StatSensor™

Point-of-Care Whole Blood Creatinine and eGFR Testing

Single-Use Creatinine Biosensor Test Strip

Virtually Painless Finger Stick Capillary Blood Sample,1.2 µL

Fast, 30 Second Analysis

Wide Measurement Range 27-1050 µmol/L (0.3-12 mg/dL)

Calculated eGFR and Creatinine Clearance

nova® biomedical

StatSensor™ Whole Blood Creatinine and eGFR

StatSensor™ Creatinine Meter

Nova StatSensor™ Creatinine Measuring System

In response to the growing need to quickly and easily assess kidney function in many point-of-care settings, Nova Biomedical introduces StatSensor Creatinine, a handheld analyzer and miniaturized, disposable biosensor for whole blood creatinine testing. StatSensor Creatinine system incorporates new, patented Multi-Well™ technology adapted from Nova's hospital glucose monitoring system. StatSensor advanced technology now enables simple, rapid, and accurate assessment of renal function by finger stick capillary blood sampling at the point of care.

It features:

- Creatinine accuracy comparable to hospital laboratory testing
- Estimated glomerular filtration rate (eGFR) by MDRD and Cockcroft-Gault equations
- Simple test procedure (single use, precalibrated disposables)
- Virtually painless, fingerstick capillary blood sampling (1.2 µL)
- Fast, 30 second results
- Wide measurement range: 27 µmol/L to 1050 µmol/L (0.3-12 mg/dL)

Creatinine with eGFR Enhances Assessment of Renal Function

The whole blood creatinine concentration has limitations when used alone to assess kidney function. While creatinine is the best single blood test for kidney function, it is influenced by age, gender, race, and body composition. For example, an elderly person could lose half of his/her kidney function before creatinine rises above the upper limit of normal. Conversely, eGFR may decline by approximately 50% of normal level before the creatinine concentration rises above the upper limit of normal.

Creatinine with eGFR is a more accurate and sensitive assessment of kidney function than creatinine alone. eGFR takes into account the creatinine concentration and other variables including: age, gender, race, and body size.

StatSensor calculates glomerular filtration rate (eGFR) by MDRD and Creatinine Clearance (CrCl) by Cockcroft-Gault equations.

eGFR and Chronic Kidney Disease

Stages Defined by National Kidney Foundation

Stage	Description	Glomerular filtration (GFR), per 1.73 m^2
1	Kidney Damage with normal or increased GFR	>90
2	Kidney Damage with mild decrease in GFR	60-89
3	Moderate decrease in GFR	30-59
4	Severe decrease in GFR	15-29
5	Kidney failure	<15 (or dialysis)

Testing

Another Technology Advance From Nova Biomedical, the World Leader In Whole Blood Testing

Nova Biomedical is the world technology leader in the development of advanced biosensors for whole blood analysis. During the past 30 years, Nova has introduced 20 biosensors, including the industry's first biosensor to directly measure whole blood glucose in 1988, and the industry's first biosensor to directly measure whole blood creatinine in 1996. These earlier biosensors are used routinely in thousands of hospital laboratories and critical care settings around the world in our Stat Profile® brand blood gas/critical care analyzers. Now Nova has incorporated its creatinine biosensor technology into a precalibrated, single use, disposable system that provides laboratory quality test results at the point of care.

