TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	1/5/2016
Department:	Core	**Due Date:**	1/31/2016
		Implementation:	**2/1/2016**

DESCRIPTION OF PROCEDURE

Name of procedure:
Troponin by i-STAT 1 System GEC.C239 v0
Description of change(s):
This is a new SOP - iSTAT troponin testing will be a backup test for the Xpand. This SOP will be implemented on February 1, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Troponin by i-STAT 1 System**
Prepared by	Leslie Barrett, Julie Negado Date: 12/7/2015
Owner	Robert SanLuis Date: 12/7/2015

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Troponin	i-STAT 1 System	PTROP

Synonyms/Abbreviations
Tropi, Troponin I, cTnI

Department
Germantown Emergency Center

2. ANALYTICAL PRINCIPLE

The i-STAT 1 Analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood. The i-STAT System incorporates comprehensive components to perform blood analysis at the point of care. The System consists of a hand-held analyzer and single-use disposable cartridges. The analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration, and continuous quality monitoring. Analyzers with thermal control capability for testing at 37°C and cartridges requiring thermal control are labeled with a 37° symbol.

Troponin I/cTnI
Is determined amperometrically using a two-site ELISA method. Antibodies specific for human cardiac troponin I (cTnI) are located on an electrochemical sensor fabricated on a silicon chip. Also deposited in another location on the sensor silicon chip is an antibody/alkaline phosphatase enzyme conjugate specific to a separate portion of the cTnI molecule. The whole blood or plasma sample is brought into contact with the sensors allowing the enzyme conjugate to dissolve into the sample. The cTnI within the sample becomes labeled with alkaline phosphatase and is captured onto the surface of the electrochemical sensor during an incubation period of approximately seven minutes. The sample, as well as excess enzyme conjugate, is washed off the sensors. Within the wash fluid is a substrate for the alkaline phosphatase enzyme. The enzyme bound to the antibody/antigen/antibody sandwich cleaves the substrate releasing an electrochemically detectable product. The electrochemical (amperometric) sensor measures this enzyme product, which is proportional to the concentration of cTnI within the sample.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Specimens are collected via routine venipuncture or arterial puncture.
Special Collection Procedures	**In-dwelling lines**: it is recommended to withdraw three to six times the volume of the catheter, connectors, and needle to remove intravenous solutions, heparin, and or medications that may contaminate the sample. Avoid drawing specimens from extremity with I.V. Avoid prolonged tourniquet use and clenching and unclenching the fist.
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	-Whole blood -None
Collection Container	-Lithium or sodium heparin tube (green top, any size)
Volume - Optimum **- Minimum**	**Arterial**: 2 ml in a syringe **Venous**: ¾ to full tube 2ml
Transport Container and Temperature	Capped syringe or collection tube at room temperature
Stability & Storage Requirements	Room Temperature: 30 minutes
	Refrigerated: Not established
	Frozen: Unacceptable
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled improperly labeled, or those that do not meet the stated criteria are unacceptable. Reject if there is evidence of clotting. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Hemolysis
Other Considerations	N/A

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
cTnI Cartridge	Abbott 03P90-25

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.

Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Assay Kit	
Reagent	i-STAT cTnI cartridge
Storage	Store at 2-8ºC Working supply is stored at room temperature (18-30°C)
Stability	Refrigerated - until expiration date printed on box Room Temperature - 14 days, re-date with new expiration date when removed from refrigerator
Preparation	A cartridge should not be removed from its protective pouch until it is at room temperature (18-30°C). Allow a single cartridge to warm at room temperature for 5 minutes and a box for 1 hour. Use a cartridge immediately after removing from the protective pouch, prolonged exposure may cause a cartridge to fail Quality Control

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
cTnI calibrator	Abbott 06P17-12

5.2 Calibrator Preparation and Storage

NOTE: Date and initial all calibrators upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech (6) any special storage instructions; check for visible signs of degradation.

