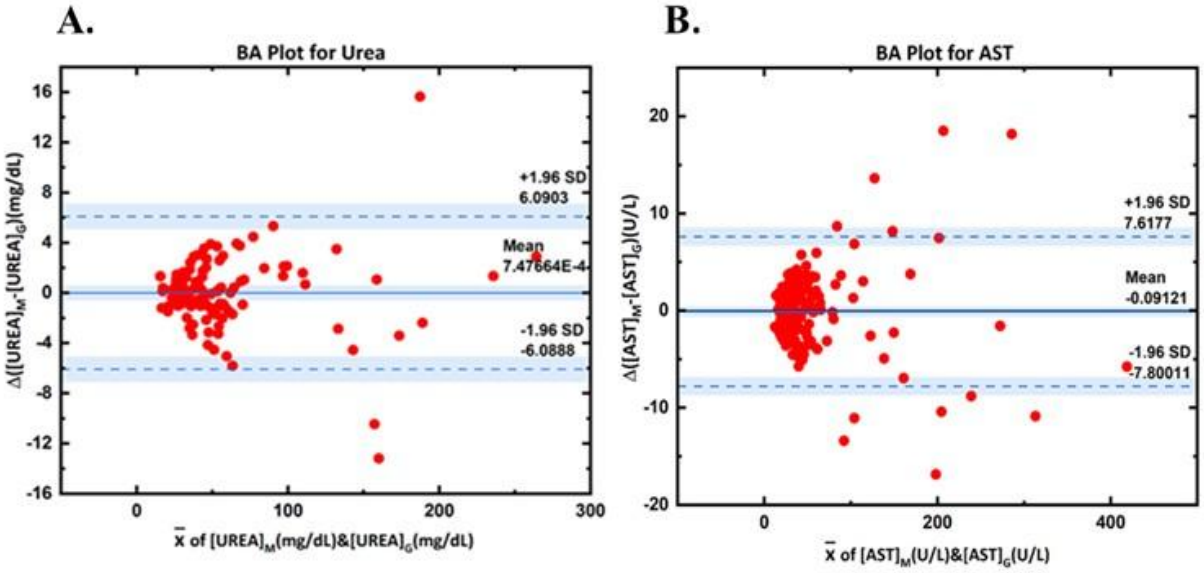

Figure 30. Bland–Altman agreement analysis between Mobilab-Duo and reference analyzer for urea and AST. (A) UREA: Differences between Mobilab-Duo and SDA 200 at GNRC hospital measurements $\Delta([UREA]^M - [UREA]^G)$ (mg/dL, y-axis) plotted against their mean ($[UREA]^M$, $[UREA]^G$, x-axis). Mean bias = 7.48 mg/dL, with 95% limits of agreement (LoA) at +6.09 and –6.09 mg/dL; three points fall outside the LoA due to random analytical error.

(B) AST: Differences $\Delta([AST]^M - [AST]^G)$ (U/L) plotted versus mean ($[AST]^M$, $[AST]^G$). Mean bias = –0.09 U/L, with 95% LoA at +7.62 and –7.80 U/L; eleven observations lie outside

the LoA, attributed to random analytical variation. Dotted blue lines denote the limits of agreement.

Figure 30 evaluates inter-method agreement between Mobilab-Duo and the standard biochemistry analyzer for serum urea and AST using Bland–Altman plots. For each analyte, the difference between paired measurements is plotted against their mean to visualize bias and dispersion across the tested range. Urea shows a small systematic bias with relatively narrow limits of agreement, indicating that Mobilab-Duo readings are generally close to reference values, with a few outliers arising from random error. AST measurements exhibit near-zero mean bias and acceptable limits of agreement for clinical use, although some values fall outside the 95% limits. Overall, these plots confirm that Mobilab-Duo provides clinically comparable results to the reference analyzer for both renal (urea) and hepatic (AST) markers.

3.7.1.3 Paired t-test

Table 13 depicts the mean values of UREA and AST that are statistically similar between the methods used in GNRC hospital and Mobilab-Duo. This is corroborated by the Pearson correlation analysis, where the values for UREA (0.99) and AST (0.99) are close to 1. This suggests a strong relationship between the results obtained from Mobilab-Duo and those from GNRC hospital. The paired t-test for the Mobilab-Duo device yielded a p-value greater than the chosen significance level of 0.05 for all tested parameters (0.99 for UREA, and 0.98 for AST). These results strongly support the null hypothesis, indicating that the test outcomes from Mobilab-Duo are comparable to those obtained at GNRC hospital.

3.7.2 Method Validation

3.7.2.1 Linearity test

The graph (Figure 31) and Table 14 indicate that all data points (concentrations) ranging from 17.7 mg/dL to 144.3 mg/dL for Urea, and 31.2 U/L to 273.6 U/L for AST align along a straight line. This suggests that the Mobilab-Duo device provides accurate results across a wide range of concentrations for all parameters.

Table 14. Summary of Linearity in the Method Validation study for all parameters compared Between Mobilab-Duo and SDA 200 (GNRC hospital) for UREA, and AST.

Method Validation (Linearity Study)	Slope	Intercept	R^{2} [a)]	Linearity
Urea	2.14	-4.86	0.99	upto 144.3 mg/dL [b)]

Aspartate Aminotransferase	1.09	-2.89	0.99	upto 273.6 U/L[d)]

R^2=Coefficient of determination; [b)] mg/dL=milligram per deciliter; [c)] g/dL=gram per deciliter; [d)] Units per liter

Figure 31 presents method-comparison linearity analyses for urea and AST across a series of calibration levels. For both analytes, Mobilab-Duo measurements display a highly linear relationship with reference UV–Vis values, as reflected by $R^2 = 0.99$ in each case. The slopes close to unity and modest intercepts indicate that Mobilab-Duo accurately tracks changes in concentration or activity over the tested analytical range. These results confirm that the device maintains proportional response for both renal (urea) and hepatic (AST) markers, supporting its suitability for quantitative point-of-care testing.

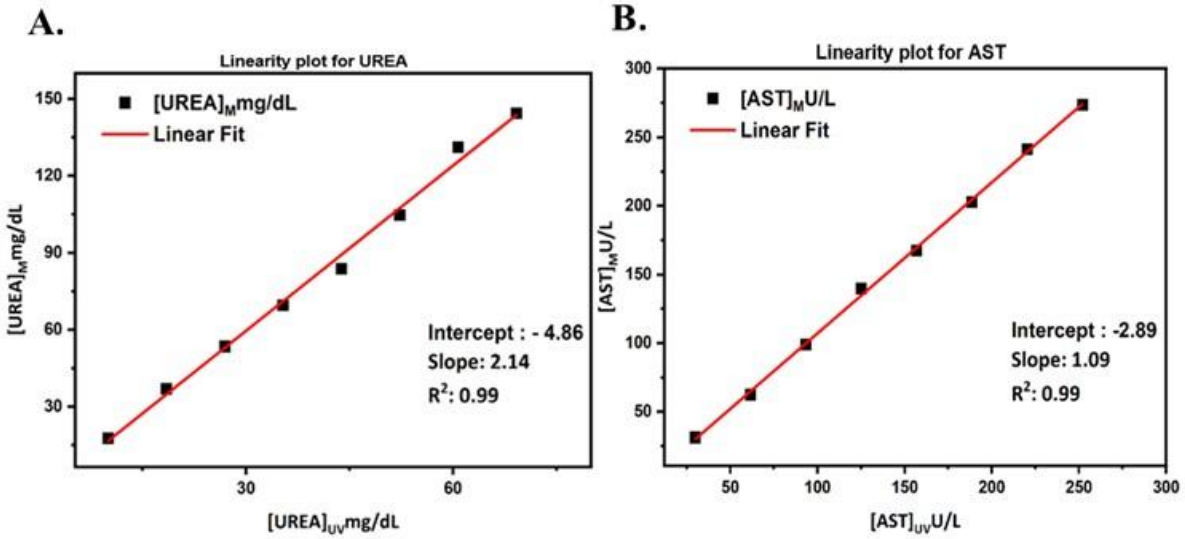

Figure 31. Linearity plots comparing Mobilab-Duo with UV–Vis spectrophotometer for urea and AST. (A) UREA: Mobilab urea readings $[UREA]^M$ (mg/dL, y-axis) plotted against UV–Vis values $[UREA]^{UV}$ (mg/dL, x-axis), yielding a linear relationship with slope = 2.14, intercept = –4.86, and $R^2 = 0.99$. (B) AST: Mobilab AST activities $[AST]^M$ (U/L) plotted versus UV–Vis readings $[AST]^{UV}$ (U/L), showing a linear fit with slope = 1.09, intercept = –2.89, and $R^2 = 0.99$.