Nova Whole Blood Measurement Technologies

Core Technology	Measured Analyte	Abbreviation	Methodology
Amperometric (whole blood or serum)	Creatinine	Crea	Immobilized three enzyme membrane + H_2O_2
	Glucose	Glu	Immobilized glucose oxidase membrane + H_2O_2
	Glutamate	Glut	Immobilized glutamate oxidase membrane + H_2O_2
	Glutamine	Gln	Immobilized glutaminase and glutamate oxidase + H_2O_2
	Lactate	Lac	Immobilized lactate oxidase + H_2O_2
	Partial Pressure Oxygen	PO_2	O_2 membrane, O_2 reduction by cathode
Conductivity	Hematocrit	Hct	Electrical resistance, Na^+ corrected
Potentiometric (whole blood or serum)	Acetate	Ace	pH electrode with acetic acid permeable membrane
	Ammonium	NH_4^+	Ammonium ISE ionophore in PVC
	Chloride	Cl^-	Chloride anion ionophore in PVC
	Hydrogen Ion Activity	pH	Hydrogen ion selective glass membrane
	Ionized Calcium	Ca^{++}	Calcium ionophore in PVC
	Ionized Magnesium	Mg^{++}	Magnesium ionophore in PVC
	Lithium	Li^+	Lithium ionophore in PVC
	Partial Pressure CO_2	PCO_2	pH electrode with CO_2 gas permeable membrane
	Potassium	K^+	Valinomycin ionophore in PVC
	Sodium	Na^+	Sodium ion selective glass membrane or sodium ionophore in PVC
	Total Calcium	TCa	Calcium electrode with acidified sample
	Total Carbon Dioxide	TCO_2	pH electrode, CO_2 membrane, acidified sample
	Urea/Urea Nitrogen/BUN	Urea	Urease enzyme membrane and ammonium ISE
Photometric (lysed whole blood)	Carboxyhemoglobin	COHb	Multi-wavelength spectral scanning of hemolyzed RBCs
	Deoxyhemoglobin	HHb	Multi-wavelength spectral scanning of hemolyzed RBCs
	Methemoglobin	MetHb	Multi-wavelength spectral scanning of hemolyzed RBCs
	Oxygen Saturation	SO_2%	Multi-wavelength spectral scanning of hemolyzed RBCs
	Oxyhemoglobin	O_2Hb	Multi-wavelength spectral scanning of hemolyzed RBCs
	Sulfhemoglobin	sHb	Multi-wavelength spectral scanning of hemolyzed RBCs
	Total Hemoglobin	tHb	Multi-wavelength spectral scanning of hemolyzed RBCs
Photometric (whole blood, nondestructive)	Cell Density	CD	Multi-wavelength fiber optic reflectance
	Hemoglobin	Hb	Multi-wavelength fiber optic reflectance plus conductivity, sodium correction
	Oxygen Saturation	SO_2%	Multi-wavelength fiber optic reflectance (oximetry)

Simple, Fast, and Accurate Creatinine/eGFR Testing

Rapid, Easy to Use, Point-of-Care Creatinine Testing

No User Calibration

StatSensor biosensors are precalibrated immediately and ready to use.

- No analyzer or biosensor preanalytical steps, such as using a calibrating reagent or entering a calibration code in the analyzer, are necessary.
- By eliminating this calibration step, StatSensor is actually simpler to operate than most meters used by diabetics at home to self-test for glucose.

Simple Test Procedure

A bright, easy to read, color screen prompts the user through the StatSensor test procedure.

1. Place the sensor in meter
2. Stick finger to create blood drop
3. Apply strip to blood drop
4. Read creatinine results

Fast, 30 Second Creatinine Results

Assessment of kidney function can be made in real time at the point of care. Patient care treatments that require prior kidney assessment can be expedited.

Creatinine with eGFR Enhances Renal Function Assessment

StatSensor can calculate eGFR by two different equations. eGFR and creatinine results are displayed along with normal ranges. Abnormal results are prominently flagged with color highlighting, text, and symbols.

Cleared for Use by Point-of-Care Personnel

StatSensor can be used by nurses, radiology technicians, or other non-laboratory personnel.

Capillary Blood Sampling is Virtually Painless

StatSensor uses a very small, 1.2 microliter blood sample (less than one drop). Samples can be obtained virtually painlessly from a capillary finger stick using the same type lancet used by diabetics at home to self-test for glucose. No venous blood drawing or phlebotomist is needed.

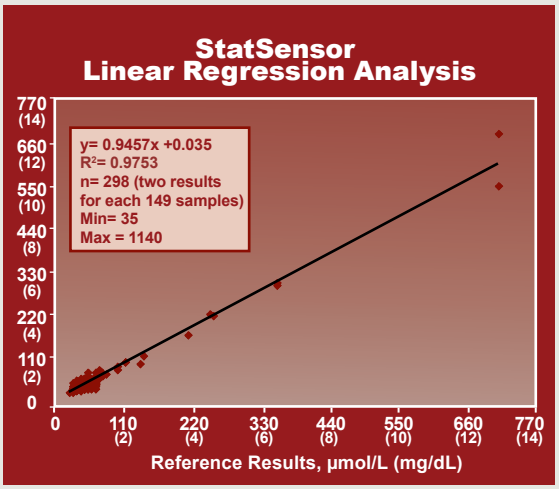
g at the Point of Care

StatSensor Accuracy is Comparable to Hospital Laboratory Testing

Point-of-care testing is often performed on a hospital's most critical patients. The test results may be used to make immediate decisions regarding patient care. Point-of-care testing demands a level of analytical performance as accurate and precise as testing performed in the hospital laboratory. Advanced StatSensor technology provides that performance.