Calibrator	**cTnI calibrator**
Preparation	Allow to equilibrate for 30 minutes at room temperature before testing.
Storage/Stability	2-8ºC, until manufacturer's expiration date

5.3 Calibration Verification Procedure

Criteria	Special Notations
Frequency	Every 6 months

Tolerance Limits	Each result must be within the acceptable ranges printed on the value assignment sheet.
Procedure	1. Program all calibrators using the quality test menu, select calibrator, and follow prompts. 2. Mix before use. 3. Open calibrator bottle and place a drop of the solution into a cartridge. 4. Immediately seal the cartridge and insert it into the analyzer.

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
cTnI control level 1	Abbott 06P17-09
cTnI control level 3	Abbott 06P17-11

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	cTnI controls
Preparation	Allow to equilibrate for 30 minutes at room temperature before testing.
Storage/Stability	2-8ºC. Controls may be stored at room temperature (18-30°C) for 5 days. Do not use after expiration date on box and bottles.

6.3 Frequency

- The instrument is programmed to run the internal Electronic stimulator every 8 hours when there is a Patient.
- The external Electronic Simulator is run once a day.
- The liquid controls are run each day of patient testing, and with each new lot or shipment of cartridges.

6.4 Tolerance Limits

Each result must be within the acceptable ranges printed on the **value assignment sheet for that analyte.**

Step	Action
1	**Run Rejection Criteria** • Anytime the established parameters are exceeded, the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
2	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.

"*" Instead of results**
Stars appear in place of results if the analyzer detects that the sensor's signal is uncharacteristic. Cartridges that have been stored improperly may show "***" instead of results. Check the supply of cartridges in use with a control solution. If the control results are starred, discontinue use of this supply of cartridges. Aged specimens may contain products of metabolism that can interfere with the test(s). A fresh sample should be tested. If the stars reappear there may be an interferent present. When flags occur**, send sample to SGMC via a STAT courier.**

6.5 Review Patient Data

Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

6.6 Documentation

QC will be documented in Unity Real Time and all values must be within acceptable range before patient testing is done.

6.7 Quality Assurance Program

- Each new lot number of cartridges and each subsequent shipment of the same lot of cartridges must be tested with external control material and all values must be within the acceptable range before patient testing is done.

- Training must be successfully completed and documented prior to performing this testing.
- The Laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

iSTAT analyzer

7.2 Equipment

Electronic Simulator
Martel Printer

7.3 Supplies

N/A

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Instrument Set-up Protocol
1.	Press the On/Off key to turn analyzer on.
2.	Press 2 for i-STAT Cartridge from the Test Menu.
3.	Scan or Enter Operator ID. Repeat if prompted.
4.	Scan or Enter Patient ID. Repeat if prompted.
5.	Scan Cartridge Lot number from the cartridge portion pack, or box.

8.2	Specimen Preparation
1.	Mix specimen well before testing.

8.3	Test Run
1.	Remove the cartridge from its pouch. Avoid touching the contact pads or exerting pressure over the calibrant pack in the center of the cartridge.
2.	Discard 1 drop of sample from the delivery device to clear unseen bubbles. Direct the dispensing tip containing the blood into the sample well.

8.3	Test Run
3.	Dispense the sample until it reaches the arrow mark on the cartridge. Leave some sample in the well.
4.	Close the cover over the sample well until it snaps into place. (Do not press over the sample well.)
5.	Insert the cartridge into the cartridge door until it clicks into place.
6.	The Time to Results countdown bar will then be displayed. Once time has elapsed, view results on analyzer's display.
7.	Remove cartridge after Cartridge Locked message disappears. The analyzer is ready for the next test immediately.
8.	Print results.

8.4	Special Handling
1.	Do not attempt to remove the cartridge while the Cartridge Locked message is displayed
2.	The analyzer must remain on a level surface with the display facing up during testing.
3.	Motion of the analyzer during testing can increase the frequency of suppressed results quality check codes

9. CALCULATIONS

The Analyzer contains a microprocessor that performs all calculations required for reporting results.

10. REPORTING RESULTS AND REPEAT CRITERIA

To enter patient results in the LIS, use function MEM and worksheet GCH1.