3.7.2.2 Analytical sensitivity

Analytical sensitivity of the device was evaluated by determining the Limit of Blank (LOB) and Limit of Detection (LOD) for Urea and Aspartate Aminotransferase (AST). The LOB represents the highest apparent analyte concentration expected when replicates of a blank sample are tested, while the LOD indicates the lowest analyte concentration that can be

reliably distinguished from the blank. For Urea, the LOB was found to be 4.30 mg/dL, and the corresponding LOD was 7.88 mg/dL. For AST, the LOB and LOD were determined to be 9.60 U/L and 28.35 U/L, respectively. These values demonstrate that the device is capable of detecting low concentrations of both analytes with acceptable analytical confidence (Table 15). Analytical sensitivity for hemoglobin (HB) could not be evaluated due to the unavailability of appropriate control whole blood materials required for LOB and LOD determination. Overall, the observed LOD values indicate satisfactory low-end sensitivity of the Mobilab system when compared with the reference SDA 200, confirming its suitability for routine clinical measurement of Urea and AST.

Table 15. Summary of Analytical Sensitivity in the Method Validation study for all parameters compared between Mobilab-Duo and SDA 200 (GNRC Hospital) for UREA and AST.

Method Validation (Analytical Sensitivity)	**LOB[a)]**	**LOD[b)]**
Urea	4.30 mg/dL	7.88 mg/dL[c)]
Aspartate Aminotransferase (AST)	9.60 U/L	28.35 U/L[e)]

a) Limit of Blank; b) LOD=Limit of Detection; c) mg/dL=milligram per decilitre; d) Units per litter

3.7.2.3 Precision test

Using Level 1 and Level 3 Bio-Rad control serum over 20 repeats, the coefficient of both serum and whole blood. By generating real-time, digitally stored patient results at the point of care, Mobilab-Duo can significantly strengthen community-level healthcare delivery, particularly in resource-limited environments where access to centralized laboratories is constrained. The device's rapid turnaround time, portability, and intuitive operation enable timely clinical decision-making in PHCs, CHCs, MMUs, and outreach camps, where delays in laboratory reporting often lead to missed opportunities for early intervention. In the longer term, such POCT solutions can contribute to reduced healthcare costs by minimizing repeat visits, avoiding unnecessary referrals, shortening hospital stays, and optimizing use of scarce diagnostic infrastructure.

The validation studies thus establish Mobilab-Duo as a reliable dual-analyte POCT device with performance comparable to conventional benchtop analyzers. Its dual-slot configuration

represents a meaningful advancement over the single-slot Mobilab-Uni, allowing simultaneous or sequential testing of AST and Urea on the same platform, thereby reducing per-patient testing time and enabling integrated assessment of liver and kidney health in a single encounter. This combination of analytical robustness, operational simplicity, and field readiness positions Mobilab-Duo as a strong candidate for scaling within decentralized diagnostic networks.

3.9. Advantages

(i) **Dual-analyte testing**

Mobilab-Duo features a dual-slot architecture that supports simultaneous or sequential measurement of AST and Urea as kinetic enzymatic assays in the UV range. In contrast, Mobilab-Uni is a single-slot system designed primarily for endpoint assays such as glucose, triglycerides, creatinine etc. in the visible range. Mobilab-Duo overcomes this limitation by providing two dedicated slots, one optimized for endpoint reactions and the other for kinetic reactions, covering both visible and UV wavelength ranges. This significantly improves efficiency by allowing an integrated assessment of wide range of parameters. For frontline clinicians and health workers, this means faster clinical decision-making, fewer missed opportunities for intervention, and a more comprehensive biochemical picture for each patient without increasing operational complexity. In busy PHCs, CHCs, and mobile medical units, where time and staffing are limited, such consolidation of tests into a dual-analyte format directly translates into higher throughput and better utilization of human and material resources.

(ii) **High analytical accuracy and clinical reliability**

Method comparison studies demonstrate that Mobilab-Duo achieves strong correlation with gold-standard laboratory analyzers ($R^2 > 0.9$), with acceptable bias and low coefficients of variation. This indicates that results generated at the point of care are sufficiently accurate for diagnostic and monitoring purposes, and can be interpreted in continuity with central laboratory data. The device's ability to produce reproducible readings across repeated runs and varying concentrations strengthens confidence among clinicians, supporting its use not only for screening but also for ongoing disease management. Importantly, such accuracy in a portable format helps bridge the quality gap between centralized laboratories and peripheral facilities.

(iii) **Low power consumption and portability**

Mobilab-Duo is designed with field constraints in mind, featuring compact dimensions and the ability to run on battery power. This makes the device suitable for deployment in rural health centres, outreach camps, mobile medical units, and disaster or emergency settings where grid electricity may be unstable or unavailable. Low power consumption also reduces dependence on inverters or generators, lowering operational costs and simplifying logistics. The ease of transport allows health programs to move the device between sites based on need, enabling dynamic allocation of diagnostic capacity during screening drives, health camps, or targeted NCD initiatives.

(iv) **User-friendly interface and simplified workflow**

The system incorporates an intuitive, guided user interface with clear prompts for each step of the testing process—sample loading, incubation, reading, and result interpretation. This minimizes the learning curve and allows nurses, laboratory technicians, and community health workers with limited formal training in biochemistry to perform tests reliably after a short orientation. Visual cues, error prompts, and standardized workflows help reduce operator-dependent variability and common pre-analytical and analytical errors. A streamlined workflow, with minimal pipetting and handling steps, also shortens the overall test cycle and improves user acceptance, which is critical for sustained use in busy primarycare environments.

(v) **Cost-effectiveness for community-level diagnostics**

By combining dual-analyte testing, low reagent volumes, and minimal infrastructure requirements, Mobilab-Duo offers an economically attractive alternative to conventional laboratory-based testing for peripheral and semi-urban settings. Reduced dependence on large analyzers, air-conditioned labs, and highly specialized staff lowers the overall cost per reportable result. Furthermore, on-site testing can prevent unnecessary referrals and repeat visits, thereby decreasing indirect costs such as patient travel, lost wages, and system-level expenditure on avoidable hospitalizations. When scaled within public health programs, the device's affordability and efficiency can support large screening and follow-up cohorts for liver and kidney diseases, contributing to better population-level outcomes at sustainable cost.

CHAPTER 4

CLINICAL VALIDATION OF THE INTEGRATED MOBICASE DIAGNOSTIC SYSTEM

Abstract

This chapter presents the design, integration, and multi-centre clinical validation of Mobicase, a fully integrated, battery-powered "lab-in-a-box" point-of-care testing (POCT) platform developed to enable decentralized biochemical diagnostics in resource-limited environments. Mobicase consolidates the Mobilab analyzer with essential pre-analytical and analytical peripherals, including a centrifuge (Mobifuge), mixer (Mobimix), incubator (Mobicube), calibrated micropipettes, and a smartphone-based digital interface, enabling complete sample-to-report workflows at the point of care without dependence on external laboratory infrastructure.

