HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY – POINT OF CARE POLICY MANUAL

ABBOTT iSTAT for Creatinine

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Cross Referenced: | **Origin:** Point of Care Tests
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SCOPE; Diagnostic Imaging – CatScan

PURPOSE: Assessment of renal function using Abbott IStat meter before giving the IV contrast at the point of care.

DEFINITIONS:

CR – Creatinine
POCC – Point of Care Coordinator
MG/DL – milligrams per deciliter
NFF – National Kidney Foundation

POLICIES:

1. The following patients will require a POC creatinine tests if the recent test result is not within 7 days of the scan or the patient has not had this test prior to the scan:
    A. Patients over the age of 60
    B. Patients with past history of renal disease (including nephrectomy).
    C. Patients with diabetes
    D. Patients with Pheochromocytoma
    E. Patients with Multiple Myeloma
    F. Patients with Sickle Cell disease
2. If GFR is below 50 (or creatinine of > 1.5mg/dl) the Radiologist shall be notified for further instruction.
3. Reportable range is 0.2 – 20.0mg/dl. Results outside of this range are flagged with a **< or >** indicating that the result is below the lower limit (0.2mg/dl) or above the upper limit (20mg/dl).
4. Reference (Normal) range is 0.6 – 1.3mg/dl.
5. Follow Standard Precautions protocol – gloves must be worn throughout patient and QC testing, hand hygiene performed, and change gloves between patients.
6. For further help in troubleshooting the meter please call the POCC in the lab or call Abbot IStat support at **800-366-8020 Press 1**. In times of an emergency borrow the meter from Emergency Room if troubleshooting can not be done immediately.
7. All Outpatients will be tested based on the CT IV Contrast Protocol (7680.017).
8. Inpatients and Emergency room patients shall require a recent Creatinine result within the past 48 hours that also include a BUN (unless the Radiologist states it is not necessary, the exam may be completed without these results).
9. Trauma studies ordered do not require lab results.

QUALITY ASSESSMENT & MONITORING:

1. Only draw sample in a lithium heparin (green top tube). Mix well to avoid clotting.

2. Monitor refrigerator temperature daily where the cartridges are stored.
3. Liquid Quality Control – 2 levels must be run before a new lot of cartridges are put into use to verify proper shipping and equilibration condition and /or every 30 days whichever comes first. Both levels of liquid controls must be acceptable before patient test is run.
4. External Simulator Test and Thermal Probe Check (+/- 0.15° C) are run every 6 months and each time there is a new Clew software update. Internal Simulator test is run every 8 hrs 24/7.
5. Cal/Verification is run each time there is a new Clew software update and/or every 6 months.
6. Only trained operators will be allowed to run the Abbott IStat meter. A six month re-certification is required on the first year of training and yearly re-certification after the initial year. Analyzer will also check the Operator's List on the data management. Overdue competency will be locked out.
7. Repeat result that gave out ****.
8. Repeat any **Code Error** with a new cartridge. If same Code Error keeps repeating, notify POCC from the lab for further troubleshooting.
9. Patient and QC results are reviewed daily and/or weekly by the Laboratory POCC. Results are reviewed and compared from the IStat database to Cerner.

STORAGE:

CR cartridges must be stored at 2-8°C/35 -46.4°F until the expiration date printed on the boxes. Cartridges can also be stored at room temperature with new expiration date of 14 days; the new expiration date should be written on each cartridge package.

Liquid Controls should be stored at 2-8°C/35 -46.4°F until the printed expiration date on the ampule labels. These can also be stored at room temperature for up to 5 days at 18-30°C. Prolonged storage at temperatures greater than 30°C may cause changes in the values of some analytes.

PATIENT TEST PROCEDURES:

1. Collect a fresh venous blood in a **green top tube (lithium heparin)** full amount and mix well.

NOTE 1: when drawing a sample from an indwelling line, back flush and clear the line of IV fluids prior to sampling to remove anticoagulants or medications which might interfere with the test. 10 ml waste must be drawn first.