10.1 Interpretation of Data

There are three conditions under which the I-STAT system will not display results:

1. Results outside the system's reportable ranges are flagged with a "<" or ">", indicating that the result is below the lower limit or above the upper limit of the reportable range respectively.
   Action: Repeat analysis and if results still have flags indicating the result is above or below the reportable range, report accordingly.

2. Results which are un-reportable based on internal QC rejection criteria are flagged with "****".
   Action: Repeat analysis using another cartridge. The results not suppressed should be reported in the usual manner. **If the result is suppressed again, send sample to SGMC via STAT courier.**

3. Results will not be reported if a test cycle has a problem with the sample, calibrant solution, and sensors, mechanical or electrical functions of the analyzer. **Action:** Refer to the I-stat System Manual's Troubleshooting section if necessary.

10.2 Rounding

N/A

10.3 Units of Measure

ng/mL

10.4 Clinically Reportable Range (CRR)

0.00 – 35.00 ng/ml

10.5 Repeat Criteria and Resulting

Repeat testing is only performed if requested by the medical staff.

11. EXPECTED VALUES

11.1 Reference Ranges

0.00 - 0.08 ng/mL

11.2 Critical Values

> 0.08 ng/mL

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Values may be increased due to

- Trauma
- Congestive heart failure
- Post-operative non cardiac surgery patients
- Drug toxicity, e.g. adriamycin
- Coronary Vasospasm
- Inflammatory diseases e.g. myocarditis
- Post Percutaneous Coronary Intervention (PCI)
- Pulmonary Embolism
- Sepsis

- Infiltrative diseases including amyloidosis, hemachromatosis, sarcoidosis, and scleroderma
- Heart transplantation
- Intracranial hemorrhage
- Strenuous exercise
- Chronic renal insufficiency

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved / Cleared
- **Validated Test Modifications:** None

Partially clotted samples can result in elevated cTnI results above the reference range, as well as quality code errors. Ensure sample is inverted gently at least 10 times for dissolution of the anticoagulant.

Grossed hemolysis can cause a decreased alkaline phosphatase activity, resulting in decreased detection of cTnI, increased assay backgrounds, and/or quality check codes.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

0.00 – 35.00 ng/mL

14.2 Precision

N/A

14.3 Interfering Substances

The following substances were found to have no significant effect (less than 10%) on the cTnI method, when added to a plasma pool containing approximately 2 ng/ml of cardiac troponin I, at the concentrations indicated:

Compound	Test Level (umol/L unless otherwise indicated)
Acetaminophen	1660
Allopurinol	294
Ascorbic Acid	227
Acetyl Salicylic Acid	3330
Atenolol	37.6
Caffeine	308
Captopril	23
Chloramphenicol	155

Diclofenac	169
Digoxin	6.15
Dopamine	5.87
Enalaprilat	0.86
Erythromycin	81.6
Furosemide	181
Sodium Heparin*	36 U/ml
Ibuprofen	2425
Isosorbide dinitrate	636
Methyldopa	71
Nicotine	6.2
Nifedipine	1.156
Phenytoin	198
Propranolol	7.71
Salicylic Acid	4340
Theophylline	222
Verapamil	4.4
Warfarin	64.9

*Heparin at 90U/ml was found to decrease the cTnI level by approximately 20%.

14.4 Clinical Sensitivity/Specificity/Predictive Values

N/A

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needle sticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

1. Laboratory Quality Control Program
2. Laboratory Safety Manual
3. Material Safety Data Sheets (MSDS)
4. Abbott i-STAT 1 System Manual
5. i-STAT cTnI Cartridge Information Sheet
6. i-STAT 1 System Maintenance Log (AG.F213)
7. i-STAT Daily QC Simulator Log (AG.F214)

17. REFERENCES

1. i-STAT 1 Systems Manual, Abbott Point of Care, 08/14/06
2. Information Sheet for i-STAT cTnI Cartridge, Abbott Point of Care, 07/01/2103
3. Information Sheet for i-STAT cTnI Control Levels 1 and 3, Abbott Point of Care, 09/15/2015
4. Information Sheet for i-STAT cTnI Calibrator and Verification Control Set, Abbott Point of Care, 09/15/2015

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval

19. ADDENDA

None