Clinical validation was conducted at two tertiary hospitals using both dry and wet chemistry reference analyzers—Vitros 5600 (GMCH) and Siemens Dimension 200 (GNRC). Parameters evaluated included triglycerides, creatinine, total bilirubin, glucose, hemoglobin, and total protein. Across all analytes, Mobicase demonstrated strong analytical agreement with reference systems, with correlation coefficients (R^2) ranging from 0.90 to 0.96, diagnostic accuracy exceeding 90%, and bias maintained within ±6%. Precision studies showed stable repeatability with low coefficients of variation. Field usability trials in primary health centres and outreach camps confirmed reliable operation by minimally trained healthcare workers under variable power and environmental conditions.

Comparative analysis against existing POCT platforms highlights Mobicase's unique capability to integrate centrifugation, mixing, incubation, biochemical measurement, and digital reporting within a single portable system. The results confirm that Mobicase achieves laboratory-grade analytical performance while overcoming key infrastructural, logistical, and manpower barriers that limit conventional diagnostics in low-resource settings.

Manuscript is under preparation

4.1 Introduction

The development of point-of-care testing (POCT) devices in this work has followed a systematic, iterative pathway aimed at meeting the increasing demand for rapid, reliable, and decentralized diagnostics in both clinical and field environments. This evolution from single analyte capability to a fully integrated diagnostic ecosystem aligns with global efforts to bring laboratory-quality testing closer to patients, particularly in regions where access to centralized laboratories is limited or delayed.

The first stage of development resulted in Mobilab-Uni, a compact portable POCT platform designed to measure five clinically essential biomarkers: total bilirubin, creatinine, triglycerides, glucose, and hemoglobin. These analytes were chosen for their central roles in metabolic, renal, hepatic, and hematologic assessment in NCD and acute-care pathways. Mobilab-Uni combined disposable cuvettes/microfluidic cartridges with a smartphone-based optical readout system, enabling quantitative biochemical assays with precision and accuracy comparable to bench analyzers when evaluated in laboratory and limited field studies . Battery operation, small form factor, and a simplified user interface allowed deployment in primary health centers, emergency units, rural clinics, and mobile medical camps, establishing UNI as a practical frontline diagnostic solution and creating a modular hardware–software architecture for further expansion.

Building on this foundation, a more focused organ-function device, Mobilab-Duo, was developed to address combined liver–kidney screening needs at the point of care. By enabling parallel measurement of AST (a key indicator of hepatocellular injury) and urea (a fundamental marker of renal excretory function), Mobilab-Duo introduced dual-analyte testing within a single optical platform, thereby reducing turnaround time and increasing patient throughput. The system incorporated refined signal-processing algorithms, improved temperature and timing control for kinetic and endpoint assays, and optimized reagent formulations to enhance stability in field conditions. Method-comparison and precision studies showed strong correlation with reference analyzers and stable performance across a range of operating environments, demonstrating that the Mobilab architecture could scale from general multi-analyte screening to more specialized diagnostic workflows.

The transition from UNI to Duo highlighted a critical insight: while portable analyzers substantially improve access to testing, true decentralization requires integration of the entire pre-analytical and analytical workflow. If operators must still depend on external centrifuges, mixers, incubators, or grid power, many of the logistical barriers remain. In response,

development efforts progressed toward an all-inclusive platform Mobicase designed as a self-contained, mobile diagnostic laboratory.

Mobicase centralizes the Mobilab-Duo analyzer together with all essential peripherals: Mobimix, a compact mixer for reagent–sample homogenization; Mobifuge, a battery powered mini-centrifuge for plasma/serum separation; Mobicube, a temperature-controlled incubator for enzyme-based assays; calibrated micropipettes and consumables; and an Android device with OTG capability for user interaction, data storage, cloud connectivity, and report generation. By integrating sample preparation, incubation, analysis, and digital reporting into a single portable kit, Mobicase enables end-to-end POCT workflows in locations where conventional laboratory infrastructure is absent.

The overarching aim of Mobicase is to evaluate whether such a fully integrated POCT platform can consistently deliver laboratory-grade accuracy, reproducibility, and reliability under real-world conditions. Clinical validation campaigns across tertiary hospitals, district health centers, and rural outreach camps have been designed to assess not only analytical performance, but also usability, portability, robustness to temperature and power fluctuations, and operator-friendliness in settings with limited technical expertise. This comprehensive evaluation framework positions Mobicase as a potentially transformative solution for decentralized diagnostics, capable of strengthening health systems by bringing high-quality biochemical testing directly to the point of care.

4.2 Rationale for Mobicase Development

The development of Mobicase was driven by the recognition that effective diagnostic decentralization requires more than innovative analyzers, it requires fully integrated diagnostic ecosystems. Although Mobilab-Uni and Duo successfully demonstrated multianalyte and parallel-analyte testing capabilities, their deployment in real-world field settings revealed key limitations. Both devices required peripheral equipment such as mixers, centrifuges, incubators, and mobile power sources to complete the diagnostic workflow. These dependencies restricted widespread adoption, particularly in remote or underserved areas where basic laboratory infrastructure is minimal or absent.

Healthcare delivery in rural and semi-urban India is often hindered by constraints such as irregular power supply, lack of trained laboratory personnel, limited access to consumables, and the absence of standardized equipment for sample preparation. These systemic gaps reduce the effectiveness of portable analyzers when deployed in isolation. As a result, the

practical utility of earlier Mobilab prototypes was limited by their reliance on fragmented and externally sourced equipment.

To address these challenges comprehensively, Mobicase was conceptualized as a lab-in-a-box, integrating every essential component required for biochemical testing within a single rugged, portable, and battery-operated unit. The rationale behind this approach includes:

(a) Eliminating workflow fragmentation: By housing all required peripherals, Mobicase ensures that the full sample-to-result workflow can be executed seamlessly by a frontline health worker, even in the absence of a laboratory setup.

(b) Enabling true portability: All devices, consumables, power backups, and digital interfaces are consolidated, allowing healthcare workers to carry the entire diagnostic facility to remote villages, disaster zones, or temporary health camps.

(c) Enhancing reliability and standardization: pre-calibrated devices, lyophilized reagents, and standardized accessories reduce human error and ensure consistent performance across sites.

(d) Supporting digital health integration: Built-in smartphone connectivity allows realtime data recording, cloud-based monitoring, integration with electronic medical records, and seamless transmission of reports through national digital health networks.

(e) Facilitating large-scale community screening: The portability and ease of operation make Mobicase ideal for public health programs focused on non-communicable diseases (NCDs), maternal and child health, infectious disease surveillance, and workforce health screening.

(f) Reducing infrastructural dependency: With a self-sufficient architecture, Mobicase overcomes barriers such as power shortages, untrained manpower, absence of stable laboratory environments, and logistics constraints associated with transporting biological samples.

By unifying analytical instruments, preparatory tools, and digital connectivity within a single platform, Mobicase is designed to bridge the gap between laboratory diagnostics and field-level healthcare delivery. It not only enhances diagnostic accessibility but also supports timely decision-making, early detection of diseases, and improved patient outcomes, critical components of modern public health.

4.3 Device specification

The Mobicase device is a compact, battery-operated point-of-care testing (POCT) platform specifically engineered to deliver rapid biochemical diagnostics in decentralized,

low-resource, and field-based settings. It has been designed as a fully integrated, modular system that can function independently of conventional laboratory infrastructure, thereby addressing critical gaps in access to timely diagnostics. Figure 32 illustrates both the external and internal configurations of the Mobicase system. In its closed configuration (Figure 32, i), the entire setup is housed within a rugged, portable hard case measuring approximately 53.34 cm in length and 35.56 cm in height.

