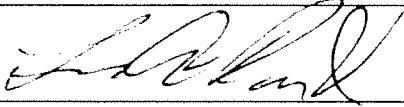
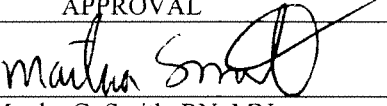
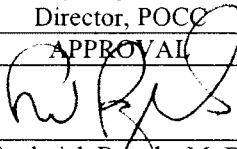


**INTERIM LSU HOSPITAL
DEPARTMENT OF PATHOLOGY
POCT
POLICY FOR i-STAT PT/INR**

UNIVERSAL STANDARD/PROCEDURE	PT/INR TESTING WITH THE i-STAT 1 SYSTEM
EFFECTIVE DATE: 4/08/2010 REVISION DATE: 7/01/2010 REVIEW DATE:	APPROVAL  Avery Ragan, Ph. D. Director, POCC
APPROVAL 	APPROVAL 
Martha G. Smith, RN, MN Associate Hospital Administrator Department of Nursing	Frederick Brazda, M. D. Deputy Director, Pathology

I. STANDARDS AND SCOPE OF PT/INR TEST BY THE i-STAT 1 SYSTEM

Unit based PT/INR testing will be performed to ensure prompt quality care through the monitoring of the PT/INR level. A PT/INR result will assist in the regulation of Coumadin therapy at the Coumadin Clinic at the Poydras Street Clinic.

II. STANDARD OF PROFESSIONAL PRACTICE

The Point of Care Coordinator (POCC) and/or designated personnel from the Pathology Department are responsible for routine QC and lab proficiency testing. They have the authority to recommend to the Departmental Director the removal of any instrument from an area that does not meet with specific standards of proficiency.

Any competent Medical Laboratory Technologist, Laboratory Technician, RN (Registered Nurse), NP (Nurse Practitioner) or Pharmacist may perform a PT/INR test to determine the INR level using patient capillary blood. A competent operator is defined as any Medical Laboratory Technologist, Laboratory Technician, RN, NP or Pharmacist whose performance has been verified in the use of the Abbott i-STAT 1 System (i.e., through orientation, in-service programs and/or annual competency verification), which includes a satisfactory repeat demonstration of the PT/INR test procedure by the operator. Competency checks are to be performed initially, at six months, and annually thereafter. Documentation of initial competency will be filed with the POCC, thereafter, competency will be available through the employees web based in-service record. In addition, the employee will be required to successfully perform a quality control check to complete the competency requirements. Any operator who does not complete competency on a yearly basis will be locked out from using the Abbott i-STAT 1 System. New employees must complete training with the POCC or a designated Trainer before being verified as users. Their operator ID and the date of their competency testing must be submitted to the POCC before they are authorized to use the instrument.

Any operator who demonstrates difficulty in performing PT/INR testing must complete an additional in-service in order to be verified as a competent operator.

**INTERIM LSU HOSPITAL
DEPARTMENT OF PATHOLOGY
POCT
PROCEDURE MANUAL
FOR
i-STAT PT/INR**

SYSTEM OVERVIEW

The i-STAT System incorporates comprehensive components needed to perform blood analysis at the point of care. The system consists of the following components:

ANALYZERS

The analyzer is the i-STAT 1 Analyzer. When a sample-filled i-STAT cartridge is inserted into an analyzer for analysis, the analyzer automatically controls all functions of the testing cycle including fluid movement within the cartridge, calibration and continuous quality monitoring.

CARTRIDGES

A single-use disposable cartridge contains microfabricated sensors, a calibrant solution, fluidics system, and a waste chamber. A whole blood sample of approximately 20 ul is dispensed into the cartridge sample well, and the sample well is sealed before inserting it into the analyzer.

CENTRAL DATA STATION OR DATA MANAGER

A dedicated desktop computer with the i-STAT Central Data application provides the primary information management capabilities for the i-STAT System. IR Links for Portable Analyzers along with Downloader/Rechargers allow for the transmission of patient records to the Central Data Station. Data can be stored, organized, edited and transferred to the laboratory information system. Cartridge usage and efficiency reports can be generated for management of the system.