2. Turn power on handheld device.
3. **Press 2** (IStat Cartridge).
4. Press and hold down the SCAN key.
5. As prompted by the handheld, **SCAN your badge for Operator's ID.** The laser beam must cover the entire length of the barcode then release the SCAN key (If your badge doesn't work, it means that you are not on the Operator's list OR that your competency has expired and it needs to be renewed) or manually enter your numbers 2X.
6. **SCAN patient's armband** for Patient ID or manually enter them 2X. Verify the ID numbers on the meter.
7. **SCAN the bar-coded cartridge lot number**. Verify that the cartridges are within the expiration date printed on the package/box.

8. Remove the cartridge from pouch being careful **NOT** to touch the electrode area, the sample well and the center of the cartridge.
9. Mix the sample thoroughly and gently to avoid quality check codes.
10. Use the disposable IStat Dispensing tip device and waste 2-3 drops of sample onto a gauze pad to make sure there are no air bubbles.
11. Hold the blunt tip needle of the device over the cartridge sample well and dispense sample until blood reaches the cartridge fill mark.
12. Fold the snap closure over the sample well until it clicks into place. Press on the tab. **Do not press directly over the sample well.** If cartridge is not sealed correctly "Unable to position" quality check code error (Code 31) will display on the screen.
13. Push the cartridge into the handheld port until it clicks into place. Do not remove the cartridge from the handheld until the "CARTRIDGE LOCKED" message is gone. Motion on the handheld device during testing can increase the frequency of suppressed results of the quality check codes. Therefore, the placing the handheld device on a stable counter is advisable or can be placed in the downloader/recharger base while it's testing. **NOTE: You have 15 mins to open cartridge, fill the cartridge, close the cartridge and insert it into the meter. After 15 mins the meter will turn off and will require re-entry of all the information.**
14. After reviewing result, enter in Cerner (see Documenting procedure below) or consult the Radiologist if results are out of range.
15. Calculate GFR by using the GFR calculator online from **National Kidney Foundation.** Enter this result in Cerner.
16. Repeat result that gave out ****.
17. Repeat any **Code Error** with a new cartridge. If same Code Error keeps repeating, notify POCC from the lab for further troubleshooting.
18. When the test is completed, remove the cartridge and dispose in biohazard container.
19. Dock the analyzer in the downloader/recharger to transmit results.

NOTE: If a sample must be sent to the lab to verify the POC result, order the test in Cerner, label the tube correctly, place the tube in a plastic bag and send it down thru the pneumatic tube in the ED for faster TAT. "STAT CT" should be written on the plastic bag to alert the lab personnel receiving the tube.

QUALITY CONTROL PROCEDURES:

1. Turn power on handheld device.
2. Press Menu to change screen to Administration Menu.
3. Press 3 for the Quality Tests menu.
4. Press 1 for Control.
5. SCAN your badge for Operator's ID (see reason above if your badge doesn't scan).
6. SCAN Control lot number from the ampule.

7. SCAN the barcoded cartridge lot number.
8. Remove cartridge from pouch.
9. Shake the ampule hard for 10 seconds.
10. Break the ampule open. Use an ampule breaker or protect fingers by covering the ampule with gauze.
11. Withdraw the control fluid slowly into a plastic pipette and dispense 1-2 drops of control fluid onto a gauze pad.
12. Fill the cartridge with the control fluid until it reaches the fill mark. Fold the closure over the sample well until it snaps into place.
13. Push cartridge into the handheld port until it clicks into place, and do not remove until the "CARTRIDGE LOCKED" message is gone.
14. Repeat steps 4-14 for the next level of control.
15. Review PASS/FAIL result. Repeat FAILED QC.
16. Dispose ampule in sharps container and cartridges in biohazard container.