This protective casing is engineered to withstand transport, rough handling, and variable environmental conditions, ensuring that the internal components remain safe and operational during field deployment, outreach camps, or inter-facility movement.

Figure 32. Mobicase: integrated portable kit for Mobilab-based point-of-care testing. (i) Closed view of the Mobicase, a portable carry unit measuring ~53.34 cm in length and 35.56 cm in height. (ii) Open view showing internal arrangement of components: (1) Mobicube – compact battery-powered incubator for simultaneous incubation of multiple samples; (2) Android smartphone running the "Mobilab Connect" app for device control and data processing; (3) Analyzer – battery-operated Mobilab unit connected via OTG cable for biochemical measurement; (4) Mobimix – automated mixer for uniform sample–reagent blending; (5) Micropipette – for precise sample and reagent dispensing; (6) Mobifuge – portable centrifuge for serum separation from whole blood.

Figure 32 illustrates the Mobicase configuration that consolidates all essential hardware required for Mobilab-based point-of-care biochemistry testing into a single portable kit. In

the closed state, the case provides a rugged, compact form factor suitable for field transport. When opened, the layout organizes the Mobicube incubator, Mobilab analyzer, Mobimix mixer, Mobifuge centrifuge, micropipette, and smartphone interface in a workflow-friendly manner—from blood collection and serum separation to incubation, mixing, analysis, and digital result display. This integrated design enables a complete "lab-in-a-box" solution that can be deployed in primary health centres, outreach camps, and other resource-limited settings.

When the case is opened (Figure 32, ii), the internal layout reveals a carefully organized, fully integrated diagnostic workstation comprising six key battery-powered components. The internal arrangement is designed for intuitive workflow, minimizing setup time and operator confusion:

(a) **Mobicube (Incubator):** Mobicube is a battery-operated external incubator that provides precise temperature control for biochemical assays. It can accommodate multiple cuvettes or reaction vessels simultaneously, allowing parallel incubation of several patient samples. Stable incubation conditions are essential for enzyme-based reactions—such as AST, Urea, and other kinetic or endpoint assays—ensuring reproducible reaction rates and accurate quantitative measurements.

(b) **Android Smartphone (Control and Display Unit):** An Android smartphone functions as the central control, processing, and display unit. It runs the dedicated "Mobilab Connect" application, which manages the entire testing workflow—from test selection and patient data entry to real-time data acquisition, processing, and report generation. The smartphone interfaces digitally with the analyzer through a USB OTG connection, enabling secure bidirectional communication, result visualization, storage, and optional cloud synchronization.

(c) **Analyzer (Core Spectrophotometric Unit):** The analyzer is a portable, batterypowered spectrophotometric device at the heart of the Mobilab platform. It is capable of performing both endpoint and kinetic assays across visible and UV wavelength ranges, depending on the cartridge and test type. The analyzer measures absorbance changes associated with biochemical reactions and transmits raw or processed data to the smartphone application for further analysis and interpretation. This modular coupling of optical hardware with a smartphone-based interface allows for continuous upgradability of algorithms and test menus via software updates.

(d) **Mobimix (Automated Mixer):** Mobimix is a compact, battery-driven mixing device designed to ensure homogeneous mixing of biological samples (whole blood or serum/plasma) with reagents in cuvettes or reaction cartridges. Uniform mixing is crucial for achieving consistent reaction kinetics and minimizing pre-analytical variability. By automating this step, Mobimix reduces operator dependency and improves reproducibility across tests, especially in high-throughput or high-variability field conditions.

(e) **Micropipettes (Precision Liquid Handling Tools):** Calibrated micropipettes of appropriate volume ranges are included for accurate aspiration and dispensing of blood samples, controls, calibrators, and reagents. Precise volumetric handling is a fundamental requirement in quantitative biochemistry; therefore, the inclusion of dedicated pipettes within Mobilab ensures that users are not dependent on external tools of unknown calibration status.

(f) **Mobifuge (Mini-Centrifuge):** Mobifuge is a compact, battery-operated centrifuge incorporated into the system to enable onsite separation of serum or plasma from whole blood, where required by specific assays. This capability allows complete preanalytical processing at the point of care, eliminating the need to send samples to distant laboratories for basic preparation steps and thereby reducing turnaround time and sample degradation risks.

(g) The fact that all core components—Mobicube, analyzer, Mobimix, Mobifuge, and the smartphone interface are battery-powered makes Mobilab particularly well-suited for environments where uninterrupted mains electricity is unreliable or unavailable. This includes rural primary health centres, mobile medical units, emergency response setups, and community outreach camps.

The portability, automated workflow, and integrated digital interface make Mobilab a robust, field-ready diagnostic solution. It functions as a true “lab-in-a-box,” enabling

Figure 33 summarizes the standardized pre-analytical workflow used to generate matched serum samples for method comparison between the Mobicase device and a reference laboratory analyzer. After venous blood collection, controlled clot formation and centrifugation yield clear serum, which is aliquoted for parallel testing on both platforms. These paired measurements were then used to evaluate analytical sensitivity, linearity, intraday precision, sensitivity, specificity, and diagnostic accuracy across multiple biochemical parameters in human serum, providing a robust framework for validating

Mobicase's performance in a clinical context. The workflow (Figure 33) begins with sample collection, typically finger-prick blood or venous blood, where necessary. The sample is either directly loaded into cartridges or processed using Mobimix and Mobifuge for plasma separation. The cuvette containing the sample and reagents is then inserted into the Mobilab device, where the colorimetric reaction is detected by LED-photodiode sensors. Results are processed by the embedded microcontroller and transmitted to the Android interface for display. IoT functionality ensures that results can be uploaded to a central server or sent to remote physicians for teleconsultation. Mobicase is an integrated laboratory solution comprising the Mobilab-Duo device, Mobimix (mixer), Mobifuge (centrifuge), Mobicube (incubator), micropipettes, and an OTG-enabled Android phone for Mobilab-Duo. This integrated workflow ensures that Mobicase functions as a standalone diagnostic laboratory, eliminating the need for external equipment and infrastructure.

