# Creatinine by Nova Stat Sensor

**Department of Clinical Laboratories**  
**The Ohio State University Wexner Medical Center**

<table>
<thead>
<tr>
<th>Laboratory:</th>
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<tr>
<td>Point of Care Testing</td>
<td>Procedure</td>
<td>02/28/2009</td>
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<tr>
<th>Document Author:</th>
<th>Document Owner:</th>
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<tr>
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<td>Testing personnel documents acknowledge of reading procedures during training and annual competency</td>
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**Approval***:

- Point of Care Division Director
- University Hospitals Laboratory Medical Director
- OSUWMC East Laboratory Medical Director
- Morehouse Laboratory Medical Director
- Spielman Laboratory Medical Director
- CarePoint East Laboratory Medical Director
- CarePoint Lewis Center Medical Director
- CarePoint Gahanna Medical Director
- Stoneridge II Medical Director

**Approval and Acknowledgements***

Refer to QPulse system and Document Details report for laboratory directors(s)’ electronic signature approval, employee acknowledgment and effective date.

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Revision 13

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1. PRINCIPLE

1.1. The Nova StatSensor Creatinine Meter is intended to quantitatively measure creatinine in capillary, venous and arterial whole blood. The Nova Biomedical Stat Sensor® is a bedside, point-of-care device that provides an instant, automated record of patient creatinine results and quality control tests. This device uploads results into the patient’s medical record through a data management system maintained by the clinical laboratory. The StatSensor must be used with Nova Stat Sensor® creatinine test strips.

1.2. The Nova StatSensor system uses an enzymatic reaction to measure creatinine in the blood amperometrically. The Nova StatSensor measures the creatinine levels in whole blood by measuring the electric current generated. The amount of current that is produced depends on the amount of creatinine in the sample.

1.3. The Nova StatSensor system utilizes strips that measure creatinine to calculate a glomerular filtration rate (GFR) for radiologic procedures prior to the injection of contrast dye. The GFR is used to monitor renal function and management of acute reactions to Iodinated Contrast Media Induced Toxicity. Refer to Clinician’s Guide to Preventing and responding to Iodinated Contrast Media Induce Toxicity.

2. SCOPE OF DOCUMENT:

2.1. This document applies to all Point of Care Nova StatSensor Creatinine testing locations.

3. RESPONSIBILITY:

3.1. The coordinators and manager are responsible for maintaining this document and ensuring biennial review. The laboratory medical director is responsible for establishing and approving all changes before activating document.

4. SPECIMEN COLLECTION:

WARNING: BODY FLUID PRECAUTION
Blood is a body fluid capable of transmitting infectious diseases. Universal precautions for the prevention of the transmission of blood borne pathogens must be in effect at all times.

4.1. Patient Preparation
   4.1.1. Verify patient identification using at least 2 identifiers. Double check the patient’s name and medical record number before the procedure begins.
   4.1.2. If the patient is able, verify the patient’s identity by asking them to state their name. Compare with name on the identification bracelet and the pre-printed barcode label.
   4.1.3. Match the patient name and medical record number on the identification bracelet with the patient’s chart.
   4.1.4. Match the pre-printed barcode label’s patient name and medical record number with the patient’s chart.
   4.1.5. For outpatient procedures, the patient’s name and date of birth must be used as double-identifiers.

4.2. Specimen type
   4.2.1. Whole blood; capillary blood collected from a single use lancing device. Single use lancing devices are disposed in a sharps container.
   4.2.2. Whole blood sample from an indwelling vascular line.
   4.2.3. Lithium heparinized whole blood samples may be obtained by venipuncture.
   4.2.4. Care should be taken to prevent the introduction of air into the sample during and after collection. If using a syringe, expel any air bubbles immediately after collection. Cap or seal the end of the collection device.
4.3. The samples are tested at the point-of-care. If the patient’s sample will be leaving the bedside to be tested in another location, the sample must be identified with the patient’s full name and medical record number to avoid sample rejection.

4.3.1. Samples must be tested as soon as possible after collection. Do not use any kind of transport media to store or transfer samples.

