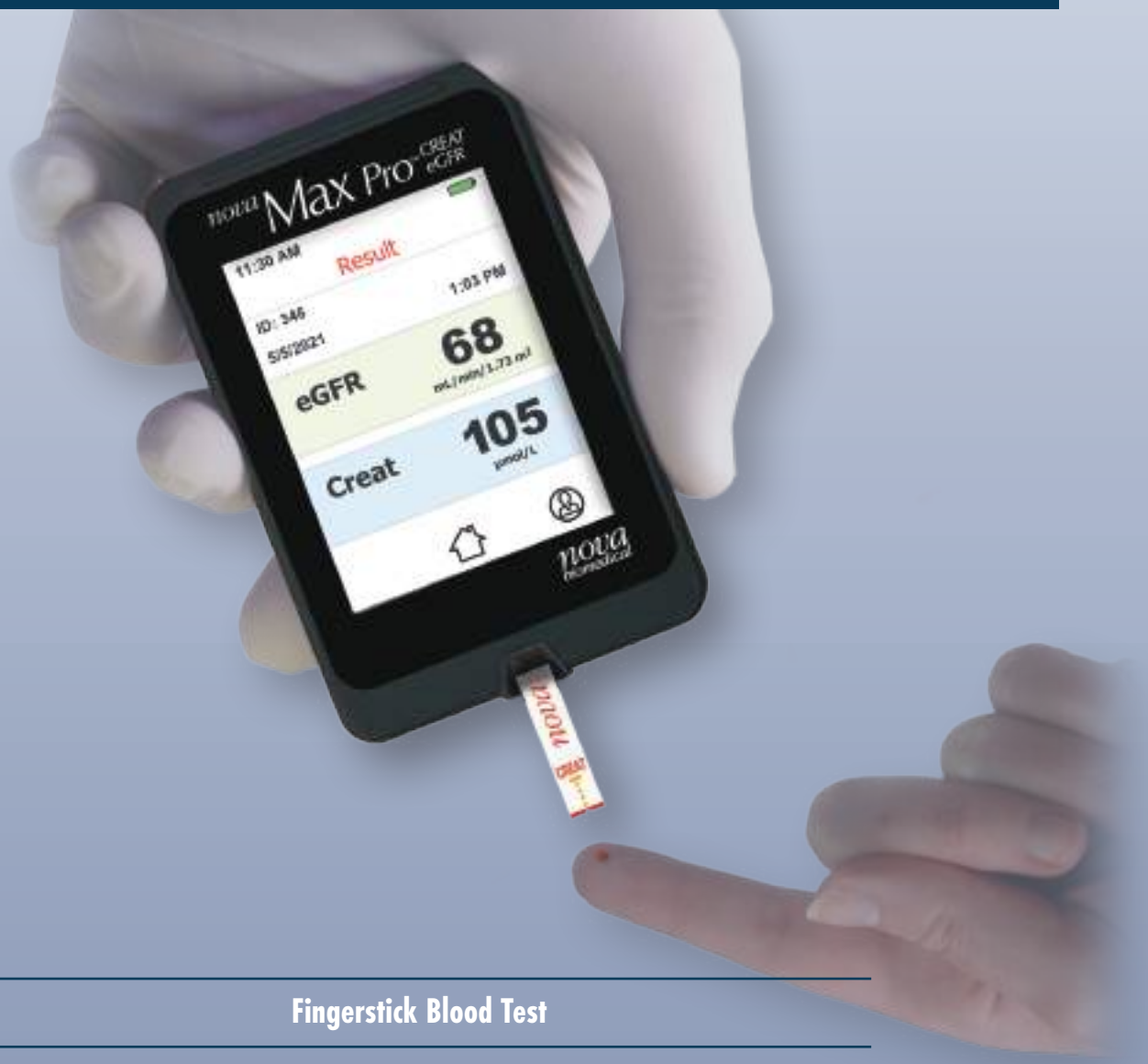
nova Max Pro™ CREAT eGFR

Detection of Kidney Disease
Outside the Hospital



Fingerstick Blood Test

As Easy to Use as Self-Testing for Blood Glucose

Allows Screening or Monitoring of Kidney Disease

Based on Nova's Proven Hospital Creatinine/eGFR Meter

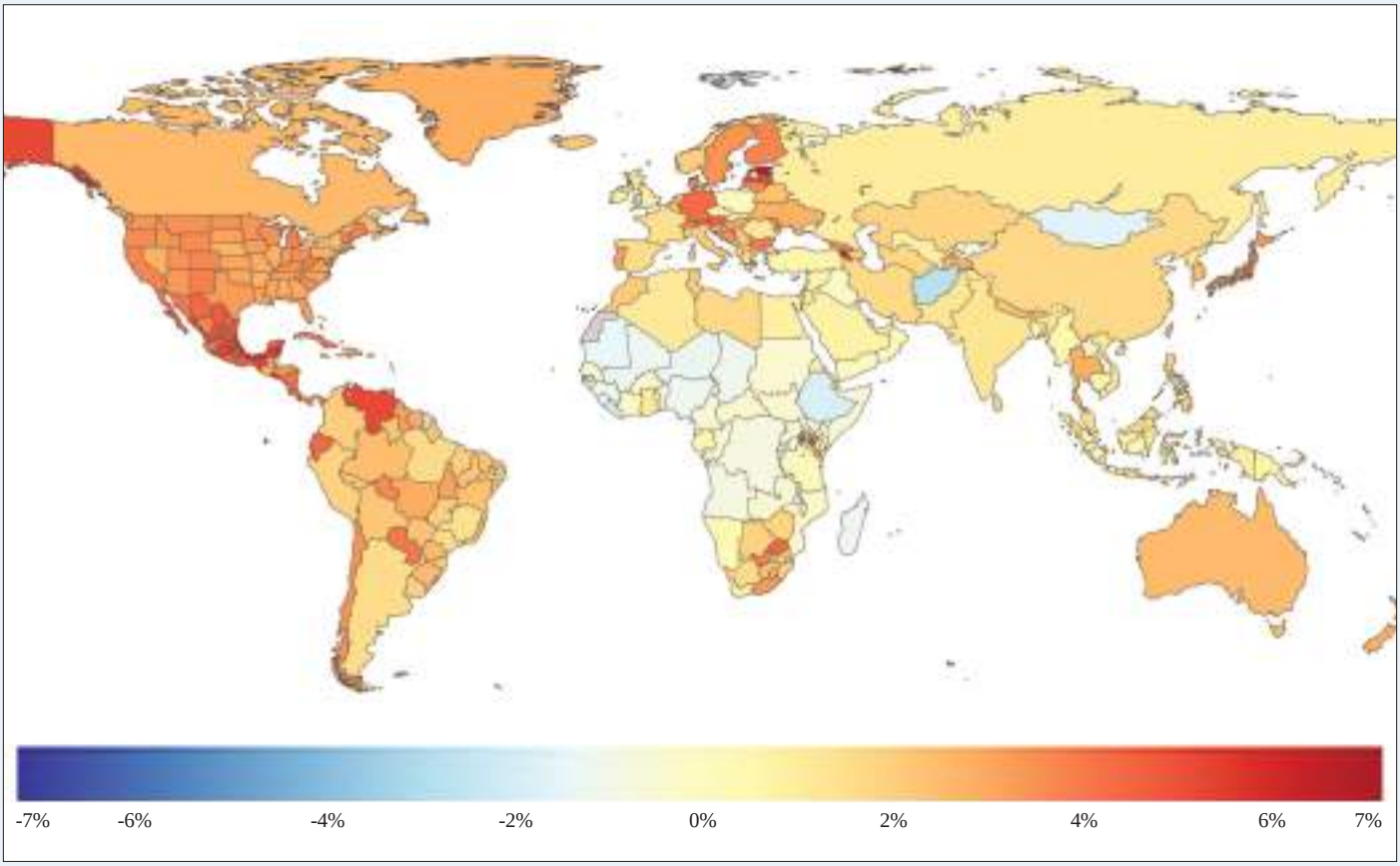
nova® biomedical

Kidney Disease is a Worldwide Healthcare Crisis

Kidney disease (CKD) is a major healthcare crisis. It is growing at an accelerated rate, rising from 13th to 10th place in the World Health Organisation ranking of most common causes of death. It currently represents a huge healthcare economic burden in every country and because of its growth it will be an even larger one in the future unless CKD can be detected and treated early.

