International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

# Comparative Evaluation of the Performance of the Neodocs Point-of-Care Creatinine Kit Versus the Conventional Laboratory Method

**Nikunj Malpani[1], Anurag Meena[2], Pratik Lodha[3]**

[1]Bachelor of Technology, IIT-Bombay, Chief Executive Officer, Neodocs Healthcare Pvt. Ltd., Powai, Mumbai, Maharashtra 400076, India

[2]Bachelor of Technology, IIT-Bombay, Chief Operating Officer, Neodocs Healthcare Pvt. Ltd., Powai, Mumbai, Maharashtra 400076, India

[3]Bachelor of Technology, IIT-Bombay, Chief Technology Officer, Neodocs Healthcare Pvt. Ltd., Powai, Mumbai, Maharashtra 400076, India

**Abstract:** ***Chronic kidney disease (CKD) poses a major and growing global health issue, with low- and middle-income nations, such as India, experiencing a disproportionately high impact. The early identification of CKD is often hindered by the lack of access to laboratory facilities in resource-limited areas. Point-of-care (POC) devices for measuring creatinine present a practical alternative, allowing for prompt evaluation and management of kidney function. This study prospectively assessed the analytical performance of the Neodocs POC creatinine kit in comparison to a standard laboratory method (Roche Cobas c 503) using 30 blood samples across three separate batches. The findings showed a strong agreement between ND and reference values, with high correlation coefficients (r = 0.992-0.993) across the tested creatinine concentration ranges (0.1-7.4 mg/dL). ND measurements were closely aligned with those of the reference device, exhibiting minimal bias in low, normal, and high creatinine levels. Precision analyses indicated coefficients of variation of 5.0% in the low range and 1.5-1.6% in the normal and high ranges, demonstrating strong reproducibility. The study supports the Neodocs device's suitability for POC creatinine testing and its potential to improve CKD screening and monitoring, especially in underserved areas. Larger studies involving broader demographic and clinical spectrums are needed to confirm these results and further validate the device's clinical utility. Overall, the Neodocs POC creatinine kit shows promising accuracy and precision, highlighting its value as an accessible, quick, and reliable tool for assessing kidney function in various healthcare settings.***

**Keywords:** Chronic Kidney Disease, Creatinine, Point of Care Device, Validation

## 1. Introduction

Chronic kidney disease (CKD) is a rapidly growing global public health crisis that affects vulnerable individuals, families, and healthcare systems at an unprecedented level [1]. Current epidemiological data suggest that between 700 and 850 million people worldwide have some form of kidney disease, highlighting the urgent need for comprehensive prevention, early detection, and intervention strategies to address the increasing burden [2]. Reportedly, one in ten adults worldwide is affected by CKD, corresponding to a prevalence of approximately 9–11.7%. This figure is likely an underestimate because of insufficient screening, particularly during the early asymptomatic stages. Alarmingly, both the global prevalence and related mortality rates have risen sharply over recent decades, with CKD now recognised as one of the fastest-growing causes of death and disability worldwide [3].

The burden of CKD is severe in low- and middle-income countries, which often lack resources and infrastructure. India, accounting for nearly 33% of global CKD cases, has a national prevalence of 13.2 %, with rural areas reaching 15.3%. CKD leads to premature death, dialysis, and reduced quality of life and imposes socioeconomic and health system costs. It significantly increases the risk of cardiovascular disease, stroke, and infections [4].

The major risk factors for CKD include diabetes mellitus, hypertension, obesity, and advancing age, with the dual epidemics of diabetes and hypertension responsible for the majority of new cases globally [5]. Social determinants such as poverty, poor access to healthcare, and environmental toxins further compound the risk among marginalised and rural populations. Despite these sobering statistics, CKD remains a silent disease in its early stages, often going undiagnosed until significant and typically irreversible kidney damage occurs. Therefore, early detection is both essential and challenging [6].