4.3.2. If not analyzing from a lancing device, heparinized whole blood must be analyzed within 30 minutes.

a. If analyzing blood collected in a syringe, it is important to test immediately after collection. If using a heparinized syringe, it is important that the sample be mixed properly to avoid clotting and to create a homogenous sample. Proper mixing is achieved by gently inverting and rolling the sample between the palms for at least 30 seconds. Expel a small amount of sample onto an absorbent surface to check for clots.

4.4. Sample size for the Nova Stat Sensor is 1.2 µL

4.5. Unacceptable specimens: Samples collected in EDTA, citrate, oxalate and sodium fluoride anticoagulant.

5. REAGENTS/SUPPLIES:

5.1. Nova StatSensor meter

5.1.1. The Nova Stat Sensor must be used at room temperature 15-40°C (59-104°F).

5.1.2. The humidity limitation for the Nova Stat Sensor ranges up to 90% (non-condensing).

5.1.3. The meter has an internal temperature monitor and testing will not occur if the temperature is out of range.

5.2. Nova StatSensor creatinine strips:

5.2.1. Each Creatinine strip is designed with an electrode that measures creatinine levels.

5.2.2. Creatinine strips are stored in the POC office (357 Doan Hall) under refrigeration (2-8°C) until manufacturer’s expiration date. Temperature is monitored by Isensix.

5.2.3. Strips are stored at room temperature (15-30°C) once distributed to the testing locations and labeled with the new expiration date, 90 days after removal from refrigeration. An expiration date must be placed on the outside of the bottle of strips to reflect the reduced shelf life. Do not use beyond expiration date.

5.2.4. Documentation of the room temperature thresholds (minimum and maximum) must be recorded in each area for each day of patient testing. Documentation is available upon request.

a. If a minimum/maximum thermometer is used to perform continuous monitoring of temperature between daily temperature readings or following a laboratory downtime (e.g., laboratory closure for weekend or holiday), both the low and high temperatures must be recorded. To ensure correct temperature readings, the minimum/maximum thermometer device must be reset prior to the monitoring period.

5.2.5. All new lots of reagent strips will have a lot to lot verification performed. Five patient specimens and five levels of linearity with known values for the analyte will be run with the new reagent lot and compared with the value obtained using the old reagent lot. CLIA standards determine the total allowable error (% difference) between the two methods and is calculated, the acceptable difference is on the data log. stored on the L: Drive.

5.2.6. Remove the test strip from the vial only when ready to test.

5.2.7. Do not use the test strip if the expiration date has passed, for this may cause inaccurate results.

5.2.8. Do not tamper with the test strip.

5.2.9. Do not freeze the test strips.

5.2.10. Use only the Nova Stat Sensor creatinine test strips for testing with the creatinine meter.

5.3. StatSensor creatinine liquid quality control solutions levels 1 and 3:

5.3.1. Each control solution vial is a buffered aqueous solution containing a known creatinine level, preservative, FD&C dye, viscosity-adjusting agent, and nonreactive agents.

5.3.2. Creatinine liquid QC is stored in the POC office (357 Doan Hall) under refrigeration (2-8°C) until manufacturer’s expiration date. Temperature is monitored by Isensix.

5.3.3. Creatinine controls must be STORED in the refrigerator (2-8°C) once distributed to the testing locations and labeled with the new expiration date, up to 90 days under refrigeration. An expiration
date must be placed on the outside of the bottle of controls to reflect the reduced shelf life. Do not use beyond whichever expiration date comes first.

5.3.4. Before running the controls, they must be AT room temperature (15-30°C). Remove from the controls from the refrigerator 10 minutes before running. After control values are deemed acceptable, place controls back in refrigerator for storage.

5.3.5. Documentation of temperature must be recorded in each area for each day of patient testing and this documentation must be available upon request.

5.3.6. Quality control values are established by the manufacturer for acceptable ranges of each level of control.

5.3.7. New QC lots are tested once by the POC team for acceptability before being distributed to the testing locations. Data is stored on the L Drive.

5.3.8. If QC exceed manufacturer recommendations, do not use the QC and contact the POC office for new lots of quality control.