SUPPLIES and STORAGE REQUIREMENTS

CARTRIDGES

Cartridges are sealed in individual pouches. Store the main supply of cartridges at a temperature between 2 to 8°C (35 to 46°F). **DO NOT ALLOW CARTRIDGES TO**

FREEZE. Cartridges may be stored at room temperature (18 to 30°C or 64 to 86°F) for 14 days. Cartridges should not be returned to the refrigerator once they have been at room temperature, and should not be exposed to room temperatures above 30°C (86°F). If the pouch has been punctured, the cartridge should not be used. Write the date on the cartridge box or individual cartridge pouches to indicate the two-week room temperature expiration date. Cartridges should remain in pouches until time of use. Do not use after the labeled expiration date.

CONTROLS for PT/INR

Store at 2 to 8°C (35 to 46°F). Do not use after expiration date on the box and vials. Controls should be used immediately after reconstitution.

BLOOD SPECIMENS

BLOOD COLLECTION EQUIPMENT

Cartridges for PT/INR

- Skin puncture: lancet only needed. Cartridge can be filled directly from the finger
- Venipuncture: plain plastic syringe without anticoagulant.

Blood Volume

20 µl of blood from a fingerstick or venipuncture using a plain syringe.

Suitable Specimens for PT/INR

- Fresh whole blood without anticoagulant collected in a plastic syringe or plastic evacuated tube without clot activators or serum separators. Device used to transfer sample to cartridge must be plastic.
- Fresh capillary whole blood dispensed directly into the cartridge from the finger.

Specimen Collection and Handling

In-dwelling Line

Back flush line with sufficient amount of blood to remove intravenous solution, heparin, or medications that may contaminate the sample. Recommendation: five to six times the volume of the catheter, connectors, and needle.

Venous Specimen

For cartridge testing of PT/INR, use only a plain, plastic syringe or collection tube

containing no anticoagulant. Use a plastic capillary tube, pipette, or syringe to transfer sample to a cartridge. Test sample without anticoagulant immediately.

Fingerstick Specimen

Do not wipe away the first drop of blood for PT/INR. Test sample immediately.

Criteria for Specimen Rejection

Specimen for PT/INR collected in glass syringes or tubes or with anticoagulant of any kind.

Precautions: Avoid the Following Circumstances

Time delays before filling cartridge for PT/INR.

PROCEDURE FOR ANALYSIS

Preparation for Use

An individual cartridge may be used after standing 5 minutes, in its pouch, at room temperature. An entire box should stand at room temperature for one hour before cartridges are used.

Procedure for PT/INR Cartridge for Patient Testing

Cartridge Test Procedure

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 enter the lot number on the number pad (you do not need to use the letters).
6. Remove cartridge from portion pack. Handle the cartridges by its edges. Avoid touching the contact pads or exerting pressure over the center of the cartridge.
7. Prepare lancet device and set aside until needed.
8. Clean and prepare the finger to be sampled. Allow the finger to dry thoroughly before sampling.
9. Prick the bottom side of the fingertip with the lancet device.
10. Gently squeeze the finger, developing a hanging drop of blood and perform the test with the first sample of blood. Avoid strong repetitive pressure, (“milking”) as it may cause hemolysis or tissue fluid contamination of the specimen.
11. Touch the drop of blood against the bottom of the sample well. Once in contact with the sample well, the blood will be drawn into the cartridge.
12. Apply sample until it reaches the fill mark indicated on the cartridge.

13. Fold the sample closure over the sample well.
14. Press the rounded end of the closure until it snaps into place. Slightly lift the finger or thumb and ensure that the cartridge is closed before completely removing the finger or thumb from the closure.
15. Insert the cartridge into the cartridge port until it snaps into place.
16. Leave the i-STAT on a flat surface. Do not move the i-STAT once the cartridge has been inserted. Moving the instrument will cause erroneous results. It must be on a vibration-free surface for testing.
17. When the test has been completed, view the results on the analyzers display screen.
18. Remove the cartridge after “Cartridge Locked” message disappears. The analyzer is ready for the next test immediately.