Creatinine, a byproduct of muscle metabolism, is mainly eliminated by the kidneys, and its level in the bloodstream indicates how well the glomeruli are filtering, which is a vital function of the kidneys [7]. Consistently high creatinine levels indicate decreased glomerular filtration rate (GFR). Routine creatinine testing offers a direct and accessible window into the renal function. A small decline in kidney clearance results in elevated blood creatinine levels [8]. Regular measurement of creatinine, along with the calculation of estimated GFR (eGFR), facilitates risk assessment, timely interventions, medication adjustments, and tracking disease progression or treatment effectiveness. This is particularly important for high-risk populations, including those with diabetes, hypertension, cardiovascular conditions, and a family history of kidney issues [9]. Although traditional laboratory tests are very accurate, they are often inaccessible or delayed in rural, remote, or resource-limited areas [10]. Challenges with sample transport, centralised lab systems, and turnaround times result in many people not receiving the recommended monitoring or being diagnosed only after significant kidney damage has occurred. To overcome this diagnostic gap, point-of-care (POC) testing is the best

alternative, as it enables rapid screening with easy access in resource-limited areas [10]. POC creatinine assays represent a significant advancement in renal diagnosis. These portable, user-friendly platforms enable immediate bedside or clinic-based creatinine measurement, providing actionable results within minutes [11]. POC testing can revolutionise CKD screening and management by empowering primary care workers, enabling one-stop management, rapid medication adjustments, and streamlining patient counselling in a single clinical encounter. The clinical performance and analytical validity of these devices must, however, be rigorously validated against laboratory-based gold standards to ensure accuracy, precision, and reproducibility. This study aimed to validate the analytical performance of Neodocs creatinine test kits against a standard laboratory analyser.

## 2. Materials and Methodology

### Materials

A smartphone, Dr. Neodocs application, Neodocs creatinine device, strips for blood sample collections, test samples, and a traditional lab analyser (Cobas c 503 analytical unit).

### Study Design and Population

A prospective, cross-sectional validation study was conducted at Jariwala Laboratory (NABL-accredited), Mumbai, India. Three lots with 30 samples ranging from 0 mg/dL to > 1.5 mg/dL were evaluated against known values from the reference method (Cobas c 503 analytical unit).

### Methodology

1) **Testing Procedure for Neodocs creatinine device**
   Download the Dr Neodocs application from the Google Play Store/iOS APP store and complete the setup process as mentioned in the application. A drop of blood is taken using a capillary, the strip is inserted in the designated slot in the device, and a drop of blood is added to the strip. To ensure the accuracy of the results, the test was repeated on different strips. The Start button was clicked to analyse the sample. The results are instantly displayed on the application dashboard.
2) **Procedure for the Reference method**
   Serum creatinine was measured using a Roche Cobas c 503 analyser, which employs a fully automated kinetic Jaffé colourimetric method. Each patient sample was mixed with alkaline picrate reagent, and the resulting colour change was quantified photometrically to determine the creatinine concentration. Instrument calibration, quality control, and data processing were performed according to the manufacturer's guidelines for analytical accuracy and reproducibility.

### Data collection and analysis

The results of Neodocs' creatinine test were captured by cloud monitoring on the Dr Neodocs' app dashboard, and the results from the lab test were documented. Statistical analysis was performed to evaluate the results obtained using the Neodocs' creatinine device and the reference method. Continuous variables, such as means, standard deviations, correlation coefficients, coefficients of variation, margins of error, and precision, were analysed.

## 3. Result

A total of 30 samples were analysed for creatinine using both the Neodocs (ND) point-of-care device and a reference laboratory analyser across three batches. The comparative evaluation is summarised in Table 1. The ND values demonstrated a strong agreement with the reference results, with correlation coefficients ($r^2$) of 0.992, 0.993, and 0.992 for batches 1, 2, and 3, respectively, indicating excellent linearity between the methods (Figure 2).