DOCUMENTING RESULTS;

1. After completing the POC test, the DI Technologist will access the Point of Care Results Entry in Cerner.
2. Input/select correct patient and encounter, verifying the patient by two forms of identification.
3. Select the Test Site as HRMC POC
4. Select the Orderable as POC Creatinine
5. Enter the date and time of the test.
6. Enter the user name of the person performing the test.
7. Enter the ordering physician. The ordering physician will be the Radiologist reading the CT and will be based on the criteria listed above.
8. Click on Procedure and enter the numerical value for the Creatinine and GFR calculations from the NKF website (National Kidney Foundation).
9. Hit **VERIFY** (result is not fully documented in patient's chart until result is verified).

NOTE:

1. If after entering the value, a red indicator appears indicating a Critical Result, the result must be communicated to the Radiologist within the time frame specified in Policy PC07 Critical Tests & Critical Results/Values (45 minutes). Right click on the numerical value to add comments. Include which Radiologist was notified, the time, and the actions i.e. test performed without contrast, referring physician notified, etc.
2. If an error has occurred in entering the result, call the POCC in the laboratory to make the correction.

PERFORMING ELECTRONIC SIMULATOR TEST: The **internal** Electronic Simulator test cycle is

automatically activated when a cartridge is inserted after the customized interval is reached. If the analyzer passes the simulator test, the cartridge test cycle proceeds. If not, the analyzer displays "ELECTRONIC SIMULATOR FAIL". Follow the procedure (External Simulator test) below when this happens.

1. Call the POCC in the lab to pick up the Electronic Simulator.
2. Press the **ON/OFF** key to turn the analyzer on.
3. Press the **MENU** key.
4. Press **3** to select **Quality Tests**.
5. Press **4** to select **Simulator**.
6. Press **Scan** to scan the **Operator ID** or manually enter the Operator ID **(2X).**
7. Press **Scan** to scan the **Simulator ID** (barcode on top).
8. Remove the cover protecting the contact pads and insert the simulator straight into the analyzer. Avoid touching the contact pads.
9. Do not attempt to remove the simulator until the results are displayed and the **"Simulator Locked"** message is removed.
10. If **PASS** is displayed, continue to use the analyzer. Remove the simulator and return it to its protective case. If **FAIL**, contact POCC from the laboratory.

NOTE: A quality check is performed on the thermal probes each time the external Electronic Simulator is used. Abbott iStat recommends that the thermal probe check be verified every six months or whenever there's a Clew software update.

COMMON ERROR CODES CAUSES AND EXPLANATION:

36 – Sample Positioned Short of Fill Mark – the cartridge was underfilled. The sample must reach the fill mark. Try another cartridge.

38 – Insufficient Sample – this is most likely due to insufficient sample in the sample well of the cartridge, but can also be caused by bubbles in the sample. Use another cartridge and ensure sufficient sample is in the sample well.

43 – Cartridge Error – this indicates that the conductometric sensor or the amperometric sensor was out of specification. This could be caused by a dirty cartridge contact pads.

46 – Cartridge Error – the analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample to not closing the snap closure on the cartridge, or to an aberrant cartridge.

47 – Cartridge Not Inserted – this code indicates the cartridge or Electronic Simulator may not be pushed in all the way. Reinsert the cartridge and if problem persists call your POCC.

69 – Cartridge Type Not Recognized – check the cartridge expiration date on the cartridge

pouch or box.

127 – Cartridge Error – A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.

130 – Cartridge Error – the analyzer detected an air bubble in the sample segment. Try another cartridge.

140 – Lot Expired – the analyzer detected an expired cartridge lot. Check the expiration date and repeat the test using a non-expired cartridge lot.

LIMITATIONS:

1. Improper collection and/or handling of blood specimens can cause pre-analytical error.
2. Clotted sample.
3. Insufficient sample.
4. Improper sample mixing.
5. Improper sampling in the cartridge i.e. air bubbles.
6. Improper cartridge storage.
7. Delay in analysis.

REFERENCED:

1. iStat 1 System Manual Configuration: Rev date 9-17-13.
2. Quick Reference Guide for the iStat 1 Handheld and iStat Chemistry Cartridge.