StatSensor Measures and Eliminates Interference Due to Hematocrit

Measurements made on whole blood samples are subject to interference due to varying hematocrit levels of the sample. One of the three StatSensor measurement wells measures and corrects for varying hematocrit levels. Accurate results are obtained throughout a broad range of hematocrit.

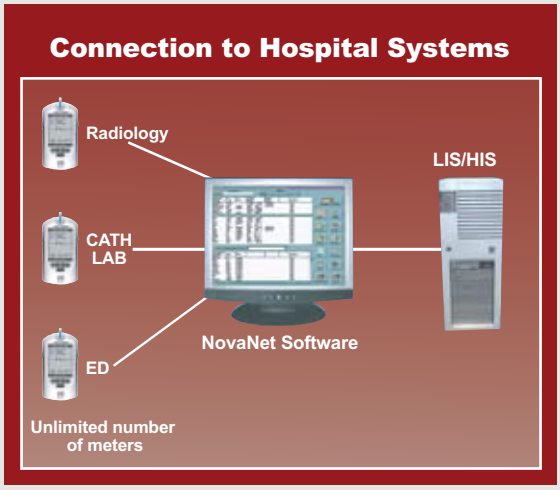


StatSensor Whole Blood vs Central Laboratory Plasma Reference Method (Enzymatic)

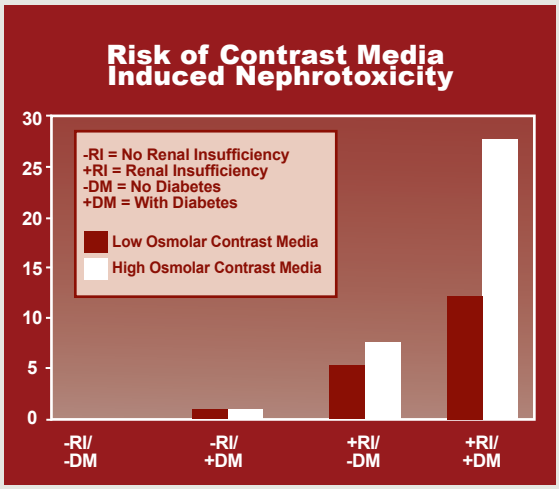
Interfaces with Hospital and Laboratory Information Systems

NovaNet™ Desktop software combined with multiple choices of interface and data management software systems provide comprehensive connectivity, management, and control for StatSensor point-of-care testing. These systems provide the critical components for successful point-of-care testing including:

- LIS/HIS Interface and Connectivity Management
- Management of Patient and QC Data
- Regulatory Compliance via Audit Logs, Reports, and Records



Point-of-Care Creatinine Testing for Radiology,



The primary risk factor for contrast media induced nephrotoxicity is pre-existing renal dysfunction, especially diabetic nephropathy[2]

For Radiology and Cardiac Catheterization

Minimize Risk of Contrast Media Induced Nephropathy

Contrast media induced nephropathy (CMIN) is the third most common cause of acute renal failure in hospitalized patients.[1] CMIN is associated with prolonged hospital stay, adverse cardiac events, and high mortality. An increasing number of imaging procedures require the use of intravenous contrast media, and the patient population subjected to these procedures is progressively older and has more pre-existing conditions. The benefits of a fast, easy POC creatinine assay are:

- StatSensor can minimize the risk of CMIN by providing comprehensive assessment of renal impairment prior to contrast media imaging.
- Comprehensive renal assessment allows renal protective strategies to be considered.
- Testing can be easily performed by radiology personnel.

Improve Productivity and Workflow

Radiology and Cath Labs are highly specialized and costly departments to operate. Procedures are carefully scheduled in order to provide efficient use of personnel and procedure rooms to reduce costs. Patients arriving for contrast media imaging procedures without prior renal assessment must be sent to the laboratory for creatinine testing. Obtaining creatinine/eGFR results from the lab can delay the procedure for hours or require rescheduling for another day. Productivity is lost when schedule openings occur.

- StatSensor point-of-care creatinine/eGFR testing can prevent costly procedure room openings, and loss of personnel and equipment productivity.
- A simple, inexpensive StatSensor test can prevent cancellation or rescheduling of a scan when kidney function testing is needed.