If Detected Early, Kidney Disease Progression can be Prevented or Delayed[1]

As many as 90% of people with kidney disease are undiagnosed.[1] In the U.S. alone 15 million adults are estimated to have CKD but 13.5 million are unaware they have it. Kidney disease is often termed the "silent killer" because it shows no symptoms until it is very late stage when there are few treatment options other than dialysis, a very difficult end-stage treatment for patients and very expensive for the healthcare system. Because kidney disease is almost always detected too late, treatment options are still associated with high mortality. Today, the availability of the first drug to retard the progression of kidney disease (Dapagliflozin/Farxiga, Astra Zeneca) makes it even more important to detect kidney disease early so treatment can be started before it is too late.[2] Other novel therapeutics are in various stages of development and also show potential to treat kidney disease.[3]



Map of Global Chronic Kidney Disease
Both sexes, all ages, annual % change, 1990 to 2019, deaths per 100,000

A New Easy to Use Tool to Detect Early Stage CKD

Nova Max Creatinine/eGFR is an important new tool to improve kidney care through detection of kidney disease early enough to successfully treat the disease. Nova Max is a fast, accurate and easy to use meter and biosensor for kidney function testing. The measurement technique is very easy to use, virtually identical to the use of a glucose meter by people with diabetes. Creatinine and estimated glomerular filtration rate (eGFR) results are reported (with or without race as a factor) using the CKD-EPI equation from a small, capillary fingerstick blood sample in just 30 seconds. Test results can be wirelessly communicated to Bluetooth enabled applications for review and intervention by healthcare professionals. Nova Max Creatinine technology is based on the Nova StatSensor Creatinine technology which has been used in hospital point-of-care (POC) applications for over 15 years.

Nova Max technology has already been proven very accurate and effective in kidney function screening in non-hospital locations such as community pharmacies, diagnostic imaging centres, healthcare clinics, and private practices. In a 700 patient study conducted at a large university medical centre and sponsored by the International Society of Nephrology (ISN), Nova Max sensor technology was proven more accurate at detecting early-stage kidney disease than the laboratory Jaffe Creatinine/eGFR method when both methods were compared to the Iohexol measured GFR.[4] In another ISN study, Nova Max sensor technology enabled early recognition and management of kidney disease in low resource, rural settings.[5] In this study, patients at high risk for kidney disease, such as those with hypertension, diabetes, cardiac disease, and workers in high heat environments were screened using Nova Max Creatinine/ eGFR sensor technology. The authors concluded:

"This multicenter, non-randomised feasibility study in low-resource settings demonstrates that it is feasible to implement a comprehensive program utilising POC testing and protocol-based management to improve the recognition and management of AKI and AKD in high-risk patients in primary care locations."[5]

Technology Characteristics

Accuracy, Correlation, Sensitivity, Specificity, and Precision

Accuracy

Nova Max uses a very accurate, enzymatic biosensor technology to measure blood creatinine, and eGFR is calculated using the National Kidney Foundation recommended CKD-EPI 2021 equation, with or without race as a factor. In a large university medical centre study sponsored by the International Society of Nephrology, Nova's biosensor technology proved more accurate at detecting early-stage kidney disease than the laboratory Jaffe creatinine/eGFR method when both methods were compared to the gold standard measured GFR (mGFR).[4]

Correlation

In a study performed for FDA regulatory submission, 517 patients at three different sites had Nova Max Creatinine eGFR tests performed on fingerstick capillary blood samples. At the same time a venous blood sample was drawn and a laboratory analysis of creatinine and eGFR was performed. The method correlations are displayed in the below graph.