5.4. Creatinine linearity kit(perform by POC department):

5.4.1. Store linearity kit in the refrigerator 2-8 °C. Refrigerator is monitored by Isensix.

5.4.2. Keep the vials tightly closed when not in use.

5.4.3. Each vial contains a buffered aqueous solution of creatinine, preservative, a viscosity adjusting agent, and other nonreactive agents.

5.4.4. The creatinine concentrations in the linearity solutions are adjusted to give equivalent results to whole blood samples containing the creatinine concentrations printed on the vials.

5.4.5. The manufacturers linearity controls represent a creatinine concentration reflecting the AMR of the test.

5.4.6. The expiration date is printed on the linearity vials. Once opened, linearity solutions are stable for up to 90 days at (2-8°C) or until the expiration date, whichever comes first. Do not use the reagents beyond the expiration date.

5.5. Blood collection materials: single use lancets, alcohol swabs, cotton gauze, orange gauze, biohazard disposal receptacle sharps container.

6. LINEARITY, CORRELATION, CLEANING and Troubleshooting: (performed by POC department)

6.1. Linearity procedure-performed biannually on each meter.

6.1.1. Remove enough test strips from the bottle and remove the 5 levels of linearity.

6.1.2. Preparation: none; linearity kits come prepared directly from the Nova manufacturer.

6.1.3. Run each level of linearity solution on each meter in duplicate.

6.1.4. Expected results:

a. The manufacturers expected range indicates the maximum deviations from the mean value that may be expected under differing laboratory conditions for instruments.

6.1.5. Use EP evaluator to graph the data points, including acceptable ranges per level, onto the statistical graphs per meter.

6.1.6. An acceptable linearity falls within manufacturers’ guidelines.

6.1.7. Identify each Stat Sensor meter on each worksheet of the linearity data.

6.1.8. Linearity data must be given to the division director for review and signatures.

6.1.9. If the meter produces results outside the value on the vials; troubleshoot before repeating any linearity data outliers, follow these steps:

a. Verify linearity ranges listed with each kit of linearity.

b. Make sure the level being tested matched the level entered or scanned into the Stat Sensor.

c. Ensure that the linearity ranges entered onto the statistical graph matches manufacturer linearity ranges.

d. Make sure that the linearity kit has not expired.

e. Ensure no bubbles or insufficient linearity material was placed on the test strip.

6.2. Correlations -performed biannually

6.2.1. Each creatinine meter is compared with the analyzer at each OSUMC primary site.

6.2.2. Data analysis:
a. The data is reviewed for identifiable, procedural, analytical, clerical and specimen handling errors.
b. Discrepant results are investigated.
c. The data is analyzed for total allowable error for acceptability using EP evaluator. 
   Manufacture guidelines suggest results should agree with a laboratory result +/- 0.2 mg/dL when the result is less than 1.0 mg/dL and 20% when the concentration is greater than 1.0 mg/dL. Acceptability is determined and reviewed by the manager and division director. There are some factors that may cause results to differ by more than 20% in some situations. See Reference 12.7 Straseski et al Clinical Chemistry 2011.
d. If the data summary is unacceptable, troubleshoot and repeat testing.
6.2.2.d.1. If a meter fails correlation, the meter will then have a 20 sample validation performed to determine if continued use is acceptable.
e. The data is stored on the L: Drive.

6.2.3. The r value and slope are calculated; an r value of ≥0.9 is acceptable with a slope between 0.8-1.2. The total allowable error is documented on the data summary page. There are some factors that may cause results to fall outside the acceptable range, results are reviewed and acceptability is determined by the manager and division director.

6.3. Repaired/New Instrument
6.3.1. A combination of Liquid QC, Linearity and Method Comparison as following:
   a. Measure 20 patient samples from CCL and compare against CCL instrumentation.
   b. Measure 5 levels of linearity in duplicate.
   c. Measure 20 Liquid QC Level 1.
   d. Measure 20 Liquid QC Level 3.

6.4. Cleaning procedure(As needed):
6.4.1. Clean the Nova analyzer surface after each use with an OSUMC approved disinfecting solution (Sani-Cloth Plus). Make sure the Sani-Cloth is not dripping wet. DO NOT immerse the meter or hold the meter under running water.