Improve Patient Satisfaction

Long delays or even cancellation and rescheduling of procedures can occur when renal status is unknown at the patient's time of appointment. Patients may be forced to wait for hours for their creatinine/eGFR blood test or to come back another day. Patient dissatisfaction is likely if these events occur.

- StatSensor provides rapid, 30 second assessment of renal function, virtually painlessly, from a finger stick.
- StatSensor point-of-care testing in the department can prevent patient dissatisfaction when renal function must be determined.

[1] **Hou, SH et al:** *Hospital-acquired renal insufficiency: a prospective study.* Am J Med 74:243-8, 1983.
[2] **Rudnick, MR et al:** *Nephrotoxicity of ionic and nonionic contrast media in 1196 patients; a randomized trial.* Kidney Int 47:254-261, 1995.

Cardiac Labs, Oncology, ED, and ICU

For Oncology

Reduce Medication Risks

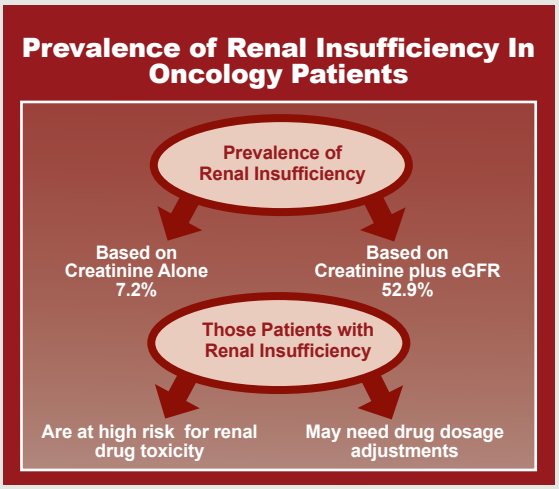
Renal impairment is frequent in cancer patients, and these patients are at high risk of drug-induced renal toxicity. This has implications for drug selection and dosing. Many chemotherapy drugs are prescribed close to the maximum therapeutic dose. Renal function determines whether there is any need to use the drug more sparingly or to avoid the drug entirely. This is especially true for drugs that are cleared primarily by the kidney and for drugs with established nephrotoxicity.

- StatSensor provides a rapid, 30 second, accurate assessment of renal function including eGFR.
- StatSensor testing can be easily performed in the oncology clinic.
- Renal safety for chemotherapy patients is assured.

Improve Patient Satisfaction

Many chemotherapy outpatients need to have their kidney function assessed before receiving their chemotherapy session. Obtaining a venous blood sample and sending it to a laboratory for creatinine/eGFR testing could delay chemotherapy for several hours. A chemotherapy session that might take a couple of hours could turn into a full day.

- With StatSensor, a capillary blood sample can be obtained and renal function can be quickly determined.
- Treatment delays and patient dissatisfaction are avoided.



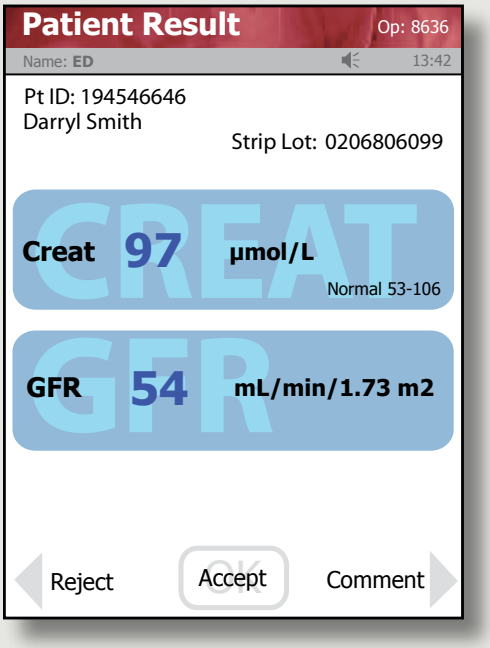
The French study Insuffisance Renale et Medicaments Anticancereux (IRMA) looked at more than 4600 cancer patients. The study found that renal insufficiency is common in cancer patients- a problem further complicated because a majority of chemotherapy drugs are nephrotoxic.[3]

For the Emergency Department

Improve Triage, Expedite Patient Care

Various patient care protocols in the emergency department such as chest pain and stroke protocols may require rapid assessment of renal function in order to triage the patient for radiologic procedures. Many other ED protocols require timely administration of drugs and adjustment of drug dosage based on renal function.