Sensitivity and Specificity

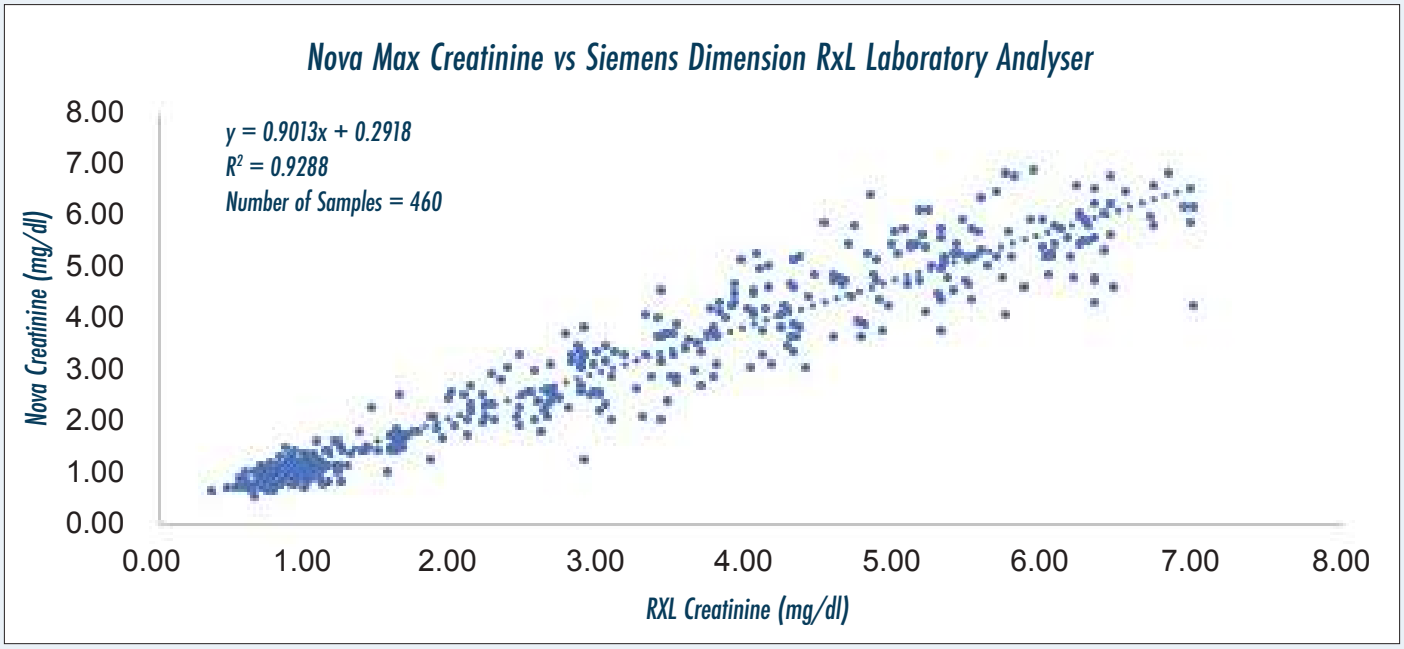
Sensitivity is the ability of a method to detect patients with the disease and specificity is the ability to detect patients without the disease. For kidney disease, patients with an eGFR>60ml/min/1.73m^2 are considered to have normal kidney function, patients with eGFR< 60ml/min/1.73m^2 are considered to have kidney disease. Nova Max uses the CKD-EPI equation to calculate eGFR. The results from this 517 patient study were:

Sensitivity 98.9% (357/361)	
Specificity 85.3% (133/156)	
True Positives = 357	False Positives = 23
True Negatives = 133	False Negatives = 4

Creatinine Precision

Day-to-Day Precision, Controls			
	Level 1	Level 2	Level 3
N	240	240	240
Mean (mg/dL)	1.5	3.4	5.5
SD/CV%	0.13	5.3%	4.5%

Within Run Precision, Whole Blood			
	Level 1	Level 2	Level 3
N	120	120	120
Mean (mg/dL)	1.5	3.4	5.5
SD/CV%	0.08	5.4%	4.0%



Simple Test Procedure

Nova Max Creatinine/eGFR testing is as easy as glucose self-testing which is done daily by millions of people with diabetes. Creatinine/eGFR testing can easily be performed by staff in pharmacies, clinics, and physician offices.

