StatSensor® CREAT

Point-of-Care Whole Blood Creatinine and eGFR Testing

StatSensor Xpress

StatSensor Hospital Meter

Single-Use Creatinine Biosensor Test Strip

Virtually Painless Finger Stick Capillary Blood Sample,1.2 µL

Results in 30 Seconds

Wide Measurement Range, 27-1056 µmol/L (0.3-12 mg/dL)

Calculated eGFR by CKD-EPI and MDRD Equations

nova® biomedical

StatSensor® Whole Blood Creatinine and eGFR Testing

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 (POC) settings, Nova Biomedical introduces StatSensor Creatinine, a handheld analyser and miniaturised, disposable biosensor for whole blood creatinine testing. StatSensor Creatinine incorporates patented Multi-Well™ technology adapted from Nova's hospital glucose monitoring system. StatSensor advanced technology enables simple, rapid, and accurate assessment of renal function by finger stick capillary blood sampling at the point of care.

Features:

- Correlates with laboratory enzymatic creatinine methods
- Estimated glomerular filtration rate (eGFR) by CKD-EPI, MDRD and Cockcroft-Gault equations
- Simple test procedure (single-use, precalibrated disposables)
- Virtually painless, finger stick capillary blood sampling (1.2 µL)
- Results in 30 seconds
- Wide measurement range: 27 µmol/L to 1056 µmol/L (0.3-12 mg/dL)

Creatinine with eGFR Enhances Assessment of Renal Function

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.

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 Creatinine calculates eGFR by CKD-EPI, 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 m²
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 36 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 biosensors are used routinely in thousands of hospital laboratories and critical care settings around the world in our Stat Profile® series of critical care blood gas analysers. Nova has incorporated its creatinine biosensor technology into a precalibrated, single-use, disposable system that provides rapid screening of kidney function 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 Potentiometric (whole blood or serum)	Hematocrit	Hct	Electrical resistance, Na^+ corrected
	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, Accurate Creatinine/eGFR Testing at the P

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

No User Calibration

StatSensor biosensors are precalibrated and immediately ready to use.

- No analyser or biosensor preanalytical steps, such as using a calibrating reagent or entering a calibration code in the analyser, 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, colour screen prompts the user through the StatSensor test procedure.

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

Creatinine Results in 30 Seconds

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 three different equations. eGFR and creatinine results are displayed along with normal ranges. Abnormal results are prominently flagged with colour 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 microlitre blood sample (less than one drop). Samples can be obtained with virtually no pain from a capillary finger stick using the same type of lancet used by diabetics at home to self-test for glucose. No venous blood drawing or phlebotomist is needed.

StatSensor Creatinine is Comparable to Hospital Laboratory Testing

StatSensor Creatinine's whole blood biosensors provide excellent correlation to central laboratory plasma reference methods. StatSensor accuracy combined with fast analysis in 30 seconds and calculated eGFR enable rapid screening of kidney function at the point of care.

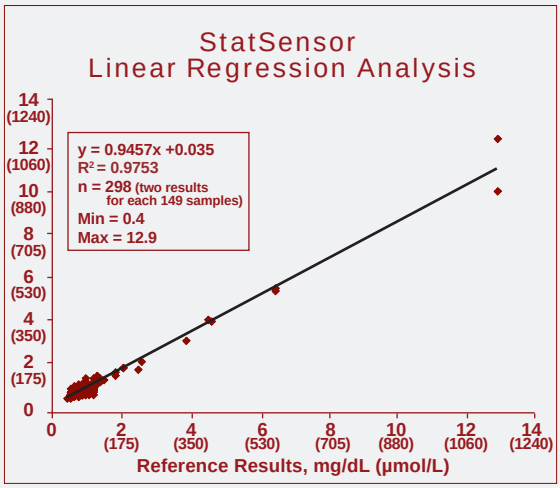
StatSensor Measures and Eliminates Interference Due to Haematocrit

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

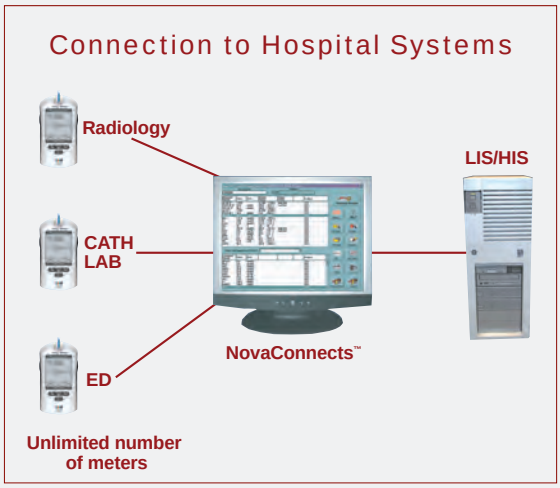
Interfaces with Hospital and Laboratory Information Systems