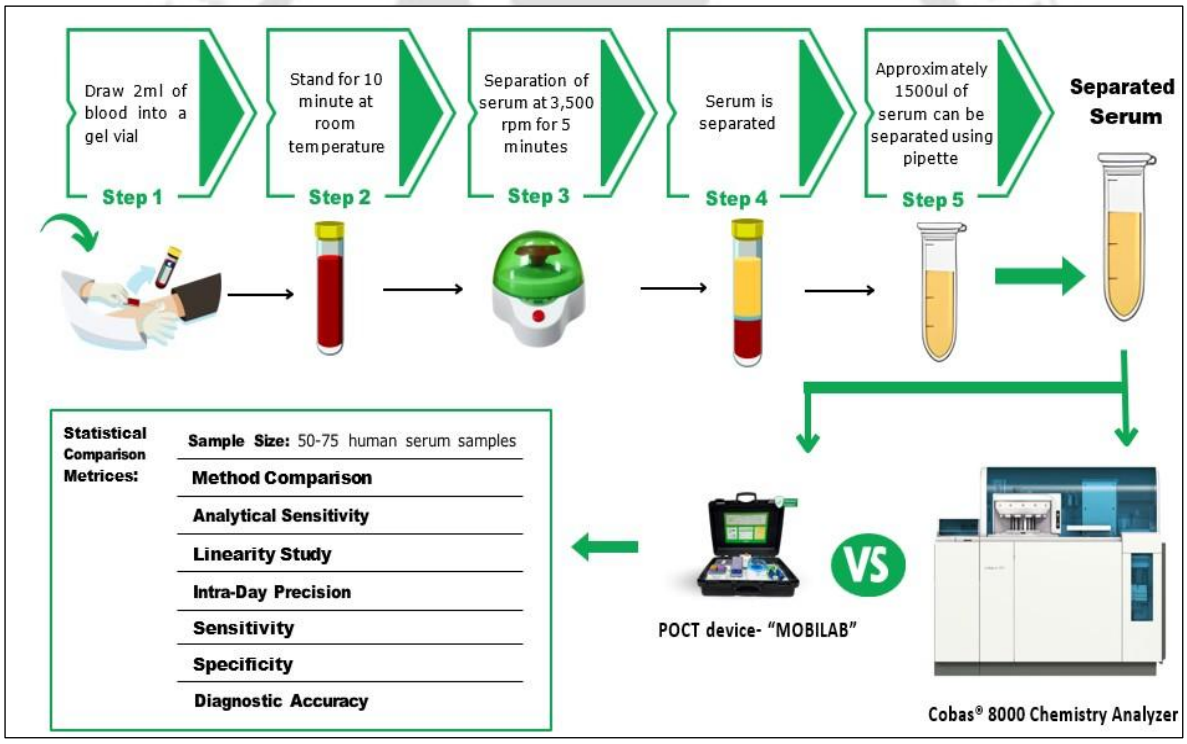

Figure 33. Workflow for serum preparation and comparative analysis using the Mobicase point-of-care device and a standard laboratory analyzer. The schematic outlines the stepwise process: (1) collection of 2 mL venous blood into a gel vial; (2) clotting at room temperature for 10 minutes; (3) centrifugation at 3,500 rpm for 5 minutes to separate serum; (4) isolation of the serum layer; and (5) transfer of approximately 1,500 µL of serum by pipette for analysis on both the Mobicase POCT device and a conventional biochemistry analyzer.

4.4 Methodology of Clinical Validation

Clinical validation of the Mobicase platform was designed as a multi-centre, multi-setting study to rigorously evaluate its analytical accuracy, clinical utility, and operational scalability. The strategy combined controlled comparisons against high-end laboratory analyzers in tertiary-care hospitals with real-world deployment in primary health centres and mobile health camps.

4.4.1 Validation in Tertiary-Care Hospital Settings

Two tertiary hospitals in Guwahati were selected as primary validation sites, each equipped with a different category of reference biochemistry analyzer (dry vs. wet chemistry). This allowed a comprehensive assessment of Mobicase performance across diverse analytical technologies.

1. Guwahati Medical College and Hospital (GMCH):

At GMCH, clinical validation focused on comparing Mobicase results with those obtained from the Vitros 5600 Integrated System, a dry biochemistry analyzer widely regarded as a reference standard in clinical laboratories.

Sample type and handling: Residual patient serum samples, collected as part of routine diagnostic workup, were used for method comparison. Only samples with adequate volume and without visible haemolysis, icterus, or lipemia beyond acceptable limits were considered.

Parameters evaluated: The following key biochemical parameters were selected for comparison due to their broad clinical relevance in NCD and acute-care pathways:

(a) Triglycerides
(b) Creatinine
(c) Total bilirubin
(d) Glucose
(e) Hemoglobin

For each eligible sample, aliquots were tested in parallel on Mobicase and on the Vitros 5600. Care was taken to minimize time delay between the two measurements to reduce preanalytical variability due to sample degradation or metabolic changes. All tests were performed following the respective standard operating procedures (SOPs) of the devices.

2. Guwahati Neurological Research Centre (GNRC):

At GNRC Hospital, Mobicase was validated against the Siemens Dimension 200, a highthroughput wet chemistry analyzer commonly used in clinical biochemistry laboratories.

Sample type and handling: Similar to GMCH, validation utilized leftover patient serum samples from routine testing, with inclusion criteria based on adequate volume and acceptable sample quality.

Parameters evaluated: The parameters selected at GNRC primarily represented liver function and protein status:

(a) Total bilirubin

(b) Albumin

(c) Total protein

Testing protocol: Each sample was analyzed on Mobicase and Siemens Dimension 200 in close temporal proximity. All measurements were carried out by trained laboratory personnel under standard laboratory conditions, ensuring that any observed differences reflected device performance rather than procedural bias.

4.5 Results and Validation

The results of the clinical validation studies (summarized in Table 14) demonstrate that Mobicase delivers analytical performance comparable to established gold-standard laboratory analyzers across multiple clinically important biochemical parameters. The validation was conducted at two tertiary-care centres, GMCH and GNRC, using different reference analyzer technologies (dry and wet chemistry), thereby providing a robust assessment of the system's versatility and reliability.

At Guwahati Medical College and Hospital (GMCH), Mobicase was evaluated against the Vitros 5600 Integrated System, a high-end dry biochemistry platform. Parameters assessed included triglycerides (TGL), creatinine (CRE), total bilirubin (TBIL), glucose (GLU), and hemoglobin (HB). The correlation coefficients (R^2) between Mobicase and the Vitros 5600 ranged from 0.91 for hemoglobin to 0.96 for glucose, indicating strong linear agreement across the analytical range. Such R^2 values reflect that changes in Mobicase readings closely tracked those of the reference analyzer, a key requirement for clinical interchangeability.

In terms of diagnostic accuracy, the mean percentage agreement between Mobicase and Vitros 5600 values exceeded 90% for all tested parameters, suggesting that the device is capable of correctly classifying the majority of patient results relative to the reference method. Importantly, bias values remained within ±5%, indicating that systematic differences between Mobicase and the Vitros 5600 were small and within commonly accepted clinical limits. This low level of bias, combined with high correlation and accuracy, supports the use of Mobicase as a reliable alternative to centralized dry chemistry analyzers in situations where immediate laboratory access is unavailable or impractical.

At the Guwahati Neurological Research Centre (GNRC), Mobicase performance was validated against the Siemens Dimension 200, a widely used wet chemistry analyzer. Parameters evaluated at this site included total bilirubin (TBIL), total protein (TP), and creatinine (CRE). Once again, strong agreement was observed between Mobicase and the reference instrument, with correlation coefficients (R^2) in the range of 0.90–0.94. These results confirm that the linear relationship between Mobicase and the Dimension 200 remained robust across different analytes and different reference technologies.

Accuracy values consistently exceeded 90%, emphasizing that Mobicase's classification performance relative to the reference analyzer was clinically acceptable for all tested parameters. The bias remained within ±6%, which is considered acceptable for most routine biochemical measurements and supports the use of Mobicase results for both screening and follow-up in routine clinical practice. Additionally, coefficients of variation (CV%) derived from repeatability and reproducibility studies demonstrated stable precision over repeated trials, indicating that the system delivers consistent results across time and varying operating conditions.

Table 16. Summary of Performance Metrics for Mobicase Clinical Validation

Validation Site	Parameters Tested	Reference Analyzer	Correlation Coefficient (R^2)	Accuracy (%)	Bias (%)
GMCH	TGL, CRE, TBIL, GLU, HB	Vitros 5600 (Dry Biochemistry)	0.91-0.96	>90	±5
GNRC	TBIL, TP, and CRE	Siemens Dimension 200 (Wet Biochemistry)	0.90-0.94	>90	±6

Beyond quantitative performance, field usability trials played a crucial role in evaluating the real-world applicability of Mobicase. These trials were conducted in primary health centres (PHCs) and mobile health camps, where healthcare workers with minimal formal laboratory training were asked to operate the system after a brief orientation.

