# Organization(s):

North Carolina Baptist Hospital (NCBH)

Lexington Medical Center (LMC)

Davie Medical Center (DMC)

Wilkes Medical Center (WMC)

High Point Medical Center (HPMC)

Wake Forest Health Network (WFHN)

Wake Forest University Health Sciences (WFUHS)

Wake Forest University School of Medicine

NCBH Outpatient Endoscopy

Wake Forest Baptist Imaging, LLC (WFBI)

# Purpose

The purpose of this policy is to quickly and accurately measure the blood creatinine level and to evaluate the effectiveness of correct treatment.

# Scope

This policy applies to Radiology and the Laboratory.

# Definitions

1. ***Policy***: A statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities. A policy may help to ensure compliance with applicable laws and regulations, promote one or more missions, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors, and others are expected to operate.
2. ***WFBH***: Wake Forest Baptist Health (WFBH) is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Wake Forest Baptist Imaging, LLC (WFBI), NCBH Outpatient Endoscopy, Wake Forest Health Network (WFHN), and Premier Surgery Center.

# Policy Guidelines

1. Policy:

1. Creatinine levels are obtained by the Radiology Department.
2. The Creatinine StatSensor is used for determining the Creatinine/eGFR prior to contrast.
3. The creatinine level is obtained as ordered by the physician and according to the department protocol.
4. The physician is notified of any critical value unless otherwise ordered or as the patient condition warrants.
5. The meter is cleaned between patients using a disinfectant wipe.
6. All 6 elements of competency must be completed by testing personnel annually.
7. Specimen:
8. Capillary (finger-stick only).
9. 1.2 uL venous whole blood in a lithium heparin tube.
10. Samples from neonates are not acceptable.
11. Alternate site testing (earlobe, forearm) is NOT allowed.
12. Equipment:
13. Equipment
    1. StatSensor Meter
    2. Docking Station
    3. Lithium Battery
14. Materials
    1. StatSensor Creatinine Test Strip
    2. StatSensor Creatinine Control Solutions, Levels 1 & 3
15. Cleaning
    1. Hospital approved bleach wipes.
16. Storage Requirements
    1. StatSensor Meter: Store at 59 to 104º F
    2. Li-Polymer Battery: Store below 140º F. Discard properly after expiration date printed on the label.
    3. StatSensor Test Strips: Expires 90 days after opened at room temperature. Unopened test strips should be stored at 36-46º F (refrigerated).
    4. StatSensore Creatinine Control Solution: Expired 90 days after opened or until the expiration date printed on the label.
17. Calibration:
18. The Nova StatSensor Meter does not require any calibration.
19. Quality Control Testing:
20. Frequency:
21. Each meter must have two levels of Quality Control Solution (Level 1 & Level 3) performed every 24 hours of use. The meters have a QC lockout function that prevents patient testing unless the QC is performed successfully by a qualified operator.
22. QC solution testing is also to be performed on new meters, by new operators, and whenever the proper performance of the test strips or meter is questioned.
23. Procedures:
24. Verify that the strip vial and QC vials are within the open expiration date – not to exceed the printed date on the vials.
25. Allow the test strips to come to room temperature.
26. From the “Welcome” screen, press the <Login> button and enter the user ID by scanning the short barcode on the employee badge.
27. From the Patient Test Screen, press the QC key.
28. Press <Scan> to enter the strip lot number and scan the barcode on the vial.
29. Verify that the lot number is correct and press <Accept>.
30. Enter the first QC lot by scanning the barcode on the vial in the same manner.
31. Verify the lot number displayed is correct and press <Accept>.
32. Insert the test strip into the meter’s strip port, gold end first.
33. Gently mix the Stat Strip Control Solution.
34. Discard the first drop of control solution from the bottle to avoid contamination.
35. Ensure the “Apply Sample” screen is illuminated.
36. Note: If the screen darkens at any time during testing, tap the screen to illuminate it before continuing.
37. Gently squeeze a drop of Control Solution from the bottle and place at the end of the test strip until the solution is drawn into the well of the test strip, maintaining contact until the 30-second countdown begins and a beep sounds.
38. Remove the test strip and discard.
39. Recap the control solution.
40. If “PASS” is displayed, press the <Accept> key and continue with the next control level, if required.

If “FAIL” is displayed, add a comment as required. Press the <Comment> key. Select the appropriate comment to document corrective action taken. Comments will display on the result screen. Press <Accept> key. Repeat any failed test.