NovaNet provides comprehensive connectivity, management, and control for StatSensor POC testing. This system provides the critical components for successful POC testing including:

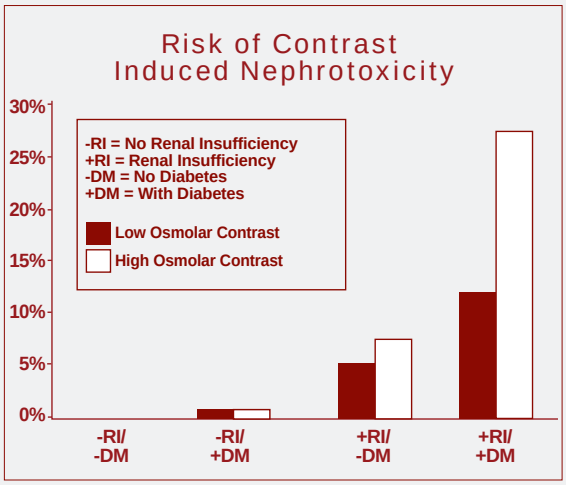
- LIS/HIS interface and connectivity management
- Management of patient and QC data
- Regulatory compliance via audit logs, reports, and records



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



Point-of-Care Creatinine Testing for Radiology, Cardiac



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

For Radiology and Cardiac Catheterization

Minimize Risk of Contrast Induced Nephropathy

Contrast induced nephropathy (CIN) is the third most common cause of acute renal failure in hospitalised patients.[1] CIN is associated with prolonged hospital stay, adverse cardiac events, and high mortality. An increasing number of imaging procedures require the use of intravenous contrast, 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 minimise the risk of CIN by providing comprehensive assessment of renal impairment prior to contrast imaging.
- Comprehensive renal assessment allows renal protective strategies to be considered.
- Testing can be easily performed by radiology personnel.

Improve Productivity and Workflow

Radiology departments and cath labs are highly specialised and costly to operate. Procedures are carefully scheduled in order to maintain productivity of personnel and procedure rooms. Patients arriving for contrast imaging procedures without valid creatinine results 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 POC 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 Creatinine provides rapid assessment of renal function in 30 seconds with virtually no pain from a finger stick.
- StatSensor POC testing in the department can prevent patient dissatisfaction when renal function must be determined.

1. Hou, S. H., Bushinsky, D. A., Wish, J. B., Cohen, J. J., & Harrington, J. T. (1983). Hospital-acquired renal insufficiency: A prospective study. *Am J Med, 74*(2), 243-248.

2. Rudnick, M. R., Goldfarb, S., Wexler, L., Ludbrook, P. A., Murphy, M. J., Halpern, E. F., …VanFossen, D. B. (1995). Nephrotoxicity of ionic and nonionic contrast media in 1196 patients: A randomized trial. The Iohexol Cooperative Study. *Kidney Int, 47*(1), 254-261.

Labs, Oncology, Emergency Department, and ICU

For Oncology

Reduce Medication Risks

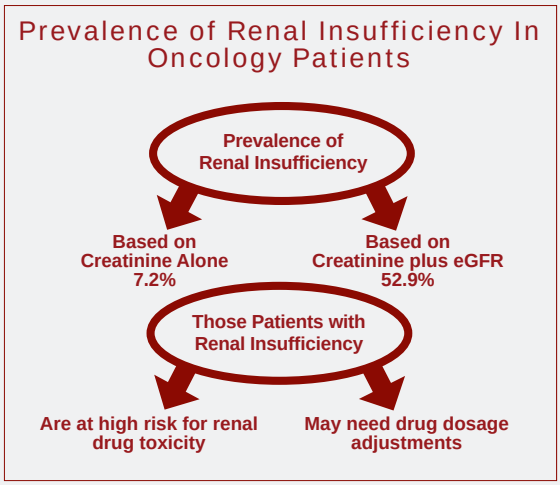
Renal impairment is frequent in cancer patients, and these patients are at high risk of drug-induced renal toxicity. This has implications for drug selection and dosing. Many chemotherapy drugs are prescribed close to the maximum therapeutic dose. Renal function determines whether there is a need to 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, accurate assessment in 30 seconds of renal function including eGFR.
- StatSensor testing can be easily performed in the oncology clinic.
- Renal safety for chemotherapy patients is ensured.

