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RESEARCH ARTICLE

# Comparison and Analytical Validation of the Nova Max Pro Creatinine/eGFR Meter against Nova StatSensor Creatinine Meter

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**ABSTRACT**

Chronic Kidney Disease (CKD) represents an escalating global and national health challenge, affecting millions of individuals and imposing substantial healthcare costs. Early diagnosis and continuous monitoring of renal function are crucial to mitigate disease progression and associated complications. Point-of-care (POC) testing devices have emerged as efficient tools for the timely assessment of kidney function outside centralized laboratories. Among these, the Nova StatSensor Creatinine Meter has been widely used to measure blood creatinine and estimate glomerular filtration rate (eGFR). The Nova Max Pro, a newer-generation POC device, integrates enhanced analytical capabilities and operational features suitable for decentralized and resource-limited healthcare environments. This study aimed to evaluate the analytical performance, clinical comparability, and operational reliability of the Nova Max Pro system relative to the Nova StatSensor device.

Objective: To assess the analytical accuracy, clinical equivalence, and reproducibility of the Nova Max Pro Creatinine/eGFR Meter System compared to the established Nova StatSensor in the measurement of whole blood creatinine across clinically relevant concentration ranges.

Methods: A comparative analytical study was performed using 14 venous whole blood samples, covering a creatinine concentration range of 0.3 to 7.0 mg/dL, representative of values observed across CKD stages. Each sample was analyzed using two Nova StatSensor meters and four Nova Max Pro meters. The mean creatinine value obtained from the StatSensor devices served as the reference comparator. Linear regression analysis was used to evaluate correlation, bias, and agreement between the two systems. Testing was conducted by trained healthcare professionals following Good Clinical Practice (GCP) standards to ensure procedural reliability and data integrity.

Results: The Nova Max Pro demonstrated excellent correlation with the Nova StatSensor, yielding a regression equation of $y = 0.9967x - 0.0014$ and a coefficient of determination $(R^2 = 0.9978)$. Minimal analytical bias was observed, and precision remained strong across the full creatinine range. All four Nova Max Pro units displayed consistent performance, indicating high reproducibility and stability. The device accurately detected creatinine values at key clinical thresholds critical for CKD staging, confirming its analytical validity.

Conclusions: The Nova Max Pro exhibited robust analytical agreement, minimal bias, and consistent precision compared to the Nova StatSensor. Its integrated Bluetooth connectivity, CKD-EPI 2021 equation support, and user-friendly design enhance its clinical applicability. These attributes position Nova Max Pro as a reliable, scalable, and field-ready solution for CKD screening and monitoring in community health programs, primary care centers, and resource-limited settings.

**Keywords**: Chronic kidney disease, Creatinine, Estimated GFR, Point of care testing(POCT), Nova Max Pro, Nova Statsensor, Analytical Validation.

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## INTRODUCTION

Point-of-care testing, or POCT, is clinical laboratory testing conducted in the vicinity of the patient care point where care or treatment is given.[1] In contrast to laboratory testing, POCT provides rapid test result reversal and can produce a result rapidly, allowing for the enforcement of appropriate treatment and improving clinical or financial outcomes.[2] Traditional laboratory testing usually involves a multi-step process that involves collecting samples from the patient at the clinic or at the patient's bedside, transporting them to a central laboratory (often located far away), and processing them using a variety of techniques.[3] Treatment delays caused by time-consuming traditional laboratory testing may hinder timely clinical decision-making. POCT addresses this problem by bringing the laboratory function in single portable device enabling health workers to perform the rapid testing.[4]

