Nova Biomedical STATSensor - Creatinine (LTR46396)

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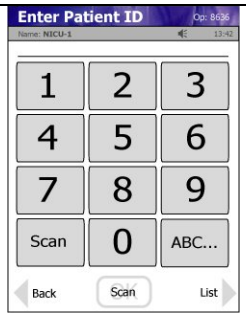
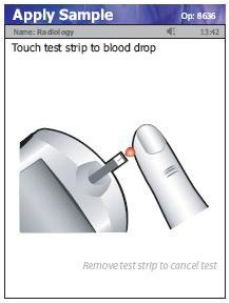
Background Information	These are the instructions for the creatinine test using the Nova Biomedical Stat Sensor.
Intended Use	This method is used to perform quantitative measurements of creatinine in whole blood.
Manufacturer	This method is manufactured by Nova Biomedical. It is performed as per the manufacturer's instructions, without any in-house modifications.
OSHS Safety Classification	This procedure is classified as a Category I potential hazard by OSHA standards. Appropriate barrier equipment and precautions must be used in performing the procedure.
CLIA Complexity Level	Non-Waived
Summary and Explanation of Test	Creatinine is breakdown product of creatine phosphate in muscle tissue. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
Principle	Creatinine is measured in whole blood by an electrochemical method.
Specimen Requirements	Whole blood collected from a finger stick.
Materials and Equipment Needed	Nova Biomedical Stat Sensor Non sterile gloves, lancet and alcohol prep pad, gauze Nova Biomedical Stat Sensor test strip Nova Biomedical Creatinine controls, levels 1 and 3
Reagent Preparation and Storage Instructions	1. Test strips and control material is stored at a refrigerated temperature of 2 to 8°C. 2. Reagent solutions once opened and refrigerated are stable for 90 days or until the expiration date which occurs first. 3. Test strip vials once opened are stable for 90 days. 4. Keep test strips tightly sealed in the storage container. 5. Sealed test strips are stable until the expiration noted on the container. 6. Discard all test strips and solutions once past their expiration date. **NOTE: Test strips MUST be brought to room temperature before use (at least 10 minutes for test strips) or else results WILL BE INACCURATE!**

Calibration	Not required
Calibration Verification	Calibration verification is performed every six months using Nova Biomedical linearity standards.
Procedure	1. From the home screen press login.  2. Enter or scan the Operator ID and press **Accept**.  3. From the Patient test screen press **Accept**.  4. Check the strip lot number and press **Accept**.  5. Scan the patient wristband, the patient identifier is the CSN. The CSN can be manually entered, however, double check the entry before acceptance to insure results post on the correct EPIC record.



6. Insert a test strip into meter.

7. Wash the patient's hand thoroughly and massage the finger to stimulate blood flow.
8. Use a safety lancet to puncture the finger. Gently squeeze the finger to form a blood drop.
9. Touch the test strip to the blood drop. The creatinine result will appear on the screen in 30 seconds.



Note: the test strip must fill completely after touching the blood droplet. If the test strip does not fill completely, do not touch the blood droplet a second time. Discard the test strip and repeat the test with a new test strip.

10. To accept the result, press **Accept**. To reject the result, press **Reject**. A comment can be appended to the result, press Comment on the right hand bottom of the result screen.

	11. To review other test results, press **Review** from the Patient Test screen. 
Calculations	None
Quality Control Preparation and Storage Instructions	1. Quality Control is stored at a refrigerated temperature of 4 to 8°C. 2. Quality Control solutions once opened and refrigerated are stable for three months (90 days) or until the expiration date whichever occurs first. 3. Discard all Quality Control solutions once they are past their expiration date. **NOTE: Quality Control material MUST be brought to room temperature before use (at least 30 minutes for QC) or else results WILL BE INACCURATE!**
Quality Control Frequency	Quality control must be performed every 24 hours to insure accuracy and precise of the device. Staff members that perform patient testing are also responsible for performing the daily quality control. If the quality control is out of range, or not performed within the 24 hour time period, the meter will lock out users until satisfactory QC is performed. **Other indications when to perform Quality Control Test** • If a patient test has been repeated and the blood creatinine results are still lower or higher than expected, • Quality control should be performed after cleaning the meter, • If there are other indications that the system is not working properly, • If the meter is dropped
Quality Control Procedure	1. Follow steps 1 and 2 in the procedure above. 2. From the Patient Test screen, press **QC**.  3. Enter the strip lot number as described above in the procedure and press **Accept**. 4. Enter the QC lot number and press **Accept**. 5. Insert the Test Strip as described above in the procedure.

