

*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  $\mu$ L**

**Fast, 30 Second Analysis**

**Wide Measurement Range 0.3-12 mg/dL (27-1050  $\mu$ mol/L)**

**Calculated eGFR and Creatinine Clearance**

*nova*<sup>®</sup>  
*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, finger stick capillary blood sampling (1.2 µL)
- Fast, 30 second results
- Wide measurement range: 0.3-12 mg/dL (27-1050 µmol/L)

## 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. As a result, a National Institutes of Health initiative, the National Kidney Disease Education Program (NKDEP), recommends reporting eGFR with every creatinine measurement.

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 <sup>2</sup>
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)

## 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	
<b>Amperometric</b> (whole blood or serum)	Creatinine	Crea	Immobilized three enzyme membrane + H <sub>2</sub> O <sub>2</sub>	
	Glucose	Glu	Immobilized glucose oxidase membrane + H <sub>2</sub> O <sub>2</sub>	
	Glutamate	Glut	Immobilized glutamate oxidase membrane + H <sub>2</sub> O <sub>2</sub>	
	Glutamine	Gln	Immobilized glutaminase and glutamate oxidase + H <sub>2</sub> O <sub>2</sub>	
	Lactate	Lac	Immobilized Lactate oxidase + H <sub>2</sub> O <sub>2</sub>	
	Partial Pressure Oxygen	PO <sub>2</sub>	O <sub>2</sub> membrane, O <sub>2</sub> reduction by cathode	
	<b>Conductivity</b> <b>Potentiometric</b> (whole blood or serum)	Hematocrit	Hct	Electrical resistance, Na <sup>+</sup> corrected
		Acetate	Ace	pH electrode with Acetic Acid permeable membrane
		Ammonium	NH <sub>4</sub> <sup>+</sup>	Ammonium ISE ionophore in PVC
		Chloride	Cl <sup>-</sup>	Chloride anion ionophore in PVC
Hydrogen Ion Activity		pH	Hydrogen ion selective glass membrane	
Ionized Calcium		Ca <sup>++</sup>	Calcium ionophore in PVC	
Ionized Magnesium		Mg <sup>++</sup>	Magnesium ionophore in PVC	
Lithium		Li <sup>+</sup>	Lithium ionophore in PVC	
Partial Pressure CO <sub>2</sub>		PCO <sub>2</sub>	pH electrode with CO <sub>2</sub> gas permeable membrane	
Potassium		K <sup>+</sup>	Valinomycin ionophore in PVC	
Sodium	Na <sup>+</sup>	Sodium ion selective glass membrane or sodium ionophore in PVC		
Total Calcium	TCa	Calcium electrode with acidified sample		
Total Carbon Dioxide	TCO <sub>2</sub>	pH electrode, CO <sub>2</sub> membrane, acidified sample		
Urea/Urea Nitrogen/BUN	Urea	Urease enzyme membrane and ammonium ISE		
<b>Photometric</b> (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 <sub>2</sub> %	Multi-wavelength spectral scanning of hemolyzed RBCs	
	Oxyhemoglobin	O <sub>2</sub> Hb	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	
<b>Photometric</b> (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 <sub>2</sub> %	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.

### FDA 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.



## StatSensor Accuracy is Comparable to Hospital Laboratory Testing

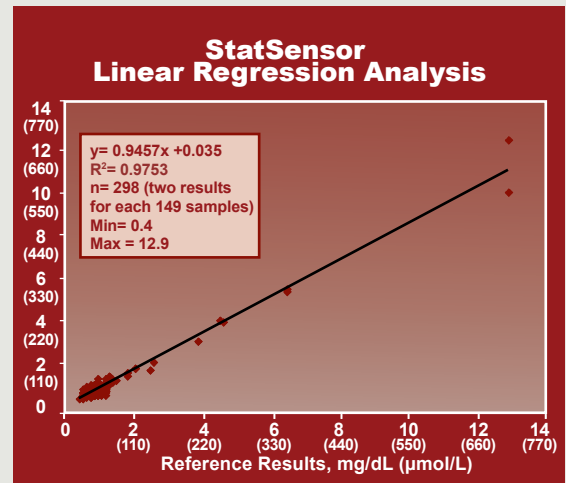
Point-of-care testing is often performed on a hospital's most critical patients. The test results may be used to make immediate decisions regarding patient care. Point-of-care testing demands a level of analytical performance as accurate and precise as testing performed in the hospital laboratory. Advanced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