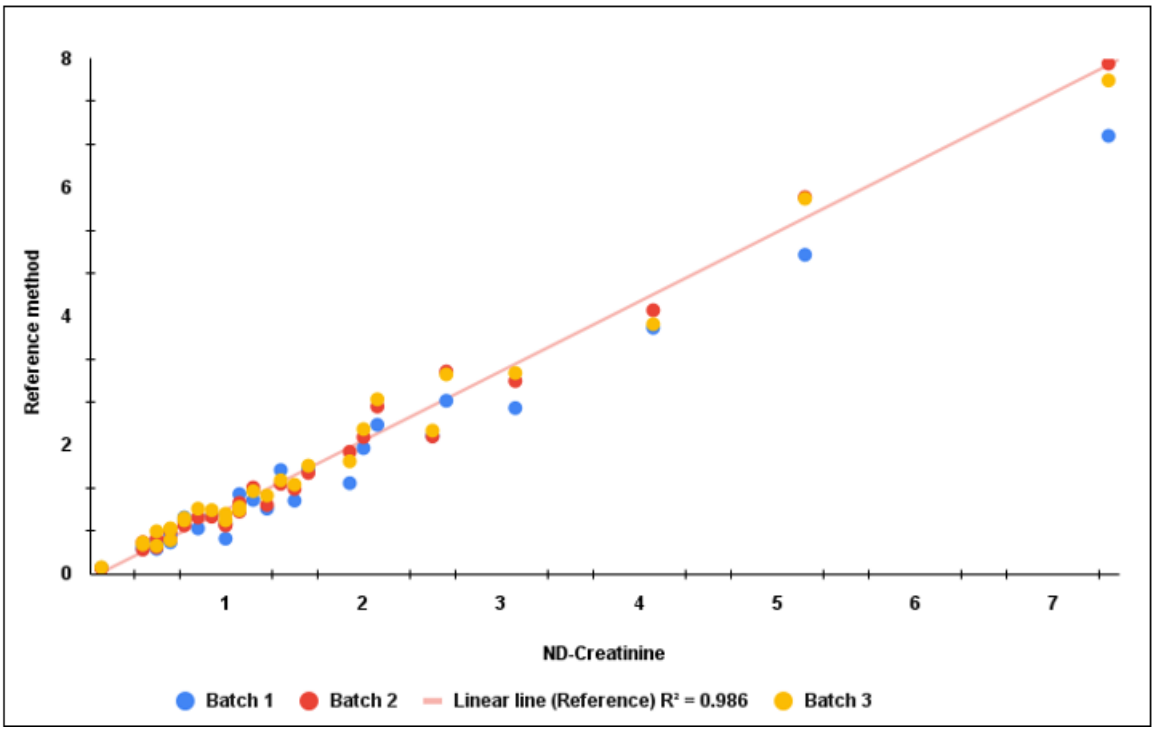


**Figure 1:** Coefficient of correlation for ND creatinine and reference method

Creatinine concentrations ranged from 0.1 mg/dL to 7.4 mg/dL. Across all intervals—low (0-0.7 mg/dL), normal (0.7-1.5 mg/dL), and elevated (>1.5 mg/dL)—ND measurements closely matched those obtained using the standard laboratory method. For instance, in the 0–0.7 mg/dL range, the mean ND value for sample ID 8504 was 0.1 mg/dL, which was concordant with the reference. At higher concentrations (e.g. sample ID 7716, 7.4 mg/dL), ND measured 6.80 mg/dL, compared to the reference value of 7.66 mg/dL.