Note: To further simplify the sample application into the test cartridge, it is possible to bring the cartridge to the finger for easier application.

RESULTS

Calculations

The i-STAT analyzer contains a microprocessor that performs all calculations required for reporting results.

Displayed Results

Results are displayed numerically with their units.

Suppressed Results

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. The <> flag indicates that the results for this test were dependent on the result of a test flagged as either < or >. **THE CRITICAL VALUE FOR THE INR IS ≥ 5.0 . IT SHOULD BE REPEATED WITH A NEW CARTRIDGE AND/OR A FOLLOW-UP SPECIMEN TO THE LAB. SENDING A FOLLOW-UP SPECIMEN TO THE LAB IS UP TO THE DISCRETION OF THE NURSE PRACTITIONER, PHARMACIST OR PHYSICIAN.**

Action: Repeat with new cartridge and/or send specimen to the laboratory for analysis, if necessary.

2. Cartridge results which are not reportable based on internal QC rejection criteria are flagged with ***.

Action: Analyze the specimen again using a fresh sample and another cartridge. If the results are suppressed again, draw a venous sample using a blue top tube and send specimen to the laboratory for analysis.

3. A Quality Check message will be reported instead of results if the analyzer detects a problem with the sample, calibrant solution, sensors, or mechanical or electrical functions of the analyzer during the test cycle.

Action: Take the action displayed with the message that identifies the problem.

Printing and Transmitting Results

Printing Results from the i-STAT Portable Clinical Analyzer to the Martel Portable Printer

1. Align the IR windows of the analyzer and the printer. Turn on the printer and the green status indicator will light.
2. To print the displayed test record, press the PRT key on the analyzer.
3. To print a stored test record(s), select “Data Review” from the Administration Menu. Select #1 (Patient) and enter the patient’s ID and press enter. The patient’s result will be displayed and to print, follow steps 1 & 2. Option 2 is at “Data Review”, select #6 which will display all of the patient results and you can scroll through the by pressing “2” until you find the desired patient you are looking for and then print the result. The third option is to select #7 under “Data Review” which will list all of the results and you can scroll through by pressing the forward or backward arrow until you find the result you are looking for. When you have found it, press the number that corresponds to the result and follow the procedure for printing.
4. Please note that results printed on thermal paper will fade with time and are, therefore, not acceptable as a permanent chartable record. You must record the patient result in the chart. The permanent chartable record will be the result that will be found in CLIQ once the analyzer has been downloaded into the Data Manager.

Transmitting Results for the i-STAT Analyzer to the Data Manager

1. Place the analyzer in the Downloader/Recharger.
2. Do not move analyzer while the message “Communication in Progress” is displayed.
3. Please download the analyzer at least once a day to ensure proper communication with the Data Manager.

QUALITY CONTROL

Daily Procedures

Analyzer Verification

Verify the performance of each handheld analyzer using the Internal or External Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. For the Coumadin Clinic, the External Electronic Simulator will be performed every Monday. Verification is required every 8 hours using the Internal Electronic Simulator for PT/INR.

Procedure for testing of the External Electronic Simulator:

1. Turn on analyzer.
2. Press "Menu" to go to the "Administration Menu".
3. Press #3.
4. Press #4.
5. Follow screen prompts-enter operator ID and then simulator ID by scanning or entering only the number (no letters).
6. Remove simulator from the insulated box and remove blue plastic covering. Insert into the analyzer.
7. When testing is completed, approximately 2 minutes, the result will be displayed on the screen.
8. If PASS is displayed on the analyzer screen, you may use the analyzer as required.

Note: If the Internal Electronic Simulator is used every 8 hours, the "PASS" message will not be displayed on the analyzer screen. The "PASS" record will appear in the analyzer's stored results for transmission to the Central Data Station.

