ABBOTT IStat in EMERGENCY ROOM DEPARTMENT

Effective Date: December 18, 2014 Cross Referenced: Reviewed Date: Revised Date: Written By: Cristina Hom MLS ASCPcm, CPOC Laboratory Point of Care Coordinator Policy No: POC ER 0004 Origin: Point of Care Tests Authority: Dr Jun Li MD PhD Laboratory Director Page: 1 of 4

SCOPE: HRMC Emergency Room Department

<u>**PURPOSE</u>**: To expedite lab TAT for critical decision making intervention in Emergency Room such as stroke, trauma, myocardial infarction, chest pains, CPR in progress, and highly infectious and communicable diseases by using the Abbott IStat device to run Chem 8 and Troponin tests.</u>

POLICY:

- 1. Cartridges will be kept in the laboratory's refrigerator until they're requested by the ED staff.
- 2. Par of 2 cartridges for each test will be kept at room temperature in ED. Expiration date of 14 days will be written on the individual pouch.
- 3. IStat Troponin will be regarded as your first clinical result when ordering a Troponin series.
- 4. ED providers must order POC IStat for either **Chem8 or Troponin** test which are either a stand alone orders or in certain **powerplans ED Stroke/TIA no TPA**.
- 5. If ordered from the powerplan, CMP can be unchecked when Chem8 is ordered and Hepatic Panel can be ordered without duplicates occurring.
- 6. QCs are done once a month or per new lot whichever comes first.
- 7. Simulator test is performed once every 6 months or for troubleshooting guide.

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. Cartridges must be at room temperature minimum of 5 minutes before using.

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 whole blood in a 3cc green top tube with lithium heparin and mix well. NOTE 2: 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. As prompted by the handheld, SCAN your badge for Operator's ID or manually enter your numbers 2X. 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.
- 5. SCAN patient's armband for Patient ID or manually enter them 2X.

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Effective Date: December 18, 2014	4 Policy No: POC ER 0004
Cross Referenced:	Origin: Point of Care Tests
Reviewed Date:	Authority: Dr Jun Li MD PhD Laboratory Director
Revised Date:	Page: 2 of 4
Written By: Cristina Hom MLS ASCPcr	m, CPOC

Laboratory Point of Care Coordinator

- 6. Verify that the cartridges are within the expiration date printed on the package/box.
- 7. SCAN the cartridge barcode lot number.
- 8. Remove cartridge from pouch being careful **NOT** to touch the electrode area, the sample well and the center of the cartridge.
- 9. Mix the tube well again then use one of the disposable dispensing tips.
- 10. Waste 1-2 drops of sample onto a gauze pad to make sure there are no air bubbles.
- 11. Hold the dispensing tip over cartridge sample well and dispense sample by pushing the tube until blood reaches the cartridge fill mark. Some blood can be left in the cartridge well.
- 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.
- 13. Push the cartridge into the handheld port until it clicks into place. Do not remove the cartridge from the handheld until the <u>"CARTRIDGE LOCKED"</u> message is gone. This can damage the meter. The handheld device must be on a flat and even surface or can be placed in the downloader/recharger base while it's testing. **DO NOT hold/carry the meter while it's testing.**
- 14. Review results on the IStat meter and enter them in Cerner on an **ORDER GENERATED** powerform named *Point of Care ISTAT HRMC*.
- 15. When the test is completed, remove the cartridge and dispose in biohazard container.
- 16. Dock the analyzer in the downloader/recharger to transmit results in data management.
- 17. Results will display in Results Review Laboratory. These will also display on the various Viewpoint screens.

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. Control/s must be in same temperature as the cartridge before using. **SCAN** Control lot number from the ampule.
- 7. Verify that the cartridges are within the expiration date printed on the package/box.
- 8. SCAN the cartridge barcoded lot number.
- 9. Remove cartridge from pouch.
- 10. **Shake** the ampule hard for 10 seconds.
- 11. Break the ampule open. Use an ampule breaker or protect fingers by covering the ampule with gauze.
- 12. Withdraw the control fluid slowly into a 1 or 3 cc plain syringe until the syringe is half filled. Dispense 1-2 drops of control fluid onto a gauze pad.
- 13. Fill the cartridge with the control fluid. Fold the closure over the sample well until it snaps into place.
- 14. Push cartridge into the handheld port until it clicks into place, and do not remove until the
- "CARTRIDGE LOCKED" message is gone.
- 15. Repeat steps 4-14 for the next level of control.

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Effective Date: December 18, 2014

Cross Referenced: Reviewed Date:

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Policy No: POC ER 0004 Origin: Point of Care Tests Authority: Dr Jun Li MD PhD Laboratory Director Page: 3 of 4

Written By: Cristina Hom MLS ASCPcm, CPOC Laboratory Point of Care Coordinator

16. Review PASS/FAIL result. Repeat FAILED QC.

17. Dispose ampule in sharps container and cartridges in biohazard container.

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.

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.

ABBOTT IStat in EMERGENCY ROOM DEPARTMENT

December 18, 2014	Policy No: POC ER 0004
	Origin: Point of Care Tests
	Authority: Dr Jun Li MD PhD Laboratory Director
	Page: 4 of 4
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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. Incorrect heparin type in the syringe.
- 3. Improper sample mixing.
- 4. Improper sample and/or cartridges storage.
- 5. Delay in analysis.

<u>REFERENCED</u>:

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