In field usability trials, healthcare workers with minimal training were able to operate Mobicase successfully. Feedback highlighted the ease of workflow, portability, and the practicality of having integrated accessories like Mobimix and Mobifuge. The device's ability

to function in resource-limited settings without stable electricity was regarded as a major strength, particularly for rural outreach programs.

4.6 Discussion

The clinical validation results demonstrate that Mobicase performs with high analytical accuracy and precision, showing strong correlation with both dry chemistry (Vitros 5600) and wet chemistry (Siemens Dimension Analyser) analyzers. This confirms that a fully integrated POCT system can achieve laboratory-grade analytical standards even in resource-limited environments, provided that assay protocols, optical systems, and quality-control workflows are rigorously optimized. Unlike its predecessors: Mobilab-Uni, Mobilab-Duo, and Mobicase not only performs biochemical analysis but also integrates centrifugation, mixing, incubation, measurement, and digital interpretation into a single portable ecosystem, thereby eliminating major infrastructural bottlenecks and reducing user dependency on external equipment.

Globally, several POCT platforms are available, including the Abbott i-STAT, Roche Cobas b 101, Alere/Abbott Afinion 2, Abaxis Piccolo Xpress, and HemoCue systems. Each device offers distinct advantages but also exhibits important limitations in terms of test-menu diversity, dependence on external infrastructure, cold-chain requirements, and per-test cost. For example, the Abbott i-STAT provides high analytical accuracy and cartridge-based convenience but requires strict cartridge storage conditions and offers a relatively narrow biochemical test range. The Roche Cobas b 101 supports HbA1c and lipid profiling but is not designed as a broad multiparameter biochemistry platform. The Afinion 2 analyzer similarly has a limited panel and demands controlled storage conditions for its cassettes. The Abaxis Piccolo Xpress offers comprehensive chemistry panels, yet it depends on stable mains power and specific rotor-compatible discs, which constrains its use in highly mobile or low infrastructure settings. HemoCue devices deliver excellent accuracy for single parameters such as hemoglobin or glucose but require separate instruments or cuvettes for each analyte, limiting scalability for multi-analyte workflows.

In comparison, Mobicase distinguishes itself as a true “lab-in-a-box,” combining the analyzer and all critical peripherals: mixer, centrifuge, incubator, pipettes, and digital interface into a single, battery-powered, field-deployable unit capable of functioning in health camps, rural clinics, mobile programs, and emergency or disaster zones.

The role of POCT in expanding diagnostic reach in low- and middle-income countries (LMICs) has been repeatedly emphasized by the World Health Organization and other global health bodies. Rapid, decentralized testing is known to reduce diagnostic delays, improve

triage, and lower overall disease burden by enabling timely treatment initiation and follow-up. With accuracy consistently above 90% across multiple biochemical parameters in validation studies, Mobicase serves as an effective intermediary between high-end laboratory analyzers and frontline healthcare needs. When integrated with IoT-based data sharing and telemedicine workflows, it supports remote clinician review, longitudinal tracking, and linkage to care, aligning with national digital health initiatives and global recommendations for strengthening community-level diagnostics.

Despite its strong performance, several practical challenges were identified. Environmental and climatic stressors such as high humidity, direct sunlight, and dust were found to impact reagent stability and, in some cases, optical readings, consistent with prior reports on the deployment of POCT systems in tropical and subtropical regions. While lyophilization and improved stabilizer chemistry enhance shelf life and robustness, extreme climatic conditions still pose a risk to enzyme-based assays and chromogenic reagents, necessitating better packaging solutions and humidity-resistant formulations. Field operations also revealed variability in pre-analytical steps such as pipetting technique, sample mixing, and timing, reinforcing literature observations that operator-dependent variability remains one of the major challenges in POCT implementation, particularly in decentralized settings with minimal formal laboratory training [181].

Battery-powered operation, though a major advantage for off-grid use, presented limitations during prolonged outreach camps, where intensive use over extended hours exhausted available charge, an issue similarly reported for other portable diagnostic platforms and field medical devices [182]. Potential solutions include larger-capacity lithium-ion packs, modular battery swapping, and integration with solar charging systems [182,183]. Intermittent or absent network connectivity in remote regions occasionally hindered real-time IoT data upload and teleconsultation, echoing broader digital health challenges reported in rural LMIC settings [184]. Implementing robust offline data-caching with asynchronous upload when connectivity becomes available is a practical strategy to mitigate this limitation [183,184].

Overall, Mobicase demonstrates analytical performance comparable to established laboratory analyzers while addressing key barriers in decentralized diagnostics, including power constraints, lack of sample-processing equipment, and workflow fragmentation [170,171]. Its integrated design, portability, multi-analyte capability, and digital connectivity offer a scalable solution for widespread deployment in primary health centres, mobile units,

emergency response, and rural outreach programs. Similar integrated POCT and lab-on-a-box models have shown transformative diagnostic impact in various global contexts [185]. Mobicase aligns with this trajectory and is particularly well-suited to LMIC health ecosystems where the need for robust, field-ready diagnostics is most acute [177,185].

4.7 Conclusion

This chapter presented the comprehensive clinical validation of Mobicase, an advanced, fully integrated portable diagnostic system engineered to function as a complete lab-in-a-box for decentralized testing. Through rigorous evaluation conducted at Gauhati Medical College & Hospital (GMCH) and GNRC Hospital, the device demonstrated high analytical accuracy, precision, and reliability, showing strong correlation with established wet and dry chemistry analyzers. Across all evaluated biochemical parameters, Mobicase consistently achieved diagnostic accuracy exceeding 90%, confirming that portable systems can attain laboratory grade analytical performance even in low-resource conditions.

Beyond analytical validation, extensive field usability assessments were performed in diverse operational environments, including community health camps and outreach settings. These trials highlighted Mobicase's suitability for primary healthcare centres, rural clinics, mobile medical units, and emergency response scenarios, owing to its compact design, battery-powered operation, low sample requirement, and minimal user dependency. The integrated workflow combining centrifugation, aliquoting, mixing, incubation, optical measurement, and digital interpretation within a single device significantly reduces preanalytical and operational errors commonly encountered in point-of-care testing (POCT).

Mobicase builds upon the progressive technological evolution of the Mobilab platform, synthesizing the modular capabilities of Mobilab-Uni (multi-analyte biochemical testing with single slot) and Mobilab-Duo (multi-analyte biochemical testing with dual slot) into one unified, scalable system. This consolidation marks a major advancement in portable diagnostics, enabling comprehensive biochemical analysis without reliance on external laboratory infrastructure, consumables, or specialized personnel.

The successful clinical validation not only establishes Mobicase as a reliable diagnostic tool but also underscores its role in bridging persistent diagnostic gaps in underserved and resource-constrained populations. By enabling early disease detection, rapid decision-making, and streamlined digital data integration through IoT connectivity, Mobicase aligns with national and global goals for strengthening community-level diagnostics and advancing universal health coverage.

Overall, the findings of this chapter affirm that Mobicase represents a transformative leap forward in the design, deployment, and scalability of point-of-care diagnostic technologies. Its demonstrated performance positions it as a viable, cost-effective solution capable of reshaping decentralized healthcare delivery and supporting large-scale public health initiatives.

In addition to analytical performance, practical considerations such as device cost, portability, and ease of operation are critical for the adoption of point-of-care diagnostic systems in decentralized healthcare settings. Compared to conventional automated clinical analyzers, which require substantial infrastructure, trained personnel, and high operational costs, the Mobilab platform is designed as a portable and low-power diagnostic system suitable for use in primary health centers, rural clinics, and mobile screening units. While a detailed techno-economic analysis was beyond the scope of the present study, preliminary assessments suggest that the simplified hardware architecture, reduced reagent consumption, and minimal infrastructure requirements could significantly lower the overall cost of diagnostic testing. Future studies may include a comprehensive techno-economic evaluation to further quantify the economic and operational advantages of the Mobilab platform in comparison with conventional diagnostic systems.