9. If FAIL is displayed on the analyzer screen, follow the steps listed below:
 - Repeat the procedure with the same external Electronic Simulator. If PASS is displayed, use analyzer as required.
 - If FAIL is displayed, repeat the procedure with a different Electronic Simulator.

If PASS is displayed with the second external Simulator, use analyzer as required. Return the questionable external Simulator to the POCC.

If FAIL is displayed with the second external Simulator:

- DO NOT analyze patient samples with the analyzer.
- Download the analyzer.
- Return the faulty analyzer to the POCC.
- Record the failure in the log along with the action taken.

Internal Electronic Simulator

When the specified time has elapsed since the last Electronic Simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted before the sample is tested, adding about 20 seconds to the testing cycle.

If the Internal Electronic Simulator fails, you must run the External Electronic Simulator following the procedure for testing of the External Electronic Simulator. In addition, run the liquid controls for verification.

Verification of Cartridge Storage Conditions

Refrigerated Cartridges

1. Verify that the cartridges stored in the refrigerator are all within the expiration date printed on the boxes. Deliver any expired cartridges to the POCC.
2. Verify that the refrigerator did not exceed the limits of 2 to 8° C (35 to 46°F).
3. Record daily temperatures of the refrigerator on the temperature chart located on the refrigerator. If the refrigerator is within the acceptable range, use the cartridges as required. If the refrigerator is outside the acceptable range, quarantine the cartridges in the storage refrigerator. Notify the POCC immediately. DO NOT USE the cartridges from this refrigerator. Record the temperature failure in the log along with the action taken.

Procedure for testing cartridges with i-STAT Level 1 and Level 2 PT/INR Controls

1. Prior to use, allow one vial each of the lyophilized plasma and calcium chloride reconstituting fluid to stand at room temperature for a minimum of 45 minutes.
2. Remove the cap and stopper from the vials and pour the entire contents of the calcium chloride vial into the lyophilized plasma vial. Place the stopper back on the reconstituted vial.
3. Allow the vial to sit for 1 minute and then mix the contents by swirling gently for 1 minutes, then inverting slowly for 30 seconds.
4. Use a plastic pipette, syringe, or capillary tube without anticoagulant to transfer the solution to the PT/INR cartridge.
5. Immediately seal the cartridge and insert it into the analyzer. This process must be completed within 30 seconds of the complete reconstitution of the control sample.
6. Compare the results to the package insert values. If the results are within the expected ranges, use the cartridges as needed. Download the analyzer.
7. If any results are outside the published expected ranges:
 - DO NOT USE cartridges from the suspect lot.
 - Quarantine the suspect lot.
 - Notify the POCC immediately.
 - Record the QC failure in the Action Log along with the action taken.
8. Liquid Controls (Level 1 and Level 2) will be run on each instrument every Monday.

Integrity Testing

For each new lot of cartridges received, use a representational number of cartridges to analyze the i-STAT PT/INR Level 1 and Level 2 PT Controls. Use the expected values published in the package inserts to verify the integrity of the cartridges. In addition, 2 patient samples will be used for correlation on each instrument.

Proficiency Testing

Proficiency Testing will be performed at the interval determined by CAP. Testing will be performed by the operators who perform patient testing. Testing on the backup instrument in the laboratory will be performed by the POCC.

Operator Competency

Operators will be trained initially by the POCC, at six months, and annually thereafter. Competency will include blind testing, direct observation of routine testing, monitoring QC performance, written test, direct observation of instrument checks and monitoring of result reporting.

PRINCIPLES OF MEASUREMENT**PT/INR**

PT/INR is determined amperometrically. The conversion of a thrombin substrate is initiated by mixing a whole blood sample (without anticoagulant) with tissue thromboplastin. The substrate used in the electrogenic assay has an amide linkage that mimics the thrombin-cleaved amide linkage in fibrinogen. The product of the thrombin-substrate reaction is the electroactive compound that is detected amperometrically. The time of detection is measured in seconds and reported as INR and/or seconds.