Improve Patient Satisfaction

Many chemotherapy outpatients need to have their kidney function assessed before 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 Creatinine, a capillary blood sample can be obtained and renal function can be quickly determined.
- Treatment delays and patient dissatisfaction are avoided.



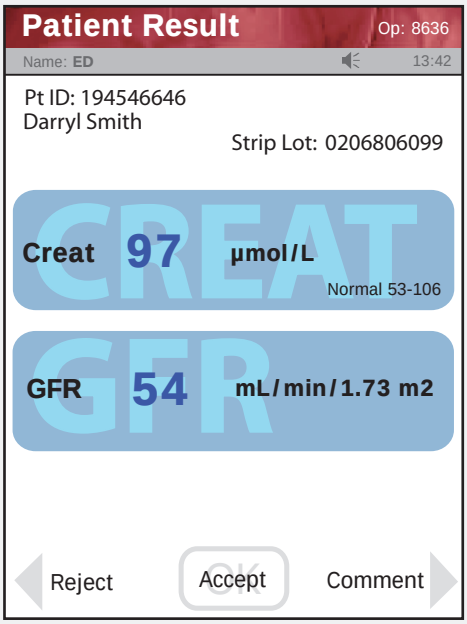
The Insuffisance Renale et Medicaments Anticancereux (IRMA) study of more than 4,600 cancer patients found that renal insufficiency is common among cancer patients–a problem that complicates drug selection and dosing.[3]

For the Emergency Department

Improve Triage, Expedite Patient Care

Various patient care protocols 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 Creatinine accurately assesses renal function with a simple test that can be easily performed in the ED in 30 seconds.



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 test in 30 seconds.
- Testing can be performed at the bedside by nursing or other POC test personnel.

3. Launay-Vacher, V., Oudard, S., Janus, N., Le Tourneau, C., Rixe, O., Pourrant, X., … Morere, J. (2006). Renal insufficiency in cancer patients: Prevalence and implications on anticancer drugs management. Results of the IRMA study [Abstract]. Retrieved from http://meeting.ascopubs.org/cgi/content/abstract/24/18_suppl/8603?sid=8b13b8a8-8eab-4e9e-a46e-f5437fb1356b

4. Uchino, S., Kellum, J. A., Bellomo, R., Doig, G. S., Morimatsu, H., Morgera, S., … Ronco, C. (2005). Acute renal failure in critically ill patients: A multinational, multicenter study. *JAMA, 297*, 813-818. doi:10.1001/jama.294.7.813

StatSensor® CREAT

StatSensor Specifications

Test Measured:.....Creatinine
Tests Reported: ..... Creatinine, eGFR
Test Time: ..... 30 seconds
Test Strip Volume: ..... 1.2 µL
Test Methodology:..... Electrochemistry
Weight:.....266g (0.6 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 – 1056 µmol/L (0.3 – 12.0 mg/dL)

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

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

eGFR and CrCl Equations:
CKD-EPI, MDRD, Cockcroft-Gault

Certifications and Compliance:
ISO 13485:2016 Quality System Registration, CSA, IVDD, CE Self Declared Tested according to: EN 61010-1:2010, EN 61010-2-101:2015, EN 60825-1/A1:2014

FDA Labeling:
For in-vitro diagnostic use

Data Storage:
Patient Tests:..... 1,000
QC Tests:..... 200
Operators: 8,000

Connectivity:
Meter Data Output:.....RJ-45 Ethernet Port
Protocol:.....TCP/IP Ethernet 100 Mbit/1 Gbit
Standard:..... POCT1-A Compliant
Setup Program: ..... NovaNet™ Web-Based Instrument Manager Software

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

StatSensor Xpress Specifications

Tests Measured Blood:..... Creatinine
Creatinine Methodology: ..... Enzyme, Amperometric Creatinine
Test Results: ..... mg/dL, µmol/L
Sample Type Whole Blood: .....Capillary, Arterial, and Venous
Creatinine Test Range: ..... 0.30 – 12.0 mg/dL
27 – 1056 µmol/L
Test Time: ..... 30 seconds
Test Strip Volumes: .....1.2 µL
Memory storage: .....400 Tests
Battery Life (nominal): .....600 Tests
Battery Type: ..... 3V coin cell
Data Cable Serial or USB

StatSensor Test Strips

Measurement Range:.....27 – 1056 µmol/L
0.3 – 12.0 mg/dL
Test Strip Stability: ....Room temperature 3 months
Refrigerated 12 months
Strip Packaging:..... Box of 50 test strips
2 vials of 25 test strips

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Specifications current as of revision date.