CHAPTER 5

CONCLUSIONS

5.1 Summary of Work

The present research was centred on the design, development, and clinical validation of portable point-of-care testing (POCT) devices with the overarching aim of addressing diagnostic challenges in resource-limited settings. Non-communicable diseases (NCDs), including liver, kidney, and metabolic disorders, account for a significant proportion of global morbidity and mortality. The lack of decentralized diagnostic infrastructure, particularly in rural and underserved regions, continues to limit early detection and timely management of these conditions. This work sought to overcome these barriers through the development of the Mobilab platform, which evolved progressively from device-specific solutions to a fully integrated diagnostic system.

In Chapter 2, the design and validation of Mobilab-Uni were presented. This device was capable of performing multiple biochemical tests glucose, triglycerides, total bilirubin, total protein, creatinine, and hemoglobin, within a compact and portable format. Validation against standard laboratory analyzers demonstrated diagnostic accuracy above 90%, with strong correlation coefficients ($R^2 > 0.9$). The results established the feasibility of multi-analyte diagnostics in a portable POCT device, thereby confirming its utility in primary healthcare environments.

Chapter 3 described the development of Mobilab-Duo, an extension of the Mobilab platform that introduced parallel testing of two key biomarkers: Aspartate Aminotransferase (AST) and Urea. This dual-slot design enabled simultaneous liver and kidney function testing, significantly reducing per-patient diagnostic time. Validation studies conducted against Roche Cobas and Siemens 200 analyzers demonstrated high reproducibility (CV < 7%), low bias (±5%), and strong correlation (R^2 0.92-0.96), confirming its capability to provide reliable organ-specific diagnostics at the point of care.

In Chapter 4, the research culminated in the development of Mobicase, a fully integrated lab-in-a-box diagnostic system. Mobicase incorporated not only the Mobilab analyzer but also essential peripherals, including Mobimix, Mobifuge, Mobicube, micropipettes, cartridges with lyophilized reagents, and an Android interface with OTG connectivity. Validation trials were conducted at Guwahati Medical College and Hospital (GMCH) and Guwahati Neurological Research Centre (GNRC), with comparisons against Vitros 5600 (dry biochemistry) and Siemens Dimension Analyzer 200 (wet chemistry) analyzers. Results demonstrated >90% diagnostic accuracy with correlation coefficients of 0.90-0.96 across multiple parameters. Field

trials further confirmed usability by minimally trained operators, portability, and independence from a stable electricity supply.

Collectively, the work established that the Mobilab platform, culminating in Mobicase, provides a scalable, reliable, and clinically validated solution for decentralized diagnostics. The devices developed in this study address the unmet need for affordable, portable, and integrated diagnostic systems suitable for both hospital-based validation and community-level healthcare delivery.

5.2 Key Contributions

The major contributions of this research include:

(a) Development and validation of Mobilab-Uni as a portable multi-analyte POCT device.

(b) Extension of the platform to Mobilab-Duo, demonstrating the feasibility of parallel analyte testing (AST and Urea) for liver and kidney health assessment.

(c) Conceptualization and realization of Mobicase, an integrated diagnostic system that combines analyzer, accessories, consumables, and data interface in a single portable case.

(d) Analytical and clinical validation of all devices against gold-standard laboratory analyzers, confirming diagnostic accuracy, reproducibility, and usability.

(e) Demonstration of device performance in real-world healthcare environments, including tertiary hospitals and rural field camps.

Table 17. Summary of Key Findings from Mobilab-Uni, Duo, and Mobicase

Device	Analytes Tested	Key Features	Validation Standard	Performance (Accuracy / R^2 / CV%)	Remarks
Mobilab-Uni	TBIL, CRE, TGL, GLU, HB	Single slot, multianalyte testing	Compared with conventional analyzers (e.g., Roche, Siemens)	Accuracy > 90%, R^2: 0.90-0.95, CV% < 8%	Demonstrated feasibility of a portable multi-analyte POCT device
Mobilab-Duo	AST, Urea	Dual-slot design enabling parallel testing	Compared with Roche Cobas and Siemens Dimension 200	Accuracy > 92%, R^2: 0.92-0.96, CV% < 7%	Enabled simultaneous organ-function (liver & kidney) testing

Mobicase	TBIL, CRE, TGL, GLU, HB, AST, Urea (expandable menu)	Integrated lab-in-a box (Mobilab + Mobimix + Mobifuge + Mobicube + Android device)	Validated at GMCH (Vitros 5600) and GNRC (Siemens Dimension Analyzer 200)	Accuracy > 90%, R^2: 0.90-0.96, CV% < 7%	Portable, field-ready, user-friendly; suitable for hospital & rural healthcare settings

5.3 Limitations

While the devices demonstrated strong performance, certain limitations were observed during the course of research:

(a) **Limited test panel:** Although multiple assays were validated, the devices do not yet encompass the full range of biochemical tests.

(b) **Reagent stability:** Lyophilized reagents improved shelf life but were still found to be sensitive to extreme environmental conditions such as high humidity and heat.

(c) **Clinical trial scale:** Validation studies were limited to specific hospitals and field camps; larger multicentre trials are required to confirm findings at scale.

5.4 Future Scope

The future scope of this work envisions the Mobilab platform evolving from a validated academic innovation into a fully scalable, collaborative, and industry-ready diagnostic ecosystem. Building on the outcomes of this research, upcoming efforts should focus on broadening the diagnostic test menu by integrating assays such as ALT, ALP, lipid subfractions, electrolytes, and inflammatory biomarkers to enhance clinical coverage across a wider range of diseases. Parallel advancements in reagent stabilization, ensuring resistance to temperature and humidity fluctuations, will be critical for maintaining analytical performance in resource limited and field-based settings.

Integrating artificial intelligence and advanced data analytics into the Mobilab system presents significant opportunities for automated result interpretation, predictive diagnostics, and personalized decision support. Additionally, IoT-enabled telemedicine connectivity will facilitate seamless data transfer, remote consultations, and interoperability with digital health platforms such as electronic health records and national health registries. These capabilities together can enable a connected, intelligent, and responsive point-of-care diagnostic network.

For widespread clinical adoption, multicentre validation studies across varied geographies, demographics, and healthcare infrastructures will be essential to establish regulatory acceptance and real-world robustness. Furthermore, strong collaborations with policymakers, government agencies, NGOs, and healthcare institutions will support commercial scaling, distribution, and integration into public health programs.

While the Mobilab platform offers advantages such as portability, affordability, and reduced sample requirements, conventional automated clinical chemistry analyzers (e.g., Roche Cobas, Abbott Architect, Siemens Dimension) remain essential for high-throughput laboratory diagnostics. These systems provide extensive test menus, automated quality control, and the ability to process large numbers of samples in centralized laboratories. In contrast, Mobilab is designed to complement these systems by enabling diagnostic testing in resource-limited settings such as rural clinics, mobile health units, and primary healthcare centers. Thus, Mobilab serves as a decentralized diagnostic solution bridging the gap between laboratory-based testing and field-level healthcare delivery.

Importantly, although Mobilab originated from academic research, its modular and scalable architecture positions it as the foundation for numerous future startups, industry partnerships, and multidisciplinary collaborations. The platform offers a fertile ground for codevelopment of new assays, biosensors, digital health tools, and integrated care pathways. As a result, Mobilab is poised not only to advance decentralized diagnostics but also to catalyze innovation, entrepreneurship, and industrial growth in the broader healthcare technology landscape.