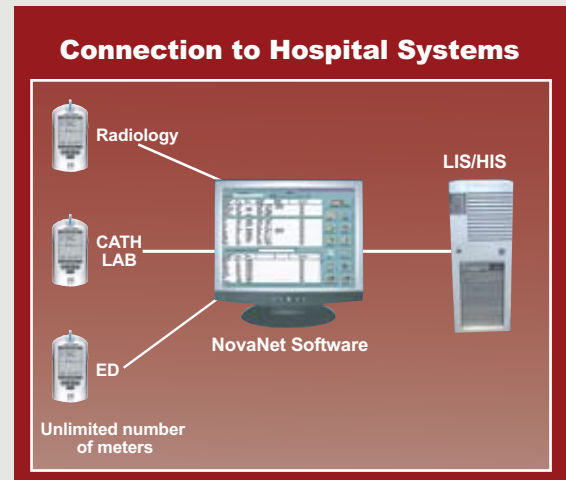
## Interfaces with Hospital and Laboratory Information Systems

NovaNet™ Desktop software combined with interface and data management software systems such as TELCOR's Quick-Line® 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:

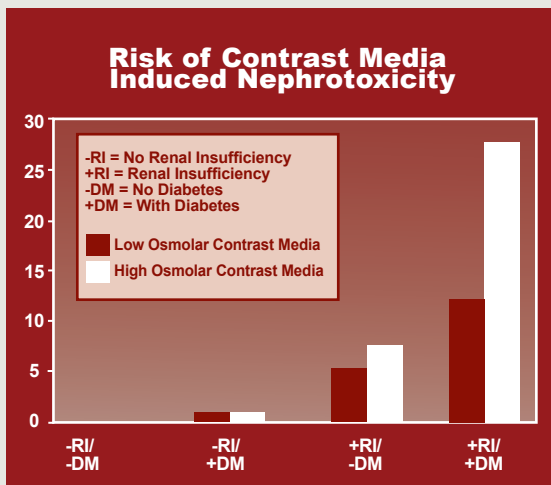
- LIS/HIS Interface and Connectivity Management
- Management of Patient and QC Data
- Regulatory Compliance via Audit Logs, Reports, and Records



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



# Point-of-Care Creatinine Testing for Radiology,



The primary risk factor for contrast media induced nephrotoxicity is pre-existing renal dysfunction, especially diabetic nephropathy<sup>2</sup>



## 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.<sup>1</sup> 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.

<sup>1</sup> Hou, SH et al: Hospital-acquired renal insufficiency: a prospective study. *Am J Med* 74:243-8, 1983.

<sup>2</sup> 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.

## 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.

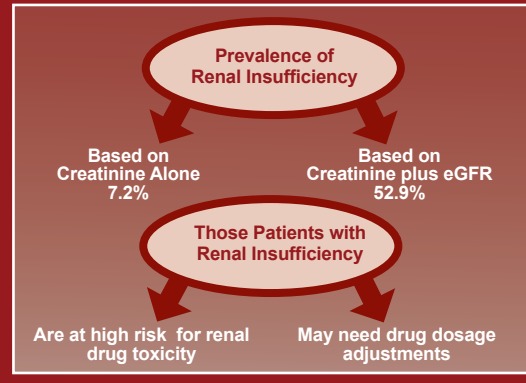
StatSensor accurately assesses renal function with a simple, 30 second test that can be easily performed in the ED.

## For the ICU

Acute renal failure is a common occurrence among patients admitted to the ICU. Results of a multinational study suggest that acute renal failure (ARF) requiring renal replacement therapy occurs in 5% to 6% of ICU patients.<sup>4</sup> 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.

## Prevalence of Renal Insufficiency In Oncology Patients



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.<sup>3</sup>

Patient Result		Op: 8636
Name: ED		13:42
Pt ID: 194546646	Darryl Smith	
	Strip Lot: 0206806099	
<b>Creat</b>	<b>1.1</b> mg/dL	Normal 0.6-1.2
<b>GFR</b>	<b>54</b> mL/min/1.73 m2	
← Reject	Accept	Comment →

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

<sup>4</sup>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:..... 0.8 lbs (360 g)  
 Size: ..... 6.0 in x 3.25 in x 1.8 in  
   (153 mm x 82.5 mm x 46 mm)

### Sample Types and Operating Modes:

Whole Blood:..... Arterial, Venous, Capillary

### Measurement Range:

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

### Operating Ranges:

Temperature:..... 59°F-104°F (15°C- 40°C)  
 Altitude: ..... Up to 15,000 feet (4,554 meters)  
 Humidity:..... 10% to 90% relative humidity

### Reagents and Strips:

Strips: ..... 25 strips per vial  
 QC: ..... Three levels (Low, Normal, High);  
   sold separately  
 Linearity:..... Five levels available

### Test Strip Stability:

Refrigerated Storage:  
 12 months 36°F-46°F (2°C-8°C)  
 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)

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