	6. Touch a drop from the QC bottle to the test strip.  7. Test strip must fill completely upon touching the QC droplet. **DO NOT add a second QC drop to the test strip. Discard the test strip and insert a new test strip into meter.** 8. Result will appear in 30 seconds  9. To accept the result press **Accept**. **NOTE:** Patient results cannot be reported unless all two levels of QC are within the acceptable range.
Quality Control Corrective Action	**Reason for Out of Range Control Results** • You may not be doing the test properly. Retest and follow the instructions carefully, • The control solutions may have expired or have become contaminated. Check the expiration date on the control solution vial. Control solution is good for only 3 months after opening. • The test strip may have expired. Check the expiration date on the test strip vial. • The test strip may have been damaged. Retest using a new test strip. • The creatinine meter may not be working. Document Corrective Action in the “Comment” section of the meter.
Result Reporting	The Stat Sensor Creatinine meter must be placed in the docking station after to facilitate the reporting of the results. The system is interfaced to Nova Net and Telcor and results will automatically flow into EPIC. The instrument sends across to NovaNet and Telcor the result, date, time performed and operator ID into Telcor.
Reference Range	Serum: Female: 0.5 - 1.2 mg/dL Male: 0.7 - 1.4 mg/dL

Reportable Range	The Nova Stat Sensor has a reportable range of 0.1-8.0 mg/dL. Patients with a result of less than 0.1 are reported out as <0.1. Patients with a result of greater than 8.0 are reported out as >8.0
Cleaning the Meter	Instruments used for Point of Care testing that are used on more than one patient must be disinfected with an approved hospital grade disinfectant after use per Infection control Policy 10.7 Non Dedicated Patient Care Equipment.
Procedure Notes	1. Acceptable creatinine range established by Radiology is 0.8 - 1.5 mg/dL. 2. Results falling outside of Radiology established range of 0.8 - 1.5 mg/dL will need to be confirmed utilizing the laboratory and notifying the ordering physician. 3. Acceptable eGFR value established by Radiology is >30ml/min for MRI procedures and >60ml/min for CT procedures. 4. GFR results of <30ml/min for MRI procedures and <60ml/min will need to be confirmed utilizing the laboratory and notifying the ordering physician. **Refer to Contrast Media Administration CP08-3732 and Gadolinium Based Contrast media Administration CP08-3721** 5. If meter is dropped, **DO NOT** use for patient testing. Call site POC Coordinator for assistance. QC and linearity testing will be run to assure there is no instrument failure. 6. If strip appears irregular in any way do not use for testing. 7. If POC creatinine testing is not available due to lack of supplies or analyzer problems, send appropriate sample to lab for testing 8. If meter is not working please call POC Coordinator at EV (772-4684) or pager 8485 for assistance during regular business hours. If problem occurs outside of regular business hours someone will contact you the next business day.
Proficiency Testing	1. POC Coordinator and operators must review and follow proficiency testing providers “Handling Instructions” prior to analysis. 2. Under the Menu option, designate the test as “Proficiency” to ensure slope and intercept adjustments are disabled. 3. Proficiency Testing samples and or validation material when tested by POC operators must be proctored by a trained/certified POC Coordinator to ensure that all steps are followed properly.
Limitations	Whole blood is the only acceptable specimen for analysis
Alternative Method	If the Stat Sensor is not working properly, order a STAT Creatinine level in EPIC and send a venipuncture collected specimen to the to the Laboratory for analysis. If meter is not working please call your site POC Coordinator or pager 8485 for assistance during regular business hours. If problem occurs outside of regular business hours someone will contact you the next business day.
References	1. Nova Biomedical Stat Sensor Procedure Manual. 2. Clinical Practice Radiology Manual, NorthShore University HealthSystem, April 2010.
Effective Date	The effective date for this procedure is June 30, 2010.
Written by	Robert Rosecrans, Ph.D.