Four Steps, Results in 30 Seconds

1. Insert test strip in the meter

2. Enter patient age and gender in meter (patient ID and race are optional)

3. Perform fingerstick with lancet to obtain a blood drop

4. Touch the end of the test strip to the blood drop. Creatinine and eGFR results are displayed in 30 seconds.

A Capillary Blood Sample Means Testing Without a Blood Draw

Capillary blood testing eliminates the need for a venipuncture by a phlebotomist, blood drawing tubes and needles. Testing for Nova Max Creatinine/eGFR requires a small (1.2 microliter) blood drop from a finger prick and is virtually painless for the patient.

CKD-EPI 2021 eGFR Equation is Used

This is the preferred method for estimation of glomerular filtration rate because of better accuracy at detecting early stages of kidney disease. The equation is offered with or without race as a factor.

Wireless Bluetooth Communication

Patient kidney data from the meter can be downloaded to healthcare professionals, medical records, or other applications.

Current Field Studies

Portable system includes carry case, meter, test strips, controls vials, lancets, charging cord with plug, quick reference guide, and meter stand

Pharmacies

A recent study highlighted the value of eGFR testing in community pharmacies in Spain.[6] The Nova creatinine eGFR meter was used to evaluate patients that were asymptomatic for CKD but were either on potentially nephrotoxic medications or at risk for chronic kidney disease. Almost 200 patients were tested in four pharmacies, with 44% of them showing an eGFR of <60 (the level indicating kidney disease). Of these patients with a low eGFR, almost half of them (43%) had medication dosages that required adjustment or discontinuation. This study highlights the value of eGFR testing in the outpatient setting, and the important patient improvements it can bring. The study is being expanded to 5,000 patients.

Another pharmacy study in the Netherlands used Nova Creatinine/eGFR to screen asymptomatic CKD patients with previously unknown kidney disease who were prescribed non-steroidal anti-inflammatory drugs. The authors found that "POC measurement of creatinine with eGFR estimation changed the prescription of NSAIDs in almost 25% of patients with previously unknown renal function."[7]

Community Screening of At-Risk Individuals

Nova Creatinine/eGFR measuring technology has proven to be an excellent tool for kidney screening and early detection of kidney disease in community health centers. One study concluded: "We effectively utilised a clinical symptom-based score and deployed POC creatinine and urine dipstick tests for screening and identification of patients with kidney dysfunction across three different low-resource settings. We described a practical approach for evaluating and classifying patients as AKD, CKD, or NKD in the absence of knowledge of their prior state of kidney health, to guide further evaluation and follow-up."[3]

Nova POC devices have also been used to assess kidney function in community healthcare clinics in Low and Middle-Income Countries (LMIC) to screen for patients at risk for kidney disease.[4, 5] Even in wealthier countries, individuals living in remote areas face obstacles in terms of access to routine laboratory testing, and Nova Max eGFR can be a cost-effective solution to allow for screening and monitoring of these populations. Importantly, there is no sacrificing quality and accuracy using the Nova device to evaluate kidney disease, as a head-to-head comparison with the Nova eGFR device showed it to be more accurate than a hospital laboratory analyser when compared to a true measured GFR.[4]

Clinics and Physician Offices

AstraZeneca has begun a study using Nova Max Creatinine/eGFR in hundreds of physician offices in 25 countries to screen asymptomatic but potentially at-risk patients for kidney disease. As with other screening studies, the thesis is that early detection will improve outcomes for patients by allowing early treatment.