In addition to biochemical markers for non-communicable diseases, the inclusion of infection and inflammation markers such as **C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and white blood cell (WBC) count** would further enhance the clinical utility of the Mobilab platform in remote healthcare settings. These parameters are important for identifying infections and guiding antibiotic therapy. Therefore, future versions of the Mobilab system may incorporate assays for CRP, ESR, and WBC estimation to enable more comprehensive point-of-care diagnostics.

Table 18. Future Scope of Mobilab Platform Development

Future Direction	Description	Expected Impact
Expansion of Test Menu	Addition of more biochemical assays (Amylase, Lipase, CRP, Iron, Thyroid, electrolytes)	Broader diagnostic coverage for NCDs and acute conditions

Reagent Stability	Development of advanced lyophilized or nano-formulated reagents resistant to heat and humidity	Reliable performance in extreme field conditions
Integration with AI & Data Analytics	Embedding algorithms for automated result interpretation, predictive diagnostics, and clinical decision support	Enhances diagnostic accuracy and supports early disease detection
IoT & Telemedicine Connectivity	Cloud-enabled data transfer, EHR integration, and remote physician access	Strengthens rural–urban healthcare linkages and continuity of care
Large-Scale Multicentre Trials	Clinical validation across diverse geographies and populations	Establishes clinical robustness and regulatory approval
Commercial Scaling & Policy Adoption	Collaboration with government agencies, NGOs, and healthcare systems	Nationwide deployment in primary health centres and rural clinics

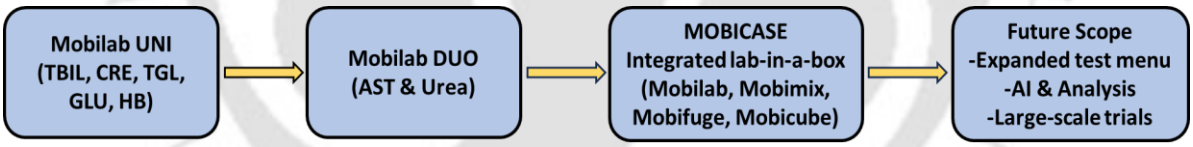

Figure 34. Evolution of Mobilab Platform UNI → Mobilab-Duo → Mobicase → Future Expansion

This research demonstrated a stepwise progression in the development of POCT devices, from Mobilab-Uni (multi-analyte testing) to Mobilab-Duo (dual analyte, organ-specific diagnostics), and finally to Mobicase (a comprehensive lab-in-a-box). Clinical validation confirmed that these devices provide accuracy and reliability comparable to gold-standard laboratory analyzers, while offering the unique advantages of portability, affordability, and usability in low-resource settings. By bridging the gap between advanced hospital diagnostics and community healthcare, the Mobilab platform has the potential to transform diagnostic accessibility, enabling early detection, timely treatment, and improved health outcomes for populations most in need.

Overall, the future scope of the Mobilab platform is expansive, encompassing scientific advancement, clinical expansion, commercial translation, and ecosystem development—ultimately enabling accessible, affordable, and high-quality diagnostics for communities worldwide. Health records. To achieve large-scale adoption, multicentre validation trials across varied geographies and populations will be necessary to establish regulatory acceptance and clinical robustness. Furthermore, collaboration with government agencies, NGOs, and healthcare providers will be vital for commercial scaling and policy integration, ultimately positioning the Mobilab platform as a cost-effective, scalable, and transformative solution for decentralized diagnostics.

Publications, Patents and Conferences

Publications:

1. Chowdhury, B. Deka, **Sahil Jagnani,** and D. Bandyopadhyay, "Centrifugable Multiplexer Targeting Frugal Point-of-Care-Testing," IEEE Journal on Flexible Electronics (J-FLEX), vol. 2, no. 5, pp. Sept. 2023, doi: 10.1109/JFLEX.2023.3291332
2. Ankit Chowdhury, **Sahil Jagnani**, Nilanjana Medhi, Saurabh Dubey, Shweta Tiwari, Suchita Markan, Rajesh Sagar, Pankaj Upadhyay, Madhumita Das, Dipankar Bandyopadhyay Clinical Diagnostic Efficacy of a Point-of-Care Testing Device for Non- Non-Communicable Diseases. IEEE Sensors, 2024 (Under review)

Patents:

1. Smartphone-Based Portable Optical System for Spectrophotometric Analysis of Chemical Compounds. Patent Granted – Patent No. 5262992.
2. Portable mixing device for low Volume Vials. Patent Granted – Patent No. 568325.
3. Portable Mini Chemistry Analysis System (Mobicase). Patent Applied – Application No. 202431072182.
4. Lens-free optical system for spectrophotometric analysis. Patent Applied – Application No. 202431079962.
5. Standalone multi-cavity incubation system for low volume vials. Patent Applied – Application No. 202431008115.
6. Low cost Electrochemical Sensor for Serum Ions. Patent Applied – Application No. 202331009162.

Conferences:

1. Global Digital Health Summit - Mumbai 2024
2. HealthX Elevate - New Delhi - October 2025
3. DIISHA to National One Health Mission, Delhi 2024
4. NE Sammelan - Delhi, February 2024
5. Academic Lab to Market - DISHA, Delhi 2025
6. Leveraging Ecosystem: Networking Opportunities, Delhi 2024
7. 2nd DHR - ICMR Health Research Excellence Summit, Delhi 202

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Appendix

List of abbreviations

ABDM	Ayushman Bharat Digital Mission
ABHA	Ayushman Bharat Health Account
AI	Artificial Intelligence
AKI	Acute Kidney Injury
ALP	Alkaline Phosphatase
ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase (SGOT)
BUN	Blood Urea Nitrogen
CBC	Complete Blood Count
CKD	Chronic Kidney Disease
COPD	Chronic Obstructive Pulmonary Disease
CV	Coefficient of Variation
DA	Diagnostic Accuracy
DM	Diabetes Mellitus
eGFR	Estimated Glomerular Filtration Rate
ELISA	Enzyme-Linked Immunosorbent Assay
EMR	Electronic Medical Record
HER	Electronic Health Record
FFAs	Free Fatty Acids
GLDH	Glutamate Dehydrogenase
GMCH	Guwahati Medical College and Hospital
GNRC	Guwahati Neurological Research Centre
GOD-PAP	Glucose Oxidase-Phenol 4-Aminophenazone
GPO-PAP	Glycerol-3-Phosphate Oxidase-Phenol 4-Aminophenazone
Hb	Hemoglobin
HbA1c	Glycated Hemoglobin
HF	Heart Failure
HPLC	High-Performance Liquid Chromatography
IoT	Internet of Things
KFT	Kidney Function Test

LFT	Liver Function Test
LMIC(s)	Low- and Middle-Income Country (Countries)
LoD	Limit of Detection
LoQ	Limit of Quantitation
MDH	Malate Dehydrogenase
MMU	Mobile Medical Unit
MOBICASE	Integrated Mobile Biochemistry Case (MOBICASE system)
Mobilab-Uni	Single-slot Mobilab Point-of-Care Biochemistry Analyzer
Mobilab-Duo	Dual-slot Mobilab Point-of-Care Biochemistry Analyzer
NAFLD	Non-Alcoholic Fatty Liver Disease
NASH	Non-Alcoholic Steatohepatitis
NCD(s)	Non-Communicable Disease(s)
NPV	Negative Predictive Value
PCR	Polymerase Chain Reaction
POC	Point of Care
POCT	Point-of-Care Testing
PPV	Positive Predictive Value
QC	Quality Control
R^2	Coefficient of Determination
RT	Real Time (or Room Temperature, as used in context)
SD	Standard Deviation
SGOT	Serum Glutamate Oxaloacetate Transaminase (AST)
SGPT	Serum Glutamate Pyruvate Transaminase (ALT)
TBIL	Total Bilirubin
WHO	World Health Organization.