**Table 1:** The comparative table for creatine testing with ND and the reference analyser

| Range | ND Values | | | |
|---|---|---|---|---|
| | Reference Method | Batch: 1 | Batch: 2 | Batch: 3 |
| 0 - 0.7 | 0.1 | 0.1 | 0.09 | 0.11 |
| 0 - 0.7 | 0.4 | 0.4 | 0.38 | 0.46 |
| 0 - 0.7 | 0.4 | 0.43 | 0.5 | 0.5 |
| 0 - 0.7 | 0.5 | 0.4 | 0.42 | 0.44 |
| 0 - 0.7 | 0.5 | 0.52 | 0.55 | 0.67 |
| 0 - 0.7 | 0.6 | 0.62 | 0.69 | 0.71 |
| 0 - 0.7 | 0.6 | 0.66 | 0.68 | 0.7 |
| 0 - 0.7 | 0.6 | 0.5 | 0.54 | 0.53 |
| 0 - 0.7 | 0.7 | 0.88 | 0.8 | 0.87 |
| 0 - 0.7 | 0.7 | 0.84 | 0.76 | 0.84 |
| 0.7 - 1.5 | 0.8 | 0.71 | 0.88 | 1.02 |
| 0.7 - 1.5 | 0.9 | 0.92 | 0.89 | 1 |
| 0.7 - 1.5 | 1 | 0.55 | 0.76 | 0.84 |
| 0.7 - 1.5 | 1 | 0.79 | 0.78 | 0.94 |
| 0.7 - 1.5 | 1.1 | 1.24 | 0.97 | 1 |
| 0.7 - 1.5 | 1.1 | 0.98 | 1.11 | 1.04 |
| 0.7 - 1.5 | 1.2 | 1.15 | 1.35 | 1.29 |
| 0.7 - 1.5 | 1.3 | 1.02 | 1.07 | 1.22 |
| 0.7 - 1.5 | 1.4 | 1.62 | 1.4 | 1.46 |
| 0.7 - 1.5 | 1.5 | 1.14 | 1.32 | 1.39 |
| > 1.5 | 1.6 | 1.63 | 1.57 | 1.69 |
| > 1.5 | 1.9 | 1.41 | 1.9 | 1.75 |
| > 1.5 | 2 | 1.96 | 2.13 | 2.25 |
| > 1.5 | 2.1 | 2.32 | 2.6 | 2.71 |
| > 1.5 | 2.5 | 2.15 | 2.14 | 2.23 |
| > 1.5 | 2.6 | 2.69 | 3.14 | 3.1 |
| > 1.5 | 3.1 | 2.58 | 3 | 3.12 |
| > 1.5 | 4.1 | 3.82 | 4.1 | 3.88 |
| > 1.5 | 5.2 | 4.95 | 5.85 | 5.83 |
| > 1.5 | 7.4 | 6.8 | 7.92 | 7.66 |

**Table 2:** Precision study data for Batch 2

| Range 0 - 0.7 mg/dL | Range 0.7 - 1.5 mg/dL | Range > 1.5 mg/dL |
|---|---|---|
| 0.1 mg/dL | 1.1 mg/dL | 4.1mg/dL |
| 0.1 | 1.22 | 4.68 |
| 0.09 | 1.26 | 4.79 |
| 0.1 | 1.23 | 4.79 |
| 0.09 | 1.21 | 4.73 |
| 0.1 | 1.24 | 4.73 |
| 0.09 | 1.21 | 4.75 |
| 0.1 | 1.23 | 4.77 |
| 0.1 | 1.2 | 4.93 |
| 0.1 | 1.21 | 4.8 |
| 0.1 | 1.23 | 4.9 |

Precision studies were performed using batch 2 because of its robust correlation. The coefficient of variation (CV) and standard deviation (S.D.) for repeated measurements were calculated for representative samples in each range. For the low range (0–0.7 mg/dL, 0.1 md/dL), CV was 5.0% with S.D. 0.005. In the normal range (0.7–1.5 mg/dL, 1.1 mg/dL), the CV was 1.5% with S.D. 1.224, and for the elevated range (>1.5 mg/dL, 4.1 mg/dL), the CV measured at 1.6% and S.D. 4.787. The individual replicate measurements are presented in Table 2. These findings demonstrate high analytical precision and reliable reproducibility of ND creatinine testing across clinically relevant concentrations. The strong correlation with the reference laboratory method supports the suitability of the ND device for routine, point-of-care creatinine assessment.