Imaging Centres

Administering contrast dyes for radiological exams is known to be potentially nephrotoxic, making kidney function assessment recommended prior to administering contrast media. Since many of these studies take place in outpatient imaging facilities, patients without recent eGFR test results may face cancellation of their exam or delays. Several studies have now evaluated the use of Nova Biomedical devices for testing in these facilities, with results that show acceptable accuracy and error rates when compared with central laboratory analysers.8-14

In the case of procedures on patients at high risk for contrast-induced nephropathy, such as cardiac catheterisation and peripheral arteriography, contrast loads can be high, and kidney injury may not be apparent for several days after the procedure. In these cases, patients could be sent home with the device to allow early detection of kidney injury.

Home Testing

There are numerous opportunities for patients to benefit from eGFR self-testing. Monitoring of eGFR at home provides convenience, cost-effectiveness, and improved outcomes by early detection of kidney disease. Populations that have been studied using the Nova meter at home include cardiac catheterisation patients (unpublished data from ongoing study), renal transplant patients, and Native American populations living in remote settings.[15-19] Ongoing home self-testing studies with the Nova meter are being conducted by the Chronic Renal Insufficiency Cohort (CRIC)* for monitoring patients with kidney disease.[20]

Home Testing for Kidney Transplant Patients

After kidney transplantation, early detection of transplant failure is mandatory to minimise harm to the patient and permanent damage to the transplanted organ. Patients therefore have laboratory eGFR/creatinine tests on average 20 times during the first year post transplantation. The high frequency of outpatient visits after kidney transplantation is burdensome to the recovering patient and to health care system capacity. A self-monitoring program can improve post transplantation care by early identification of acute rejection due to higher frequency of testing, decrease the high number of outpatient visits, increase patient satisfaction, all of which may improve kidney-graft survival. A study is beginning at the UK National Health Service (NHS) to monitor kidney transplant patients at home by having their self-test results transmitted automatically to clinical staff for evaluation and intervention.

*CRIC Study members include University of Pennsylvania, Kaiser Permanente, Johns Hopkins University, University of Maryland, University of California, San Francisco, University Hospitals/Case Medical Center Cleveland, The Cleveland Clinic, MetroHealth Medical Center Cleveland, University of Michigan, University of Illinois Chicago, Tulane University, and Wayne State University.

Nova Max Pro Specifications

Test Measured: ..... Creatinine
Tests Reported: ..... Creatinine, eGFR
Test Time: ..... 30 seconds
Test Strip Volume: ..... 1.2 µL
Test Methodology: ..... Electrochemistry
Weight: ..... 75g (0.2 lbs)
Size: ..... 2.36 in x 3.7 in x .62 in (6 cm x 9.4 cm x 1.6 cm)

Sample Types and Operating Modes:
Whole Blood: ..... Capillary

Measurement Range:
Creatinine: ..... 0.30-7.00 mg/dL or 27-619 µmol/L

Operating Ranges:
Temperature: ..... 59˚F – 104˚F (15˚C – 40˚C)
Altitude: ..... 15,000 feet (Up to 4,500 meters)
Humidity: ..... 10% to 90% relative humidity

Test Strips and Reagents:
Test Strip Refrigerated Storage: ..... 12 months 36˚F – 46˚F (2˚C – 8˚C)
Test Strip in Use Stability: ..... 3 months
Quality Control ..... 3 levels (low, normal, high)

Data Storage:
Patient and QC Tests: 400

eGFR and CrCl Equations: ..... CKD-EPI 2009 and 2021

FDA Labeling: ..... For in-vitro diagnostic use, 510K clearance pending

Connectivity:
Meter Data Output: ..... Wireless Bluetooth connectivity

Battery: ..... 3.7V Li Polymer Rechargeable Battery

Additional Features:
• LCD large colour display • Traditional QC with target values assigned to QC materials • Units of measure based on meter (mg/dL or µmol/L) • Automatic shut-off when not in use • Automatic sample detection and analysis • Automatic sample counting with date/time stamp for data tracking

Optional Carry Case:
Robust plastic storage/carry case holds meter, test strips, controls vials, lancets, charging cord with plug, quick reference guide, and meter stand

Certifications and Compliance:
ISO 13485:2016 Quality System Registration, VDR Class A, IVDD, CE Self Declared, Tested according to: EN 61010-1:2010, EN 61010-2-101:2015

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