5.4 Troubleshooting:
5.4.1 If the meter fails to turn on, or gives errors upon testing, contact the point-of-care testing department by email at path.glucose@osumc.edu. For more urgent concerns call the point-of-care testing department at 685-6610.
5.4.2 Meters may be required to be returned to the vendor for repairs. If available, loaner meters may be given to the department while their meter is out for repairs.

7. QUALITY CONTROL:
7.1. Quality control Information:
7.1.1. The Stat Sensor creatinine analyzer has 2 quality control levels with known concentrations of creatinine. The control solution test results will report as pass or fail on instrument. Both levels of control solution must pass before patient testing can be performed.
7.1.2. Quality control solutions must be tested for both levels of QC for each day (24 hours) of patient testing.
7.1.3. Quality control solutions will be labeled with updated expiration date of 90 days from the date the solutions are opened or the original expiration date of the bottle, whichever comes first.
7.1.4. If QC fails, corrective action must be documented.
7.1.5. QC testing is done in exactly the same manner as a patient test with the exception that the control solution is used rather than patient blood, and you are in the QC testing function of the meter.
7.1.6. When to perform a Quality Control Test:
   a. Daily when in use.
   b. If a patient test had been repeated and the blood creatinine results are still lower or higher than expected.
   c. After cleaning the meter.
if there are other indications that the system is not working properly.

b. If you drop the meter.

d. If there are other indications that the system is not working properly.

e. If you drop the meter.

7.2. Quality Control Process (Testing Personnel)

7.2.1. Scan your badge ID.

7.2.2. Press the QC soft key.

7.2.3. Scan the strip lot number.

7.2.4. Scan the QC lot number.

7.2.5. If QC fails, repeat quality control testing to ensure adequate solution was added to the strip. Make sure the QC material was properly mixed. Make sure there are no air bubbles in the drop.

7.2.6. Document the reason for QC failure on the meter.

a. Available reasons:
   7.2.6.a.1. Wrong QC Level.
   7.2.6.a.2. Application Error.
   7.2.6.a.3. Will repeat QC.
   7.2.6.a.4. Error suspected.

7.2.7. If QC continues to fail, contact the point-of-care testing department to obtain another set of quality controls.

7.2.8. All results, quality control and patient, will upload into Telcor upon placing the meter in the docking station.

7.2.9. Repeat steps 7.2.1 through 7.2.8 for the next level of QC.

7.3. Quality Control Review (Point of Care Department)

7.3.1. A monthly summary of the performance of quality control is prepared for review by the division director.

7.3.2. All quality control errors are reviewed.

7.3.3. Follow up corrective action for QC failures is performed and documented.

7.3.4. All values 3SD and greater are excluded from the QC data summary.

7.3.5. See monthly quality control report for error summary.

7.3.6. QC data is analyzed for mean, SD and CV per package insert.

8. TEST PROCEDURE:

8.1. The creatinine instrument is always on and can be start up by tapping the screen, if a shutdown is required remove the battery and re-insert a new battery to continue testing.

8.2. Collect appropriate specimen.

8.2.1. If sample collected by venipuncture or indwelling vascular line:

a. Obtain a square orange gauze and place it absorbent side down.

b. Mix the sample between the palms and by gentle inversion, then place a medium sized (0.1cc) blood droplet on the gauze.

8.2.2. If sample collected by finger stick:

a. https://clinicallabs.osumc.edu/Pages/Laboratory-Policies-and-Procedures.aspx

8.3. From the Patient Test screen, select GFR if ordered. The test option automatically defaults to creatinine only. Enter Accept key when complete.

8.4. Enter or scan strip lot number.

8.5. Enter CSN number by scanning the patient’s barcode.

8.6. Choose the sample type on the meter (operating systems 0.0.5.3, 0.0.4.4 and 0.0.52 are not supported).

8.6.2. Venous – Sample drawn into a lithium heparin tube.

8.7. If GFR was selected, input the patient’s age, gender, and race.

8.8. Insert a strip into the meter, touch the tip of the strip to the droplet of blood and allow it to fill via capillary action. The test strip must fill completely upon touching the blood droplet. If the test strip does not fill completely, do not touch the test strip to the blood droplet a second time. Discard the test strip and repeat the test with a new strip.