With the help of new POC devices sensor technologies, important biological factors can be detected and tracked in patients with Acute Kidney Injury (AKI) and Chronic Kidney Disease (CKD). These developments have made it possible to measure and detect important biomarkers early and accurately while investing little money and resources.[5] According to *KDIGO 2024 Clinical Practice Guideline for Evaluation and Management of Chronic Kidney Disease*, there are several possible advantages to POCTs for both creatinine and urine albumin. POCT may result in an earlier CKD diagnosis and, consequently, an earlier course of treatment. Additionally, they can be used to track the progression of CKD, allowing for quicker treatment decisions. Other significant advantages of POCT include quick reporting, affordability, and ease of use for individuals with CKD in comparison to central laboratory testing.[6] Chronic kidney disease (CKD) is defined as abnormalities of kidney structure or function, present for a period of at least 3 months, with various health consequences .The burden of CKD is significant because it directly affects morbidity and mortality at both global and individual patient level as well as through its effects on cardiovascular damage and the progression of CKD can lead to end-stage kidney disease (ESKD). Chronic kidney disease is characterized based on cause, estimated glomerular filtration rate (eGFR) category (G1 - G5) less than 60 mL/min/1.73 $m^2$, and albuminuria category (A1 - A3) greater than 30 mg/g. Worldwide, chronic kidney disease (CKD) now touches about 13.4% of adults, roughly 4.9 to 7.1 million people who eventually need renal replacement therapy, often called end-stage kidney disease (ESKD). Projections from the Global Health Observatory warn that by 2030 CKD will claim 14 lives for every 100,000. Over the past thirty years the numbers have surged; both prevalence and incidence have nearly doubled, jumping 87% and 89% respectively between 1990 and 2016.[7] In India, the number of CKD cases has reached epidemic levels. Population-based studies show that the prevalence of CKD in India ranges from 4% to 20%. A systematic review conducted in 2021 found CKD prevalence in various regions of India to be between 12% and 21%. Although some studies have looked into the burden of chronic kidney disease over the years, there has not been a national estimate of CKD prevalence in India.[8,9] Due to rising prevalence of CKD globally and nationwide, screening and diagnosis becomes a crucial step for early detection of CKD to allow timely intervention. Since most of the CKD patients remains asymptomatic, early detection of disease enables to more timely treatment decisions.[10]

Both the StatSensor and the Nova Max Pro are point-of-care creatinine/eGFR monitoring devices made by Nova Biomedical, but they differ in designs, target environments, and clinical uses and application. Early kidney disease detection and remote monitoring are made possible by the Nova Max Pro's optimization for decentralized environments, including pharmacies, clinics, and homes. It is easy to use for self-testing and community screening because it has a colour touchscreen, Bluetooth connectivity, and calculates eGFR using the CKD-EPI 2021 equation. On the other hand, the StatSensor (including the Xpress-i variant) is mostly utilized in acute care and hospital settings for quick evaluation of renal function prior to treatments like chemotherapy or contrast imaging. With features like barcode scanning and MDRD, traceable IDMS MDRD, Schwartz, Counahan-Barratt, and Cockroft-Gault equation for eGFR measurement, it is intended for clinician-operated testing and uses the same enzymatic technology as the Nova Max Pro; however, it lacks Bluetooth connectivity. While both device uses 1.2 µL of blood sample and deliver the result in just 30 seconds.[11,12]

## MATERIAL AND METHODS

### Study Conduct and Participants

Ethical approvals and required protocols were approved by the Institutional Review Board (IRB) to ensure the safety, rights, and welfare of the human subject donating the blood for the study. The study collected the Venous whole blood samples from the informed donors in Lithium Heparin Tubes. Participants were excluded if they were unable to provide consent or any required information necessary for the study. Specimens and associated data of the subject were kept confidential by assigning a unique identification number. The study conformed to Good Clinical Practice (GCP) Guideline under 21 CFR parts 50, 56, and 812 to ensure the safety and rights of the human subjects donating the Blood. The Sample size of 14 was selected for feasibility purposes.

### Sample Preparation and Test Execution

In order to simulate different creatinine levels in blood, a total of 14 venous whole blood samples were generated that covered the clinically relevant creatinine range of 0.3 to 7.0 mg/dL. Higher values were obtained by augmenting samples with a 1,000 mg/dL creatinine stock, whereas the lowest creatinine sample (0.3 mg/dL) was prepared via plasma exchange with saline. The remaining 13 samples were adjusted by adding different high creatinine stock solutions, levelling up to 7 mg/Dl. Under 21 CFR Parts 50, 56, and 812, all specimens were handled and kept anonymous in compliance with Good Clinical Practice recommendations. Trained, individual operators

tested two Nova StatSensor devices and four different Nova Max Pro meters. The average of the two StatSensor readings per sample was used as the comparator reference, and four Nova Max Pro meter took one measurement each sample. This method made it possible to assess inter-system agreement as well as instrument consistency.