## 4. Discussion

This study evaluated the analytical performance of the Neodocs (ND) point-of-care (POC) device for measuring creatinine and compared it that with of a conventional reference laboratory analyser. The results demonstrated a strong agreement between ND and the reference method, with correlation coefficients exceeding 0.99 across various sample batches, indicating the device's reliability and accuracy for POC testing. ND values were closely aligned with laboratory results across low, normal, and elevated creatinine ranges, exhibiting minimal bias even at the extremes, highlighting its potential for the rapid assessment of kidney function in critical clinical settings, such as emergency departments and nephrology clinics. In terms of precision, a coefficient of variation (CV) of 5.0% was noted at the low range (0–0.7 mg/dL), which was attributed to biological and analytical variability; however, performance in the normal and high ranges (CV 1.5%-1.6%) was comparable to established laboratory methods, establishing its utility for routine screening and monitoring of chronic kidney disease (CKD) or renal impairment. The methodological design included multiple replicates and evaluation of different batches, enhancing the robustness of the findings and confidence in the device consistency, which is especially vital for decentralised testing in resource-limited settings. The implications of implementing reliable POC creatinine testing include improved early diagnosis and monitoring of renal diseases, enhanced clinical decision-making, and potential applications in public health campaigns and epidemiological studies. Nevertheless, limitations exist, including a small sample size of 30 individuals, and more extensive studies are needed to confirm the findings across diverse demographics and clinical scenarios. Addressing lot-to-lot and operator variability is essential for validation before broader deployment of the ND device.

## 5. Conclusion

The Neodocs creatinine device exhibited high accuracy and precision compared to standard laboratory methods across a range of clinically relevant concentrations. Its strong correlation and reproducibility underscore its potential as a reliable point-of-care tool for assessing kidney function in various clinical settings.

## References

[1] Xie K, Cao H, Ling S, Zhong J, Chen H, Chen P, et al. Global, regional, and national burden of chronic kidney disease, 1990-2021: a systematic analysis for the global

burden of disease study 2021. Front Endocrinol (Lausanne). 2025;16:1526482.
[2] Li PK, Garcia-Garcia G, Lui SF, Andreoli S, Fung WW, Hradsky A, et al. Kidney Health for Everyone Everywhere-From Prevention to Detection and Equitable Access to Care. Kidney Int Rep. 2020;5(3):245-51.
[3] Kovesdy CP. Epidemiology of chronic kidney disease: an update 2022. Kidney International Supplements. 2022;12(1):7-11.
[4] Stanifer JW, Muiru A, Jafar TH, Patel UD. Chronic kidney disease in low- and middle-income countries. Nephrol Dial Transplant. 2016;31(6):868-74.
[5] Mallamaci F, Tripepi G. Risk Factors of Chronic Kidney Disease Progression: Between Old and New Concepts. J Clin Med. 2024;13(3).
[6] Koye DN, Magliano DJ, Nelson RG, Pavkov ME. The Global Epidemiology of Diabetes and Kidney Disease. Adv Chronic Kidney Dis. 2018;25(2):121-32.
[7] Ávila M, Mora Sánchez MG, Bernal Amador AS, Paniagua R. The Metabolism of Creatinine and Its Usefulness to Evaluate Kidney Function and Body Composition in Clinical Practice. Biomolecules. 2025;15(1):41.
[8] Nguyen MK, Bandaru D. Importance of Creatinine Generation Rate in Estimating Glomerular Filtration Rate. Cureus. 2025;17(3):e80441.
[9] Vassalotti JA, Francis A, Soares dos Santos AC, Correa-Rotter R, Abdellatif D, Hsiao L-L, et al. Are Your Kidneys Ok? Detect Early to Protect Kidney Health. Kidney International Reports. 2025;10(3):629-36.
[10] Heidt B, Siqueira WF, Eersels K, Diliën H, van Grinsven B, Fujiwara RT, et al. Point of Care Diagnostics in Resource-Limited Settings: A Review of the Present and Future of PoC in Its Most Needed Environment. Biosensors (Basel). 2020;10(10).
[11] Gbinigie O, Price CP, Heneghan C, Van den Bruel A, Plüddemann A. Creatinine point-of-care testing for detection and monitoring of chronic kidney disease: primary care diagnostic technology update. Br J Gen Pract. 2015;65(640):608-9.