1. Repeat procedure for the next level of Quality Control.
2. Return controls to the main lab refrigerator after use.
3. Patient Testing:

Note: To prevent contamination and spread of infection, clean gloves must always be used to remove a strip from the test strip vial.

1. Preparation:
2. Gloves are donned
3. Identify the patient
4. Tap the screen of the Stat Sensor Meter
5. Press <Login> button. “Enter Operator ID” will appear at the top of the screen.
6. Press <Scan> and scan the user barcode
7. Press <Accept>. The “Patient Test” screen will appear

Note: If the padlock symbol appears with the words “Creat Locked,” proceed to the Quality Control Testing section above.

1. From the “Patient Test” screen, press the <eGFR> key. If a GFR calculation is required, press the <Accept> key
2. When the “Enter Strip Lot” screen displays, press <Scan> and scan the strip lot number and press <Accept>
3. From the “Enter Patient ID: screen, press scan and scan the patient’s armband for the CSN number
4. Verify the patient information on the screen and press <Accept>
5. Press “Capillary” on the screen and then press <Accept>
6. If eGFR is selected, enter the patient’s age, sex, & race, using the touch screen. Select <Accept> after each entry
7. The “Insert Strip” screen will appear
8. Insert the test strip into the meter’s strip port, gold end first. The “Apply Sample” screen will appear
9. Specimen Collection:

Note: To prevent contamination and spread of infection, clean gloves must always be used to remove test strips from the test strip vial.

* 1. A sterile puncture is performed used a stab technique. The first drop of blood is wiped off
  2. The “Apply Sample” screen is illuminated
  3. Squeeze the puncture site gently to form a drop of blood
  4. Touch the end of the test strip to the blood drop, maintaining contact until the 30-second countdown begins and a beep sounds. Alternatively, apply a drop of well-mixed heparinized whole blood from a tube or syringe
  5. Once the creatinine and eGFR results appear, remove the test strip
  6. Discard the used test strip into the appropriate waste container
  7. Select <Accept> or <Reject>

1. If “Accept” is selected, the meter will be ready for the next patient test
2. If “Reject” is selected, repeat the test with a fresh blood sample or request a laboratory eGFR to be performed
   1. Return the strips to the refrigerator in the main lab after use
3. Cleaning Procedure:
   1. Clean the meter by wiping the external surface of the meter thoroughly with a fresh germicidal disinfecting bleach wipe
   2. Remove any residue with a soft cloth that is dampened with water
4. Docking/ Charging Station:
   1. Once testing is complete, return the meter to the docking station. Ensure that the meter is securely seated in the dock and that all indicator lights are illuminated.
   2. When the meter is not in use, place it into the docking station. This enables the meter to remain fully charged and connects the meter to the computer network.
5. Patient Results:
   1. Reference Ranges 0.60- 1.10 mg/dl
6. Results below 0.3 mg/dl will display “LO”
7. Results above 12.0 mg/dl will display “HI”
8. Routine Battery Replacement:
9. You will have a spare fully charged battery; it can be changed to allow for continuous operation
10. Press down on the tow cover latches to release the cover. Take the battery cover off the back of the meter
11. Push up on the battery latch. Remove the drained battery
12. Replace with a fully charged battery
13. Replace the battery cover
14. Place the drained battery into the docking station
15. Dock the meter
16. Troubleshooting:

|  |  |  |
| --- | --- | --- |
| **CONDITION** | **EXPLANATION** | **ACTION** |
| Low Battery | The battery charge is too low to continue | Replace the battery or return the meter to the docking station. |
| Analysis Error- Analysis Cancelled | The test strip was removed or loosened | Repeat the test with a new test strip. Leave the strip in place until the result is displayed on screen. |
| Analysis Error- Temperature Error | The temperature must be 59-104º F | Relocate the meter to an environment within the specified temperature range. |
| Analysis Error-  Bad Sample | The sample cannot be accepted | Repeat the test with a new test strip. If the error reoccurs, use an alternate testing method. |
| Analysis Error-  Replace Strip | The test strip is damaged | Repeat the test with a new test strip. |
| Analysis Error-  Flow Error | The sample is insufficient or the sample application is incorrect | Repeat the test with a new test strip. If the error reoccurs, use an alternate testing method. |

This policy is published as a guide to employees. The standard of care or procedure, for any particular situation is dependent on many factors, which impact decisions and the care given to patients. We recognize the applications of policies are subject to common sense, good judgements, laws, rules, and regulations surrounding each circumstance.

# References

Nova StatSensor Instruction Manual

# Attachments

None

# Revision Dates

1/19; 3/23