### Method Principle

The Nova Max Pro Creatinine and eGFR Meter measures creatinine levels and determines estimated glomerular filtration rate (eGFR) from tiny blood samples using a sophisticated enzymatic biosensor technology. The test uses an electrochemistry method by a multi-enzyme reaction involving creatinine. Within 30 seconds of applying a blood sample to the single-use test strip, the meter detects and measures the electrical current produced by the enzymatic reaction, which is proportionate to the creatinine content. The device uses the CKD-EPI 2021 equation to calculate eGFR, and it just needs the patient's age and sex as basic demographic data to deliver an accurate assessment of kidney function.[12]

Nova StatSensor also uses similar enzymatic principles, the primary areas of difference are form factor, data output integration, and potential interface enhancements. The Nova StatSensor Creatinine Meter also measures creatinine levels directly from a tiny sample of whole blood in a quick and precise manner using the enzyme-based electrochemical detection method. A biochemical cascade involving many enzymes is started when a drop of blood is placed to the meter's test strip. Among these, the essential component is creatinine. Additionally, based on user-entered demographic inputs including age, sex, and ethnicity, the device can compute estimated glomerular filtration rate (eGFR) using equations such MDRD, IDMS traceable MDRD, Schwartz, Counahan-Barratt, and Cockroft-Gault. The Multi-Well™ technology of the meter guarantees accurate sample dispersion throughout the biosensor surface.[11]

All Blood sample testing with both Nova Max Pro and Statsensor Creatinine device were performed independently by a different set of health professionals, and they were unaware of the specific amount of creatinine dilution in the sample.

**Table 1:** Average Creatinine Test Results of Nova StatSensor and Nova Max Pro Meter devices

| *S. No.* | *Nova StatSensor Creatinine Meter Average (x)* | *Nova Max Pro Meter Average (y)* |
|---|---|---|
| 1 | 0.34 | 0.35 |
| 2 | 0.64 | 0.65 |
| 3 | 0.96 | 0.91 |
| 4 | 1.42 | 1.38 |
| 5 | 1.9 | 1.94 |
| 6 | 2.52 | 2.52 |
| 7 | 3.16 | 3.12 |
| 8 | 3.63 | 3.61 |
| 9 | 4.37 | 4.31 |
| 10 | 5.07 | 4.99 |
| 11 | 5.41 | 5.43 |
| 12 | 6.04 | 5.95 |
| 13 | 6.46 | 6.61 |
| 14 | 6.9 | 6.81 |

### Data and Statistical Analysis

Using 14 levels of venous whole blood specimens with creatinine concentrations ranging from 0.3 to 7.0 mg/dL, a thorough statistical comparison was carried out to assess the performance of the Nova Max Pro Creatinine/eGFR Meter System in comparison to the Nova StatSensor Creatinine Monitoring System. Four separate Nova Max Pro meters were used to collect single-point measurements for each specimen. The findings were compared to the reference technique, which was the average of two independent readings from the StatSensor meters. To evaluate correlation and agreement throughout the measurement range, the resultant data were subjected to linear regression analysis. With an associated coefficient of determination ($R^2$) of 0.9978, the regression analysis yielded a best-fit line that was characterized by the equation $y = 0.9967x – 0.0014$. With little variation between the tested creatinine concentrations, this high $R^2$ result shows great alignment between the two approaches. The analytical consistency of the Nova Max Pro system is further supported by the near-unity slope and small intercept, which indicate that both proportional and constant biases are minimal. Overall, the statistical data support the accuracy and dependability of the Nova Max Pro device for clinical creatinine measurement in whole blood samples, showing that it produces findings that are very close to those of the StatSensor system.

## RESULT AND DISCUSSION

The Nova Max Pro Creatinine and eGFR Meter System's analytical performance, concordance, and clinical equivalency were assessed in this study in comparison to the Reference standard, Nova StatSensor Creatinine Meter, a commonly used point-of-care (POC) Device

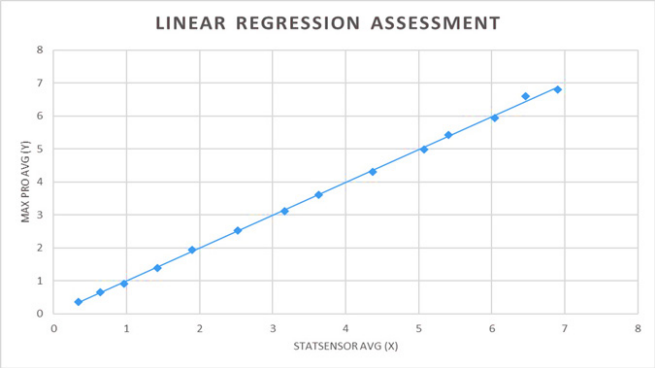


**Figure 1:** Linear Regression Assessment between StatSensor Creatinine Meter and Nova Max Pro Meter

**Analytical Performance and Statistical Accordance**

Across all 14 concentration levels, the creatinine readings determined by Nova Max Pro were shown to be closely consistent with the StatSensor. A comparison between StatSensor (x-axis) with Nova Max Pro (y-axis) using linear regression analysis showed:

- Regression Equation: $y = 0.9967x – 0.0014$.
- Coefficient of determination: $R^2 = 09978$

Excellent proportional agreement between the two devices is indicated by the near-unity slope (0.9967), while the negative intercept (–0.0014) suggests that there is very little systematic bias. Strong linearity throughout the whole analytical range is indicated by the $R^2$ value of 0.9978, which verifies that the StatSensor data can account for more than 99.78% of the variability in Nova Max Pro observations.

**Clinical Equivalence and Interpretations**

The Nova Max Pro system consistently detected creatinine across important clinical thresholds, necessary for the screening for Stages of CKD. Performance remained consistent across:

- Borderline and Subclinical values (0.5–1.5 mg/dL), which are essential for risk assessment and early detection.
- Moderate increases (2–4 mg/dL) are frequently observed in CKD that is advancing.
- Severe increases (>5 mg/dL) may indicate the necessity to start dialysis or significant renal failure.

**Device Precision and Consistency**

There was little variation between the four distinct Nova Max Pro meters, and the results were consistent. Strong meter-to-meter reliability and great manufacturing consistency are attributed to the lack of regular variances among the devices. This conclusion is especially relevant to deployment in multi-device decentralized healthcare settings or screening programs.

## DISCUSSION

The results of the device comparison study show that the Nova Max Pro Creatinine and eGFR Meter, a point-of-care (POC) device for renal disease screening, is analytically and clinically similar to the Nova StatSensor Creatinine Meter. The Nova Max Pro has performance characteristics that strongly support its use for creatinine testing and eGFR estimation, including a high correlation coefficient ($R^2 = 0.9978$), minimal proportional and constant bias, and robust agreement across a wide range of clinically relevant creatinine concentrations (0.3–7.0 mg/dL). A nearly 1:1 relationship between the Nova Max Pro and StatSensor readings is indicated by the linear regression equation ($y = 0.9967x – 0.0014$), indicating that the two systems are quantitatively equivalent. The high level of concordance was preserved throughout the whole measurement range, including concentrations. The system's analytical stability is further supported by the data point's close grouping, lack of outliers, and precision across four distinct Nova Max Pro Creatinine and eGFR units. For Clinical Relevance and Utility, Early diagnosis, CKD staging, and continuous monitoring are made easier by the Nova Max Pro's accurate creatinine level detection, which also makes it possible to estimate eGFR using the CKD-EPI 2021 equation. This is especially helpful for screening in primary care, community-based settings, and resource-constrained environments where quick, close-to-patient testing is essential. Nova Max Pro is a reliable point-of-care like StatSensor, offering similar accuracy, a robust correlation, and ease of use. Its extra features, like Bluetooth connectivity for data sharing, an easy-to-use interface, and a low blood volume requirement, improve its clinical usefulness, especially for general care, outreach, and non-hospitalized patients. These characteristics make Nova Max Pro a desirable option for outreach initiatives, primary care facilities, mobile health units, and tertiary care, especially in nations like India, where the prevalence of CKD is increasing and access to laboratory testing is still a challenge in many regions. In Limitations, the Study includes Venous whole blood samples, which were carried out in a regulated lab setting. Although methodological rigor is guaranteed by this arrangement, variability that is not reflected in this analysis may be introduced by real-world performance in capillary blood or in outdoor settings. Furthermore, the sample size included (n = 14) was chosen for practical reasons and might make it more difficult to identify uncommon or severe deviations. To generalize these results, more research with bigger, more varied populations and capillary sample circumstances would be beneficial.

## CONCLUSION

With a near-perfect correlation ($R^2 = 0.9978$), low bias, and high precision, the Nova Max Pro Creatinine and eGFR Meter System and the Nova StatSensor exhibit outstanding analytical agreement over a clinically relevant creatinine range. These results validate the suitability of Nova Max Pro for eGFR computation using venous whole blood and point-of-care creatinine testing. It is especially useful for community-based screening programs, decentralized clinics, and basic healthcare settings because of its contemporary design characteristics, which include wireless connectivity, CKD-EPI 2021 integration, and ease of use. Given the rising prevalence of CKD, particularly in rural and low-resource populations, the Nova Max Pro provides a workable, dependable, and scalable way to increase kidney disease monitoring and diagnosis.

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