StatSensor accurately assesses renal function with a simple, 30 second test that can be easily performed in the ED.



For the ICU

Acute renal failure (ARF) is a common occurrence among patients admitted to the ICU. Results of a multinational study suggest that ARF requiring renal replacement therapy occurs in 5% to 6% of ICU patients.[4] Mortality for ARF in the ICU setting may be as high as 70%. Early detection and therapy is critical in reducing morbidity and mortality from ARF.

- StatSensor Creatinine with eGFR provides real time assessment of kidney function with a simple, 30-second test.
- Testing can be performed at the bedside by nursing or other point-of-care personnel.

[3] **Launay-Vacher v. et al.** *Insuffisance Renale et Medicaments Anticancereux (IRMA), ASCO 42nd Annual Meeting Abstract 8603.* Presented June 3, 2006.

[4] **Uchino S, Kellum JA, Bellomo R, et al.** *Acute renal failure in critically ill patients: A multinational, multicenter study.* JAMA; 294:813-818, 2005.

StatSensor™

StatSensor Specifications

Test Measured:..... Creatinine
Tests Reported: ..... Creatinine
eGFR
Test Time: ..... 30 seconds
Test Strip Volume: ..... 1.2 µL
Test Methodology:..... Electrochemistry
Weight:..... 360 g (0.8 lbs)
Size: ..... 153 mm x 82.5 mm x 46 mm
(6.0 in x 3.25 in x 1.8 in)

Sample Types and Operating Modes:
Whole Blood:..... Arterial, Venous, Capillary

Measurement Range:
Creatinine: ..... 27-1050 µmol/L (0.3-12.0 mg/dL)

Operating Ranges:
Temperature:..... 15˚C- 40˚C (59˚F-104˚F)
Altitude: ..... Up to 4,454 meters (15,000 feet)
Humidity:..... 10% to 90% relative humidity

Reagents and Strips:
Strips:..... 25 strips per vial/box of 50
QC:..... Three levels (Low, Normal, High);
sold separately
Linearity:..... Five levels available

Test Strip Stability:
Refrigerated Storage:
12 months 2˚C-8˚C (36˚F-46˚F)
Room Temperature Storage:
3 months

eGFR and CrCl Equations:
MDRD for Glomerular Filtration Rate (eGFR) and
Cockcroft-Gault for Creatinine Clearance (CrCl)

Certifications and Compliance:
ISO 9001 Quality System Registration, CSA, TÜV, IVDD,
CE Self Declared Complies to EN 61010, EN 50081,82

FDA Labeling:
For in-vitro diagnostic use

Data Storage:
Patient Tests: .....1,000 tests
QC Tests:.....200 tests
Users: .....4,000 users

Connectivity:
Data Output Port:.....Ethernet (10 Mbit)
Meter Data Output:.....RJ-45 Ethernet Port
Protocol:.....TCP/IP Ethernet 10 Mbit
Standard: .....POCT1-A Compliant
Setup Program: .....NovaNet™ Web-Based
Instrument Manager Software

Battery Information:
Type: .....3.7V Li Polymer Rechargeable Battery
Features:.....Rechargeable/Replaceable
Life:.....8 hours in use (approximately 40 tests
w/barcode scans) / 12-24 hours standby

Docking Station:
Optional accessory; desk or wall mount charging station with RJ-45 Ethernet jack. 3 LED indicator lights showing connection status, transmit/receive data, and charging status. Extra battery slot included for recharging and storage of spare battery.

Additional Features:
Color touch screen • Built-in barcode scanner • Traditional QC with target values assigned to QC materials • Numeric or pass/fail QC • QC prompting or QC lock out • Abnormal and critical ranges flagged by color highlighting • Canned or free text user comments • Rejecting of results at meter (optional) for repeat testing • Accepting patient ID or accession number • Use of operator password (lock-out) • Entry of ICD-9 Diagnosis codes • Ordering physicians I.D. • Slope and intercept adjustment • Web-based meter configuration by location • Custom meter configuration by medical unit • Connect to hospital ADT • Connect to all LIS/EMR • POCT1-A data output • Optional Carrying Case

Nova Biomedical Patent Numbers:
US 6,767,441 CA 2,470,465 (Patent Pending)

Specifications subject to change without notice.

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