8.9. Upon completion of patient testing, the options to accept or reject the results are located at the bottom of the screen. If rejected, document on the meter the reason for rejection and repeat testing using the above steps.

9. CALCULATIONS:

9.1. No manual calculations are required to obtain results; the meter is programmed to display the numeric creatinine result and calculated GFR.

9.2. Meter software calculates the GFR based upon creatinine result, race, age and gender. The higher the creatinine, the lower the GFR.

10. INTERPRETATION AND REPORTING RESULTS

10.1. Refer to master listing chart for reference intervals, OneSource/Clinical Laboratory test Catalog

10.1.1. MDRD GFR: The estimated GFRs are based on the MDRD formula for assessment of stable or slowly declining kidney function in adults. Estimated GFR values are not accurate in: the very old or very young (<18 years), races other than Caucasian or African-American and people with acute illnesses, amputations or acute kidney failure. Estimated GFR should be interpreted in clinical context and an alternative method such as timed urine collection for creatinine clearance used to verify questionable results.

10.2. Refer to master listing chart for analytical measurement range (technical range): OneSource/Laboratory Guide to Services.

10.3. Refer to master listing chart reportable range (reportable range) CRR: OneSource/ S Clinical Laboratory test catalog.

10.4. Refer to Critical Result/Critical Value policy for critical values: OneSource/ Clinical Laboratory test catalog.

10.4.1. Critical Values send to lab for confirmation: creatinine >10 mg/dL.

10.4.1 a. Critical Value Documentation: All critical values must be called to patient’s provider and documentation of first and last name of provider notified, date and time is to be entered into IHIS.

10.5. Results reported to IHIS via Telcor middleware.

10.5.1. In case of a system downtime the results will be stored in the creatinine meter and will transmit to the medical record once the system is up and running and the meter is docked.

11. LIMITATION OF PROCEDURE:

11.1. Improper collection and/or handling of blood specimens can cause pre-analytical error. Possible sources of error include: incorrect anticoagulant type, the speed at which the collection device is filled, improper sample mixing, improper sample storage, clotted samples and delays in analysis.

11.2. Heparin concentrations may be 20 I.U. per mL to over 100 I.U. per mL. Avoid excessive liquid heparin as it may cause dilution errors.

11.3. Interfering substances: EDTA, citrate, oxalate, and sodium fluoride are not recommended for use.
11.4. The StatSensor creatinine meter exhibits no interference from the following substances up to the following concentrations:

<table>
<thead>
<tr>
<th>Tested Interfering Substances</th>
<th>Tested Concentration Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Ascorbic acid</td>
<td>3.5 mg/dL</td>
</tr>
<tr>
<td>Bilirubin</td>
<td>15.0 mg/dL</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>1000.0 mg/dL</td>
</tr>
<tr>
<td>Creatine</td>
<td>4.0 mg/dL</td>
</tr>
<tr>
<td>Dopamine</td>
<td>10.0 mg/dL</td>
</tr>
<tr>
<td>Glucose</td>
<td>500 mg/dL</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>30-60 %</td>
</tr>
<tr>
<td>Heparin</td>
<td>120 units/dL</td>
</tr>
<tr>
<td>L-Dopa</td>
<td>300.0 mg/dL</td>
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<tr>
<td>D(+) Maltose Monohydrate</td>
<td>100.0 mg/dL</td>
</tr>
<tr>
<td>Oxygen</td>
<td>All concentrations</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>1000.0 mg/dL</td>
</tr>
<tr>
<td>Uric acid</td>
<td>20.0 mg/dL</td>
</tr>
</tbody>
</table>

12. REFERENCES:
12.5. CLSI Document H3-“Procedures for Collection of Diagnostic Blood Specimens by Venipuncture”
12.6. CLSI Document H4-“Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens”

13. RELATED DOCUMENTS
13.1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms